GLOBAL MATERIALS COMPLIANCE HANDBOOK

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PREFACE

This book is primarily directed to assisting those individuals who are responsible for material compliance (MC). The term MC refers to activities and processes used to ensure an organization is compliant with legislation related to hazardous (regulated) goods across all aspects of its business; for example, purchasing, research and development, testing, manufacturing, selling, documenting and distribution of regulated materials. Currently, companies spend hundreds of billions of dollars to satisfy these regulatory requirements. Examples of job functions related to MC include the following:

- Personnel who generate and distribute regulatory documents, e.g., safety data sheets, workplace safety cards, labels.
- Staff or third party contractors who train personnel on hazard communication requirements and import/export legislation.
- Personnel involved in the purchase, importation, manufacture or use of hazardous (regulated materials).
- Personnel who take new orders, transport goods locally/internationally or export hazardous (regulated materials).
- Research personnel involved in the development of new/modified formulations or products.

The primary purpose of the hazard communication documents is to prevent injury to workers or consumers, identify potential danger to the environment and be able to quickly and effectively respond to an incident, for example, tanker spill along a roadway or consumption of product by a child.

The book was designed to assist readers to answer the following questions relative to their organization:

- What is MC legislation?
- What components of global MC legislation should my business care about?
- How do I keep track of all this legislation?
- What are the components of a good material compliance system (MCS)?
- What is a MCS-information system (IS) and how can I incorporate one into our business?

In many cases, a lack of knowledge or poor execution of global MC requirements has prevented companies from filling international orders. Most companies now realize that the successful management of MC activities provides a competitive advantage for companies doing business globally, especially as North America and Europe "de-industrialize" and companies move their businesses abroad to capture lower labor costs. Key components of a successful MC management program include a well-defined process, personnel knowledgeable in both regulatory matters and supply chain issues and technology for information transfer.

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1

INTRODUCTION

1.1 OVERVIEW

Whether a company operates facilities across the globe or merely imports or exports goods to a single jurisdiction, company personnel and their advisors must be aware and understand regulatory requirements pertinent to their activities. The term *material compliance* (MC) refers to activities and processes used to ensure an organization is compliant with legislation related to hazardous (regulated) goods across all aspects of its business, for example, purchasing, research and development, testing, manufacturing, selling, documenting, and distribution of regulated materials. Currently, companies spend hundreds of billions of dollars to satisfy these regulatory requirements.

In many cases, a lack of knowledge or poor execution of the requirements has prevented companies from filling international orders. More and more companies are realizing that the successful management of MC activities provides them a competitive advantage. This is becoming more critical as North America and Europe companies move their businesses abroad to capture lower labor costs.

Within a company's supply chain activity there are multiple areas that need to interact with a proper MC process. These include, as a minimum, the following:

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- Review of suppliers' Material Safety Data Sheets (MSDS) or Safety Data Sheets (SDS) to ensure material can be imported and that documentation addresses pertinent regulatory requirements.
- Approval of vendors for specific chemicals, taking into consideration import/export legislation (e.g., embargos).
- Create Workplace Safety Cards (WSC), primarily in Europe, and labels using key information from suppliers' MSDS/SDS and country-specific regulatory information.
- Train workers on how to use these chemicals and make the MSDS/SDS and WSC readily available.
- Use a new chemical within a research and development activity and identify potential regulated criteria that will be associated with new or modified finished products (product optimization) that use this new chemical.
- Create MSDS/SDS and WSC for the newly design product.
- Verify registration and import quantity limitations for targeted countries.
- Verify the inventory listing for each substance (pure product) that is used to create the new product.
- Verify export information (banned list, embargo screening, etc.).
- Create label (potentially multilingual) information for product selling and shipment.
- Send MSDS/SDS to client prior to shipment (distribution by mail, fax, e-mail) in appropriate language and jurisdiction.
- Create driver instruction cards, in appropriate language, for road shipment (Tremcards).
- Print all documentation needed with the shipment, addressing local languages and legislation for areas through which the shipment may pass.

It is important to note that the primary "purpose" of the hazard communication documents listed above is to prevent injury to workers or consumers, to identify potential danger to the environment, and to be able to quickly and effectively respond to an incident, for example, a tanker spill along a roadway or accidental consumption of product by a child.

To effectively manage MC on a global scale, the following are required:

- well-defined process
- personnel knowledgeable in both regulator matters and supply chain issues
- technology for information transfer

Most companies who ship or receive goods internationally have developed material compliance systems (MCS) that address these regulatory require-

ments. These MCS are typically labor intensive, address mainly the primary business location (e.g., U.S. or German operations only), and are not updated in a timely manner as legislation changes. More and more proactive companies are automating the screening of orders and generation of regulatory documents while incrementally expanding regulatory content to address global requirements.

This book provides guidance to companies importing, exporting, or transporting hazardous (dangerous) goods around the world. The terms *hazardous* and *dangerous* are used here in general context; both can have very specific meanings within particular legislation. Key issues addressed by the book include:

- proper classification of hazardous goods according to import/export, health and safety, and transportation legislation,
- review of prohibition rules related to shipments of hazardous goods to and from countries and product registration requirements,
- preparation of proper shipping/transportation documents, labels, WSC, and MSDS/SDS,
- proper screening of shipments to ensure compliance with import/export legislation,
- helpful hints on antiterrorism activities to ensure ongoing security of shipments, and
- development of global MCS and MCS information systems.

The book also provides information on the important components of successful MCS and MCS information systems. The proposed components were derived from the International Organization for Standardization quality (ISO 9000) and environmental (ISO 14000) series of standards and the U.S. Bureau of Industry and Security (BIS), formerly the Bureau of Export Administration, Export Management System (EMS) guidelines. Components, if not properly addressed, can quickly translate into:

- Development of new products that contain ingredient(s) that may cause significant risk and, in some cases, are banned from being imported into some countries.
- Delays and uncertainties in custom clearance that result in parts shortages and the requirement to provide excess inventory.
- Return or impoundment of goods as prohibited from entering/leaving a country due to prohibition on material, incorrect containers, or documentation.
- Monetary fines, civil and/or criminal prosecution.
- Prohibitions on the import/export of goods by the company.

- Damage to company reputation as a result of incident or prosecution.
- Audits of shipments and operations by government agencies.

The presence of a MCS by itself will not relieve an organization of criminal and administrative liability under law if a violation occurs. A well-designed MCS, however, should greatly reduce the risk of noncompliance events and will serve as a mitigating factor during an investigation should a violation occur. This role of an effective MCS may be further highlighted as U.S. Customs implements its "informed compliance strategies" for importers; a strategy that shifts focus from a transaction-based operation to an account-based processing.

The evolution of global MC legislation related to business processes can be "generally" described as follows:

Command and control period—In the early 1980s, companies began implementing the precursor to MCS to ensure ongoing regulatory compliance. Their focus shifted from simply executing import/export and transportation, to managing the quality of the processes and resulting output. A shift that may have been accelerated by the United States' introduction of the Enhanced Proliferation Control Initiative (EPCI) and a rewrite of Export Administration Regulations (EAR). These regulations placed emphasis on the end use and end-users of the exported products. Companies quickly came to see corporate control of compliance processes and output as critical to meeting regulatory requirements, however, it was still considered a labor intensive "operational" issue, with a focus on only key manufacturing sites in the United States or Europe, depending upon the location of the company's corporate headquarters.

Costs/risks aversion period—In the 1990s, most major corporations mastered (or believed they had) basic MC issues related to government reporting and refocused on cost reduction and risk aversion—especially when they realized how much money it was costing to ensure ongoing compliance. As a result, MCS moved from being an "operational" issue to a "tactical," issue with a significant amount of MC transactions (document generation, screening, etc.) being automated or semi-automated. However, systems were still primarily U.S. or European Union (EU) regulatory focused, with other jurisdictions being addressed partially, if at all, using local personnel and storage of data with no central repository of MC information.

Management period—In the early 2000s, multinational companies began to reevaluate their MCS as they realized that their country-specific, independent, unilingual systems did not reinforce their integrated business process, but rather hindered it and were expensive to operate. In doing so, they also realized that the "ship button" present on a company's internal/external Web system is linked to a series of time-consuming, manual activities that frequently involve complex regulatory matters or the processing of significant amounts of data.

They also realized that a well-designed MCS that includes a central data repository of MC data, integrated with other key business systems, can:

- significantly reduce costs
- promote dialogue with suppliers on hazard information and testing requirements
- standardize business processes
- ensure trade and regulatory compliance
- minimize business risks of current and proposed legislation
- in the event of government action, show "reasonable care," as per U.S. Customs Informed Compliance Strategy, and potentially mitigate penalties

Examples of key business information systems include the following: Laboratory Information Management Systems (LIMS), courier tracking systems, formulation systems, Enterprise Resource Planning (ERP), Supply Chain Management (SCM), or Manufacturing Resource Planning (MRP) software systems, and government reporting/content databases, for example, specific requirements for interfacing with U.S., British, and Canadian Custom systems.

The overall business objective for most companies is to drive costs out of the supply chain and improve services levels. Key activities related to MCS that support this objective include:

- Ensuring compliance with global regulatory requirements.
- Reducing the time period for preparation of new documents especially if multi lingeral, and provide more accurate data.
- Minimizing the time goods sit in customs, thereby decreasing the need for excess inventories (especially customs holding areas).
- Developing a single product that can be sold in numerous markets and complies with legislation in every country rather then regional products that must be rolled out separately, avoiding costly product launch delays and, potentially, prohibitions on entering some markets.
- Potentially allowing chemists to run "what-if" scenarios to find out what the consequences of adding/eliminating a particular component are in terms of where it is to be sold.
- Integrate business information systems to minimize manual data entry.

These all have significant impact on costs, with some companies reporting decreases of up to 50% of supply chain costs and significant expansion to new markets.

By assessing MC issues at the "strategic" level, companies can account for

compliance strengths and weaknesses when deciding against which competitors, in which markets, using what products (to develop, introduce, or phase out), or how best to deploy company resources to maximize market opportunities. This new direction allows all personnel in the enterprise, from the shipping clerk to the CEO, to have visibility into compliance and hazardous materials issues impacting their decisions, from checking whether an MSDS is valid, to choosing to expand sales into a new country. Each person has access and the tools necessary to draw the right conclusions for minimizing costs and ensuring compliance at all levels.

It is important to note that automation can reduce cost and ensure high quality when processing large amounts of data. Significant cost savings, however, typically only come from the integration of systems, as it eliminates manual data entry as well as associated errors.

1.2 TYPES OF LEGISLATION

MC legislation has become significantly more complex over the last few years. Historically, some companies have believed that the generation of documentation in English, in conformance to U.S. legislation, is adequate to ship goods anywhere in the world. However, companies must be aware of and comply with local legislation (approximately 126 countries have local MSDS requirements) and linguistic requirements. This legislation, when compiled, would fill several large bookshelves. In some areas, these requirements are significantly different, and potentially more stringent, than U.S. requirements, for example, the approach to MSDS used in the EU versus the United States.

Several types of instruments are used by government agencies to manage or regulate MC legislation:

- acts, statutes, regulations, directives, and standards
- permits, certificates, licenses, and orders
- local/municipal ordinances and by-laws
- codes of practice, policies, criteria, objectives, and guidelines

Legislative bodies pass acts or statutes (laws passed by legislators). Acts or statutes are typically general in nature in terms of requirements and have a broader policy perspective. Regulations or directives are made pursuant to authority set out in an act or statute and provide specific operational details on the general powers listed in the act or statute. A bill is a proposed law that, following passage by the legislative body, becomes an act or statute. Typically, standards are numerical values stipulated in a statute regarding allowable levels, for example, emission levels, occupational exposures, etc.

In the United States, the rule-making process involves the publication of proposed regulations in the Federal Register, allowing the public an opportu-

nity to comment on the regulation. The final regulation is also published in the Federal Register and has the effect and force of law when it becomes effective. Annually, the regulations are combined into the Code of Federal Regulations (C.F.R.).

It is important to note that there are three key dates for acts, statutes, regulations, and directives: publication of the proposed/draft legislation; the date final legislation is published (often referred to as the promulgation date); and the date the legislation or key components become effective (also referred to as the enforcement date). Typically, the more a piece of legislation will impact the business community, the longer the time period between the date of promulgation and enforcement date, for example, significant EU legislation typically has a transition period of 18 months. It is important to note that for some regulatory changes, for example, occupational exposure limits (OEL), the transition period, if any, may be very short, depending upon the jurisdiction.

Permits, certificates, or licenses are issued to specific parties by government agencies. Some acts, statutes, regulations, or directives require such instruments. Orders are issued to specific parties by government agencies, usually in response to failure by the party to comply with an act, statute, regulation, or directive, or on the strong suspicion that noncompliance has occurred or could occur.

Codes of practice, policies, criteria, objectives, and guidelines are used by government agencies to address many MC issues. Although not legally binding on their own, these types of instruments need to be reviewed and assessed as part of MC compliance. They can illustrate an agency's position toward a particular situation. If these are incorporated into the terms of a license, permit, or other approval, or referred to in a regulation or directive, these types of instruments can be legally binding.

There exist potentially five levels of legislation:

- international (e.g., United Nations)
- regional (e.g., EU)
- national (federal)
- state or provincial
- municipal

For the purpose of MC legislation, and thus this book, the primary focus is on the first three levels, that is, items of national concern. Generally provinces/states are not precluded from enforcing criteria more stringent than those required by federal laws, and are given considerable leeway to follow enforcement interpretations that may not be fully consistent with those applied at the federal level. Thus, the laws and interpretations used to apply and enforce federal laws may vary considerably from province/state to province/state and these variations may not be readily apparent.

Note that under the U.S. Constitution's commerce clause (Article I, Section

8), Congress has the authority to regulate commerce with foreign nations, among several states, and with Indian tribes. If the courts find that the state statutes or regulations impermissibly burden interstate commerce, then they are found to be unconstitutional and unenforceable.

1.3 GOVERNMENT ENFORCEMENT

Failure to comply with MC legislation may result in the following government agency responses:

- Delays in clearing of goods by customs personnel
- Audit of shipments and operations
- Orders to perform specific activities
- Return or impoundment of goods as prohibited from entering/leaving a country due to prohibition on material, incorrect containers, or documentation
- Prohibitions on the import/export of goods by the company
- Monetary fines (ranging from ticketable offences to several million dollars depending upon offence and jurisdiction), criminal prosecution of employees and executives, and civil prosecution of the company.

One of the largest fines to date was against Sony Corporation by the Dutch authorities for importing game consoles containing cadmium levels above the limit allowed under regulations. Sony corporation estimated an impact on sales of approximately EUR 110 million and on operating profit of approximately EUR 52 million, including costs of rework, on a consolidated basis for the fiscal year ending March 31, 2002 (S&EA EN, 2002).

In many cases, the fine associated with incorrect MC document (e.g., MSDS or transportation manifest) is relatively minor, however, the resulting impact from personnel using this documentation can be catastrophic (e.g., damage from spillage/fires/explosions resulting from the incorrect storage of hazardous materials or inappropriate response to an emergency condition resulting in worker injury/death and damage to equipment/property).

An example of this type of incident is the explosion at the Motiva Refinery in Delaware City, Delaware, in July 2002. The incident resulted in the death of an employee, injury to eight other workers, and the release of a large quantity of acid into the Delaware River, killing fish and other aquatic life. A spark from the work crew's welding tools ignited hydrocarbon vapors from a 415,300-gallon spent sulfuric acid storage tank. Motiva's MSDS for spent sulfuric acid did not include important information about the mixture's flammability. In addition, Motiva had assigned a zero for the National Fire Protection Association (NFPA) rating on the MSDS (US CSHIB, 2002).

A commonly asked question by companies when discussing a government

agency's response, outside of the United States, is "do they really enforce the legislation?" The answer is that, unfortunately for workers and the public, the response depends upon the jurisdiction. In almost all developed countries, any event that triggers injury to workers or the public, loss of life, or significant damage to the environment will result in significant penalties and government intervention. In nondeveloped countries, the response can vary significantly.

In the United States, enforcement has been relatively steady for MC legislation, and, if anything, is increasing related to import/export of hazardous goods because of the threat of terrorism. Many developing nations are also taking a much more stringent look at what hazardous goods are being imported/exported.

The EU is starting to increase enforcement activities via the European Classification and Labelling Inspections of Preparations (ECLIPS), including SDS. The objective of the ECLIPS project is first to assure a harmonized European enforcement of the Directive 99/45/EEC (legislation related to SDS) and secondly to show the necessity of appropriate classification and labelling as well as complete and correct SDS of dangerous preparations, also focusing on chemicals classified as carcinogenic, mutagenic, and/or toxic for reproduction.

Main goals of this project include the following:

- exchange of information and experience between the member states to avoid differences in the way the directive is enforced in the different member states and as a consequence to avoid different competitiveness of the relevant enterprises
- finding enforcement strategies for each country that are suited for its national situations
- reduction of risks to workers, public and environment requires high quality of safety data sheets and an appropriate classification and labeling of preparations containing dangerous substances
- equal market conditions
- correct labeling of dangerous preparations as a tool to attract attention of the users (workers and public in large) in order to interfere in the buying decision

Agreement on ECLIPS was reached in the following countries: Austria, Belgium, Denmark, France, Finland, Greece, Germany, Ireland, The Netherlands, Norway, Spain, and Sweden. The Czech Republic and Slovakia are interested in the project as observer. A working group, consisting of Austria, Germany, Spain, and Sweden, has adapted the ECLIPS project proposal.

The project is currently in the operational phase, whereby the national authorities are selecting companies and inspections of the companies will be carried out. Inspections will include:

- checking whether preparations are classified and labeled correctly,
- checking safety data sheets, and
- support and information for the companies.

To review what happens to companies that do not comply with U.S. regulatory requirements, please review the U.S. government BIS Web site under "Press Release" or compliance and enforcement section of the U.S. EPA web site.

1.4 CONTENT

This text provides easy to understand guidance on MC to shipping/receiving personnel, safety inspectors, MSDS/label authors, and transportation and logistics managers. It also provides senior management insight into the complexities of shipping goods globally and a quick guide to the basic components of well-run MCS and MCS-IS. The book was designed to assist readers answer the following questions relative to their organization:

- What is MC legislation?
- What components of global MC legislation should my business care about?
- How do I keep track of all this legislation?
- What are the components of a good MCS?
- What is an MCS-IS and how can I incorporate one into our business?

This book is divided into two parts: Part 1 is an overview of global MC legislation and requirements imposed on organization that import, export, and/or transport hazardous (dangerous) goods and Part 2 covers Material Compliance Systems. In this part of the book, MC, MCS—Information Systems, and antiterrorism activities are discussed. The latter is provided to assist companies respond to a new business risk that can have a profound impact on the movement of hazardous goods.

If a chapter deals with regulatory requirements, we have subdivided the section into the following geographic regions: North America, Europe, and Pacific Rim. North America addresses legislation pertinent to the United States, Canada, and Mexico. In the EU sections, legislation pertinent to the current 15 EU member states is addressed: Austria, Belgium, Denmark, France, Finland, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, and the United Kingdom. Where information was available, we also tried to address countries that have a high probability of being accepted as EU member states in 2003: Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, and Slovenia. In the Pacific Rim sections the five largest trading partners with the United States were selected: Japan, China, Taiwan, Korea, and Australia.

The following are brief descriptions of each section of the book and how they assist readers in addressing key business requirements:

Part I—Regulatory Requirements

Chapter 2 covers chemical registration, notification, and listing as derived from product registration and national inventory legislation. This type of legislation can prohibit a material from being allowed into a country, limit its use (e.g., research and development), or require a company to provide a significant amount of documentation as part of a very timely registration process.

Chapter 3 addresses the regulatory requirements related to **generation and distribution of MSDS**, the second most generated document in many organizations. Efforts are underway to harmonize the requirements around the world, however, individual countries continue to put forward their unique requirements that in several instances result in a conflict between jurisdictions. The concept of a single system is still seen by many as an elusive dream.

In **Chapter 4**, legislation pertinent to **product label requirements** is presented. The chapter deals primarily with precautionary labels for products and shipments and presents the key requirements in an easy to understand format that promotes comparison jurisdiction.

Chapter 5 presents requirements related to **transportation** of hazardous goods. These include the classification and preparation of shipping documents for all modes of transportation: air, water, rail and roadway.

Chapter 6 provides an overview of global **import compliance**. Key components include classification, prohibitions, custom notification and foreign trade zone execution.

Chapter 7 presents information on **export compliance** in a manner similar to Chapter 2. The key components include classification, prohibitions (e.g., restricted parties and embargoes), and customs notification.

Part II—Material Compliance Systems

Chapter 8 covers the impact of **terrorism on the supply chain**. Topics addressed include effect on cargo movements, planning for the next attack, and countermeasures.

Chapter 9 presents the basic components of **material compliance systems** along with the proposed links to well-defined business systems, that is, the International Organization for Standardization (ISO) publications on quality and environment management systems and the U.S. BIS Export Management Systems (EMS) guidelines.

Chapter 10 discusses key issues associated with **MCS–Information Systems**: business drivers for implementing a MCS-IS, overall components of MCS, needs analysis/financial feasibility studies, preimplementation, implementation activities, and ongoing system maintenance.

There are **appendixes**, that list the following: a glossary of terms: government audit/inspection checklists; material compliance Web sites; import and export Web sites; and legislation on occupational exposure limits.

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PART I

REGULATORY REQUIREMENTS

2

CHEMICAL REGISTRATION, NOTIFICATION, AND LISTING

2.1 INTRODUCTION

Several countries have put in place legislation to ensure that they have sufficient information on chemicals that are imported, manufactured, or exported from their borders. The legislation requires all new chemical substances to go through an approval process before being listed on a National Inventory List (NIL). Typically, a country will have a NIL for existing chemicals and one for new chemicals. Chemicals that are not on a NIL for a given country have to go through a registration process prior to being imported, manufactured, or exported. Depending upon the country, exemptions are available for specific types of chemicals, for example, polymers in Europe and the United States, or usage of very small quantities for research and development (R&D) purposes. In addition to the approval process, specific reporting requirements may be required for NILs, including their inclusion on a (M)SDS. Table 2.1 presents a summary of key NILs.

2.2 REQUIREMENTS FOR NORTH AMERICA

2.2.1 United States

The U.S. Toxic Substances Control Act (TSCA) was first enacted in 1976 and has since been significantly amended three times. TSCA was enacted by Con-

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TABLE 2.1. List of Key National Inventory Lists

Country	List Acronym	List Name
Australia	AICS	Australian Inventory of Chemical Substances
Canada	DSL	Canadian Domestic Substances List
Canada	NDSL	Canadian Non-Domestic Substances List
China	IECS	Inventory of Existing Chemical Substances in China
Europe	EINECS	European INventory of Existing commercial Chemical Substances
Europe	ELINCS	European List of New Chemical Substances
Japan	ENCS	Existing and New Chemicals SubstanceList (same as MITI and MHW)
Korea	ECL	Existing Chemicals List
Philippines	PICCS	Philippines Inventory of Chemicals and Chemicals Substances
United States	TSCA 8b	Toxic Substances Control Inventory Act

gress to give the Environment Protection Agency (EPA) the ability to track 75,000 industrial chemicals currently produced or imported into the United States. TSCA is a federally managed law and is not delegated to states. The EPA Office of Pollution Prevention and Toxics (OPPT) oversees the law. The EPA repeatedly screens these chemicals and can require reporting or testing of those that may pose an environmental or human health hazard. The EPA can ban the manufacture and import of those chemicals that pose an unreasonable risk (OPPT, 2003).

The EPA also has put in place a process to track the thousands of new chemicals that industry develops each year with either unknown or dangerous characteristics. Depending upon the risk posed by the chemical, the EPA can control these chemicals as necessary for the protection of human health and the environment.

A major objective of the TSCA is to characterize and evaluate the risks posed by a chemical to humans and the environment before the chemical is introduced into commerce. TSCA accomplishes this through the requirement that manufacturers perform various kinds of health and environmental testing, use quality control in their production processes, and notify the EPA of information they gain on possible adverse health effects from the use of their products. Under TSCA, manufacturing is defined to include importing, and thus all requirements applicable to manufacturers also apply to importers (EPA, 2003).

The EPA has authority not only to ban the manufacture or distribution of given chemicals but also to limit their use, require labeling, or place other restrictions. Among the chemicals EPA regulates under TSCA are asbestos, chlorofluorocarbons (CFCs), and polychlorinated biphenyls (PCBs).

Under TSCA, EPA classifies chemical substances as either "existing" chemicals or "new" chemicals. To determine how a substance is classified, consult the TSCA Chemical Substance Inventory (commonly referred to as the Inventory), which lists existing substances. Searches of the nonconfidential, public inventory are available at the Cornell University's TSCA Inventory or commercial content providers (e.g., Atrion International RegDB Online). Searches of the confidential inventory require an EPA bona fide search.

The following are key sections of TSCA. It is important to note that Section 5 should be assessed before proceeding with Section 4 requirements (EPA, 2003).

- Section 4—Testing requirements
- Section 5—Premanufacture Notice (PMN)
- Section 6—Protection against unreasonable risk
- Section 7—Imminent hazards
- Section 8, 12(b) and 13—Record keeping and reporting of chemicals usage

In the following paragraphs, additional information on each section is provided.

Section 4—Testing Requirements TSCA Section 4 requires manufacturers, importers, and processors of certain chemical substances and mixtures to conduct testing on the health and environmental effects of chemical substances and mixtures, unless they qualify for an exemption. Testing requirements cover existing chemicals (but not new chemicals, since these are addressed in the PMN process), and also cover mixtures as well as individual substances. The EPA has established a "master testing list" that lays out testing priorities, based on risk and exposure potential (EPA, 2003).

For example, the EPA is currently working with manufacturers to encourage testing on chemicals that are produced and used in large volumes (High Production Volume Testing). At present, these tests are voluntary, but the EPA has the authority to develop a testing rule if it determines such a rule to be necessary (EPA, 2003).

Requirements related to TSCA Section 4 can be found in 40 CFR Parts 790, 791, 792, 799, and 766. The OPPT Web page also provides extensive information on testing requirements (EPA, 2003).

Section 5—Premanufacture Notice (PMN) Section 5 of TSCA regulates anyone who plans to manufacture or import a "new" chemical substance for commercial purposes. Under Section 5, the EPA requires notice before manufacture or importation of nonexempt substances so that the EPA can evaluate whether the chemical substance poses a threat to human health or the environment. This notice is called a PMN and must be submitted at least 90

days prior to the activity. New chemicals include certain genetically modified microorganisms and the list is available from the EPA Web site. Manufacturers must also submit information on "significant new uses" of existing chemicals to the EPA for its review. Again, the TSCA inventory establishes what existing uses are (EPA, 2003).

Submittals are to include information on the manufacturing process, disposal method, and health and environmental effects of the substance. The EPA assesses whether the chemical substance presents an unreasonable risk of injury to health or the environment by weighing the risks versus the social and economic benefits of introducing the chemical into commerce. After its review of the PMN or Significant New Use information the EPA may choose among a broad range of options that may limit, restrict, or prohibit the manufacture, use, distribution, and/or disposal of the chemical substance (EPA, 2003).

There are some exclusions and exemptions to the PMN requirements. For example, drugs and pesticides are excluded because they are covered under separate laws, that is, FDDCA and FIFRA, respectively. In addition, there are about 15 different exemptions, including exemptions for R&D activities; test marketing; low-volume and low-release/low-exposure chemicals; certain polymers; impurities, by-products, and nonisolated intermediaries; and so forth. It is therefore important to check with the applicable regulations to insure coverage. The PMN applicability flowchart that is provided by the EPA may also be helpful (EPA, 2003).

Requirements related to TSCA Section 5 can be found in 40 C.F.R. Parts 700, 720, 723, 725, and 747. The OPPT Web page also provides extensive information on PMN requirements (EPA, 2003).

Section 6—Protection Against Unreasonable Risk TSCA Section 6 regulates certain hazardous chemical substances and mixtures and authorizes the EPA to take regulatory action to protect against unreasonable risk of injury to human health or the environment due to the manufacture, import, processing, distribution in commerce, use, or disposal of a chemical substance or mixture. For example, the EPA has promulgated regulations under Section 6 of TSCA applicable to PCBs and asbestos. Various guidance materials on these chemicals can be found at the TSCA publication Web site. Specific requirements can be found in 40 C.F.R. Parts 745, 747, 749, 750, 761, and 763 (EPA, 2003).

Section 7—Imminent Hazards TSCA Section 7 authorizes the EPA to commence a judicial action for seizure of a chemical substance, mixture, or article containing such a chemical substance or mixture that the EPA has determined is imminently hazardous, and/or for other relief against any person who manufactures, imports, processes, distributes in commerce, uses, or disposes of an imminently hazardous chemical substance or mixture (EPA, 2003).

Sections 8, 12(b), and 13—Data Gathering and Reporting TSCA Sections 8, 12(b), and 13 mandate data gathering activities to provide data that the EPA and others can utilize to identify, assess, manage, and reduce actual or potential risks posed by exposure to existing chemical substances and include import and export reporting requirements. The OPPT data gathering Web site provides extensive information on these requirements (OPPT, 2003).

Section 8 of TSCA authorizes the EPA to require persons engaged in the manufacture (including importing), processing, and distribution of TSCA-covered chemical substances and mixtures to perform certain record keeping and reporting activities (OPPT, 2003).

In TSCA Section 8(a), the Inventory Update Rule (IUR) states that companies that manufacture or import more than 10,000 lbs. of certain chemicals that are included on the TSCA Chemical Substance Inventory (primarily organics) are required to report current data on the production volume, plant site, and site-limited status of these chemicals. Reporting under the IUR takes place at four-year intervals that began in 1986. Small businesses as defined by 40 C.F.R. 710.29 are excluded (OPPT, 2003).

Examples of reporting information that can be required include the following (OPPT, 2003):

- chemical or mixture identity
- categories of uses
- quantity manufactured or processed
- by-product description
- health and environmental effects information
- number of individuals exposed
- method(s) of disposal

Section 8(a) regulations can be tailored to meet unique information needs (e.g., via chemical-specific rules) or information can be obtained via use of "model" or standardized reporting rules. An example of a model TSCA Section 8(a) reporting rule is the "Preliminary Assessment Information Rule" (or PAIR) (OPPT, 2003).

Under PAIR, producers and importers of a listed chemical are required to report the following site-specific information on a two-page form (OPPT, 2003):

- Quantity of chemical produced and/or imported
- Amount of chemical lost to the environment during production or importation
- Quantity of enclosed, controlled, and open releases of the chemical
- Per release, the number of workers exposed and the number of hours of exposure

Exemptions for such reporting are as follows:

- Production or importation for the sole purpose of R&D
- Production or importation of less than 500 kilograms during the reporting period at single plant site
- Companies whose total annual sales from all sites owned by the domestic or foreign parent company are below $30 million for the reporting period and who produced or imported less than 45,400 kilograms of the chemical
- Production or importation of the listed chemical solely as an impurity, a nonisolated intermediate, and under certain circumstances as a by-product

TSCA Section 8(a) on PAIR states that companies must report site-specific information on the manufacture or importing for commercial purposes of any chemicals listed in 40 C.F.R. 712.30. The information includes quantity of chemical, amount lost to the environment during production or importation, quantity of releases (controlled and noncontrolled) of the chemical, and per release worker exposure information (OPPT, 2003).

TSCA Section 8(c) on the Allegations of Significant Adverse Reactions Rule states that companies are required to keep a file of allegations of significant adverse reactions (to human health or the environment) of any chemical they manufacture, import, process, or distribute. Companies must also provide this information to the EPA upon request (OPPT, 2003).

In TSCA Section 8(d) on Unpublished Health and Safety Studies Rule, companies may be required to submit to EPA a list and/or copies of unpublished studies that address the health or safety issues of certain listed chemicals (OPPT, 2003).

Section 8(e), Substantial Risk Information Requirements, states that companies are under a duty to report to EPA within 15 days any new information they have that reasonably supports the conclusions that a substance or mixture they manufacture, import, process, or distribute presents a substantial risk of injury to health or the environment (OPPT, 2003).

In Section 12(b), Export Notification Rule, the requirements (see 40 C.F.R. Part 707 Subpart D) apply to chemical substances or mixtures covered by various proposed or final actions under TSCA Sections 4, 5, 6, or 7. Notification of export is generally not required for articles, as provided by 40 C.F.R. section 707.60(b) (OPPT, 2003).

Section 13, Import Notification, requires that any chemical substance, mixture, or article containing a chemical substance or mixture be in compliance with TSCA and, in addition, the EPA requires import certification (OPPT, 2003).

It is important to mention that both the American National Standards Institute (ANSI) and OSHA Chemical Hazard Communication System (CHCS) also known as HCS (M)SDS standards in the United States regulate the information that should be shown on the MSDS. The TSCA information belongs

to "Section 15 Regulatory Information" of an (M)SDS. The latest version of ANSI standards also proposes a few display examples.

The reporting requirements for the NIL related to (M)SDS include the following (OPPT, 2003):

- must report if a single component is or isn't on a given inventory and
- must report if all components of a mixture are exempted from or are on a given inventory or
- must report at least one component of a mixture if it is not listed on a specific inventory.

2.2.2 Canada

Anyone (person or company) who wants to import, manufacture, or sell any new substance is required to notify the appropriate Canadian regulatory authority so the new substance can be evaluated for potential effects on human health and the environment prior to the importation, manufacturing, or sale (as the case may be).

The Canadian Environmental Protection Act (CEPA) is the key authority for the government to ensure that all new substances are assessed for their potential to harm human health or the environment. Recognizing that other acts also provide for such an assessment process, CEPA includes a provision whereby substances regulated by other acts are exempt from the new substance notification requirements of CEPA. This avoids regulatory duplication, while ensuring that standards for protection of the environment and human health are met, and applied to all substances.

The domestic substances list (DSL) is the sole basis for determining whether a substance is new for the purposes of the Canadian Environmental Protection Act, 1999 (CEPA, 1999). Substances on the DSL do not require notification unless they are proposed for a significant new activity (SNA) as indicated on the DSL. Substances not appearing on the DSL are considered to be new to Canada and are subject to notification under the New Substances Notification Regulations (NSNR) of CEPA, 1999 (Environment Canada, 2003).

The nondomestic substances list (NDSL) specifies substances that are not on the DSL but are in commercial use in the United States. As a basis for this list, Environment Canada used the U.S. TSCA. Substances on the NDSL are subject to notification under the NSNR of CEPA, 1999 but require less detailed notification packages.

2.3 EUROPEAN REQUIREMENTS

2.3.1 Current Requirements

The concern regarding the potential risks of chemicals and in particular existing chemicals was already a policy priority in the late 1980s. The Council of

the European Communities, in approving the Fourth Community Action Program on the Environment (1987–1992), stated that one of the priority areas was the evaluation of the risks to the environment and human health posed by chemical substances. This action program underlined the need for a legislative instrument that would provide a comprehensive structure for the evaluation of the risks posed by "existing" chemicals. In particular, the action program stated that such a legislative instrument "will establish a procedure for treating priority lists of chemicals for immediate attention, as well as setting out the means for gathering information, requiring testing and evaluating the risks to people and the environment." Consequently, the European Commission proposed a series of legal instruments, which were aimed at meeting the objectives outlined in the action program. One of these instruments was the Existing Substances Regulation (CEC 1986).

In the Organization for Economic Co-operation and Development (OECD), the importance of the work carried out on "existing" chemicals had already been recognized with the 1987 Decision-Recommendation of the OECD Council on the Systematic Investigation of Existing Chemicals. This OECD act stated that "Member Countries should establish or strengthen national programs to systematically investigate existing chemicals." In 1988, the OECD launched an extensive program on "existing" chemicals, an area in which some EU member states were already active. (OECD, 1987)

The existing chemicals work started and aimed its activities to be aligned with the strategy for implementing an environmentally sound management of toxic chemicals, outlined in Chapter 19 of the Agenda 21 Rio Declaration, adopted at the United Nations Conference on Environment and Development (UNCED) in 1992. On the international level, this group is responsible for scientific and technical inputs to the OECD existing chemicals program and several UN initiatives on chemicals (ECB).

In 1993, the Council adopted Council Regulation (EEC) 793/93 or the Existing Substances Regulation (ESR), thereby introducing a comprehensive framework for the evaluation and control of "existing" chemical substances. It is important to note that European INventory of Existing commercial Chemical Substances (EINECS) was drawn up by the European Commission in application of Article 13 of Directive 67/548, as amended by Directive 79/831, and in accordance with the detailed provisions of Commission Decision 81/437. It lists and defines those chemical substances, which were deemed to be on the European Community market between January 1, 1971, and September 18, 1981. In terms of Article 1 of the amended Directive 67/548, these are substances to which the premarketing notification provisions of the Directive do not apply (ECB).

The Regulation was intended to complement the already existing rules governed by Council Directive 67/548/EEC for "new" chemical substances. Any chemical substance, which has been marketed after September 18, 1981, is called a new chemical. An existing chemical substance is in the EU defined as any chemical substance listed in the EINECS, an inventory containing 100,195 substances.

New chemicals, introduced subsequently, form a cumulative index the European LIst of New Chemical Substances (ELINCS), which is periodically updated as an official journal. Exemption categories include consumer products pertaining to pharmaceuticals, cosmetics, and foodstuffs. The Directive is not applicable to pesticides, radioactive materials, wastes, and substances used in scientific research.

The Regulation 793/93 foresees that the evaluation and control of the risks posed by existing chemicals will be carried out in four steps:

Step I.	Data collection
Step II.	Priority setting
Step III.	Risk assessment
Step IV.	Risk reduction

Step I: Data Collection The regulation initially addressed the so-called High Production Volume Chemicals (HPVCs). HPVCs are those substances that are covered by the data collection phases I and II of the regulation, that is, which have been imported or produced in quantities exceeding 1000 tons per year and produced or imported between March 23, 1990, and March 23, 1994. In phase III of the data collection step, companies that produce or import existing substances in quantities between 10 and 1000 tons per year, Low Production Volume Substances (LPVCs), were required to submit a reduced data set by June 4, 1998. All the data had to be submitted in a specific electronic format, Harmonized Electronic DataSET (HEDSET), and is managed by the International Uniform ChemicaL Database (IUCLID). Furthermore, all companies that have submitted a data set in any of the three data collection phases are required to update the information, at least once every three years (ECB).

There is also notification that is required for substances imported or produced in quantities from 10 kg to 5 tons and should be reported according to Annex VII of the Directive by Commission Directive 1993/105/EEC. These requirements are described in Annex VII A, B and C. Table 2.2 presents the type of notification according to the annual quantity and the cumulative quantity.

TABLE 2.2. Type of Notification according to Annual and Cumulative Quantity

Type of Notification	Annual Quantity	Cumulative Quantity
Level 2 (1000 tons)	>1000 tons	>5000 tons
Level 1 (100 tons)	>100 tons	>500 tons
Level 1 (10 tons)	>10 tons	>50 tons
VII A	>1 ton	> 5 tons
VII B	>100 kg and <1 ton	>500 kg
VII C	>10 kg and <100 kg	<500 kg

Again, the notification schemes identify the charge levied and the content of the test package that is required in proportion to the level of supply. This reduces both animal testing and the costs to notifiers, who may be in the early stages of marketing a substance.

Once a supplier has breached either the upper limit of the annual supply tonnage or the cumulative supply tonnage of the band, then the notification must be upgraded to the next level and provide the extra data.

HPVC Reporting Without prejudice to Article 6 (1), any manufacturer who has produced or any importer who has imported an existing substance, as such or in a preparation, in quantities exceeding 1000 tons per year, at least once in the three years preceding the adoption of this regulation and/or the year following its adoption, must submit to the commission, in accordance with the procedure laid down in Article 6 (2) and (3), the following information, as specified in Annex III, within 12 months of entry into force of this regulation in the case of a substance appearing in Annex I and within 24 months in the case of a substance appearing in EINECS but not in Annex I:

(a) the name and the EINECS number of the substance
(b) the quantity of the substance produced or imported
(c) the classification of the substance according to Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions of the member states relating to the classification, packaging and labeling of dangerous substances or the provisional classification according to the said Directive, including the class of danger, the danger symbol, the risk phrases and the safety phrases
(d) information on the reasonably foreseeable uses of the substance
(e) data on the physico-chemical properties of the substance
(f) data on pathways and environmental fate
(g) data on the ecotoxicity of the substance
(h) data on the acute and subacute toxicity of the substance
(i) data on carcinogenicity, mutagenicity, and/or toxicity for reproduction of the substance
(j) any other indication relevant to the risk evaluation of the substance

Manufacturers and importers must make all reasonable efforts to obtain existing data regarding points (e) to (j). However, in the absence of information, manufacturers, and importers are not bound to carry out further tests on animals in order to submit such data.

LPVC Reporting Without prejudice to Article 6 (1), any manufacturer who has produced, or any importer who has imported, an existing substance, as such

or in a preparation, in quantities exceeding 10 tons per year but no greater than 1000 tons per year, at least once in the three years preceding the adoption of this Regulation and/or the year following its adoption, shall submit to the Commission, in accordance with the procedure laid down in Article 6 (2) and (3), the following information, as specified in Annex IV, within a period of 24 months, to start once the Regulation has been in force for three years:

(a) the name of the substance and the EINECS number
(b) the quantity of the substance produced or imported
(c) the classification of the substance according to Annex I to Directive 67/548/EEC or the provisional classification according to the said Directive, including the class of danger, the danger symbol, the risk phrases and the safety phrases
(d) information on the reasonably foreseeable uses of the substance.

Step II: Priority Setting Article 8 of the regulation states that the commission, in consultation with the member states, will regularly draw up lists of priority substances which require immediate attention because of their potential effects to man or the environment. The commission and member states utilize the information collection during step 1 of the regulation as a basis for selecting priority substances. Since 1994, four such priority lists have been published (ECB).

Step III: Risk Assessment Substances on priority lists must undergo an in-depth risk assessment covering the risks posed by the priority chemical to people (covering workers, consumers, and people exposed via the environment) and the environment (covering the terrestrial, aquatic, and atmospheric ecosystems and accumulation through the food chain). This risk assessment follows the framework set out in Commission Regulation (EC) 1488/94 and implemented in the detailed technical guidance documents (TGD) on risk assessment for new and existing substances. The first draft of the risk assessment reports are written by the member states that act as "rapporteurs." The commission mediates the meetings, which attempt to reach consensus on the conclusions of the risk assessments. After adoption of the risk assessment, three publications are produced (ECB):

- The comprehensive risk assessment report as a book, on the ECB homepages and in the IUCLID
- A summary thereof as an EUR report and on the ECB homepages
- A listing of the conclusions in the Official Journal of the European Communities

Step IV: Risk Reduction As one of the potential conclusions, a risk assessment may conclude for a "substance of concern, further risk reduction meas-

ures, beyond those already in place, are required." In these cases, a risk reduction strategy must be developed. The elaboration of such a strategy is done utilizing the TGD on risk reduction. Directive 76/769/EEC on the restrictions in marketing and use of dangerous substances is one of the legal frameworks that could be invoked to manage the risks identified by the risk assessment (ECB).

The commission, in consultation with the member states, shall determine the cases in which it is necessary to request the manufacturers and importers of the substances declared in pursuance of paragraph 1 to submit additional information, in the framework of Annex III, on the physico-chemical properties, toxicity, and ecotoxicity of such substances, exposure, and any other aspect relevant to the risk evaluation of the substances. However, without prejudice to Article 12 (2), manufacturers and importers are not bound to carry out further tests on animals for that purpose.

The specific information to be submitted and the procedure to be followed for this submission shall be determined in accordance with the procedure laid down in Article 15.

Procedure for Data Reporting In the case of a substance produced or imported by several manufacturers or importers, the information referred to in Article 3 and Article 4 (2) may be submitted by one manufacturer or importer acting, with their agreement, on behalf of other manufacturers or importers concerned. The latter shall nevertheless submit to the commission the information specified in points 1.1 to 1.19 of the data set laid down in Annex III and, in doing so, shall make reference to the data set submitted by the manufacturer or importer.

In submitting the information referred to in Article 3 and in Article 4 (1), the manufacturers and importers shall use only the special software package on diskette made available free of charge by the commission. Member states may provide that manufacturers and importers established in their territory shall be required to submit simultaneously to their competent authorities the same information as that forwarded to the commission pursuant to Articles 3 and 4.

On receipt of the data referred to in Articles 3 and 4, respectively, the commission shall forward copies to all the member states. Manufacturers and importers who have submitted information on a substance in accordance with Articles 3 and 4 shall update the information forwarded to the commission. In particular, they shall submit, where appropriate:

(a) New uses of the substance that substantially change the type, form, magnitude, or duration of exposure of people or the environment to the substance.
(b) New data obtained on the physico-chemical properties or toxicological or ecotoxicological effects where this is likely to be relevant to the evaluation of the potential risk presented by the substance.

(c) Any change in the provisional classification under Directive 67/548/EEC.

They shall also be required to update the information regarding the production and import volumes referred to in Articles 3 and 4 every three years, if there is a change in relation to the volumes specified in Annex III or Annex IV.

Any manufacturer or importer of an existing substance that acquires knowledge that supports the conclusion that the substance in question may present a serious risk to people or the environment shall immediately report such information to the commission and to the member state in which it is located. Upon receipt of the data referred to in paragraphs 1 and 2, the commission shall submit copies thereof to all the member states.

Current Status Since adoption of the 7th Amendment of the directive, more than 800 notifications were submitted with a risk assessment report completed by the competent authority. Most substances, about 56%, were of no immediate concern. Thirty-four percent of the notifications with a risk assessment report, the need for further information was seen, either when the next tonnage trigger is reached (about 20%) or immediately (about 14%). In about 10% of the cases, the competent authorities considered the substance of concern and risk reduction measures were required. However, the proposed measures covered a wide range of quite different actions. Simple risk reduction measures included modifications, for example, to the classification and labeling of the substance, to the SDS, or to the recommended methods and precautions. Some substances were withdrawn from the market by a voluntary agreement of the notifier and for a number of substances restrictions of marketing and use (Directive 76/769/EEC) are under discussion. Over 5300 notifications in total, representing more than 3200 substances, have been submitted since 1981.

2.3.2 REACH Program

Working with various stakeholders, the EU Commission is currently developing new legislation for the management of chemicals—the Registration, Evaluation and Authorization of CHemicals (REACH) program. The following is a brief summary of key elements of the current proposal:

The schedule for legislation was a follows:

- EU Commission white paper (achieved in February 2001)
- Council conclusion (achieved in June 2001)
- Parliament resolution (achieved in October 2001)
- EU Commission working group outcome (achieved in February 2002)
- Draft legislation (achieved in the spring of 2003)

Key elements of the proposed program include the following:

- All chemicals substances that are produced or imported in excess of 1 ton per year and risks assessed within 10 years; it is the responsibility of the producers and commercial users to provide this information. Producers and users of chemicals, at different stages of the supply chain, will be made collectively responsible for prevention of risks throughout the whole life cycle.
- For chemicals of very high concern, the chemical will be taken off the market unless the producer/user can prove that the need for the product (through a socioeconomic analysis) and/or prove negligible risk.
- Animal testing will be avoided where the information requirement can be met by other means.
- Independent evaluation of the registration dossier will be incorporated into the system. If the chemicals are produced or imported in excess of 100 tons per year, government agency will carry out the evaluation. The authorities will also evaluate chemicals below the 100 tons per year threshold if there is a concern.
- Improved communication up and down the supply chain in order to link hazard information to exposure information and risk evaluation.
- More hazard and risk-related information should be made publicly available.

The key potential dates for activities are as follows (Harvey, 2001):

- Registration
  - All substances >1000 tons by the end of 2005
  - All substances >100 tons by the end of 2008
  - All substances >1 ton by the end of 2012
- Evaluation
  - Substances >1000 tons by 2008
  - Substances >100 tons by 2012

2.4 PACIFIC RIM REQUIREMENTS

2.4.1 China

Management Regulation on Registration of Hazardous Chemicals (Decree No.19) was issued by the State Economic and Trade Commission (SETC) on September 11, 2000, and came into effect on October 1, 2000, according to the Safety Management Regulation on Hazardous Chemicals. The regulation aims to strengthen the safety management of hazardous chemicals and to control

chemical risks. The State Chemical Registration Center is assigned by the SETC to be in charge of technical issues, including registration and consultation.

The hazardous chemicals covered by regulation are listed in the Classification and Labels for Commonly Used Hazardous Chemicals (GB13690-1992). The registration's main contents include products labeling, physical characteristics, exposure characteristics, fire fighting measures, stability, feasibility, health risk, emergency response measures, operational handling, protection measures, and emergency response to leakage.

Enterprises that apply for registration shall fill out the Registration Application Form for Hazardous Chemicals, in compliance with the General Rules to Drafting Safety Data Sheet for Chemicals (GB16483-2000) and General Rules to Drafting Safety Labels (GB15258-1999).

A certificate for hazardous chemicals will be issued after registration. Enterprises are not allowed to manufacture and/or use these materials without these certificates. Enterprises cannot sell their products without the registration certificates and safety labels (one label for each certificate). A fine of up to RMB 30,000 (RenMinBi is the official Chinese currency), which is roughly $3600 USD, shall be imposed on enterprises found to be in violation of the regulation. Local governments are authorized to shut down the enterprises in the event of violation accidents.

"Regulations for Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals" had already been implemented for five years since May 1, 1994. According to Article 11 of the regulations, "The registration for environmental management on chemicals, obtained by a foreign business concern or its agents for their first export of chemicals to China, shall be valid for five years. If there is need to extend the registration before its expiration, the original applicant must apply for registration to renew its certificate six months before the date of expiration."

Under Chapter III, on registration and management, multiple articles are available, as seen in other regulations before. The following is an overview of some relevant articles.

Article 9—When foreign business concerns or their agents are exporting to China any chemicals (except for pesticides) that have not been registered in China, they must

- apply to the NEPA for Registration of Environmental Management on the First Import of Chemicals
- fill in the application Form for Registration of Environmental Management on the First Import of Chemicals
- provide samples for experiment (in quantities generally not less than 250 grams) free of charge

Registration and management for the first sale of pesticides to China by foreign business must be made in accordance with Registrations for Regis-

tration of Pesticides. The Ministry of Agriculture and the NEPA shall regularly exchange registration information.

Article 10—If an application conforms to the provision for registration of environmental management, NEPA will approve the application and issue a registration certificate permitting the import of chemicals. If a chemical is not deemed fit for import to China, registration shall not be permitted and a certificate shall not be issued. Applicants shall receive notification of this. If, upon examination, it is considered that a first import of chemicals must undergo further tests and a fairly long period of observation before its hazard can be determined, a temporary registration may be granted and a temporary registration certificate issued. It is not permitted to import chemicals for which a registration certificate for environmental management on import of chemicals or a temporary registration certificate has not been granted.

Article 11—The registration for environmental management of chemicals, obtained by a foreign business concern or its agents for their first export of chemicals to China, is valid for five years. If there is need to extend the registration before its expiration, the original applicant must apply for registration to renew its certificate six months before the date of expiration.

Temporary registration is valid for one year. It must be reconfirmed whether or not formal registration shall be permitted before expiration of the validity period. Under special circumstances, extension can be made upon approval of registration authorities. The period of extension may not exceed one year.

Article 12—If foreign business concerns or their agents export to China, or domestic businesses import from abroad, industrial chemicals or pesticides included in the list, they must apply in advance to the NEPA for registration of environmental management on import of toxic chemicals. The Registration Certificate for Environmental Management on the Import/Export of Chemicals and the clearance notification for environmental management on the import (export) of toxic chemicals (hereinafter referred to as the "clearance notification") shall be issued to them upon approval. The clearance notification is issued each time for each import/export of chemicals in the list. Each clearance notification can only be used for customs declaration once within its valid date.

Article 13—If an organization wants to export chemicals that are included in the list, it should apply to the NEPA for the registration of environmental management on the export of toxic chemicals. The NEPA, after accepting the application, shall notify the responsible department of the importing country, and, after receiving notification of import permission from the responsible department of the importing country, shall issue the Registration Certificate for Environmental Management on the Import/Export of Chemicals, allowing the applicant to export toxic chemicals. No registration shall be issued and no chemical export shall be allowed without permission from the responsible department of importing country. The applicant shall be duly notified of this.

Article 14—The Registration Certificate for Environmental Management on the Import/Export of Chemical, which is signed and issued by the NEPA, shall be stamped with the seal of the People's Republic of China NEPA, thereby denoting approval of the registration request. A green Registration Certificate of Environmental Management on the Import/Export of Chemicals applies to import or export toxic chemicals included in the list by local businesses. A pink certificate applies to foreign business concerns or their agents for the first export of chemicals to China; a temporary certificate is white.

Article 15—The Clearance Notification for Environmental Management on the Import/Export of Toxic Chemicals is issued to applicant for customs declaration. A copy of the clearance notification must be kept by NEPA and a copy sent to the State Administration of Import and Export Commodity Inspection of the People's Republic of China.

Article 16—The examination period of the application for the Registration of Environmental Management on the Import and/or Export of Chemicals is calculated from the date after receiving the application, which conforms to the requirement of registration. The period of examination of the application for registration of the first import of chemicals cannot exceed 180 days. The period of examination for that of import and export of toxic chemicals included in the list cannot exceed 30 days.

Article 17—When examining and approving the application for the Registration for Environmental Management on the Import and Export of Chemicals, the NEPA has a right to address inquiries to applicants and to ask for related supplementary materials. The NEPA is supposed to maintain secrecy regarding technical matters connected with the materials and samples submitted with an application.

Article 18—NEPA will supervise the manufacture of standardized application forms for the Registration of Environmental Management on the First Import of Chemicals and on the Import and Export of Toxic Chemicals; the Registration Certificate and Temporary Registration Certificate for Environmental Management on the Import and Export of Chemicals; and the Clearance Notification of Environmental Management on the Import and Export of Toxic Chemicals.

Existing Chemical Substances in China In order to strengthen the environmental management of chemical substances, implement the regulation of chemical pollution prevention, perfect the system and measures of environmental management of chemical substances, and achieve equivalency with the international chemical management principles, the Chemical Registration Center of the State Environmental Protection Administration (SEPA) manages the compilation and supplement of the Inventory of the Existing Chemical Substances in China. This regional center receives its authority from SEPA. Chemical substances that are included in the inventory are managed by the regulations of the existing chemical substances. Chemicals that are not

included in the inventory are regarded as new chemical substances and must be managed by the regulations of the new chemical substances. A supplement of the inventory is produced periodically to cover the chemical substances that have been manufactured, used or sold in China, or imported into China. The requirements for details are as follows:

1. Chemical substances that have been manufactured, used, or sold in China, or imported into China from January 1, 1992, to December 31, 2001, are acceptable.
2. Applicants can be the manufacturer, user, seller, or importer or those who export chemical substances to China.
3. The supplement for the inventory will be based upon the Inventory of Existing Chemical Substances in China 2000 (China, 2000). Chemical substances that have not yet been included in this publication must apply, whereas those that are in the inventory need not apply.
4. The Technical Document on Reporting for the Inventory of the Existing Chemical Substances in China (English Version) provides the requirements of the last supplement.

2.4.2 Australia

The Australian Inventory of Chemical Substances (AICS) is the legal document that distinguishes new from existing chemicals. AICS is a listing of all industrial chemicals in use in Australia between 1 January 1977 and 28 February 1990. In addition, it includes newly assessed chemicals and corrections as required.

The AICS is maintained under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and contains over 38,000 chemicals that are used in Australia. The AICS is a list of chemical identity data; it does not contain information on toxicity, use, manufacturers, or importers. It consists of a nonconfidential (public) section and a confidential section.

Any chemical not included in AICS is regarded as a new industrial chemical unless it is outside the scope of the Industrial Chemicals (Notification and Assessment) Act 1989 and its amendments or is otherwise exempt from notification. New industrial chemicals must be notified and assessed before being manufactured or imported into Australia.

Existing Chemicals Existing chemicals are those industrial chemicals available for use in Australia. They include all the chemicals that are listed on the AICS. Due to their large number (over 38,000), NICNAS assesses existing chemicals on a priority basis in response to concerns about their health or environmental effects, or both (Australia, 2003).

Any person or organization with a concern about the public health, occupational health and safety, or environmental effects of an industrial chemical

may nominate it for assessment. Recommendations on the safe use of these chemicals are made in the reports. Refer to the assessment reports on priority existing chemicals (PECs) that are available on the NICNAS Web site. NICNAS also has a series of safety information fact sheets for use in the workplace (ALII, 2003).

A full PEC assessment aims to find out the risks (if any) to workers, members of the public, or the environment of importing, manufacturing, using, storing, handling, or disposing of a chemical, or a group of chemicals. It will recommend ways to reduce any risks and may take into account all uses of the chemical, or only specified uses (ALII, 2003).

Less detailed assessments, known as "preliminary assessments," aim to provide information on particular aspects of a chemical, such as its properties, uses to which it is put, any adverse effects on persons or the environment that the chemical has the intrinsic capacity to cause, or the extent to which persons or the environment are or will be exposed to the chemical (ALII, 2003).

The publication of assessment reports provides a basis for informed and scientifically based regulatory and other action on the chemicals that have been subject to assessment. The six-step review process includes the following (ALII, 2003):

- nomination
- screening and information gathering
- declaration
- assessment
- public comment
- outcomes

New Chemicals Based on information supplied by the importer or manufacturer, NICNAS produces an assessment report with recommendations for safe use of the chemical. The Australian government bodies then issue a certificate or permit to the importer or manufacturer with conditions to ensure safe use of a new industrial chemical. Full details of how to notify NICNAS are contained in the NICNAS Handbook for Notifiers and are available for downloading from their Web site (Australia, 2003).

The registration process operates for the priority on existing chemicals. This way the cost of investigating health and environment issues to the benefit of those using the chemicals is spread across industry. Under company registration, NICNAS maintains a Register of Industrial Chemical Introducers. NICNAS company registration specifically applies to the introduction of relevant industrial chemicals. NICNAS definition of "introducing a chemical" is either importing a chemical into Australia or manufacture the chemical there (Australia, 2003).

If a company imports and/or manufacturers relevant industrial chemicals or products containing relevant industrial chemicals (the total value of these

chemicals exceeding $500,000 in that year), they must register with NICNAS. The annual registration is from September 1 to August 31. Normally, registration is made in advance, by August 1, that is, before the start of the registration year. Registered companies cover a wide range of business activities, like printing, distributing business machines, cosmetics and plastic resins, manufacturing automotive parts, formulating paints, packaging, and chemicals wholesaling (Australia, 2003).

There are two levels of registration: lower and upper. Your registration level, and hence registration cost, is based on the total value of relevant industrial chemicals imported and/or manufactured each year. If you import or manufacture less than $500,000 per year, you are not required to register. If you import or manufacture more than $500,000 but less than $5,000,000, then the annual registration cost should be roughly of $1200. If you have more than $5,000,000, then the cost should be of roughly $7000 (Australia, 2003).

If you are registered at the lower level, you are obliged to submit a final statement of introduction to NICNAS after the registration year has ended. In September each year, NICNAS will send you a form for this submission. In your statement you will need to indicate the total value of chemicals actually introduced in the year. The purpose of this exercise is to confirm that you were registered at the appropriate level. You have until October 31 to return this statement to NICNAS. A refund of $900 will be provided to the registered if the total introductions are confirmed to be under the registrable threshold. The $300 administrative component of the registration fee is not refundable. If it turns out that you are above the $5,000,000 threshold, this means that the registered have introduced $5,000,000 or more of relevant industrial chemicals, you will have to upgrade your registration and pay an additional amount of $5800. The registered will have to keep for five years all records relating to the introductions that are necessary to calculating the registration charge payable (Australia, 2003).

If you are registered at the upper level, the above requirements in relation to the final statement do not apply to you as you are entitled to unlimited introductions (Australia, 2003).

Registrations are renewed on an annual basis. In July each year, NICNAS will send a reminder and renewal form. The registered simply has to complete the form and return it to NICNAS with the necessary payment. They have until August 1 of each year to renew their registration (Australia, 2003).

A registrable company that does not register is in breach of the act. The act allows NICNAS to prevent an offending company from introducing any chemicals until it has met the requirements of the act. NICNAS believes in achieving compliance through information dissemination and working cooperatively with industry (Australia, 2003).

Companies may therefore be subject to audits from time to time, and may be required to justify the determination of their value of introductions. The relevant provisions for the company registration program appear in Section 80 of the act. These became operational in July 1997. The act can be accessed

via the Australasian Legal Information Institute Web site or SCALEplus Web site of the Australian Attorney General's Department (Australia Attorney General, 2003).

2.4.3 Philippines

The Philippine government is devoting significant resources to the control of new industrial chemicals that play a role in providing higher living standards. Republic Act 6969 (RA 6969) came into effect January 1, 1994, under the administration of the Department of Environment and Natural Resources (DENR). Title II requires notification by way of a technical data package to the DENR for chemicals not included in the country chemical database or the Philippine Inventory of Chemicals and Chemical Substances (PICCS), whether imported or manufactured locally (ACC, 2003).

The PICCS is a list of chemicals in commerce by December 31, 1993. Those not listed (with some exemptions) are defined as new chemicals, the entry of which into commerce either through importation or manufacturing in the country requires appropriate notification to DENR. An orientation manual on the implementing rules and regulations of RA 6969 was published to give specific guidance on the notification process and data requirements (ACC, 2003).

DENR considers PICCS to be the final version. However, there are still omissions and errors. Despite the fact that many chemicals met the criteria for inclusion, and were properly nominated to PICCS on time, they have been omitted. This situation results in costly and time-consuming notification for chemicals that have legally been on the Philippine market for many years (ACC, 2003).

Multiple industries are asking that a period be made available within one year to allow corrections and resubmission of any missing substances should be from the original nominations. New substances placed on the market since the 1994 enactment of RA 6969 and publication of PICCS in 1999 should be granted "transitional" status and be added to inventory at the next update without having to be notified (ACC, 2003).

Industry supports DENR strategies for R&D to stimulate innovation. The exemption from notification allowed for quantities at less than 1000 kg but as yet has not been adopted into law. There is no procedure to apply for quantities greater than 1000 kg per year for R&D purposes. In the United States, for instance, there is no maximum quantity for the R&D exemption; instead, quantities used must be "not greater than reasonably necessary for R&D purposes." The U.S. EPA recognizes that the amount of material required for legitimate R&D varies considerably depending on the category and use of the substance, and the nature and stage of R&D activities (ACC, 2003).

A major problem facing industry is that confidential information will seemingly have to be handled by agents or even potential customers. This has significant implications to precommercialized products and may deter the introduction of the new products or technologies into the Philippines.

For chemicals already in use in another country with a review process similar to the Philippines, an abbreviated form may be used to submit data. Polymers are included in PICCS and notification is required unless exempted. Polymers are high molecular weight compounds that do not cross biological membranes and are generally considered to be safe. For this reason, under U.S. law, the review period on notifications of new polymers is 21 days rather than 90 days. The test requirements under RA 6969 for chemical substances (non-polymers) are not appropriate for polymers, and often technically impossible to conduct on polymers (ACC, 2003).

Section 15 of RA 6969 already requires the submission of a greater amount of data than is required in many other countries. More data are required if the chemical has not been reviewed in another country or if the manufacturer or importer cannot adequately document the safety of the new chemical used elsewhere. Recent guidance for testing new chemicals goes far beyond that published in the IRR. If additional data are required, RA 6969 will effectively prevent the introduction of new and safer technology in the Philippines. Experience has shown that some submissions have been under review for nearly four years. More and more industries request that a notification be considered approved if no concerns have been raised within the review period unless DENR notifies the requester prior to expiration of the 90-day period that additional time (a reasonable period only) is required to further assess the chemical (ACC, 2003).

2.4.4 Korea

The Toxic Chemicals Control Law (TCCL) regulates the manufacture and import/export of virtually all chemicals. Chemicals are defined as "elements and substances created by chemical reaction" and are classified into four groups by the degree of hazards:

- toxic chemicals
- prohibited/restricted chemicals
- observational chemicals
- other chemicals

The TCCL strictly regulates the manufacture and import/export of the regulated chemicals (i.e., toxic chemicals, prohibited/restricted chemicals, and observational chemicals). The TCCL requires that any business entity that manufactures, distributes, holds, stores, or transports the toxic chemicals register with the Ministry of Environment (MOE), except that such registration is not required for handling of toxic chemicals in an amount less than 240 tons per year or experimental usage of such chemicals. The MOE may prohibit or restrict the manufacture, import, or use of chemicals that are severely harmful to human health and the environment, and 55 chemicals are prohibited for this reason.

For the restricted chemicals, a business entity that intends to manufacture, use, import, or export such chemicals must obtain the permit for such business from the MOE, and for the observation chemicals, annual amount for manufacture or import must be reported. Such business entities must keep records related to the appropriate business activities. The presence of toxic chemicals must be identified on the containers or cases, at the place where they are stored or displayed, and on the transporting vehicles. The TCCL imposes premanufacture/import notification requirements on persons handling new chemicals. Further, before they are manufactured or imported, such chemicals must pass a toxicity review administered by the MOE.

Existing Chemicals List Under the TCCL, the "existing chemicals list" refers to the list of the chemicals that had been distributed domestically and commercially prior to the effective date (February 2, 1991) of the TCCL. Under the ISHL, "existing chemicals" means the chemicals listed on the "existing chemicals list" among the chemicals that are not subject to toxicity review under Article 40 of the law or the chemicals whose names had been proclaimed by the administrative organizations that enforce other laws prior to June 30, 1991. The MOE published the existing chemicals list in February 1991 under the TCCL, and also the MOL published the existing chemicals list in December 1993 under the ISHL, respectively. In December 1996, the combined existing chemicals list was published for users' convenience. Access to the existing chemicals list is available via Publication, STN or CHEMLIST online DB (of CAS), CAS Surveyer CD rom (of CAS) or Atrion International RegDB Online. The composition of the existing chemicals list is as follow:

- A total of 35,661 chemicals are listed in alphabetical order, with each chemical being described by its KE serial number (KE No.), chemical name, CAS registry number, and molecular formula.
- CAS registry numbers indexes the existing chemicals list. The CAS registry number can be used to assess if a chemicals is listed or not listed.
- International Union of Pure and Applied Chemistry (IUPAC) names.
- Chemical Abstracts (CA) names or the common names used internationally are listed.

New Chemical Notification At present, a person and/or a company who intends to manufacture or import the new chemical must file the new chemical notification with the National Institute of Environmental Research ("NIER"). The Korean MOE and Ministry of Labor (MOL) have delegated its authority for the toxicity review of new chemicals. The review period is a maximum of 45 days for the two procedures. This duplicating submission requirement to the MOL and MOE have been changed by the amendment of the TCCL and the ISHL and the proposed amendment did unify the two procedures and designate the MOE as one channel for such application. Under

the TCCL, there are three types of notification: full notification, reduced notification, and polymer notification. The chemicals subject to the "reduced notification" refer to the chemicals that are listed on the chemicals list of two or more foreign countries (the European Union is regarded as one nation) prior to February 2, 1991. The "polymer notification" is applied to the chemicals that fall under OECD's polymer definition. For the polymer, the notifier may submit the "reduced notification," submitting the pertinent toxicity data or biodegradability test data.

For each notification type, in addition to application form, and information regarding exposure to the environment (i.e., route, released amount, etc.), the following test data are required:

Data Requirement for Notification Under the TCCL.

Reduced notification requires one of following sets:

- Acute oral test plus Ames test;
- Acute oral test plus chromosomal aberration test; or
- Biodegradability test

For polymer notification, the following are required:

- Number average molecular weight and GPC data
- Content (%) of low molecular weight species (lower than 1000)
- Amount of residual monomers
- Stability test in acidic and basic condition
- Monomers' identity, constitutional ratio (%) of monomers
- Full acute oral test plus Ames test plus chromosomal aberration test
- Notification plus biodegradability test

Under the ISHL New Chemical Notification the report form, MSDS, flow chart of manufacturing or use process, and matters for use and handling are required.

Confidentiality Claim. In case the notifier requests a confidentiality claim for the protection of information submitted to the NIER and the MOL, the authority protects the information from being disclosed to the public. Under the TCCL, the claimed information is protected for five years and under the ISHL, for three years. If an applicant wishes to extend the protection period, the applicant must request such extension prior to the expiration date of the protection period. The protection of chemical identity, testing data, use, and so on may be protected. However, the protection of information on chemicals of which chemical names are disclosed on the lists of foreign countries or on chemicals that are classified as the regulated chemicals from the toxicity review result is not granted.

Customs Clearance of Chemical Products. For customs clearance of chemical products, importers must have an "approval number" from a "confirma-

tion certificate" that is issued by the Korea Chemical Management Association (KCMA). In order to receive a confirmation certificate from the KCMA, the following two methods are available: The first method is for the applicant to submit the information on components disclosing all components of the imported chemical product and import-related document. The second method is for the applicant to submit an application, a "self-certification" in which no component is disclosed, and import-related documents. Upon KCMA's approval, the confirmation certificate is then issued. Where confidentiality of the components of the imported chemical product is to be protected, an applicant may directly send the information on components to the KCMA without any intermediary. Alternately, the applicant may also choose to employ the self-certification for the complete protection.

Further Direction. The MOE is currently considering an amendments to the TCCL. The purpose of the amendment is to strengthen chemical accident response system and information management system on chemicals, to improve the existing management system for hazardous chemicals and new chemical notification, and to establish a system to adopt international agreements and conventions. Following is a summary of major change related to the trade in the proposed amendment:

- The proposed amendment of TCCL states confirmation on the components of chemical products by manufacturer or importer (i.e., self-certification). A confirmation certificate can be issued and used according to their need.
- The MOE will also impose a duty for record keeping of documents pertaining to confirmation on chemical products, PMN (see earlier in this chapter for PMN definition), and so on on manufacturers and/or importers.
- Under the present system, a notifier must submit PMN to both the MOE and the MOL. The proposed amendment will unify two procedures and designate MOE as the only channel for PMN. Also, the Industrial Safety and Health Law of MOL also will be amended to reflect TCCL's amendment.

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3

MATERIAL SAFETY DATA SHEETS

3.1 INTRODUCTION

A Material Safety Data Sheet (MSDS), referred to as a Safety Data Sheet (SDS) in the European Union (EU) and parts of Pacific Rim, must be prepared and supplied with each regulated material used or manufactured in a workplace and, in many cases, accompany the actual shipment. Depending upon the jurisdiction, the document may have to be in the local language, contain specific information, for example, contents of the product and safe handling requirements, and require periodic update. It is important to note that MSDS are the second-most printed documents for a company, with the first being invoices and are viewed by some companies as a key document for marketing their products.

Figure 3.1 presents a summary of the local regulatory requirements pertinent to (M)SDS and the information contained within them, that is, the language a document is written in, information on product registrations and notifications and occupational exposure limits (OELs). Companies that ship or manufacturer their products globally must ensure that they are aware of these requirements and have translated them into a Material Compliance System—Information Systems (MCS-IS). Additional information on product registrations and notifications is presented in Chapter 2, and information on OELs is presented in Appendix 5.

In this chapter an overview of global (M)SDS legislation is presented along with country-specific requirements for key countries contained in the follow-

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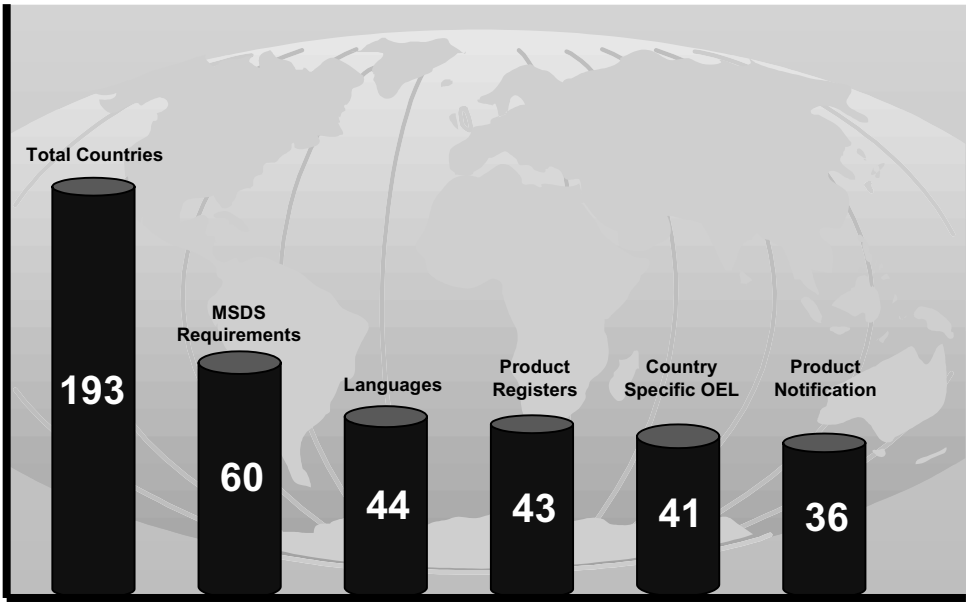

Figure 3.1. Local Regulatory Requirements.

ing geographic regions: North America, European Union, and Pacific Rim. Table 3.1 presents a summary of information on those countries that do have specific (M)SDS requirements.

3.2 GLOBAL MSDS REQUIREMENTS

As more manufacturers establish international operations and more countries establish regulatory requirements, better management of MSDS authoring and distribution is critical to avoid product refusals, entry denials, fines, and potential worker or consumer liability. Often overlooked are the potential impacts on schedule attainment, utilization, customer fill rates, and turns. In short, global management of MSDS is a must to ensure ongoing operational efficiency and competitiveness. More and more, MSDS and inventory screening are viewed as a critical portion of the product life cycle management (PLM) that helps any enterprise resource planning (ERP) system make proper decisions.

MSDS Formats In 1967, EU legislation required the preparation of SDS. In 1983, Germany published the first standard on SDS. The United States introduced OSHA Form-20 in 1985, a nine sections document, and Canada introduced its Workplace Hazard Management Information System (WHMIS), in ten sections. Both Canada and the United States adopted a 16-section ANSI

TABLE 3.1. Summary of Localized MSDS Requirements*

Country Name	Classification and Labeling**	(M)SDS	Pertinent Legislation	Specified (M)SDS Languages
Australia	NOHSC	Currently being revised (EU approach)	National Code of Practice for the Preparation for the Preparation of MSDS-NOHSC: 2011(1994)—currently being revised 2011(2003 with enforcement in 2006. Standard for the Uniform Scheduling of Drugs and Poisons #15 2000; Approved Criteria for Classifying Hazardous Substances NOHSC: 1008(1999); List of Designated Hazardous Substances NOHSC: 10005(1999)	English
Austria	EU DSD & DPD implemented	EU SDS	ChemG 1996; ChemV 1999; Gift informations -Verordnung 1999	German
Belgium	EU DSD & DPD implemented	EU SDS	See EU	Dutch, French
Canada	WHMIS	Combination of US and EU (9 &16)	Hazardous Product Act; Controlled Products Regulations 1987; Workplace Hazardous Materials Information System (WHMIS) 988; Canadian Environmental Protection Act CEPA 1988–2000	English, French
China	GB13690-92 (1999)	GB16483-2000 (ISO approach)	Regulations for Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals 1994; Classification and Identification of	Chinese, simplified

TABLE 3.1. ***Continued***

Country Name	Classification and Labeling**	(M)SDS	Pertinent Legislation	Specified (M)SDS Languages
			Common Hazardous Chemicals GB 57-92; General Rules to Drafting a Chinese Safety Data Sheet for Chemicals (GB16483-2000)	
Czech Republic	EU DSD & DPD implemented	EU SDS and localized legislation	Law on Chemical Substances and Chemical Preparations 157/1998 Coll. & 352/1999 Coll. 2000; Gov. order No. 25/1999 Coll. Dealing with classification of chemical substances and preparations	Czech
Denmark	EU DSD & DPD implemented	EU SDS	See EU	Danish
Estonia	EU DSD & DPD implemented	EU SDS and local legislation	Chemicals Act 339/98 1998; Regulation MOSA on rules for classification, packaging and labeling of dangerous chemicals #64 1998; Regulation MOSA on classification of dangerous preparations 2000	Estonian
European Union	EU DSD & DPD implemented	Directive 91/155/EEC & 2001/58/EC	Dangerous Substance Directive (DSD)——67/547/EEC and 28th ATP—2001/59/EC, Dangerous Preparation Directive (DPD)—1999/45/EC and 1st ATP—2001/60/EC, Safety Data Sheet (SDS) Directive—2001/58/EC	EU member languages
Finland	EU DSD & DPD implemented	EU SDS	See EU	Finnish, Swedish

TABLE 3.1. ***Continued***

Country Name	Classification and Labeling**	(M)SDS	Pertinent Legislation	Specified (M)SDS Languages
France	EU DSD & DPD implemented	EU SDS	See EU	French
Germany	EU DSD & DPD implemented	EU SDS	See EU	German
Greece	EU DSD & DPD implemented	EU SDS	See EU	Greek
Hungary	EU DSD & DPD implemented	EU SDS and local legislation	Chemical Safety Act 2001; Governmental Decree on regulation of the procedure of dangerous substances and preparations 233/1996 1997; Decree Min. Welfare /1997 on the execution on Gov. Dec. 233/1996 on the Procedure Pertaining to Dangerous Substance and Dangerous Preparation; Law on Protection from the Harmful Impact of Chemical Substances, Preparations and Products 2002; Publ. Act. XXV 2000.	Hungarian
Ireland	EU DSD & DPD implemented	EU SDS	See EU	English
Italy	EU DSD & DPD implemented	EU SDS	Legislative Decrec of July 16, 1998, no. 285. Directive regarding classification, packaging and labelling for dangerous preparation. Article 38 of April 24, 1998, no. 128.	Italian

TABLE 3.1. ***Continued***

Country Name	Classification and Labeling**	(M)SDS	Pertinent Legislation	Specified (M)SDS Languages
Japan	OSHL (Occupational Safety and Health Law	Japanese OSHL (16 sections)	Law concerning the examination and regulation of manufacture, etc. of chemical substances 1994–1987; Industrial Safety and Health Law (ISHL) 1979; Poisonous and Deleterious Substances Control (PDSC) Law; Fire Law; and several other lists and laws	Japanese
Latvia	EU DSD & DPD implemented	EU SDS and local legislation	Law on Chemical Substances and Chemical Products 1998; Order of Classification, Labeling and Packaging of Chemical Substances and Chemical Products #228 999; Order of Compilation and Supplying Safety Data Sheets (SDS) of Chemical Substances and Chemical Products #418 (1998, 1999)	Latvian
Lithuania	EU DSD & DPD implemented	EU SDS and local legislation	Regulation on labeling of goods to be sold in Lithuania MOE #137 1998; Draft Law on Chemical Substances and Preparations 2000–2002	Lithuanian
Luxembourg	EU DSD & DPD implemented	EU SDS	See EU	French, German
Malaysia	Directive 67/548/EEC	Local legislation that leverages EU/Australian approach	Occupational Safety and Health Regulations concerning Classification, Packaging and Labeling of Hazardous Chemicals 1998 and 1999	Bahasa Malay, English

TABLE 3.1. ***Continued***

Country Name	Classification and Labeling**	(M)SDS	Pertinent Legislation	Specified (M)SDS Languages
Mexico	SHMAT	SHMAT	NOM-114-STPS-1994 (C&L, MSDS); Environmental Protection General Law 1988; Chemical Regulation 1998; Reglamento Federal de Seguridad, Higiene y Medio Ambiente de Trabajo (SHMAT) (1997)	Spanish
Netherlands	EU DSD & DPD implemented	EU SDS	See EU	Dutch
Norway	EU DSD & DPD implemented	EU SDS	See EU	Norwegian
Poland	EU DSD & DPD implemented	EU SDS and local legislation	Act on Poisonous Substances 1963; Regulation on Chemical Substances entailing risk for health or life 1997; Draft Act on chemical substances and preparations 2000–2002	Polish
Portugal Portuguese —EU	EU DSD & DPD implemented	EU SDS	See EU	
Romania	EU DSD & DPD implemented	National Agency ANSPCP	Safety at Work and Safety Data Sheets, law #90/1996; Environmental Protection Act #137/1995; Toxic Products and Substances Regime, decree #466/1979	Romanian
Slovakia	EU DSD & DPD implemented	EU SDS and local legislation	Regulation on hygienic requirements on chemical substances and preparations 1986;	Slovakian

TABLE 3.1. ***Continued***

Country Name	Classification and Labeling**	(M)SDS	Pertinent Legislation	Specified (M)SDS Languages
			Gov. Decree on some poisonous and human health harmful substances #206/1988; Act on the protection of human health #272/94; Draft Act on Chemical Substances and Preparations 2000–2002	
Slovenia	EU DSD & DPD implemented	EU SDS and local legislation	Chemicals Act #36/99 1999	Slovenian
South Korea	TCCA	TCCA and ISHL (EU approach)	Toxic Chemicals Control Act TCCA 1991; NIER Publ. Not. #1997-2/3 Industrial Safety and Health Law (ISHL) 1997; MOL Publ. Not. #1997-27 (MSDS)	Korean
Spain	EU DSD & DPD implemented	EU SDS	See EU	Spanish —EU
Sweden	EU DSD & DPD implemented	EU SDS	See EU	Swedish
Switzerland	EU DSD & DPD implemented	EU SDS	Ordinance on substances (Osubst) 1986; Swiss poison law 1969; Verordnung über Sicherheitsdatenblätter für Gifte und umweltgefährliche Stoffe 1998	German, French, Italian
Thailand	HSA	HSA (ISO approach)	Hazardous Substances Act (HSA) 1992	Thai
Turkey	EU DSD & DPD implemented	EU SDS	Regulation regarding control over harmful chemicals and products thereof, 1993	Turkish
United Kingdom	EU DSD & DPD implemented	EU SDS	See EU	English

TABLE 3.1. ***Continued***

Country Name	Classification and Labeling**	(M)SDS	Pertinent Legislation	Specified (M)SDS Languages
United States	Yes	ANSI Z4001 (1985)	For MSDS, refer to by OSHA 29 CFR 1910. 1200 and ANSI Z400 and ANSI Z129.1	English

* The information above was compiled from a variety of sources during the winter of 2003 and has not been verified by government representatives. Readers should contact local government agencies (refer to Appendix 3 for Web Site) or consultants who regularly deal with the jurisdiction in question to obtain the most current status of the legislation. An up to-date listing of all government websites pertinent to material compliance activities is provided on the Atrion International Internet Site ‹http://www.atrionintl.com/›. Select the Atrion Exchange area and then register for the "ChemAware" tool which can be accessed free of charge.

** In the context of this table, "classification" and "labeling" means the results of the hazard assessment. Labeling is not defined as label that you apply to a container but rather the necessary information to rapidly identify the risk of a chemical.

Z400.1 MSDS that is similar to the EU 16-section document. These documents are now legal documents that contain detailed information, in some cases, more than the worker needs to know, that holds the companies and authors legally bounded to its content. The additional information was provided for experts to be able to make an informed decision when assessing exposure or emergency response.

MSDS typically are comprised of regulatory sections (considering the 16-section format: Sections 2, 8, 11, 14, and 15) and nonregulatory, often referred to as interpretative sections. Interpretative sections refer to sections whose requirements are not prescriptive under legislation, but rather it is up to professional judgment as per broad regulatory requirement. A good example would be Section 4, first aid, where no established rules have been defined and only guidelines are being followed. Professional judgment is used to write this section properly to protect all individuals who would use this product. Major guidelines exist in this section to address all routes of entry: ingestion, inhalation, skin contact, and eye contact.

Several organizations have published prescribed formats over the years for MSDS:

- EU (91/155/EEC), now replaced by 2001/58/EC.
- American National Standards Institute (ANSI Z400 and Z129.1).
- International Organization for Standardization (ISO) Safety Data Sheet for Chemical Products—Part 1, Standard 11014-1, first edition, 1994-03-15.
- Country-specific requirements (typically regulations and not standard).

The ISO 11014 standards was developed for worldwide application and follows the SDS model as outlined in EC Commission Directive 91/155/EEC defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations, and the United States Chemical Manufacturing Association (CMA) Interim guideline for the preparation of MSDS, with only minor deviations in the text of the section headings.

MSDS Distribution MSDS may have to be sent to customers at the same time of the shipment of the regulated material. More and more customers are now asking to receive their MSDS in advance so that they can incorporate this into their "new" chemical approval process. Companies are also using the MSDS information to identify whether a chemical could have potential danger to their workers or their work environment before even ordering the chemical.

In the early 1990s, MSDS were sent with each shipment. The result was the consumption of a significant amount of paper as these documents typically were six pages in length. In recent years, more and more companies send them electronically and refer their customers to their Web site. With the advent of electronic commerce, electronic data interface (EDI) standard was also proposed in the later 1990s without success. In the last few years there has been a promulgation of XML standards for MSDS or chemical information exchange. One organization that is active in this area is the Chemical Information Data Exchange (CIDX), which is trying to have the largest 500 companies use their standard. As companies are still trying to "push" their own specific EDI requirements, the potential for a common universally accepted standard diminishes. In addition, several countries are publishing specific requirements regarding XML, for example, Norway recently released its official XML base format for SDS and product registration. This standard is being closely reviewed by other Nordic countries and may be adopted after it has been accepted by industry.

Global Harmonization System At the Earth Summit in Rio de Janeiro in 1992, the United Nations Conference on Environment and Development (UNCED) agreed to develop "a globally harmonized hazard classification and compatible labeling system, including material safety data sheets and easily understandable symbols." This initiative has come to be known as the Globally Harmonized System (GHS). The United Nations Committee of Experts on the Transport of Dangerous Goods and Globally Harmonized System of Classification and Labeling of Chemicals (UNCETDG & GHS) has international responsibility for the GHS.

The following three organizations were identified as the focal point for the development of a harmonized classification system:

1. The Organization for Economic Co-operation and Development (OECD), which includes most industrialized nations as members, is coor-

dinating the development of health and environmental hazard classification criteria for pure substances as well as the classification criteria for mixtures.
2. The UNCETDG and the International Labor Organization (ILO) are coordinating the development of criteria for physical hazards.
3. The ILO serves as the Secretariat for overall coordination of the harmonization effort and hosts the hazard communication (labels, MSDS, training and trade secrets) working group.

Representatives from governments, industry, organized labor, and the international bodies listed above have reached consensus on technical components of the GHS, that is, harmonized classification criteria and hazard communication for the physical, health, and environmental properties of chemicals. With the exception of pharmaceutical and cosmetic products intended for consumer use, the scope of the harmonization is anticipated to encompass all chemicals and to include all sectors, that is, workplace, consumer, and transport. The GHS was supposed to be adopted by the UNCETDG & GHS in December 2002 and will then be available for countries to implement in 2003. To obtain the latest draft of the document, go to *http://www.unece.org/trans/danger/publi/ghs/draft_ghs.html*. Key agreements in the GHS document include the following:

- Classification criteria of substances and mixtures for human health and environmental effects (Part 3). The work on hazard classification for substances and mixtures has now been completed, and criteria have been developed for the following health and environmental endpoints: acute toxicity, skin irritation and corrosion, eye irritation and corrosion, mutagenicity, carcinogenicity, skin and respiratory sensitization, reproductive toxicity (including teratogenicity and embryotoxicity), target organ systemic toxicity (single and repeated dose), and aquatic toxicity.
- Classification criteria for physical hazards (Part 2). Criteria have been established for explosives, flammable gases, flammable aerosols, oxidizing gases, gases under pressure, flammable liquids, flammable solids, self-reactive substances, pyrophoric liquids, pyrophoric solids, self-heating substances, substances that, in contact with water, emit flammable gases, oxidizing liquids, oxidizing solids, organic peroxides, and substances that are corrosive to metals.
- The process by which GHS will be implemented by countries (or regions, such as the EU) has yet to be finalized. It is important to note that as organizations like the United Nations, or for that matter EU, move forward on standardizing MSDS, individual countries continue to add country-specific requirements.
- Based upon available information, it may be several years before the new GHS is fully (or partially) adopted in any country. These recommenda-

tions will be nonbinding and it will be up to the individual countries/EU to implement all or a portion of the GHS.

- The UN ECE published a press release in Geneva on 17 December 2002 regarding "A New Global Classification and Labelling System for Chemicals (GHS)" (UNECE, 2002). A new global system that is able to protect people from the mismanagement of chemicals, classify chemicals according to their hazard, and create a labeling system based on universally understandable pictograms has been adopted in Geneva. This system is now available for worldwide implementation.
- Through the different steps, from their production to their handling, transport and use, chemicals could be a real danger for human health and the environment. People of any age, from children to the elderly, using many different languages and alphabets, belonging to various social conditions, including illiterates, are daily confronted to dangerous products (hazardous chemicals, pesticides, etc); the youngest, poorest, and least educated are the most vulnerable.
- To face this danger, governments decided to harmonize existing communication systems on chemicals in order to develop a single, globally harmonized system to address classification of chemicals, labels, and (M)SDS. This was not a totally novel concept because harmonization of classification and labeling was already largely in place for physical hazards and acute toxicity in the transport sector, but had not been achieved in the workplace or consumer sectors. Moreover, transport requirements in countries were often not harmonized with those of other sectors in the same country.
- The GHS for the Labeling and Classification of Chemicals was adopted by the UN Committee of Experts on the Transport of Dangerous Goods and the GHS of Classification and Labeling of Chemicals (CETDG/GHS), an ECOSOC subsidiary body serviced by the UNECE secretariat, in Geneva after a decade of efforts and cooperation amongst a broad number of countries and organizations, notably the committee, ILO, and OECD under the umbrella of the Inter-Organization Programme for the Management of Chemicals (IOMC).
- The international mandate that provided the impetus for this work was adopted in the 1992 United Nations Conference on Environment and Development (UNCED), as reflected in Agenda 21, para. 19.27. In its Plan of Implementation (para. 22.(c)) adopted in Johannesburg on 4 September 2002, the World Summit on Sustainable Development encouraged countries to implement the new GHS as soon as possible with a view to having the system fully operational by 2008. Implementation has already started with pilot countries introducing the system in their national practices in different regions of the world.

Additional information on GHS is provided at the end of this chapter in Sections 3.3.2 and 3.7.

3.3 NORTH AMERICAN REQUIREMENT

3.3.1 United States Requirement

The U.S. regulatory approach to preparing MSDS relies on the following:

- A significant amount of professional judgment, whereas the EU approach is based upon prescribed level of hazards.
- Typically refers to Hazard Rating and Hazard Communications Hazard Evaluation rather than EU and Canadian systems of classification.
- The MSDS goes directly to the workplace. In the EU, a qualified individual transfers the information contained within the SDS into a Workplace Instruction Card.

Key requirements of the U.S. approach include:

- The system needs to be documented. The hazard rating, as well as the output of every section, must be explainable and justifiable.
- OSHA regulation (C.F.R. 29 Section 1910.1200) and ANSI standard Z400.1 for MSDS must be employed during the analysis.
- MSDS must be in English only.
- Data of all levels of the product (mixture) must be considered. If testing is done on intermediates, it must (legally and logically) be taken into account. The U.S. system emphasizes the testing of the finished product whenever possible for all physical properties such as corrosivity, flammability, and so on.
- Relevant data that were used to help classify the finished product, even if more complex than just specifying if a classification is applicable or not. For example, if a company has information showing that a component makes a mixture corrosive only when above 50% (instead of the prescribed cut-off of 1% of OSHA/ANSI), this data must be taken into account. The U.S. system emphasis is on testing the product whenever possible for all physical properties.

Content of an MSDS. Table 3.2 presents key requirements of a 16-section U.S. MSDS as recommended by OSHA 29 C.F.R. 1910.1200 and ANSI Z400 and ANSI Z129.1. The ANSI standards provide interpretation on how to implement the OSHA requirements. Additional information on each section presented in Table 3.2 can be obtained from OSHA 29 C.F.R. 1910.1200; however, the OSHA requirements leave considerable room for interpretation and workers require proper training to ensure they fully understand the hazards.

Other guidelines have been developed and are sometimes added to the U.S. MSDS in Section 16. As an example, the HMIS (Hazardous Material Information System) is a labeling system developed by the National Paint and

TABLE 3.2. Content for a U.S. MSDS

Section 1:

Identity used on label (exceptions for trade secrets)
Chemical Name (single substance)
Common Name (single substance)
Common name of mixture (tested mixture)
Date of MSDS preparation or last modification
Name, address, telephone number for additional information on material
Name, address, telephone number for additional information on appropriate emergency procedures

Section 2:

Chemical name ingredient contributing known hazard (tested mixture)
Common name ingredient contributing known hazard (tested mixture)
Chemical name of health hazardous ingredients (>1% or >0.1% carc) (untested mixture)
Chemical name of health hazardous ingredients (<1% or <0.1% carc) if there is evidence that OEL (OSHA or ACGIH) could be exceeded or present a health risk to employees (untested mixture)
Common name of health hazardous ingredients (<1% or <0.1% carc) if there is evidence that OEL (OSHA or ACGIH) could be exceeded or present a health risk to employees (untested mixture)
Chemical name of physical hazardous ingredients (untested mixture)
Common name of physical hazardous ingredients (untested mixture)
OELs—OSHA, ACGIH, and from manufacturer

Section 3:

Health hazards (not specified)
Signs and symptoms of exposure (specifically listed)
Medical conditions aggravated
Primary routes of entry
Carcinogenicity per NTP, IARC, or OSHA

Section 4:

Aid procedures

Section 5:

Potential for fire
Potential for explosion
Flash point (specifically listed)

Section 6:

Procedures for clean-up of spills and leaks

TABLE 3.2. ***Continued***

Section 7:
Generally applicable precautions for safe handling and use
Appropriate hygienic practices
Section 8:
Protective measures during repair and maintenance of contained equipment
Generally applicable control measures
Appropriate engineering controls
Work practices
Personal protective equipment
OELs—OSHA, ACGIH, and from manufacturer
Section 9:
Physical and chemical characteristics (not specified)
Vapor pressure (specifically listed)
Flash point (specifically listed)
Section 10:
Potential for reactivity
Section 11:
Toxicological information to humans and animals
Section 12:
Ecological information
Section 13:
Waste information
Section 14:
DOT transportation information (See Chapter 5 for more information regarding transportation regulations)
Section 15:
Federal information
State information (inventory listing)
International regulation (not required)
Section 16:
Other information the supplier would like to give on his product

Coatings Association (NPCA). The system uses a label with four color bars and a space at the top where the name of the chemical should be written. The blue, red, and yellow bars indicate, respectively, the health, flammability, and reactivity hazard associated with the material. These three bars use a numbering scale ranging from 0 to 4. A value of 0 means that the material poses essentially no hazard; a rating of 4 indicates extreme danger. Although the details of how numbers are assigned may vary somewhat between systems, this is essentially the same overall scheme as is used in the National Fire Protection Association (NFPA) system described below.

Note that the NPCA has copyrighted these guidelines and they have an exclusivity agreement for the distribution and use of their guidelines to a company called J.J. Keller, which requests a royalty fee to use this system.

The NFPA system, which consists of the colored diamond, uses almost the same numbering schema but refers to the danger of the chemical in presence of fire. Compared with the NPCA and J.J. Keller, NFPA can be used without any fee for copyright, if you make a request to them for the use of NFPA 49 Hazardous Chemicals Data, NFPA 325 Guide to Fire Hazard Properties of Flammable Liquids, Gases and Volatile Solids, NFPA 491 Guide to Hazardous Chemical Reactions, and NFPA 704-2001, Identification of the Hazards of Materials for Emergency Response.

Once you have the agreement in place, you will have to use a statement like "Reprinted with permission from NFPA 491 Guide to Hazardous Chemicals Reactions and Copyright ©1997, National Fire Protection Association, Quincy, MA 02269. This reprinted material is not the complete and official position on the National Fire Protection Association, on the referenced subject which is represented only by the standards in its entirety." Same kind of sentence applies for the other standards.

Ingredients Cut-off (Section 2). The different default cut-offs, level at which an ingredient needs to be disclose, are presented in Table 3.3. These values correspond to those prescribed by OSHA/ANSI:

- 100% for physical hazard (mixture should generally be tested)
- 0.1% for carcinogens
- 1% for all other hazard (health, irritation, etc.)

To specify that a hazard is not applicable, the default cut-off is always 100%. This is because it is risky to assume that a given hazard does not apply to a mixture on the basis that some of its components are known not to show this hazard (other untested components could present the hazard).

Cut-off for Hazard Classification (Section 11). Table 3.4 presents the cut-off values for classification of hazards: toxicity, target organs, carcinogenicity, and so on. The results of acute lethality tests are expressed in terms of the concentration of the chemical estimated to cause the death of 50% of the test organisms. This is referred to as the 50% Lethal Concentration (or the LC_{50} value). The LC_{50} value and its 95% confidence limits can be calculated or

TABLE 3.3. Ingredient Cut-Offs (Section 2 of MSDS)

Hazard List	Sub-Hazard	Cutoff
Toxicity by inhalation	Highly Toxic	1
	Toxic	1
	Not toxic	100
Toxicity by ingestion	Highly toxic	1
	Toxic	1
	Harmful	1
	Not toxic	100
Toxicity by skin contact	Highly toxic	1
	Toxic	1
	Harmful	1
	Not toxic	100
Corrosivity / irritation for skin	Severe corrosive	1
	Corrosive	1
	Severe irritant	1
	Irritant	1
	Moderate irritant	1
	Slight irritant	1
	Not an irritant	100
Corrosivity / irritation for lungs	Severe corrosive	1
	Corrosive	1
	Severe irritant	1
	Irritant	1
	Moderate irritant	1
	Slight irritant	1
	Not an irritant	100
Corrosivity / irritation for the eyes	Severe corrosive	1
	Corrosive	1
	Severe irritant	1
	Irritant	1
	Moderate irritant	1
	Slight irritant	1
	Not an irritant	100
Sensitizer for the skin	Severe sensitizer	1
	Sensitizer	1
	Not a sensitizer	100
Sensitizer for the lungs	Severe sensitizer	1
	Sensitizer	1
	Not a sensitizer	100
Target organs effects	Proven	1
	Possible	1
	Not applicable	100
Carcinogenicity	Proven	0.1
	Suspected	0.1
	Possible	0.1
	Not applicable	100
Mutagenicity	ANSI mutagen cat. 1	1

TABLE 3.3. ***Continued***

Hazard List	Sub-Hazard	Cutoff
	ANSI mutagen cat. 2	1
	ANSI mutagen cat. 3	1
	ANSI mutagen cat. 4	1
	Not applicable	100
Teratogenicity	Applicable	1
	Not applicable	100
Developmental toxicity	Applicable	1
	Not applicable	100
Explosibility	Highly explosive	100
	Explosive	100
	Not an explosive	100
Organic peroxide	Applicable	100
	Not applicable	100
Water reactivity	Applicable	100
	Not applicable	100
Pyrophoricity	Applicable	100
	Not applicable	100
Unstability	Applicable	100
	Not applicable	100
Flammability	Highly flammable	100
	Flammable	100
	Combustible	100
	Nonflammable	100
Oxidizer	Applicable	100
	Weak oxidizer	100
	Not applicable	100
Pressure hazard	Applicable	100
	Not applicable	100

determined graphically by plotting percentage mortality against chemical concentration.

3.3.2 U.S. Approach to GHS

The process of revising the U.S. hazard communication system toward the GHS has begun with the initiation of a working group to review and revise the ANSI Z400.1 Standard for Material Safety Data Sheets. The council is the ANSI (American National Standards Institute) secretariat for this standard, and is responsible for revising it every five years. The Z400.1 Standard is widely used by individuals responsible for developing and reviewing MSDS on materials and hazardous chemicals used and handled in the United States and subject to the Hazard Communication Standard. It has also become increas-

TABLE 3.4. Cut-off Values for Hazard Classification (Section 11 of MSDS)

Property	Influence Hazard	Value of Property	Degree of Hazard
LC_{50}—rat only, dust, 1 hour	Toxicity by inhalation	≤2 mg/kg	Highly toxic
		>2 ≤20 mg/kg	Toxic
		>20 mg/kg	Not toxic
LC_{50}—rat only, vapor or gas	Toxicity by inhalation	≤3000 ppm	Highly toxic
		>3000 ≤5000 ppm	Toxic
		>5000 ppm	Not toxic
LD_{50} by ingestion —rat only	Toxicity by ingestion	≤50 mg/kg	Highly toxic
		>50 ≤500 mg/kg	Toxic
		>500 ≤2000 mg/kg	Harmful
		>2000 mg/kg	Not toxic
LD_{50} by skin contact —rat or rabbit	Toxicity by skin contact	≤200 mg/kg	Highly toxic
		>200 ≤1000 mg/kg	Toxic
		>1000 ≤2000 mg/kg	Harmful
		>2000 mg/kg	Not toxic
Target organs	Target organs effects		Proven
			Possible
Carcinogenic classifications	Carcinogenicity	OSHA A1, NTP Known, IARC 1	Proven
		OSHA A2, NTP Reasonably Anticipated, IARC 2a or 2b	Possible
		OSHA A3, IARC 3	Suspected

ingly influential internationally, and a significant portion of the work involved in this current revision of the standard will entail ensuring its compatibility with international hazard communication systems and standards. The action team's goal is to ensure that the commitments made during the GHS negotiations to standardize SDS are reflected in the revised standard.

How OSHA or any other agency affected by the GHS will implement it, is an important question. OSHA has stated that it intends to keep the current scope and application of the OSHA hazard communication standard (HCS), including the jurisdictions (e.g., FDA, CPSC, waste) and all "interpretations and practical accommodations from the last 18 years." Although OSHA intends to keep the current framework, the standards for MSDS, product labels in the workplace, and classification will generally be changed to reflect the GHS. Whether this occurs through legislation or rulemaking remains to be determined by the U.S. government.

The GHS can ultimately achieve the promotion of sustainable development and the facilitation of international trade. Within this context it is recognized that chemical use is essential in many aspects of life, and that the safe use of chemicals is a prerequisite for the promotion of sustainable development. The aim of the GHS is to ensure consistency of hazard information and the safe handling and use of chemical products. If we are to achieve true global harmonization consistent with the objectives, we need a commitment by all countries to implement the GHS in a consistent manner.

On January 27, 2003, the Occupational Safety and Health Administration (OSHA) said that it is conducting a thorough review of its requirements for MSDS and is planning to report its findings publicly. The spokesman said the review is being conducted by OSHA's Directorate of Standards and Guidance and will be completed "later this year." One specific topic to be addressed in the review, according to the spokesman, is the Globally Harmonized System (GHS) of Classification and Labeling of Chemicals. GHS standardizes the definitions of key terms used in MSDS, such as flammability, which now vary from country to country, and will use pictograph warnings on MSDS, rather than simply words.

3.3.3 Canadian Requirements

Key differences in the Canadian MSDS versus the U.S. ANSI include the following:

Classification. The Hazard Communication Standard (HCS) hazard evaluation established by OSHA is mirrored by a system called Workplace Hazardous Material Information System (WHMIS) and is a blend of the EU and U.S. approaches. Mixtures are classified by criteria, calculated acute toxicity values, and "mixture rule" (1% cut-off or 0.1% for carcinogens, reproductive toxins, tetratogens, mutagenic to reproductive system, respiratory sensitizers). Also, the IARC carcinogen listing is used for classification but not for ingredient disclosure list.

Workplace classification includes six hazard classes:

A) Compressed gas
B) Flammable and combustible material
C) Oxidizing material
D) Poisonous and infectious material (acute inhalation endpoint is four hours versus one hour for OSHA)
E) Corrosive material
F) Dangerously reactive material

Regarding the transportation information, the U.S. DOT (Department of Transportation) regulation is different from the TDG (Transportation of Dangerous Goods). Again, this regulation is more in line with the UN regulation.

There is also an agreement between Canada and the United States on classification and labeling in both countries, it eases part of the process.

Hazard Symbols. The WHMIS regulation contains pictograms (hazard symbols) that identify the different danger associated with chemicals. In case of emergency, people can view and understand the danger associated with the material. Symbols (or pictogram) are available for each class that ranges from A, B, C, D1 (poisonous), D2 (toxic), D3 (radioactive), E, and F. For examples of these pictograms, please refer to Chapter 4 of this book, Labeling Requirements.

Sections. The Controlled Products Regulations (CPR) propose a nine-section MSDS, but the 16-section ANSI Z-400.1 format is acceptable provided the following statement is included: "This product has been classified according to the hazard criteria of the Controlled Products Regulations, and the MSDS contains all required information" and the MSDS contains all required information according to CPR. Federal and National lists and Occupational Exposure Limits are also available and supersedes any U.S. list in Section 15 of the MSDS.

Languages. A major difference in Canada is the language requirement of the MSDS. For any products that are sold to a government agency or to a company that have facilities in the Province of Quebec, the MSDS must be supplied in French and in English if requested. It is not true that all MSDS must come in, in both languages. Other provinces must have the MSDS in English and available in French if requested.

Trade Secrets. In order to classify an ingredient as a Trade Secret the following is required: up-front justification; significant fee for application; must be renewed every three years; and includes detailed review of MSDS and label.

Update. MSDS must be renewed and updated every three years or as soon as possible if any substantial change occurred within that period.

3.3.4 Mexican Requirement

Mexico is growing rapidly and it is starting to have a large and prosperous industrial economy. A significant portion of the population is not well educated and as such, the Mexican Ministry of Labor has promulgated a hazard communication system that places greater emphasis on training and instruction of the worker within the work place. Many components of the training requirements are considered more advance than U.S. or European hazard communication legislation. Workers are instructed to take protective action based on a simple system of numeric classification of danger.

The overall Mexican hazard communication system is based on a series of related but separate regulatory documents referred to as NOMs. The NOM that defines chemical hazard classification, and the requirements for MSDS and labels, is NOM-114-STPS-1994. Other NOMs establish other elements of a complete hazard communication program, for example, exposure limits for various chemicals are found in NOM-010-STPS-1994.

Material Safety Data Sheet Requirements The Mexican requirements for MSDS preparation should be quite familiar to those preparing a U.S. OSHA compliant MSDS or those following the requirements of the ANSI Guideline for the Preparation of Material Safety Data Sheets, ANSI Z400.1. Mexico has no specific format requirement, although the specification of data elements that are required is quite detailed. The U.S. OSHA specification of the MSDS is "performance oriented," meaning that the requirements for an acceptable MSDS are spelled out only in broad outline. The Mexican MSDS requirements are much more detailed to the guidelines laid out in the ANSI Z400.1 MSDS guidelines. Aside from the difference in detail, the most notable differences between the requirements of the OSHA Hazard Communication Standard, 29 C.F.R. 1910.1200 (g), and those specified in NOM-114 include the following:

- To provide the "degree of risk" for each hazardous component
- To provide the Immediately Dangerous to Life or Health (IDLH) value for each component
- Indication of whether the chemical is mutagenic
- Information on ecology

In addition, the Mexican MSDS must be in Spanish.

Health Effects Classification System In this system, an important element is the risk (hazard) severity value. These values are derived from a unique Mexican hazard classification system. In general, the health and flammability break points do not conform to U.S., EU, or the proposed harmonized health effects classification (refer to Section 3.7). Table 3.5 summarizes the different severity categories.

3.4 EUROPEAN SAFETY DATA SHEETS

The current 15 EU member states include Austria, Belgium, Denmark, France, Finland, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, and United Kingdom. In 2003, there is a potential of accession of ten new European countries and two other non-EU countries: Bulgaria, Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovakia, and Slovenia.

3.4.1 Overview of Labeling (Classification)

The EU approach to MSDS is more focused on prescribed levels of hazard compared to the United States approach that relies heavily on professional judgment. Article 27 of Directive 67/548/EEC (92/32/EEC) introduces the requirement for safety data sheets for substance, whereas Article 10 of Directive 88/379/EEC describes these for preparations:

TABLE 3.5. Mexican Severity Categories

Grade	Health	Fire	Reactivity
Severe risk, Grade 4	Oral LD_{50}: <20 mg/kg Dermal LD_{50}: <20 mg/kg Inhalation LC_{50}: <0.2 mg/L<20 ppm	Flash point <22.8 °C and boiling point <37.8 °C	Violently react or explode at room temperature
Serious risk, Grade 3	Oral LD_{50}: >20 to ≤50 mg/kg Dermal LD_{50}: >20 to ≤200 mg/kg Inhalation LC_{50}: >0.2 to ≤2 mg/L or>20 to ≤200 ppm	Flash point <22.8 °C and boiling point ≥37.8 °C; or flash point ≥22.8 °C to <37.8 °C	Violently react or explode at room temperature
Moderate risk, Grade 2	Oral LD_{50}: >50 to ≤500 mg/kg Dermal LD_{50}: >200 to ≤1000 mg/kg Inhalation LC_{50}: >2 to ≤20 mg/L or >200 to ≤2000 ppm	Flash point≥37.8 °C to <83.4 °C	Violent reaction at high temperature
Slight risk, Grade 1	Oral LD_{50}: >500 to ≤5000 mg/kg Dermal LD_{50}: >1000 to ≤5000 mg/kg Inhalation LC_{50}: >20 to ≤200 mg/L or >2000 to 10,000 ppm	Flash point >83.4 °C	Unstable at high temperature
Minimum risk, Grade 0	Oral LD_{50}: >5000 mg/kg Dermal LD_{50}: >5000 mg/kg Inhalation LC_{50}: >200 mg/L or >10,000 ppm	Does not burn	Stable

> To enable professional users in particular to take the necessary measures as regards the protection of the environment and health and safety at the workplace, at, or if appropriate, before the first delivery of a dangerous substance, any manufacturer, importer or distributor shall communicate to the recipient a safety data sheet. This sheet must contain the information necessary for protection of man and the environment.

Table 3.6 provides a summary of EU legislation pertinent to SDS. Key legislation includes the following (note that ATP refers to "Adapting to Technical Progress):

TABLE 3.6. Summary of EU Legislation Pertinent to SDS

Directive 91/155/EEC of 5 March 1991, OJ L 76 of 1991, amended by:

Directive 93/112/EC of December 10, 1993, OJ L 314 of 1993, and

Directive 2001/58/EC of 27 July 2001, OJ L 212 of 2001.

Annexes of DSD 67/548/EEC and its amendments:

- Annex 1—Provides a list of dangerous substances in order of the atomic number of the element most characteristic of their properties. The most recent adaptation is Directive 2001/59/EC of 6.VIII.01 (28th technical adaptation) OJ L 225 2001, p. 1.
- Annex 2—Symbols and indicators of danger. Most recent adaptation is Directive 2001/59/EC of 6.VIII.01 (28th technical adaptation) OJ L 225 2001, p. 1.
- Annex 3—Risk phrases, nature of special risks. Most recent adaptation is Directive 2001/59/EC of 6.VIII.01 (28th technical adaptation) OJ L 225 2001, p. 1.
- Annex 4—Safety phrases. Most recent adaptation is Directive 2001/59/EC of 6.VIII.01 (28th technical adaptation) OJ L 225 2001, p. 1.
- Annex 5—Test methods for determination of physicochemical, toxicological, and ecotoxicological properties listed in Annexes VII and VIII: Most recent adaptation is Directive 2001/59/EC of 6.VIII.01 (28th technical adaptation) OJ L 225 2001, p. 1.
- Annex 6—General classification and labeling requirements for dangerous substances and preparations. The most recent adaptation is Directive 2001/59/EC of 6.VIII.01 (28th technical adaptation) OJ L 225 2001, p. 1.
- Annex 7—Information required under Article 7(1) for the technical dossier ("base set"). The most recent adaptation is Directive 2001/59/EC of 6.VIII.01 (28th technical adaptation) OJ L 225 2001, p. 1.
- Annex 8—Additional tests and information required under Article 7(2). The most recent adaptation is Directive 2001/59/EC of 6.VIII.01 (28th technical adaptation) OJ L 225 2001, p. 1.
- Annex 9—Provisions relating to child-proof fastening and tactile warning devices: Directive 91/410/EEC (14th technical adaptation) OJ L 228 1991, p. 67.

- Dangerous Substance Directive (DSD)—67/547/EEC and 28th ATP—2001/59/EC
- Dangerous Preparation Directive (DPD)—88/379/EEC, replaced by 1999/45/EC and 1st ATP—2001/60/EC
- Safety Data Sheet (SDS) Directive—91/155/EEC, replaced by 2001/58/EC

The requirements of Directives 2001/59/EC and 1999/45/EC are intended to provide a primary means by which the general public and persons at work are given essential information about dangerous substances and preparations.

Under EU legislation, "labeling" refers to identification of the material as per the information listed below and not labels for packaging.

1) *Letter* assigned to the substance for Category of Danger, for example, "T" for Toxic, as per Annex II of the Directive 67/548/EEC.
2) *Risk (R) phrase(s)*, denoted as a series of numbers following the letter "R," indicating the nature of the special hazards. The numbers are separated by either a dash (-), to denote separate statements concerning special risks (R), or an oblique stroke (/), to denote a combined statement, in a single sentence, of the special risks as set out in Annex III.
3) *Safety (S) phrases*, denoted as a series of numbers following the letter "S," indicating the recommended safety precautions. The numbers are separated by either a dash or an oblique stroke; the significance of recommended safety precautions are set out in Annex IV. The safety phrases shown apply only to substances. S phrases for preparations are selected according to a series of rules discussed below.
4) *Concentration limits* are associated classifications necessary to classify dangerous preparations containing the substance in accordance with DPD (Directive 1999/45/EC)—disclosure limits for liquid/solid and gas and default cut-offs for liquids/solid and gas. Unless otherwise shown, the concentration limits are a percentage by weight of the substance calculated with reference to the total weight of the preparation. Where no concentration limits are given, the concentration limits to be used when applying the conventional method of assessing health hazards are those in Annex II, and when applying the conventional method of assessing environmental hazards are those in Annex III DPD—Directive 1999/45/EC (OJ L 200, 30.7.1999, p. 1).

Letter for Category of Danger (Annex II). The process of classification consists of placing a substance in one or more categories of danger (as defined in Article 2(2) of Council Directive 92/32/EEC (OJ L 154, 5.6.1992, p. 1)) and assigning the qualifying R-phrase or phrases. The classification for each category of danger is normally presented in the form of an abbreviation representing the category of danger together with the appropriate risk phrase(s).

In Table 3.7, the letters for each category of danger are presented as per Annex II (see Article 23(2)(c)). In some cases, such as substances classified as flammable or sensitizing and some substances classified as dangerous for the environment, the risk phrase by itself is used. Additional R-phrases that have been assigned to describe other properties (see R-Phrase section below) are shown although they are not formally part of the classification.

Risk Phrases (Annex III). Table 3.8 presents the list of R-phrases employed to classify material in accordance with Annex III (see Article 23(2)(d)). Also presented are the main criteria for each R-phrase. Depending upon the substance or preparation, combination of R-phrases may be used. Table 3.9 presents the combined R-phrases as per Annex III.

TABLE 3.7. Classification for each Category of Danger as per Annex II

Category of Danger	Letter
Explosive	E
Oxidizing	O
Extremely flammable	F+
Highly flammable	F
Flammable	—
Very toxic	T+
Toxic	T
Harmful	Xn
Corrosive	C
Irritant	Xi
Sensitizing	Xi Xn
Carcinogenic	T Xn
Mutagenic	T Xn
Toxic for reproduction	T Xn
Dangerous for the environment	N

Safety Phrases (Annex IV). Table 3.10 presents the list of S-phrases in accordance with Annex IV (see Article 23(2)(e)). Also presented are the main criteria for each S-phrase. The S-phrases shown in Annex IV apply to substances only. There are four types of S-phrases:

- obligatory—consumer
- obligatory—industrial
- recommended—consumer
- recommended—industrial

To determine the S-phrase for preparations, the following rules must be used:

- Mandatory S-phrases for certain dangerous substances and preparations sold to the general public.
- S1, S2, and S45 are obligatory for all very toxic, toxic, and corrosive substances and preparations sold to the general public.
- S2 and S46 are obligatory for all other dangerous substances and preparations sold to the general public other than those that have only been classified as dangerous for the environment.
- Safety phrases S1 and S2 are shown in brackets in Annex I and can only be omitted from the label when the substance or preparation is sold for industrial use only.
- S-phrase can be deduced from the symbol or the R-Phrase applicable to the substance or preparation.

TABLE 3.8. R Phrases with Summary of Main Criteria (as per Annex III)

R Phrase	Letter for C. of D.	Type	Criteria
R1	—	Physio/chemical	Explosive when dry For explosive substances and preparations put on the market in solution or in a wetted form, e.g., nitrocellulose with more than 12.6% nitrogen
R2	E	Physio/chemical	Risk of explosion by shock, friction, fire or other sources of ignition Substances and preparations except those set out in R3.
R3	E	Physio/chemical	Extreme risk of explosion by shock, friction, fire, or other source of ignition Substances and preparations that are particularly sensitive such as picric acid salts or PETN
R4	—	Physio/chemical	Forms very sensitive explosive metallic compounds For substances and preparations that may form sensitive explosive metallic derivatives (e.g., picric acid, styphnic acid)
R5	—	Physio/chemical	Heating may cause an explosion For thermally unstable substances and preparations not classified as explosive (e.g., perchloric acid >50%)
R6	—	Physio/chemical	Explosive with or without contact with air For substances and preparations that are unstable at ambient temperatures (e.g., acetylene)
R7	O	Physio/chemical	May cause fire Organic peroxides that have flammable properties even when not in contact with other combustible material For reactive substances and preparations (e.g., fluorine, sodium hydrosulphite)
R8	O	Physio/chemical	Contact with combustible material may cause fire Other oxidizing substances and preparations, including inorganic peroxides, which may cause fire or enhance the risk of fire when in contact with combustible material
R9	O	Physio/chemical	Explosive when mixed with combustible material Other substances and preparations, including inorganic peroxides, which become explosive when mixed with combustible materials (e.g., certain chlorates)

TABLE 3.8. ***Continued***

R Phrase	Letter for C. of D.	Type	Criteria
R10	—	Physio/chemical	Flammable Liquid substances and preparations having a flash point equal to or greater than 21 °C, and less than or equal to 55 °C
R11	F	Physio/chemical	Highly flammable Solid substances and preparations that may readily catch fire after brief contact with a source of ignition and which continue to burn or to be consumed after removal of the source of ignition Liquid substances and preparations having a flash point below 21 °C but which are not extremely flammable
R12	F+	Physio/chemical	Extremely flammable Liquid substances and preparations that have a flash point lower than 0 °C and a boiling point (or in case of a boiling range the initial boiling point) lower than or equal to 35 °C Gaseous substances and preparations that are flammable in contact with air at ambient temperature and pressure
R14	—	Physio/chemical	Reacts violently with water For substances and preparations that react violently with water (e.g., acetyl chloride, alkali metals, titanium tetrachloride)
R15	F	Physio/chemical	Contact with water liberates extremely flammable gases Substances and preparations that, in contact with water or damp air, evolve extremely flammable gases in dangerous quantities, at a minimum rate of 1 L/kg per hour
R16	—	Physio/chemical	Explosive when mixed with oxidizing substances For substances and preparations that react explosively with an oxidizing agent (e.g., red phosphorus)
R17	F	Physio/chemical	Spontaneously flammable in air Substances and preparations which may become hot and finally catch fire in contact with air at ambient temperature without any input of energy
R18	—	Physio/chemical	In use, may form flammable/explosive vapor-air mixture For preparations not classified as flammable, which contain volatile components which are flammable in air

TABLE 3.8. ***Continued***

R Phrase	Letter for C. of D.	Type	Criteria
R19	—	Physio/chemical	May form explosive peroxides For substances and preparations which may form explosive peroxides during storage (e.g., diethyl ether, 1,4-dioxan)
R20	Xn	Toxicological	Harmful by inhalation Acute toxicity results: LC_{50} inhalation, rat, for aerosols or particulates: $1 < LC_{50} \leq 5$ mg/L/4 hr; LC_{50} inhalation, rat, for gases or vapors: $2 < LC_{50} \leq 20$ mg/L/4 hr
R21	Xn	Toxicological	Harmful in contact with skin Acute toxicity results: LD_{50} dermal, rat or rabbit: $400 < LD_{50} \leq 2000$ mg/kg
R22	Xn	Toxicological	Harmful if swallowed Acute toxicity results: LD_{50} per oral, rat: $200 < LD_{50} \leq 2000$ mg/kg, discriminating dose, oral, rat, 50 mg/kg: 100% survival but evident toxicity, less than 100% survival at 500 mg/kg, rat oral by the fixed dose procedure. Refer to the evaluation table in the test method B.1 bis of Annex V, or high mortality in the dose range >200 to ≤ 2000 mg/kg oral, rat, by the acute toxic class method (for test result interpretation see flow charts in Annex 2 of test method B.1 tris of Annex V)
R23	T	Toxicological	Toxic by inhalation Acute toxicity results: LC_{50} inhalation, rat, for aerosols or particulates: $0.25 < LC_{50} \leq 1$ mg/L/4 hr; LC_{50} inhalation, rat, for gases and vapors: $0.5 < LC_{50} \leq 2$ mg/L/4 hr
R24	T	Toxicological	Toxic in contact with skin Acute toxicity results: LD_{50} dermal, rat or rabbit: $50 < LD_{50} \leq 400$ mg/kg
R25	T	Toxicological	Toxic if swallowed Acute toxicity results: LD_{50} oral, rat: $25 < LD_{50} \leq 200$ mg/kg Discriminating dose, oral, rat, 5 mg/kg: 100% survival but evident toxicity, or high mortality in the dose range >25 to ≤200 mg/kg oral, rat, by the acute toxic class method (for test result interpretation see flow charts in Annex 2 of test method B.1 tris of Annex V)
R26	T+	Toxicological	Very toxic by inhalation Acute toxicity results: LC_{50} inhalation, rat, for aerosols or particulates: ≤0.25 mg/L/4 hr; LC_{50} inhalation, rat, for gases and vapors: ≤0.5 mg/L/4 hr
R27	T+	Toxicological	Very toxic in contact with skin Acute toxicity results: LD_{50} dermal, rat or rabbit: ≤50 mg/kg

TABLE 3.8. ***Continued***

R Phrase	Letter for C. of D.	Type	Criteria
R28	T+	Toxicological	Very toxic if swallowed Acute toxicity results: LD_{50} oral, rat ≤25 mg/kg, less than 100% survival at 5 mg/kg oral, rat by the fixed dose procedure, or high mortality at doses ≤25 mg/kg oral, rat, by the acute toxic class method (for test result interpretation see flow charts in Annex 2 of test method B.1 tris of Annex V)
R29	—	Toxicological	Contact with water liberates toxic gas For substances and preparations that, in contact with water or damp air, evolve very toxic/toxic gases in potentially dangerous amounts (e.g., aluminum phosphide, phosphorus pentasulphide)
30	—	Physio/chemical	Can become highly flammable in use For preparations not in themselves classified as flammable, which may become flammable due to the loss of non-flammable volatile components
R31	—	Toxicological	Contact with acids liberates toxic gas For substances and preparations that react with acids to evolve toxic gases in dangerous amounts (e.g., sodium hypochlorite, barium polysulphide). For substances used by members of the general public, the use of S50 (do not mix with . . . (to be specified by the manufacturer)) would be more suitable
R32	—	Toxicological	Contact with acids liberates very toxic gas For substances and preparations that react with acids to evolve very toxic gases in dangerous amounts (e.g., salts of hydrogen cyanide, sodium azide). For substances used by members of the general public, the use of S50 (do not mixwith . . . (to be specified by the manufacturer)) would be more suitable
R33	—	Toxicological	Danger of cumulative effects For substances and preparations when accumulation in the human body is likely and may cause some concern that, however, is not sufficient to justify the use of R48 For comments on the use of this R-phrase, see Section 4.2.3.3 for substances and Annex V, Part A.3. of Directive 1999/45/EC for preparations
R34	C	Toxicological	Causes burns if, when applied to healthy intact animal skin, full thickness destruction of skin tissue occurs as a result of up to four hours exposure, or if this result can be predicted, organic hydroperoxides, except where evidence to the contrary is available

TABLE 3.8. ***Continued***

R Phrase	Letter for C. of D.	Type	Criteria
R35	C	Toxicological	Causes severe burns if, when applied to healthy intact animal skin, full thickness destruction of skin tissue occurs as a result of up to three minutes exposure, or if this result can be predicted
R36	Xi	Toxicological	Irritating to eyes Substances and preparations that, when applied to the eye of the animal, cause significant ocular lesions that occur within 72 hours after exposure and persist for at least 24 hours Ocular lesions are significant if the mean scores of the eye irritation test cited in Annex V have any of the following values: —cornea opacity equal to or greater than 2 but less than 3, —iris lesion equal to or greater than 1 but not greater than 1.5, —redness of the conjunctivae equal to or greater than 2.5, —oedema of the conjunctivae (chemosis) equal to or greater than 2, or, in the case where the Annex V test has been completed using three animals if the lesions, on two or more animals, are equivalent to any of the above values except that for iris lesion the value should be equal to or greater than 1 but less than 2 and for redness of the conjunctivae the value should be equal to or greater than 2.5 In both cases all scores at each of the reading times (24, 48, and 72 hours) for an effect should be used in calculating the respective mean values Substances or preparations that cause significant ocular lesions, based on practical experience in humans. Organic peroxides except where evidence to the contrary is available
R37	Xi	Toxicological	Irritating to respiratory system Substances and preparations that cause serious irritation to the respiratory system based on: —practical observation in humans —positive results from appropriate animal tests

TABLE 3.8. ***Continued***

R Phrase	Letter for C. of D.	Type	Criteria
R38	Xi	Toxicological	Irritating to skin Substances and preparations that cause significant inflammation of the skin that persists for at least 24 hours after an exposure period of up to 4 hours determined on the rabbit according to the cutaneous irritation test method cited in Annex V Inflammation of the skin is significant if: —the mean value of the scores for either erythema and eschar formation or oedema formation, calculated over all the animals tested, is 2 or more; or —in the case where the Annex V test has been completed using three animals, either erythema and eschar formation or oedema formation equivalent to a mean value of 2 or more calculated for each animal separately has been observed in two or more animals In both cases, all scores at each of the reading times (24, 48 and 72 hours) for an effect should be used in calculating respective mean values Inflammation of the skin is also significant if it persists in at least two animals at the end of the observation time. Particular effects (e.g., hyperplasia, scaling, discoloration, fissures, scabs, and alopecia) should be taken into account Relevant data may also be available from nonacute animal studies (see comments on R48, section 2.d). These are considered significant if the effects seen are comparable to those described above Substances and preparations that cause significant inflammation of the skin, based on practical observations in humans on immediate, prolonged, or repeated contact Organic peroxides, except where evidence to the contrary is available Paresthesia: Paresthesia caused in humans by skin contact with pyrethroid pesticides is not regarded as an irritant effect justifying classification as Xi; R38. The S-phrase S24 should however be applied for substances seen to cause this effect.

TABLE 3.8. ***Continued***

R Phrase	Letter for C. of D.	Type	Criteria
R39	T+ or T	Toxicological	Danger of very serious irreversible effects Strong evidence that irreversible damage other than the effects referred to in Chapter 4 is likely to be caused by a single exposure by an appropriate route, generally in the above-mentioned dose range In order to indicate the route of administration/exposure one of the following combinations shall be used: R39/26, R39/27, R39/28, R39/26/27, R39/26/28, R39/27/28, R39/26/27/28
R40	Xn	Health	Carcinogen category 3: substances classified as carcinogenic category 3 shall be assigned the symbol"Xn" and the risk phrase R40—Limited evidence of a carcinogenic effect.
R41	Xi	Toxicological	Risk of serious damage to eyes Substances and preparations that, when applied to the eye of the animal cause severe ocular lesions which occur within 72 hours after exposure and persist for at least 24 hours Ocular lesions are severe if the means of the scores of the eye irritation test in Annex V have any of the values: —cornea opacity equal to or greater than 3, —iris lesion greater than 1.5 The same shall be the case where the test has been completed using three animals if these lesions, on two or more animals, have any of the values: —cornea opacity equal to or greater than 3, —iris lesion equal to 2 In both cases all scores at each of the reading times (24, 48, and 72 hours) for an effect should be used in calculating the respective mean values Ocular lesions are also severe when they are still present at the end of the observation time Ocular lesions are also severe if the substance or preparation causes irreversible coloration of the eyes Substances and preparations that cause severe ocular lesions, based on practical experience in humans

TABLE 3.8. ***Continued***

R Phrase	Letter for C. of D.	Type	Criteria
R42	Xn	Toxicological	May cause sensitization by inhalation if there is evidence that the substance or preparation can induce specific respiratory hypersensitivity; where there are positive results from appropriate animal tests; or if the substance is an isocyanate, unless there is evidence that the specific isocyanate does not cause respiratory hypersensitivity
R43	Xi	Toxicological	May cause sensitization by skin contact If practical experience shows the substance or preparation to be capable of inducing a sensitization by skin contact in a substantial number of persons, or where there are positive results from an appropriate animal test
R44	—	Physio/chemical	Risk of explosion if heated under confinement For substances and preparations not in themselves classified as explosive in accordance with Section 2.2.1 above but which may nevertheless display explosive properties in practice if heated under sufficient confinement. For example, certain substances that would decompose explosively if heated in a steel drum do not show this effect if heated in weaker containers
R45	T	Health	Carcinogen categories 1 and 2: Substances classified as carcinogenic category 1 or 2 shall be assigned the symbol "T" and the risk phrase R45—May cause cancer However for substances and preparations that present a carcinogenic risk only when inhaled, for example, as dust, vapor or fumes (other routes of exposure, e.g., by swallowing or in contact with skin do not present any carcinogenic risk), the following symbol and specific risk phrase should be used: T; R49—May cause cancer by inhalation
R46	T	Heatlh	Mutagenic categories 1 and 2: Substances classified as mutagenic category 1 or 2 shall be assigned the symbol "T' and the risk phrase R46—May cause heritable genetic damage

TABLE 3.8. ***Continued***

R Phrase	Letter for C. of D.	Type	Criteria
R48	T or Xn	Toxicological	Danger of serious damage to health by prolonged exposure T and Xn = Serious damage (clear functional disturbance or morphological change which have toxicological significance) is likely to be caused by repeated or prolonged exposure by an appropriate route T = Substances and preparations are classified at least as toxic when these effects are observed at levels of one order of magnitude lower (i.e., 10-fold) than those set out for R48 in Section 3.2.3 Xn = Substances and preparations are classified at least as harmful when these effects are observed at levels of the order of: —oral, rat ≤50 mg/kg (bodyweight)/day —dermal, rat or rabbit ≤100 mg/kg (bodyweight)/day —inhalation, rat ≤0.25 mg/L, 6 h/day These guide values can apply directly when severe lesions have been observed in a subchronic (90 days) toxicity test. When interpreting the results of a subacute (28 days) toxicity test these figures should be increased approximately three-fold. If a chronic (two years) toxicity test is available it should be evaluated on a case-by-case basis. If results of studies of more than one duration are available, then those from the study of the longest duration should normally be used Xn = In order to indicate route of administration/exposure one of the following combinations shall be used: R48/20, R48/21, R48/22, R48/20/21, R48/20/22, R48/21/22, R48/20/21/22 T = In order to indicate the route of administration/exposure one of the following combinations shall be used: R48/23, R48/24, R48/25, R48/23/24, R48/23/25, R48/24/25, R48/23/24/25
R49	T	Health	Carcinogen Categories 1 and 2: Substances classified as carcinogenic category 1 or 2 shall be assigned the symbol "T" and the risk phrase R45—May cause cancer

TABLE 3.8. ***Continued***

R Phrase	Letter for C. of D.	Type	Criteria
			However, for substances and preparations that present a carcinogenic risk only when inhaled, for example, as dust, vapor, or fumes (other routes of exposure, e.g., by swallowing or in contact with skin do not present any carcinogenic risk), the following symbol and risk phrase should be used: T; R49—May cause cancer by inhalation
R50	N	Environment	Very toxic to aquatic organisms Acute toxicity: 96 hr LC_{50} (for fish) <1 mg/L or 48 hr EC_{50} (for Daphnia) <1 mg/L or 72 hr IC_{50} (for algae) <1 mg/L
R51	N	Environment	Toxic to aquatic organisms Acute toxicity: 96 hr LC_{50} (for fish) 1 mg/L < LC_{50} < 10 mg/L or 48 hr EC_{50} (for Daphnia) 1 mg/L < EC_{50} < 10 mg/L or 72 hr IC_{50} (for algae) 1 mg/L < IC_{50} < 10 mg/L
R52		Environment	Harmful to aquatic organisms Substances not falling under the criteria listed above in this chapter, but which on the basis of the available evidence concerning their toxicity may nevertheless present a danger to the structure and/or functioning of aquatic ecosystems
R53		Environment	May cause long-term adverse effects in the aquatic environment Substances not falling under the criteria listed above in this chapter, but which, on the basis of the available evidence concerning their persistence, potential to accumulate, and predicted or observed environmental fate and behavior may nevertheless present a long-term and/or delayed danger to the structure and/or functioning of aquatic ecosystems For example, poorly water-soluble substances, that is, substances with a solubility of less than 1 mg/L will be covered by this criterion if: (a) they are not readily degradable; and (b) the log Pow ≥3.0 (unless the experimentally determined BCF ≤100) Log Pow is the partition coefficient of a substance between water and a lipophilic solvent (n-Octaud). BFC is the bioconcentration factor and is

TABLE 3.8. ***Continued***

R Phrase	Letter for C. of D.	Type	Criteria
			measured as the ratio between the concentration in water and the concentration in fish tissues at a steady state.
R54	N	Environment	Nonaquatic environment Toxic to flora
R55	N	Environment	Nonaquatic environment Toxic to fauna
R56	N	Environment	Nonaquatic environment Toxic to soil organisms
R57	N	Environment	Nonaquatic environment Toxic to bees
R58	N	Environment	Nonaquatic environment May cause long-term adverse effects in the environment
R59	N or —	Environment	Dangerous for the ozone layer Substances that on the basis of the available evidence concerning their properties and their predicted or observed environmental fate and behavior may present a danger to the structure and/or the functioning of the stratospheric ozone layer. This includes the substances that are listed in Annex I to Council Regulation (EC) No 2037/2000 on substances that deplete the ozone layer (OJ No L 244, 29.9.2000, p.1) and its subsequent amendments Preparations shall be classified on the basis of a conventional method referred to in Article 7 and Annex III, Parts A and B of Directive 1999/45/EC
R60	T	Health	Toxic to Reproduction Category 1: for substances that impair fertility in humans Substances classified as toxic to reproduction category 1 shall be assigned the symbol "T" and the risk phrase R60—May impair fertility for substances that cause developmental toxicity Substances classified as toxic to reproduction category 1 shall be assigned the symbol "T" and the risk phrase R61—May cause harm to the unborn child
R61	T	Health	Toxic to reproduction, category 1 and 2: for substances that impair fertility in humans Substances classified as toxic to reproduction category 1 shall be assigned the symbol "T" and the risk phrase R60—May impair fertility for substances that cause developmenal toxicity

TABLE 3.8. ***Continued***

R Phrase	Letter for C. of D.	Type	Criteria
			Substances classified as toxic to reproduction category 1 shall be assigned the symbol "T" and the risk phrase R61—May cause harm to the unborn child
R62	Xn	Health	Toxic to reproduction category 3: for substances which cause concern for human fertility Substances classified as toxic to reproduction category 3 shall be assigned the symbol "Xn" and the risk phrase R62—Possible risk of impaired fertility for substances that cause concern for humans owing to possible developmental toxic effects Substances classified as toxic to reproduction category 3 shall be assigned the symbol "Xn" and the risk phrase R63—Possible risk of harm to the unborn child
R63	Xn	Health	Toxic to reproduction category 3: for substances that cause concern for human fertility Substances classified as toxic to reproduction category 3 shall be assigned the symbol "Xn" and the risk phrase R62—Possible risk of impaired fertility for substances that cause concern for humans owing to possible developmental toxic effects Substances classified as toxic to reproduction category 3 shall be assigned the symbol "Xn" and the risk phrase R63—Possible risk of harm to the unborn child
R64	—	Toxicological	May cause harm to breastfed babies For substances and preparations that are absorbed by women and may interfere with lactation or which may be present (including metabolites) in breast milk in amounts sufficient to cause concern for the health of a breastfed child For comments on the use of this R-phrase see Section 4.2.3.3 for substances and Annex V, Part A.4. of Directive 1999/45/EC for preparations
R65	Xn	Toxicological	Harmful: may cause lung damage if swallowed Liquid substances and preparations presenting an aspiration hazard in humans because of their low viscosity

TABLE 3.8. ***Continued***

R Phrase	Letter for C. of D.	Type	Criteria
			(a) For substances and preparations containing aliphatic, alicyclic, and aromatic hydrocarbons in a total concentration equal to or greater than 10% and having either a flow time of less than 30 seconds in a 3 mm ISO cup according to ISO 2431 (April 1996/July 1999 edition) relating to "Paints and varnishes—Determination of flow time by use of flow cups", a kinematic viscosity measured by a calibrated glass capillary viscometer in accordance with ISO 3104/3105 of less than 7×10^{-6} m^2/sec at 40 °C (ISO 3104, 1994 edition, relating to "Petroleum products—Transparent and opaque liquids—Determination of kinematic viscosity and calculation of dynamic viscosity"; ISO 3105, 1994 edition, relating to "Glass capillary kinematic viscometers—Specifications and operating instructions"), or a kinematic viscosity derived from measurements of rotational viscometry in accordance with ISO 3219 of less than 7×10^{-6} m^2/sec at 40 °C (ISO 3219, 1993 edition, relating to "Plastics — Polymers/resins in the liquid state or as emulsions or dispersions—Determination of viscosity using a rotational viscometer with defined shear rate")
			Note that substances and preparations meeting these criteria need not be classified if they have a mean surface tension greater than 33 mN/m at 25 °C as measured by the du Nouy tensiometer or by the test methods shown in Annex V Part A.5
			(b) For substances and preparations, based based on practical experience in humans
R66	—	Toxicological	Repeated exposure may cause skin dryness or cracking
			For substances and preparations that may cause concern as a result of skin dryness, flaking, or cracking but that do not meet the criteria for R38 based on either: —practical observation after normal handling and use, or —relevant evidence concerning there predicted effects on the skin

TABLE 3.8. ***Continued***

R Phrase	Letter for C. of D.	Type	Criteria
R67	—	Toxicological	Vapors may cause drowsiness and dizziness For volatile substances and preparations containing such substances, which cause clear symptoms of central nervous system depression by inhalation and which, are not already classified with respect to acute inhalation toxicity (R20, R23, R26 , R68/20, R39/23 or R39/26) The following evidence may be used: (a) Data from animal studies showing clear signs of central nervous system depression such as narcotic effects, lethargy, lack of co-ordination (including loss of righting reflex), and ataxia either: at concentrations/ exposure times not exceeding 20 mg/L/ 4 hr or, for which the ratio of the effect concentration at ≤4 hr to the saturated vapor concentration (SVC) at 20 °C is ≤1/10. (b) Practical experience in humans (e.g., narcosis, drowsiness, reduced alertness, loss of reflexes, lack of co-ordination, vertigo) from well-documented for reports under comparable exposure conditions to the effects specified above for animals
R68	Xn	Toxicological and health	Possible risk of irreversible effects strong evidence that irreversible damage other than the effects referred to in Chapter 4 is likely to be caused by a single exposure by an appropriate route, generally in the above mentioned doserange In order to indicate route of administration/exposure one of the following combinations shall be used: R68/20, R68/21, R68/22, R68/20/21, R68/20/22, R68/21/22, R68/20/21/22 Mutagenic category 3: Substances classified as mutagenic category 3 shall be assigned the symbol "Xn" and the risk phrase R68—Possible risk of irreversible effects

TABLE 3.9. The Combined R-phrases in Annex III

Combined R-Phrase	Description
R14/15	Reacts violently with water, liberating extremely flammable gases
R15/29	Contact with water liberates toxic, extremely flammable gas
R20/21	Harmful by inhalation and in contact with skin
R20/21/22	Harmful by inhalation, in contact with skin and if swallowed
R20/22	Harmful by inhalation and if swallowed
R21/22	Harmful in contact with skin and if swallowed
R23/24	Toxic by inhalation and in contact with skin
R23/24/25	Toxic by inhalation, in contact with skin and if swallowed
R23/25	Toxic by inhalation and if swallowed
R24/25	Toxic in contact with skin and if swallowed
R26/27	Very toxic by inhalation and in contact with skin
R26/27/28	Very toxic by inhalation, in contact with skin and if swallowed
R26/28	Very toxic by inhalation and if swallowed
R27/28	Very toxic in contact with skin and if swallowed
R36/37	Irritating to eyes and respiratory system
R36/37/38	Irritating to eyes, respiratory system and skin
R36/38	Irritating to eyes and skin
R37/38	Irritating to respiratory system and skin
R39/23	Toxic: danger of very serious irreversible effects through inhalation
R39/23/24	Toxic: danger of very serious irreversible effects through inhalationand in contact with skin
R39/23/24/25	Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed
R39/23/25	Toxic: danger of very serious irreversible effects through inhalation and if swallowed
R39/24	Toxic: danger of very serious irreversible effects in contact with skin
R39/24/25	Toxic: danger of very serious irreversible effects in contact with skin and if swallowed
R39/25	Toxic: danger of very serious irreversible effects if swallowed.
R39/26	Very toxic: danger of very serious irreversible effects through inhalation
R39/26/27	Very toxic: danger of very serious irreversible effects through inhalation and in contact with skin
R39/26/27/28	Very toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed
R39/26/28	Very toxic: danger of very serious irreversible effects through inhalation and if swallowed
R39/27	Very toxic: danger of very serious irreversible effects in contact with skin
R39/27/28	Very toxic: danger of very serious irreversible effects in contact with skin and if swallowed
R39/28	Very toxic: danger of very serious irreversible effects if swallowed
R40/20	Harmful: possible risk of irreversible effects through inhalation
R40/20/21	Harmful: possible risk of irreversible effects through inhalation and in contact with skin
R40/20/21/22	Harmful: possible risk of irreversible effects through inhalation, in contact with skin and if swallowed
R40/20/22	Harmful: possible risk of irreversible effects through inhalation and if swallowed
R40/21	Harmful: possible risk of irreversible effects in contact with skin

TABLE 3.9. ***Continued***

Combined R-Phrase	Description
R40/21/22	Harmful: possible risk of irreversible effects in contact with skin and if swallowed
R40/22	Harmful: possible risk of irreversible effects if swallowed
R42/43	May cause sensitization by inhalation and skin contact
R48/20	Harmful: danger of serious damage to health by prolonged exposure through inhalation
R48/20/21	Harmful: danger of serious damage to health by prolonged exposure through inhalation and in contact with skin
R48/20/21/22	Harmful: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed
R48/20/22	Harmful: danger of serious damage to health by prolonged exposure through inhalation and if swallowed
R48/21	Harmful: danger of serious damage to health by prolonged exposure in contact with skin
R48/21/22	Harmful: danger of serious damage to health by prolonged exposure in contact with skin and if swallowed
R48/22	Harmful: danger of serious damage to health by prolonged exposure if swallowed
R48/23	Toxic: danger of serious damage to health by prolonged exposure through inhalation
R48/23/24	Toxic: danger of serious damage to health by prolonged exposure through inhalation and in contact with skin
R48/23/24/25	Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed
R48/23/25	Toxic: danger of serious damage to health by prolonged exposure through inhalation and if swallowed
R48/24	Toxic: danger of serious damage to health by prolonged exposure in contact with skin
R48/24/25	Toxic: danger of serious damage to health by prolonged exposure in contact with skin and if swallowed
R48/25	Toxic: danger of serious damage to health by prolonged exposure if swallowed
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
R51/53	Toxic to aquatic organisms may cause long-term adverse effects in the aquatic environment
R52/53	Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment
R68/20	Harmful: possible risk of irreversible effects through inhalation
R68/20/21	Harmful: possible risk of irreversible effects through inhalation and in contact with skin
R68/20/21/22	Harmful: possible risk of irreversible effects through inhalation, in contact with skin and if swallowed
R68/20/22	Harmful: possible risk of irreversible effects through inhalation and if swallowed
R68/21	Harmful: possible risk of irreversible effects in contact with skin
R68/21/22	Harmful: possible risk of irreversible effects in contact with skin and if swallowed
R68/22	Harmful: possible risk of irreversible effects if swallowed

TABLE 3.10. S Phrases as per Annex IV

S-Phrase	Sentence	Applicability	Criteria for Use
S1	Keep locked up	Very toxic, toxic and corrosive substances and preparations	Obligatory for those substances and preparations mentioned above if sold to the general public
S2	Keep out of the reach of children	All dangerous substances and preparations	Obligatory for all dangerous substances and preparations sold to the general public, except for those only classified as dangerous for the environment
S3	Keep in a cool place	Organic peroxides Other dangerous substances and preparations having a boiling point ≤40 °C	Obligatory for organic peroxides unless S47 is used Recommended for other dangerous substances and preparations having a boiling point ≤40 °C
S4	Keep away from living quarters	Very toxic and toxic substances and preparations	Normally limited to very toxic and toxic substances and preparations when desirable to supplement S13; for example, when there is an inhalation risk and the substance or preparation should be stored away from living quarters. The advice is not intended to preclude proper use of the substance or preparation in living quarters
S5	Keep contents under . . . (appropriate liquid to be specified by the manufacturer)	Spontaneously flammable solid substances and preparations	Normally limited to special cases (e.g., sodium, potassium or white phosphorous)
S6	Keep under . . . (inert gas to be specified by the manufacturer)	Dangerous substances and preparations which must be kept under an inert atmosphere	Normally limited to special cases (e.g., certain organo-metallic compounds)

TABLE 3.10. ***Continued***

S-Phrase	Sentence	Applicability	Criteria for Use
S7	Keep container tightly closed	Organic peroxides Substances and preparations that can give off very toxic, toxic, harmful or extremely flammable gases Substances and preparations that in contact with moisture give off extremely flammable gases Highly flammable solids	Obligatory for organic peroxides Recommended for the other fields of application mentioned above
S8	Keep container dry	Substances and preparations that may react violently with water Substances and preparations that on contact with water liberate extremely flammable gases Substances and preparations, which on contact with water, liberate very toxic or toxic gases	Normally limited to the fields of application mentioned above when necessary to reinforce warnings given by R14, R15 in particular, and R29
S9	Keep container in a well-ventilated place	Volatile substances and preparations that may give off very toxic, or harmful vapors Extremely flammable or highly flammable liquids and extremely flammable gases	Recommended for volatile substances and preparations that may give off very toxic, toxic, or harmful vapors

TABLE 3.10. ***Continued***

S-Phrase	Sentence	Applicability	Criteria for Use
S12	Do not keep the container sealed	Substances and preparations, which will by giving off gases or vapors, are liable to burst the container	Normally limited to the special cases mentioned above
S13	Keep away from food, drink and animal feeding stuffs	Very toxic, toxic and harmful substances and preparations	Recommended when such substances and preparations are likely to be used by the general public
S14	Keep away from . . . (incompatible materials to be indicated by the manufacturer)	Organic peroxides	Obligatory for and normally limited to organic peroxides. However, may be useful in exceptional cases when incompatibility is likely to product a particular risk
S15	Keep away from heat	Substances and preparations that may decompose or which may react spontaneously under the effect of heat	Normally limited to special cases, for example, monomers, but not assigned if risk phrases R2, R3 and/or R5 have already been applied
S16	Keep away from sources of ignition—no smoking	Extremely flammable or highly flammable liquids and extremely flammable gases	Recommended for the substances and preparations mentioned above but not assigned if risk phrases R2, R3, and/or R5 have already been applied
S17	Keep away from combustible material	Substances and preparations, which may form explosive or spontaneously flammable mixtures with combustible material	Available for use in special cases, for example, to emphasize R8 and R9
S18	Handle and open container with care	Substances and preparations liable to produce an overpressure in the container	Normally limited to the above-mentioned cases when there is risk of damage to the eyes and/or when the substances and preparations are likely

TABLE 3.10. ***Continued***

S-Phrase	Sentence	Applicability	Criteria for Use
		Substances and preparations that may form explosive peroxides	to be used by the general public
S20	When using do not eat or drink	Very toxic, toxic and corrosive substances and preparations	Normally limited to special cases (e.g., arsenic and arsenic compounds; fluoracetates) in particular when any of these are likely to be used by the general public
S21	When using do not smoke	Substances and preparations that produce toxic products on combustion	Normally limited to special cases (e.g., halogenated compounds)
S22	Do not breathe dust	All solid substances and preparations dangerous for health	Obligatory for those substances and preparations mentioned above to which R42 is assigned Recommended for those substances and preparations mentioned above which are supplied in the form of an inhalable dust and for which the health hazards following inhalation are not known
S23	Do not breathe gas/fumes/ spray/spray (appropriate wording to be specified by the manufacturer)	All liquid or gaseous substances and preparations dangerous to health	Obligatory for those substances and preparations mentioned above to which R42 is assigned Obligatory for substances and preparations intended for use by spraying. Either S38 or S51 must be ascribed in addition Recommended when it is necessary to draw the attention of the user to inhalation risks not mentioned in the risk phrases, which have to be ascribed
S24	Avoid contact with skin	All substances and preparations dangerous for health	Obligatory for those substances and preparations to which R43 has been ascribed, unless S36 has also been

TABLE 3.10. ***Continued***

S-Phrase	Sentence	Applicability	Criteria for Use
			ascribed Recommended when it is necessary to draw the attention of the user to skin contact risks not mentioned in the risk phrases (e.g., paresthesia), which have to be ascribed. However, may be used to emphasise such risk phrases
S25	Avoid contact with eyes	All substances and preparations dangerous to health	Recommended when it is necessary to draw the attention of the user to eye contact risks not mentioned in the risk phrases that have to be applied. However, may be used to emphasize such risk phrases Recommended for substances ascribed R34, R35, R36 or R41 that are likely to be used by the general public
S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice	Corrosive or irritant substances and preparations	Obligatory for corrosive substances and preparations and those to which R41 has already been ascribed Recommended for irritant substances and preparations to which the risk phrase R36 has already been ascribed
S27	Take off immediately all contaminated clothing	Very toxic, toxic or corrosive substances and preparations	Obligatory for very toxic substances and preparations to which R27 has been ascribed and which are likely to be used by the general public Recommended for very toxic substances and preparations to which R27 has been ascribed used in industry. However, this safety phrase should not be used if S36 has been ascribed Recommended for toxic substances and preparations to which R24 has been ascribed as well as corrosive substances and preparations that are likely to be used by the general public

TABLE 3.10. ***Continued***

S-Phrase	Sentence	Applicability	Criteria for Use
S28	After contact with skin, wash immediately with plenty of . . . (to be specified by the manufacturer)	Very toxic, toxic or corrosive substances and preparations	Obligatory for very toxic substances and preparations Recommended for the other substances and preparations mentioned above, in particular when water is not the most appropriate rinsing fluid Recommended for corrosive substances and preparations that are likely to be used by the general public
S29	Do not empty into drains	Extremely or highly flammable liquids immiscible with water Very toxic and toxic substances and preparations Substances and preparations dangerous for the environment	Obligatory for substances and preparations dangerous for the environment and assigned the symbol "N", which are likely to be used by the general public, unless this is the intended use Recommended for other substances and preparations mentioned above that are likely to be used by the general public, unless this is the intended use
S30	Never add water to this product	Substances and preparations that react violently with water	Normally limited to special cases (e.g., sulphuric acid) and may be used, as appropriate, to give the clearest possible information, either to emphasize R14 or as an alternative to R14
S33	Take precautionary measures against static discharges	Extremely or highly flammable substances and preparations	Recommended for substances and preparations used in industry that do not absorb moisture. Virtually never used for substances and preparations as placed on the market for use by the general public
S35	This material and its container must be disposed of in a safe way	All dangerous substances and preparations	Recommended for substances and preparations where special guidance is needed to ensure proper disposal

TABLE 3.10. ***Continued***

S-Phrase	Sentence	Applicability	Criteria for Use
S36	Wear suitable protective clothing	Organic peroxides Very toxic, toxic, or harmful substances and preparations Corrosive substances and preparations	Obligatory for very toxic and corrosive substances and preparations Obligatory for those substances and preparations to which either R21 or R24 has been ascribed Obligatory for category 3 carcinogens, mutagens and substances toxic to reproduction unless the effects are produced solely by inhalation of the substance or preparation Obligatory for organic peroxides Recommended for toxic substances and preparations if the LD_{50} dermal value is unknown but the substance or preparation is likely to be toxic through skin contact Recommended for substances and preparations used in industry that are liable to damage health by prolonged exposure
S37	Wear suitable gloves	Very toxic, toxic, harmful or corrosive substances and preparations Organic peroxides Substances and preparations irritating to the skin or causing sensitization by skin contact	Obligatory for very toxic and corrosive substances and preparations Obligatory for those substances and preparations to which either R21, R24 or R43 has been ascribed Obligatory for category 3 carcinogens, mutagens and substances toxic to reproduction unless the effects are produced solely by inhalation of the substances and preparations Obligatory for organic peroxides Recommended for toxic substances and preparations if the LD_{50} dermal value is unknown but the substance

TABLE 3.10. ***Continued***

S-Phrase	Sentence	Applicability	Criteria for Use
			or reparation is likely to be harmful by skin contact Recommended for substances and preparations irritating to the skin
S38	In case of insufficient ventilation, wear suitable respiratory equipment	Very toxic or toxic substances and preparations.	Normally limited to special cases involving the use of very toxic or toxic substances and preparations in industry or in agriculture
S39	Wear eye/face protection	Organic peroxides Corrosive substances and preparations, including irritants that give rise to risk of serious damage to the eyes Very toxic and toxic substances and preparations	Obligatory for those substances and preparations to which R34, R35 or R41 have been ascribed Obligatory for organic peroxides Recommended when it is necessary to draw the attention of the user to eye contact risks not mentioned in the risk phrases which have to be ascribed Normally limited to exceptional cases for very toxic and toxic substances and preparations, where there is a risk of splashing and they are likely to be easily absorbed by the skin
S40	To clean the floor and all objects contaminated by this material use . . . (to be specified by the manufacturer)	All dangerous substances and preparations	Normally limited to those dangerous substances and preparations for which water is not considered to be a suitable cleansing agent (e.g., where absorption by powdered material, dissolution by solvent and so on is necessary) and where it is important for health and/or safety reasons to provide a warning on the label
S41	In case of fire and/or explosion do not breathe fumes	Dangerous substances and preparations that on combustion give off very toxic or gase	Normally limited to special cases

TABLE 3.10. ***Continued***

S-Phrase	Sentence	Applicability	Criteria for Use
S42	During fumigation/ spraying wear suitable respiratory equipment (appropriate wording to be specified by the manufacturer)	Substances and preparations intended for such use but which may endanger the health and safety of the user unless proper precautions are taken	Normally limited to special cases
S43	In case of fire use . . . (indicate in the space the precise type of fire-fighting equipment. If water increases the risk add: Never use water)	Extremely flammable, highly flammable, and flammable substances and preparations	Obligatory for substances and preparations which, in contact with water or damp air, evolve extremely flammable gases Recommended for extremely flammable, highly flammable, and flammable substances and preparations, particularly when they are immiscible with water
S45	In case of accident or if you feel unwell seek medical advice immediately (show the label where possible)	Very toxic substances and preparations Toxic and corrosive substances and preparations Substances and preparations causing sensitization by inhalation	Obligatory for the substances and preparations mentioned above
S46	If swallowed, seek medical advice immediately and show this container or label	All dangerous substances and preparations other than those that are very toxic, toxic, corrosive, or dangerous to the environment	Obligatory for all dangerous substances and preparations mentioned above which are likely to be used by the general public, unless there is no reason to fear any danger from swallowing, particularly by children
S47	Keep at temperature not exceeding . . . °C (to be specified by the manufacturer)	Substances and preparations that become unstable at a certain temperature	Normally limited to special cases (e.g., certain organic peroxides)

TABLE 3.10. ***Continued***

S-Phrase	Sentence	Applicability	Criteria for Use
S48	Keep wetted with . . . (appropriate material to be specified by the manufacturer)	Substances and preparations that may become very sensitive to sparks, friction or impact if allowed to dry out	Normally limited to special cases. (e.g., nitrocelluloses)
S49	Keep only in the original container	Substances and preparations sensitive to catalytic decomposition	Substances and preparations sensitive to catalytic decomposition (e.g., certain organic peroxides)
S50	Do not mix with . . . (to be specified by the manufacturer)	Substances and preparations that may react with the specified product to evolve very toxic or toxic gases	Recommended for substances and preparations mentioned above that are likely to be used by the general public, when it is a better alternative to R31 or R32
		Organic peroxides	Obligatory with certain peroxides that may give violent reaction with accelerators or promoters
S51	Use only in well-ventilated areas	Substances and preparations likely to or intended to produce vapors, dusts, sprays, fumes, mists, and so on that give rise to inhalation risks or to a fire or explosion risk	Recommended when use of S38 would not be appropriate. Thus important when such substances and preparations are likely to be used by the general public
S52	Not recommended for interior use on large surface areas	Volatile, very toxic, toxic, and harmful substances and preparations containing them	Recommended when damage to health is likely to be caused by prolonged exposure to these substances by reason of their volatilization from large treated surfaces in the home or other enclosed places where persons congregate
S53	Avoid exposure —Obtain special instructions before use	Substances and preparations that are carcinogenic, mutagenic and/or toxic to reproduction	Obligatory for the above mentioned substances and preparations to which at least one of the following R phrases has been assigned: R45, R46, R49, R60 or R61

TABLE 3.10. ***Continued***

S-Phrase	Sentence	Applicability	Criteria for Use
S56	Dispose of this material and its container to hazardous or special waste collection point	All dangerous preparations	Recommended for all dangerous substances and preparations likely to be used by the general public for which special disposal is required
S57	Use appropriate containment to avoid environmental contamination	Substances and preparations that have been assigned the symbol "N"	Normally limited to substances and preparations not likely to be used by the general public
S59	Refer to manufacturer for information on recovery/ recycling	All dangerous substances and preparations	Obligatory for substances and preparations dangerous for the ozone layer Recommended for other substances and preparations for which recovery/recycling is recommended
S60	This material and its container must be disposed of as hazardous waste	All dangerous substances and preparations	Recommended for substances and preparations not likely to be used by the general public and where S35 is not assigned
S61	Avoid release to the environment. Refer to special instructions/ safety data sheet	Substances and preparations dangerous for the environment	Normally used for substances and preparations which have been assigned the symbol "N" Recommended for all substances and preparations classified dangerous for the environment not covered above
S62	If swallowed, do not induce vomiting: seek medical advice immediately and show this container or label	Substances and preparations classified as harmful with R65 in accordance with the criteria in Section 3.2.3 Not applicable to substances and preparations that are placed on the market in aerosol	Obligatory for substances and preparations mentioned above, if sold to, or likely to be used by the general public, except when S45 or S46 are obligatory Recommended for the substances and preparations mentioned above when used in industry, except where S45 or S46 are obligatory

TABLE 3.10. ***Continued***

S-Phrase	Sentence	Applicability	Criteria for Use
		containers (or in containers fitted with a sealed spray attachment), see sections 8 and 9	
S63	In case of accident by	Very toxic and toxic substances and	Obligatory for substances and or preparations to which
R26,	inhalation: remove casualty to fresh air and keep at rest	preparations (gases, vapors, particulates, volatile liquids) Substances and preparations causing respiratory sensitization	R23, R42 has been assigned that are likely to be used by the general public in a way that could result in inhalation
S64	If swallowed, rinse mouth with water (only if the person is conscious)	Corrosive or irritant substances and preparations	Recommended for the above that substances and preparationsthat are likely to be used by the general public and where the above treatment is suitable

Similarly to R-phrases, S-phrases may be used in combination depending upon the substance or preparation. Table 3.11 presents the combined S-phrase as per Annex IV.

3.4.2 Substance Versus Preparation

Under EU legislation it is critical to understand the difference between "substances" and "preparations." *Substances* refers to chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product, and any impurity deriving from the production process used but excludes any solvent that may be separated without affecting the stability of the substance or changing its composition. A substance may be chemically very well defined (e.g., acetone) or a complex mixture of constituents of variable composition (e.g., aromatic distillates). *Preparations* refers to mixtures or solutions composed of two or more substances.

Substances. In general, the classification of substances is done by "self-classification." However, for more than 1000 substances, the European Commission has published the classification that must be applied. This classifica-

TABLE 3.11. Combined S Phrases in Annex IV

Combined S-Phrases	Descriptions
S1/2	Keep locked up and out of the reach of children
S20/21	When using do not eat, drink or smoke
S24/25	Avoid contact with skin and eyes
S27/28	After contact with skin, take off immediately all contaminated clothing, and wash immediately with plenty of . . . (to be specified by the manufacturer)
S29/35	Do not empty into drains; dispose of this material and its container in a safe way
S29/56	Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point
S3/14	Keep in a cool place away from . . . (incompatible materials to be indicated by the manufacturer)
S3/7	Keep container tightly closed in a cool place
S3/7/9	Keep container tightly closed in a cool, well-ventilated place
S3/9	Keep in a cool, well-ventilated place
S3/9/14	Keep in a cool, well-ventilated place away from . . . (incompatible materials to be indicated by the manufacturer)
S3/9/14/49	Keep only in the original container in a cool, well-ventilated place away from . . . (incompatible materials to be indicated by the manufacturer)
S3/9/49	Keep only in the original container in a cool, well-ventilated place
S36/37	Wear suitable protective clothing and gloves
S36/37/39	Wear suitable protective clothing, gloves, and eye/face protection
S36/39	Wear suitable protective clothing and eye/face protection
S37/39	Wear suitable gloves and eye/face protection
S47/49	Keep only in the original container at a temperature not exceeding . . . (to be specified by the manufacturer) °C
S7/47	Keep container tightly closed and at a temperature not exceeding . . . (to be specified by the manufacturer) °C
S7/8	Keep container tightly closed and dry
S7/9	Keep container tightly closed and in a well-ventilated place

For additional assistance on what S-Phrases should be selected based upon R-Phrases or Hazard Letter of their substance or preparation, contact your industrial association or material compliance consultant or software vendor.

tion (mostly simple substances and a few complex) is presented in the Annex 1 of the Directive 67/548/EEC. The current version of the Annex 1 is the 28th Adaptation to Technical Progress (ATP) to the Dangerous Substances Directive, that is, Directive 2001/59/EC that has been enforced since July 30, 2002.

In the case of substances, the following information is also required:

- Name of the substance under an internationally recognized chemical nomenclature. The preferred name being the one used in the European

INventory of Existing commercial Chemical Substances (EINECS), or in the European LIst of Notified Chemical Substances (ELINCS).
- EC number.
- Name, address, and telephone number of the person established in the community who is responsible for placing the substance on the market.

The aforementioned information is available in Annex 5 of Directive 2001/59/EC.

Preparations and Complex Substances. For those substances not in 28th Adaptation (i.e., the most recent version of Annex 1) and all preparations, classification involves the identification of all the physicochemical, toxicological, and eco-toxicological properties that may constitute a risk during normal handling or use. Having identified any hazardous properties the substance or preparation must then have the appropriate classification and symbol to indicate the hazard(s) in order to protect the user, the general public and the environment.

The classification/symbol/R&S phrase should:

- draw the attention of persons handling or using substances and preparations to the inherent danger of certain such materials;
- take into account all of the potential hazards that are likely to be faced in the normal handling and use of dangerous substances and preparations when in the form in which they are placed on the market, but not necessarily in any different form in which they may finally be used, for example, diluted.

Annex 6 of the 28th Adaptation provides information to assist with the labeling of preparations and complex substances (i.e., those not addressed in Annex 1):

- classification of the basis on physiochemical property
- classification on the basis of toxicological properties criteria for classification, choice of symbols, indication of danger, and choice of R-phrases

3.4.3 Environmental Classification

As indicated above, the Dangerous Substances Directive (67/548/EEC) plus amendments is concerned with the classification and labeling of substances. A first amendment introduced the environmental classification to identify the hazards of the substance to the environment. Under the amendment, substances had to be classified and labeled for environmental hazards but preparations were exempted. Directive 1999/45/EC brings preparations into line with substances and hence requires the environmental classification for preparations. Directive 1999/45/EC replaces Directive 88/379/EEC and its amendments and contains the full text for all classifications. The legislation also made a modification to keep the classification of substances and preparations

in line. The 28th ATP to the DSD introduces R68 in place of R40 for mutagenic substances; the 1st ATP to the DPD introduces R68 for mutagenic preparations.

The major impact of this directive is to implement the environmental classification (refer to Table 3.12) for information on environmental classifications for preparations. This relatively new classifications has an impact on the following SDS sections:

- Section 2—Hazardous Ingredients Lists
- Section 3—Environmental Effects
- Section 15—R-Phrases and Labeling (refer to Table 3.13 for those pertinent to environmental classification)

Table 3.14 presents the environmental classification precedence for environment.

For preparations, the analyses required for N;R50/53, N;R51/53, R52/53, N;R50, R52 and R53 are based on the same principles as the Health Classification for Acute Lethal Effects:

- The component substances are examined for the presence of one of these phrases.
- A table of cut-off concentration limits (or individual limits if specified in Annex 1) applies.
- If substances are present at or above the appropriate limit then the substance classification applies.
- If they are present at or above lower limits then the "down-graded" substance classification applies.
- If a classification is relevant but the concentration is below the limit, a quotient of concentration/limit is calculated.
- The quotients of like-classified substances are added together (the "additive" calculation) to determine whether the classification is relevant.

The analysis required for N;R59 and R59 is based on a simple cut-off limit. The additive calculations do not apply in this case.

3.4.4 SDS Format

Directive 2001/58/EC, being the 2nd ATP to Directive 91/155/EEC (the SDS Directive) concerns major changes to the format of the SDS and its content. The Directive further refines and defines the content of all EU SDS and extends its scope to cover all nondangerous substances and preparations, refer to Table 3.15 for additional information on each section.

The Directive should have been implemented since July 30, 2002. This is also the date for implementation of the new DPD Directive and its first ATP and the 28th ATP to the DSD Directive.

TABLE 3.12. Environmental Classification and Associated Data

Classification	Category of Danger	Abbreviated Category of Danger	R-Phrases	Hazard Symbol	Hazard Words	Hazard Letter
N;R50/53	Dangerous for the environment, N	N	R50/53		Dangerous for the environment	N
N;R51/53	Dangerous for the environment, N	N	R51/53		Dangerous for the environment	N
R52/53	Dangerous for the environment	—	R52/53	—	—	—
N;R50	Dangerous for the environment, N	N	R50		Dangerous for the environment	N
R52	Dangerous for the environment	—	R52	—	—	—
R53	Dangerous for the environment	—	R53	—	—	—
N;R54	Dangerous for the environment, N	N	R54		Dangerous for the environment	N
N;R55	Dangerous for the environment, N	N	R55		Dangerous for the environment	N
N;R56	Dangerous for the environment, N	N	R56		Dangerous for the environment	N
N;R57	Dangerous for the environment, N	N	R57		Dangerous for the environment	N
N;R58	Dangerous for the environment, N	N	R58		Dangerous for the environment	N

TABLE 3.12. ***Continued***

Classification	Category of Danger	Abbreviated Category of Danger	R-Phrases	Hazard Symbol	Hazard Words	Hazard Letter
N;R59	Dangerous for the environment, N	N	R59		Dangerous for the environment	N
R59	Dangerous for the environment, Ozone	—	R59	—	—	—

TABLE 3.13. Environmental R-Phrases

R-Phrases and combined R-Phrases	Descriptions
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
R51/53	Toxic to aquatic organisms may cause long-term adverse effects in the aquatic environment
R52/53	Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment
R50	Very toxic to aquatic organisms
R51	Toxic to aquatic organisms
R52	Harmful to aquatic organisms
R53	May cause long-term adverse effects in the aquatic environment
R54	Toxic to flora
R55	Toxic to fauna
R56	Toxic to soil organisms
R57	Toxic to bees
R58	May cause long-term adverse effects in the environment
R59	Dangerous for the ozone layer

3.4.5 Languages

The current legislation requires the SDS to be in the languages of the EU member state. Currently this includes the following languages: German (Austria), French/Dutch (Belgium), Danish (Denmark), French (France), Finnish (Finland), German (Germany), Greek (Greece), English (Ireland and UK), Italian (Italy), French/German (Luxembourg), Dutch (The Netherlands), Portuguese (Portugal), Spanish (Spain), and Swedish (Sweden). In 2003, the EU commissions agreed to add ten new European countries: Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, and Slovenia.

TABLE 3.14. Environmental Classification Precedence

Classification	Supersedes
N;R50/53	N;R51/53
	R52/53
	N;R50
	N;R52
	N;R53
N;R51/53	R52/53
	N;R52
	N;R53
R52/53	N;R52
	N;R53
N;R50	N;R52
N;R59	R59

Bulgaria, Romania, and Turkey may become member states in a couple of years. Therefore, the list of additional languages for EU SDS will be limited to Czech, Estonian, Latvian, Lithuanian, Hungarian, Maltese, Polish, Slovenian, and Slovekian.

3.5 PACIFIC RIM MSDS

In the following section an overview of MSDS legislation in the Pacific Rim is provided. As many of these jurisdictions follow American or European legislation with minor adaptation only the differences are discussed.

3.5.1 MSDS for Japan

The MSDS for Japan follows the standard 16 sections, with a significant amount of information required in Section 15. The Japanese regulation is mainly list base driven. This means that chemicals are listed on different regulated lists and need to be disclosed on the MSDS. The normal authoring process for a Japanese MSDS would be to find all appropriate (applicable) legislation for Japan and fill up section 15. Once this is achieved, each individual class can be put into a more general hazard class and then write the interpretative sections. There are guidelines published by the Japanese Paint Manufacturer's Association that helps create the general hazard class and write the interpretative sections. The MSDS does not use the Standard European R and S phrases but follows generally the American standard.

For interpretative sections, the hazard classification applicable to a product (substance or preparation) must be known. The legislation offers plenty of

TABLE 3.15. Content of a EU SDS

Section 1		Identification of the substance/preparation and of the company/undertaking
1.1	Identification of the substance or preparation	The term used for identification must be identical to that provided on the label as set out in, Annex VI to Directive 67/548/EEC Other means of identification available may also be indicated
1.2	Use of the substance/ preparation	Indicate the intended or recommended uses of the substance or preparation as far as they are known. Where there are many possible uses, only the most important or common uses need be listed. This should include a brief description of what it actually does (e.g., flame retardant, antioxidant, etc.).
1.3	Company/ undertaking identification	Identify the person responsible for placing the substance or preparation on the market within the community, whether it is the manufacturer, importer or distributor. Give the full address and telephone number of this person. In addition, where this person is not located in the member state where the substance or preparation is placed on the market, give a full address and telephone number for the person responsible in that member state, if possible.
1.4	Emergency telephone	In addition to the abovementioned information, supply the emergency telephone number of the company and/or relevant official advisory body (this may be the body responsible for receiving information relating to health, which is referred to in Article 17 of Directive 1999/45/EC)
Section 2	Composition/ information on ingredients	The information given should enable the recipient to identify readily the hazards of the components of the preparation. The hazards of the preparation itself should be given under heading 3.
2.1		It is not necessary to give the full composition (nature of the ingredients and their concentration), although a general description of the components and their concentrations can be helpful
2.2		For a preparation classified as dangerous according to Directive 1999/45/EC, the following substances shall be indicated, together with their concentration or concentration range:

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TABLE 3.15. ***Continued***

	(i) substances presenting a health or environmental hazard within the meaning of Directive 67/548/EEC, if they are present in concentrations equal to or greater than those laid down in the table set out in Article 3(3) of Directive 1999/45/EC (unless lower limits are given in Annex I to Directive 67/548/EEC or in Annexes II, III or V to Directive 1999/45/EC); (ii) and substances for which there are Community workplace exposure limits, which are not already included under (i).
2.3	For a preparation not classified as dangerous according to Directive 1999/45/EC, the following substances shall be indicated, together with their concentration or concentration range, if they are present in an individual concentration of ≥1% by weight for nongaseous preparations and ≥0.2% by volume for gaseous preparations: —substances presenting a health or environmental hazard within the meaning of Directive 67/548/EEC(2); —and substances for which there are community workplace exposure limits.
2.4	The classification (deriving either from Articles 4 and 6 or from Annex I to Directive 67/548/EEC) of the above substances shall be given, including the symbol letters and R phrases that are assigned in accordance with their physicochemical, health and environmental hazards. The R phrases do not need to be written out in full here: reference should be made to heading 16, where the full text of each relevant R phrase shall be listed.
2.5	The name and the EINECS or ELINCS number of the above substances should be given in accordance with Directive 67/548/EEC. The CAS number and IUPAC name (if available) may also be helpful. For substances listed by a generic name, according to Article 15 of Directive 1999/45/EC or the footnote to point 2.3 of this Annex, a precise chemical identifier is not necessary.

TABLE 3.15. ***Continued***

2.6		If, in accordance with the provisions of Article 15 of Directive 1999/45/EC or the footnote to point 2.3 of this Annex, the identity of certain substances is to be kept confidential, their chemical nature shall be described in order to ensure safe handling. The name used must be the same as that which derives from the above procedures.
Section 3	Hazards identification	Give here the classification of the substance or preparation that arises from application of the classification rules in Directives 67/548/EEC or 1999/45/EC. Indicate clearly and briefly the hazards the substance or preparation presents to man and the environment. Distinguish clearly between preparations that are classified as dangerous and preparations that are not classified as dangerous according to Directive 1999/45/EC. Describe the most important adverse physicochemical, human health and environmental effects and symptoms relating to the uses and possible misuses of the substance or preparation that can reasonably be foreseen. It may be necessary to mention other hazards, such as dustiness, suffocation, freezing or environmental effects such as hazards to soil-dwelling organisms, etc., which do not result in classification but which may contribute to the overall hazards of the material. The information shown on the label should be given under heading 15.
Section 4	First aid measures	Describe the first-aid measures. Specify first whether immediate medical attention is required. The information on first aid must be brief and easy to understand by the victim, bystanders and providers of first-aid. The symptoms and effects should be briefly summarized. The instructions should indicate what is to be done on the spot in the case of an accident and whether delayed effects can be expected after exposure. Subdivide the information according to the different routes of exposure, that is, inhalation, skin and eye contact and ingestion, under different subheadings.

TABLE 3.15. ***Continued***

		Indicate whether professional assistance by a doctor is needed or advisable. For some substances or preparations it may be important to emphasize that special means to provide specific and immediate treatment must be available at the workplace.
Section 5	Fire-fighting measures	Refer to requirements for fighting a fire caused by the substance or preparation, or arising in its vicinity by indicating: —suitable extinguishing media —extinguishing media which must not be used for safety reasons —special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases —special protective equipment for fire-fighters
Section 6	Accidental release measures	Depending on the substance or preparation involved, information may be needed on: —personal precautions such as: removal of ignition sources, provision for sufficient ventilation/respiratory protection, control of dust, prevention of skin and eye contact —environmental precautions such as: keeping away from drains, surface- and ground-water and soil, possible need to alert the neighborhood —methods for cleaning up such as: use of absorbent material (e.g., sand, diatomaceous earth, acid binder, universal binder, sawdust, etc.), reduction of gases/fumes with water, dilution. Also consider the need for indications such as: "never use, neutralize with. . . ." Note: If appropriate, refer to headings 8 and 13.
Section 7	Handling and storage	Note: Information in this section should relate to the protection of health, safety, and the environment. It should assist the employer in devising suitable working procedures and organizational measures according to Article 5 of Directive 98/24/EC.
7.1	Handling	Specify precautions for safe handling including advice on technical measures such as: containment, local and general ventilation, measures to prevent aerosol and dust generation and fire, measures required to protect the environment (e.g., use of filters or

TABLE 3.15. ***Continued***

		scrubbers on exhaust ventilation, measures for collection and disposal of spillages, etc.) and any specific requirements or rules relating to the substance or preparation (e.g., procedures or equipment that are prohibited or recommended) and if possible give a brief description.
7.2	Storage	Specify the conditions for safe storage, such as specific design for storage rooms or vessels (including retention walls and ventilation), incompatible materials, conditions of storage (temperature and humidity limit/range, light, inert gas, etc.), special electrical equipment, and prevention of static electricity Give advice if relevant on quantity limits under storage conditions. In particular indicate any special requirements such as the type of material used in the packaging/containers of the substance or preparation.
7.3	Specific use(s)	For end products designed for specific use(s), recommendations should refer to the intended use(s) and be detailed and operational. If possible, reference should be made to industry- or sector-specific approved guidance
Section 8	Exposure controls/ personal protection	
8.1	Exposure limit values	Specify currently applicable specific control parameters including occupational exposure limit values and/or biological limit values. Values should be given for the Member state where the substance or preparation is placed on the market. Give information on currently recommended monitoring procedures. For preparations, it is useful to provide values for those constituent substances, which are required to be listed in the safety data sheet according to heading 2.
8.2	Exposure controls	For the purposes of this document exposure control means the full range of specific protection and prevention measures to be taken during use in order to minimize worker and environmental exposure

TABLE 3.15. ***Continued***

8.2.1	Occupational exposure controls	This information will be taken into account by the employer in carrying out an assessment of risk to the health and safety of workers for the substance or preparation under Article 4 of Directive 98/24/EC, which requires the design of appropriate work processes and engineering controls, the use of adequate equipment and materials, the application of collective protection measures at source, and finally the use of individual protection measures, such as personal protection equipment. Therefore provide suitable and adequate information on these measures to enable a proper risk assessment to be carried out under Article 4 of Directive 98/24/EC. This information should complement that already given under heading 7.1. Where personal protection is needed, specify in detail which equipment will provide adequate and suitable protection. Take into account Council Directive 89/686/EEC(3) and make reference to the appropriate CEN standards: comité Européen de Normalisation
8.2.1.1	Respiratory protection	For dangerous gases, vapors, or dust, specify the type of protective equipment to be used, such as self-contained breathing apparatus, adequate masks, and filters
8.2.1.2	Hand protection	Specify clearly the type of gloves to be worn when handling the substance or preparation, including: —the type of material, —the breakthrough time of the glove material, with regard to the amount and duration of dermal exposure. If necessary indicate any additional hand protection measures
8.2.1.3	Eye protection	Specify the type of eye protection equipment required, such as safety glasses, safety goggles, or face shield
8.2.1.4	Skin protection	If it is necessary to protect a part of the body other than the hands, specify the type and quality of protection equipment required, such as apron, boots, and full protective suit. If necessary, indicate any additional skin protection measures and specific hygiene measures.

TABLE 3.15. ***Continued***

8.2.2	Environmental exposure controls	Specify the information required by the employer to fulfill his commitments under community environmental protection legislation.
Section 9	Physical and chemical properties	To enable proper control measures to be taken, provide all relevant information on the substance or preparation, particularly the information listed under heading 9.2.
9.1	General information	Appearance: Indicate the physical state (solid, liquid, gas) and the color of the substance or preparation as supplied. Odors: If odor is perceptible, give a brief description of it.
9.2	Important health, safety and environmental information	PH: Indicate the pH of the substance or preparation as supplied or of an aqueous solution; in the latter case, indicate the concentration.
9.3	Other information	Indicate other important safety parameters, such as, miscibility, conductivity, melting point/melting range, gas group (useful for European Parliament and Council Directive 94/9/EC)(4), auto-ignition temperature etc. Note 1: The above properties should be determined in accordance with the specifications of Part A of Annex V to Directive 67/548/EEC or any other comparable method. Note 2: For preparations, information should normally be given on the properties of the preparation itself. However, if it is stated that a particular hazard does not apply, clearly differentiate between cases where no information is available to the classifier, and cases where negative test results are available. If it is considered necessary to give information about the properties of individual components, please indicate clearly what the data refers to.
Section 10	Stability and reactivity	State the stability of the substance or preparation and the possibility of hazardous reactions occurring under certain conditions of use and also if released into the environment
10.1	Conditions to avoid	List those conditions such as temperature, pressure, light, shock, etc., which may cause a dangerous reaction and if possible give a brief description

TABLE 3.15. ***Continued***

10.2	Materials to avoid	List materials such as water, air, acids, bases, oxidizing agents or any other specific substance which may cause a dangerous reaction and if possible give a brief description
10.3	Hazardous decomposition products	List hazardous materials produced in dangerous amounts upon decomposition. Note: Address specifically: —the need for and the presence of stabilizers, —the possibility of a hazardous exothermic reaction, —safety significance, if any, of a change in physical appearance of the substance or preparation, —hazardous decomposition products, if any, formed upon contact with water, —possibility of degradation to unstable products.
Section 11	Toxicological information	This section deals with the need for a concise but complete and comprehensible description of the various toxicological (health) effects, which can arise if the user comes into contact with the substance or preparation. Include dangerous-to-health effects from exposure to the substance or preparation, based on both experiences and conclusions from scientific experiments. Include information on the different routes of exposure (inhalation, ingestion, skin and eye contact), and describe the symptoms related to the physical, chemical and toxicological characteristics. Include known delayed and immediate effects and also chronic effects from short- and long-term exposure: for example, sensitization, narcosis, carcinogenicity, mutagenicity and reproductive toxicity (developmental toxicity and fertility). Taking account of the information already provided under heading 2, composition/information on ingredients, it might be necessary to make reference to specific health effects of certain components in preparations.
Section 12	Ecological information	Describe the possible effects, behavior, and environmental fate of the substance or preparation in air, water, and/or soil. Where available, give relevant test data (e.g. LC_{50} fish ≤1 mg/L).

TABLE 3.15. ***Continued***

		Describe the most important characteristics likely to have an effect on the environment owing to the nature of the substance or preparation and likely methods of use. Information of the same kind shall be supplied for dangerous products arising from the degradation of substances and preparations.
12.1	Ecotoxicity	This should include relevant available data on aquatic toxicity, both acute and chronic for fish, daphnia, algae and other aquatic plant. In addition, toxicity data on soil micro- and macro-organisms and other environmentally relevant organisms, such as birds, bees and plants, should be included when available. Where the substance or preparation has inhibitory effects on the activity of micro-organisms, the possible impact on sewage treatment plants should be mentioned.
12.2	Mobility	The potential of the substance or the appropriate constituents of a preparation (5), if released to the environment, to transport, to groundwater or far from the site of release. Relevant data might include: —known or predicted distribution to environmental compartments, —surface tension, —absorption/desorption. For other physicochemical properties see heading 9.
12.3	Persistence and degradability	The potential of the substance or the appropriate constituents of a preparation (6) to degrade in relevant environmental media, either through biodegradation or other processes such as oxidation or hydrolysis. Degradation half-lives should be quoted where available. The potential of the substance or appropriate constituents of a preparation (7) to degrade in sewage treatment plants should also be mentioned.
12.4	Bioaccumulative potential	The potential of the substance or the appropriate constituents of a preparation (8) to accumulate in biota and pass through the food chain, with reference to the Kow and BCF, if available.
12.5	Other adverse effects	If available, include information on any other adverse effects on the environment, as example, ozone depletion potential, photochemical ozone creation potential and/or global warming potential.

TABLE 3.15. ***Continued***

		Remarks: Ensure that information relevant to the environment is provided under other headings of the safety data sheet, especially advice for controlled release, accidental release measures, transport and disposal considerations under headings 6, 7, 13, 14 and 15.
Section 13	Disposal considerations	If the disposal of the substance or preparation (surplus or waste resulting from the foreseeable use) presents a danger, a description of these residues and information on their safe handling shall be given. Specify the appropriate methods of disposal of both the substance or preparation and any contaminated packaging (incineration, recycling, land filling, etc.). Note: Refer to any relevant community provisions relating to waste. In their absence, it is useful to remind the user that national or regional provisions may be in force.
Section 14	Transport information	Indicate any special precautions that a user needs to be aware of or needs to comply with in connection with transport or conveyance either within or outside his premises. Where relevant, provide information on the transport classification for each of the modal regulations: IMDG (sea), ADR (road, Council Directive 94/55/EC (9)), RID (rail, Council Directive 96/49/EC (10)), ICAO/IATA (air). This might include inter alia: —UN number, —class, —proper shipping name, —packing group, —marine pollutant, —other applicable information.
Section 15	Regulatory information	Give the health, safety and environmental information shown on the label according to Directives 67/548/EEC and 1999/45/EC. If the substance or preparation covered by this safety data sheet is the subject of specific provisions in relation to protection of man or the environment at community level (e.g., restrictions on marketing and use set out in Council Directive 76/769/EEC (11)) these provisions should, as far as is possible, be stated.

TABLE 3.15. ***Continued***

		Also mention, where possible, the national laws that implement these provisions and any other national measures that may be relevant.
Section 16	Other information	Indicate any other information that the supplier assesses as being of importance for the health and safety of the user and for the protection of the environment, for example: —list of relevant R phrases. Write out the full text of any R phrases referred to under headings 2 and 3 of the safety data sheet, —training advice, —recommended restrictions on use (i.e. non-statutory recommendations by supplier), —further information (written references and/or technical contact point), —sources of key data used to compile the data sheet, —for a revised safety data sheet, indicate clearly the information which has been added, deleted or revised (unless this has been indicated elsewhere).

triggers for hazard. Table 3.16 presents a summary of the legislation pertinent to hazard classification. When one of the laws is found applicable to a substance or preparation, the hazard classification applies. The hazard classifications constitute the base information for determining interpretative sections statements. The hazards found applicable for a given product are listed in the name of category in Section 3 of the Japanese SDS. We should also mention that for some legislation cut-off concentrations are also taken into consideration and differ with the EU and U.S. ones. Those authoring MSDS in Japan must then use specific databases for such information.

Here is a summary of the requirements for pertinent legislation:

Fire Fighting Law. For the Class 1 to 6, an author would have to enter, for a given substance, whether it is listed by particular chapters of the regulation. Sometimes, fire-fighting laws classes are divided in subclasses, in which case the user must enter the precise list designation. For a substance in a preparation listed under the fire-fighting law, a cut-off of 5% applies to determine whether or not the law and hazard category applies to the preparation. If a liquid substance or preparation has a flash point greater than –20 °C and lower than 40 °C or an autoignition temperature below 100 °C, it should automatically be listed as "Special" under "Class 4: Flammable Liquid" classification. This is the only physical criterion used to determine a fire-fighting law class.

TABLE 3.16. Laws and Their Corresponding Hazard Classification

Legislation	Hazard Classification
Explosive control law	Explosive
High-pressure gas control law	High-pressure gas
OSHL Appendix 1-5 combustible gas	Flammable gas
Fire law Class 4 flammable liquid	Flammable liquid
OSHL Appendix 1-4 flammable liquid	
Fire law Class 2 flammable solids	Flammable solid
OSHL Appendix 1-2 Combustible solid	
Fire law Class 3 spontaneous combustible	Spontaneous combustible
Maritime safety law Annex 6 spontaneous combustible	
OSHL Appendix 1-2 spontaneous combustible	
Fire law Class 3 water reactive	Water reactive
Maritime safety law Annex 6 water reactive	
OSHL Appendix 1-2 water reactive	
Fire law Class 1 oxidizer	Oxidizer
Fire law Class 6 oxidizing liquid	
Maritime safety law Annex 7 oxidizer	
OSHL Appendix 1-3 oxidizer	
Fire law Class 5 self-reactive	Self-reactive
OSHL Appendix 1-1 self-reactive	Corrosive
Maritime safety law Annex 3 corrosive	
Work conditions law clause 326	Acute toxic
Notification issued by labor standard bureau (Article 477)	
Maritime safety law Annex 4 toxic/class	
Poisoning prevention (organic solvents)	
Poison and toxin Clause 1 poison	
Poisons and toxins Clause 2 toxin	
Article 28-3 (lead content)	Other hazardous substances
Article 57	
Regulation of the use of Specified Chemical Substance/Class	
Lead/regulation	
Marine pollutant	
Law/examination and regulation of manufacture	
Notification issued by labor standard bureau (Article 312-2)	

Maritime Safety Law. Annex 1 to 8 specifies whether your substance is "listed" or "not listed." If a substance is "listed" on an Annex of the Maritime Safety Law, and it is present in a preparation, the Annex will be applicable to the preparation automatically (no concentration cut-off applies). There are some exceptions where a cut-off can apply for a particular classification for a particular substance.

Occupational Safety and Health Law (OSHL). Is comprised of the following key components:

- OSHL Appendix fields—The Appendix 1-1 to 1-5 are used to specify if a given substance is listed or not under an Appendix. For a substance in a preparation listed on any Appendix, a cut-off of 5% is applied to determine whether or not the law applies to the preparation.
- Lead regulation—The lead regulation is again like an inventory list for substances. Roll up for classification determination in preparations operates on a 1% cut-off (not additive).
- Article 57—The Article 57 works similarly to the Maritime Safety Law Annexes, in such that you can impose a cut-off for a substance. The default cut-off for "listed" substances is 1%.
- Work condition law (Clause 326)—The work condition law, Clause 326 is again a list regulation. For pure substances, data is reported in section 15, if the law is applicable (product listed). No analysis is performed for preparations in order to display information in section 15. On the other hand, this regulation will trigger a "corrosive" hazard class for a pure substance, or such a substance in a preparation at a concentration greater or equal than 5%.
- Carcinogenic (Art. 28-3)—The carcinogenic (Art. 28-3) is again a simple list. Roll up for classification determination in preparations operates on a 1% cut-off (not additive).
- Mutagen (312-2)—The mutagen (312-2) is also a list that proceeds with a 1% cut-off for preparations.
- Dangerous substance—Finally, the dangerous substance acts like a general hazard class for the following list in the OSHL frame: Appendix 1-1 to 1-5, Lead/Regulation, Article 57, Work Conditions law Clause 326, Carcinogen (Art. 28-3) and Mutagen (312-2).

Regulation of the Use of Specified Chemical Substances. Regulation of the use of specified chemicals substances contains two major criteria. The first is to specify the cut-off (when substance is in a mixture) and the second is to specify the class applicable to the substance. When a preparation contains two substances, with different applicable classes (say substance A is class 1 and substance B is class 3), only the worst classification will be displayed (in that case class 1) in section 15 (use of specified chemical substances).

Poisoning Prevention (Organic Solvents). The poisoning prevention is used to designate on which list a given substance is classified. For this regulation there is also a cut-off of 5% in order to determine whether a given class is applicable to a preparation. This cut-off is additive, meaning that all concentration needs to be sum for all substances of a given class and must be compared against the cut-off. The "worst case" is class 1. Also, for calculation purposes, class 1 is considered to include classes 2 and 3, and class 2 includes

class 3. The following is an example of a preparation that contains three substances (classification is for the poisoning prevention regulation). Such a preparation would be classified as class 2.

Substance A	Class 1	2%
Substance B	Class 2	3%
Substance C	Class 3	20%

Law of Examination and Regulation of Manufacture. This list is specified if a substance is designated class 1, class 2, or not listed. The applicable class will be reported in section 15 of the Japanese SDS for the substance. No special analysis is done for preparations.

Explosive Control Law. The explosive control law allows the following entries "Explosive powder / Explosives / Processed goods / Not applicable." The data is reported in Section 15 and this information needs to be imposed also on your mixture. No substance information is taken into consideration to list your preparation.

High-Pressure Gas Control Law. This list is used to identify the high-pressure gas and is designated by either high-pressure gas, liquified petroleum gas, or not applicable. Here again, this value needs to be defined for your preparation because substance information are not taken into consideration.

Marine Pollutant Regulation. Addresses the IMDG classification related to marine pollutants. IMDG is defined in Chapter 5 as International Maintime Dangerous Good.

Other regulations. Several other local laws apply in Japan and should be reviewed prior to shipping materials within Japan.

The following are examples of lists, pertinent to a substance that must be disclosed on a MSDS:

MITI number—The MITI number is a required number from a list that needs to be displayed in Section 15. MITI number is assign by the Ministry of International Trade and Industry.

MOL number—The MOL number is related to a simple list with different number for different danger and is related to the laws hazard classes mentioned above. MOL number is assign by the Ministry of Labor.

Poisonous and deleterious materials—Both the poison and toxic lists can have specific cut-offs for substances. The default is set to 1%.

Pollutant Release and Transfer Registry (PRTR)—The PRTR list allows for class 1, class 2, or not applicable. Again, this needs to be identified in your preparation. Furthermore, in case of a PRTR substance, the exact concentration should be mentioned in Section 2.

3.5.2 SDS for Korea

The MSDS for Korea follows the standard European SDS 16 sections with some minor deviations. Legislation pertinent to Korean SDS includes:

- Official Korean public notice from Ministry of Labor's Public Notice No. 1997-27.
- Standards on preparing and keeping on file the MSDS (Ministry of Labor's Public Notice No. 1996-58) in accordance with Article 41 of the Industrial Safety and Health Law (ISHL).

The following is a summary of requirements for a Korean MSDS.

- Employ the EU definition for a substance and preparation.
- The MSDS must be in Korean language; provided, however, that proper nouns including chemical names or name of foreign entity may be written in English.
- If the MSDS is for a reagent being used in laboratories for the purpose of R&D, it does not have to be translated into Korean.
- If test results include tests performed under the standard of good laboratory practice (GLP), these results should take priority over other results.
- If at least one test result turns out positive under prescribed standards, the material is deemed hazardous.
- In case of translating a MSDS that is written in a foreign language, the original entity and date of generating the MSDS shall be written on it to ensure reliability. In case of preparing the MSDS by using other types of reference materials, the sources of such reference materials shall be identified.
- The terms used in the MSDS shall be in conformance with "the Guideline on Interpretation of MSDS" unless other terms are deemed to be proper; a document issued by the Korean Industrial Safety Corporation.
- The unit of measurement to be used in the MSDS shall comply with the provisions of the Law for Weighing and Measuring.
- Each items shall, to the extent possible, be prepared without omission; provided, however, that the words "no available information" shall be written for the items on which the necessary information cannot be obtained, and the words "not applicable" shall be written for the items that are not applicable to a particular case in question.
- In cases when business owners prepare the MSDS, they shall prepare the MSDS in good faith in conformity with the purpose of protecting health of the employees handling the substances.

Table 3.17 presents the criteria to be used in the classification of products in Korea (as Ministry of Labor's Public Notice No. 1997-27). These classifications are similar to the EU criteria. In Table 3.18, the required components of each section of an SDS are presented as per Provisions of Article 41, Industrial Safety & Health Law.

TABLE 3.17. Criteria for Classification of RCSs and Hazard Marks

Classification	Definition	Hazard Mark
Explosive substances	Substances or gases in the state of solid, liquid, paste, or gelatin, which exothermically react while rapidly liberating gas without oxygen in the air and explodes or rapidly explodes accompanying smoke	
Oxidizing substances	Substances that may cause fire through self-oxidation or that cause fire or explosion mixing with other substances or while in contact with other substances, especially combustible substances	
Extremely flammable substances	Liquid substances that have a flash point lower than 0 °C and a boiling point of 35 °C or less, or gaseous substances that are flammable in contact with air at ambient temperature and pressure	
Highly flammable substances	Liquid substances that have an ignition point lower than 21 °C, or substances that exothermically react and then finally ignite, in contact with air at ambient temperature without the input of energy	
Flammable substances	Liquid substances that have an ignition point of 21 °C or more and 55 °C or less	
Water-prohibiting substances	Substances that, in contact with water or damp air, emit explosive or flammable gases in dangerous quantities	
Very toxic substances	Substances, very small amounts of which, cause death or acute or chronic damage when inhaled, ingested, or absorbed through the skin and which fall within any of the following items: When administered orally, • $LD_{50} \leq 25$ mg/kg (rat) When administered through the skin for 24 hours, • $LD_{50} \leq 50$ mg/kg (rat or rabbit) When continuously inhaled for 4 hours, • gas or vapor: $LC_{50} \leq 0.5$ mg/L/4 hr (rat) • particle or aerosol: $LC_{50} \leq 0.25$ mg/L/4 hr (rat)	
Toxic substances	Substances, a small amount of which, causes death or acute or chronic damage when inhaled, ingested, or absorbed through the skin and which fall within any of the following items: When administered orally, • $25 \leq LD_{50} \leq 200$ mg/kg (rat) When administered through the skin for 24 hours, • $50 \leq LD_{50} \leq 400$ mg/kg (rat or rabbit) When continuously inhaled for 4 hours, • gas or vapor: $0.5 \leq LC_{50} \leq 2$ mg/L/4 hr (rat) • particle or aerosol: $0.25 \leq LC_{50} \leq 1$ mg/L/4 hr (rat)	

TABLE 3.17. ***Continued***

Classification	Definition	Hazard Mark
Harmful substances	Substances that are likely to cause acute or chronic damage when inhaled ingested or absorbed through the skin and which fall within any of the following items: (1) Acute toxicity When administered orally, • $200 \le LD_{50} \le 2000$ mg/kg (rat) When administered through the skin for 24 hours, • $400 \le LD_{50} \le 2000$ mg/kg (rat or rabbit) When continuously inhaled for 4 hours, • Gas or vapor: $2 \le LC_{50} \le 20$ mg/L/4 hr (rat) • Dust or particles: $1 \le LC_{50} \le 5$ mg/L/4 hr (rat) (2) Chronic toxicity (NOEL means No Observable Effect Level) When administered orally, • NOEL ≤ 50 mg/kg/90 days (rat) When administered through the skin, • NOEL ≤ 100 mg/kg/90 days (rat) When continuously inhaled for 6 hours, • NOEL ≤ 0.5 mg/L/6 hr/90 days (rat) (3) Others 1. Death or serious damage, when exposed to relevant chemical substances repeatedly or chronically 2. Significant functional damage of central or peripheral nervous system, including visual, hearing, and smelling sensation, on the assessment of clinical observation or other appropriate method 3. Consistent changes occur clinically, such as reduction of bone marrow cell production of blood 4. Damage to target organs, including liver, kidney, nerve system, lung, and so on 5. Damage to blood or the hematogenous system, such as damage of hemoglobin function, and so on 6. Functional damage or irreversible changes to the organs of the body	
Corrosive substances	Substances that destroy the tissue when in contact with animal or human skin (including reactions with strong acid of pH 2 or less or alkaline substances of pH 11.5 or more)	
Irritant substances	When inhaled, in contact with skin or eyes, substances that fall within any of the following items:	

TABLE 3.17. ***Continued***

Classification	Definition	Hazard Mark
	Skin irritants: substances that cause serious dermatitis continued for 24 hours when exposed to skin for 4 hours in a skin irritation test or that actually cause serious dermatitis in human skin *Eye irritant*s: substances that cause corneal opacity, hyperemia conjunctiva, edema conjunctiva, or damage to the iris within 72 hours after exposure and such reactions continue for more than 24 hours thereafter, as a result of an eye irritant test and substances that actually induce focus in human eyes *Respiratory irritant*: substances that induce a serious irritation in human respiratory organs	
Sensitizing substances	Substances that fall within any of the following items: *Respiratory sensitization*: substances that create more frequent reactions than expected as a result of respiratory sensitivity tests on general populations *Skin sensitization*: substances that create sensitive reactions on many humans or animals during skin contact experiments	
Carcinogenic substances	Recognized carcinogenic substances (A1), or suspected carcinogenic substances (A2) as defined by the American Conference of Governmental Industrial Hygienists (ACGIH)	
Mutagenic substances	Substances that, when inhaled, ingested, or absorbed through the skin, are likely to cause mutation or damage of gene or to increase the occurrence rate of damage	
Toxic substances for reproduction	Substances that, when inhaled, ingested, or absorbed through the skin, are likely to cause a nonhereditary adverse effects to posterity and generative function of females and males or increase the rate of such occurrences	
Hazardous substances to environment	Substances that fall within any of the following items: (1) Ecotoxicity LC_{50} (96 hr) ≤ 1 mg/L (fish) or EC_{50} (48 hr) ≤ 1 mg/L (daphnia) or IC_{50} (72 hr) ≤ 1 mg/L (algae) (2) Substances that are nonbiodegradable or/and have an octanol/water partition coefficient (log Pow) of 3 or more (excluding bioconcentration coefficient of 100 or less) and the environmental ecotoxicity falls within any of following items: (3) 1 mg/L ≤ LC_{50} (96 hr) ≤ 10 mg/L (fish) or 1 mg/L ≤ EC_{50} (48 hr) ≤ 10 mg/L (daphnia) or 1 mg/L ≤ IC_{50} (72 hr) ≤ 10 mg/L (algae)	

TABLE 3.18. Contents of a Korean MSDS

1. Chemical Product and Company Identification

Product name, general characteristics, hazard classification, product use, information on manufacturer, name and address of manufacturing company, company telephone number, emergency telephone number, information on supplier/distributor, company name, address, information service or emergency telephone number, responsible charge, responsible person, office and name of preparer, preparation date, revision number, and latest revision date

2. Name and Contents of Components

Chemical name, other name, CAS (Chemical Abstract System) number or identification number, content (%), hazard identification, and essential risk

3. Hazard Information

Effects on eye, effects on skin, inhalation effects, ingestion efects, chronic signs and symptoms

4. First Aid Measures

If substance contacts eyes, if substance contacts skin, if substance is inhaled, if substance is ingested, and note to attending physicians

5. Fire-Fighting Measures

Flash point, autoignition temperature, lower and upper explosive (flammable) limits, classification under the Fire Services Law and Matters Regulated, extinguished media, fire-fighting procedures and equipment, hazardous combustion products, and extinguishing media not to be used

6. Spill Response Measures

Measures required for personal protection, measures required for environment protection, and clean-up and removal method

7. Handling and Storage Procedures

Directions for safe handling and storage method

8. Exposure Prevention Measures/Personal Protective Equipment

Engineering control methods, protection of respiratory system, eye protection, hand protection, body protection, hygienic precautions, and exposure limits (Time Weighted Average and Short Term Exposure limits).

Chemical Name Composition (%) Permissible Level TWA STEL

9. Physical and Chemical Properties

Appearance, odor, pH, solubility, boiling point/boiling range, melting point/melting range, explosiveness, oxidizing properties, vapor pressure, specific gravity, partition coefficient, vapor density, viscosity, and molecular weight

TABLE 3.18. ***Continued***

10. Stability and Reactivity
Chemical stability, conditions to avoid, materials to avoid, hazardous decomposition products, and potential for hazardous polymerization
11. Toxicological Information
Acute oral effects, acute inhalation effects, acute dermal effects, subacute effects, chronic effects, mutagenic effects, fertility (toxicity to reproduction), carcinogenicity, and others
12. Effects on the Environment
Aquatic toxicity and ecotoxicity, soil mobility, residual properties and degradability, and possibility of bioaccumulation.
13. Precautions for Disposal
Regulatory status under the Wastes Management Law, disposal method and precaution for disposal
14. Transport Information
Classification and regulations under the "Regulation on Ship-Transportation and Storage of Dangerous Substances," cautions for transport, and international classification and restrictions
15. Regulatory Information
ISHL, regulations based on TCCL or other environmental-related laws, and other regulations based on foreign laws
16 Other Information
Source of reference material and other information

3.5.3 SDS for China

Recently, the Chinese government launched a nation-wide campaign to ensure that regulations on hazardous chemicals were being followed. Unlicensed production, distribution, transportation, and use of the hazardous chemicals that are not in accordance with regulatory requirements will be banned.

The key regulatory requirements for SDS are derived from the "General Rules for Preparation of Chemical Safety Data Sheet" (GB 16483-2000). The legislation requires the SDS to follow the International Organization for Standardization (ISO) 11014-1, 1994 Safety Data Sheet for Chemical Products—Part 1 requirements. The ISO 11014 has been developed for worldwide application and follows the SDS model as outlined in, for instance, EC Com-

mission Directive 91/155/EEC, defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations, and the Chemical Manufacturing Association (CMA), which is now recognized under the Council. Interim guidelines for the preparation of SDS, with only minor deviations in the text of the section headings have been prepared.

The National Standard of People's Republic of China issued the GB 16483-2000 on January 5, 2000, with an effective date of June 1, 2000. This was issued by the State Agency for Quality and Technology Supervision. The main differences with the GB 16483-1996 are that now they have changed to 16 sections instead of 8 sections. They have created a hazard identification summary and added fire-fighting measures and toxicological and ecological information.

A Chemical Safety Data Sheet (CSDS) provides various kinds of information on safety, health, and environment protection. Even though you will see CSDS in some literature, they also adopted the general SDS definition. The provision includes other standards that are part of the general rules, and these are as follows:

- GB 6944-1986 Classification and Name Code of Dangerous Goods
- GB 13690-1992 Classification and Labels of Dangerous Chemical Substances Commonly Used
- GB 15098-1994 Classification Principle for Transportation and Package of Dangerous Goods
- UN RTDG
- Management Principles of the Transportation of Dangerous Goods issued by the Ministry of Railways in 1995

Because the ISO 11014 format follows the European format, the following are clarifications and differences with the Chinese SDS legislation:

- The name of the chemical product in Chinese can be chemical name, trade name, or product name
- The signal words *danger*, *warning*, or *caution* are used to indicate the degree of severity of hazards of chemicals
- The EU risk phrase is acceptable
- The EU safety phrase is acceptable
- For the hazard pictogram, Chinese criteria for the classification shall be followed. However, due to the similarity of the Chinese criteria and that of EU, in most cases the EU criteria are acceptable; exemptions include the classification of flammable products
- For the transport pictogram, the Chinese pictogram (largely identical to that of the UN) shall be used. Also, the GHS UN transport-based pictograms can be used; EU pictograms, which are at present not included in the Chinese standard, may be included as optional

- The emergency telephone number must be a Chinese number accessible 24 hours a day

According to their main dangerous properties, the dangerous chemical substances commonly used are divided into the following eight categories as per GB 13690-1992:

Category 1: explosive chemicals. Under the effects from outer sphere (heated, pressed, and impacted, etc.), these chemical substances can produce acute chemical reactions, releasing a great amount of gas and heat instantly, which makes the ambient pressure increase sharply, creating an explosion, which does harm to the ambient environment. Moreover, those chemical substances that do not have the danger of integral explosion, but possess properties of burning, projection and little danger of explosion are also included in this category.

Category 2: compressed and liquefied gases. These chemical substances are gases that will dissolve when they are compressed, liquefied or pressurized. They must conform to either of the following two conditions:

a. Those compressed or liquefied gases whose vapor pressures are more than 294 kPa when the critical temperature is less than or equal to 50 °C.
b. Those compressed gases whose absolute pressures are more than 275 kPa at 21.1 °C, or 715 kPa at 54.4 °C or those liquefied gases or pressurized dissolved gases that have a vapor pressures of more than 275 kPa at 37.8 °C.

Category 3: inflammable liquids. These chemical substances are inflammable liquids, inflammable mixtures of liquids, or liquids that contain solid substances. However, liquids classified into other categories are not included in this category because of their dangerous properties. The close cup flash point is less than or equal to 61 °C.

Category 4: flammable solids, substances prone to spontaneous combustion, and substances emitting inflammable gases when wet. Inflammable solids are solids that have a low igniting point and are sensitive to heat, impact, and friction. They are easily ignited, burning quickly and probably releasing toxic smoke or gases. But those classified into explosive substances are not included. Substances liable to spontaneously combust are those that have a low ignition point and that are easy to produce oxidation-reduction reactions in the air, releasing heat and igniting automatically. Substances emitting inflammable gases when wet are chemicals that can produce acute chemical reactions in water or moisture, releasing a great number of inflammable gases and heats. Some can burn or explode without being exposed to fire.

Category 5: oxidizing substances and organic peroxides. Oxidants are chemicals that are at high oxidation state, have strong oxidation, and can decompose easily, releasing oxygen and heat. They also includes inorganic substances that have a peroxide group. They may not be ignited, but they can make other

inflammable substances burn, and make up explosive mixture with soft powder of inflammable substances. They are sensitive to heat, vibration, and friction. Organic peroxides are organic substances that have a peroxide group in their molecules. They are easy to burn, explode, and decompose and are sensitive to heat, vibration, and friction.

Category 6: toxic chemicals. These chemical substances are chemicals that can produce biochemical reactions or biophysical reactions with body fluids and tissues of organs after they enter the human body and accumulate to a certain amount. They can disturb or destroy the normal physiological functions of human body, make some organs or systems change pathologically, temporarily, or permanently, and even endanger one's life. The amounts taken in by mouth causing half of the testing group to die are, for solids, LD_{50} (lethal dose) ≤ 500 mg/kg, and for liquids, $LD_{50} \leq 2000$ mg/kg. For skin contact for 24 hours, the amount of causing half of the testing group to die is $LD_{50} \leq 1000$ mg/kg. The amount of dust, smoke, and vapor inhalation causing half of the testing group to death in LC_{50} (lethal concentration) ≤ 10 mg/L for solids and liquids.

Category 7: radioactive chemical substances. These chemical substances are those with radioactive-specific activities more than 7.4×10^4 Bq/kg.

Category 8: corrosive chemical substances. These chemical substances are liquids and solids that can burn tissues of human body and destroy metals and other materials. Contacting with skin for 4 hours, these chemicals will cause obvious necrosis. These liquids and solids have an average corrosion rate to the surface of No. 20 steel exceeding 6.25 mm/year at the temperature of 55 °C.

3.5.4 SDS for Australia

Australian SDS legislation is predominately based on other international or regional legislation with the classification criteria being based upon EU R and S phrases. The following is a summary of current Australian requirements. A draft version of proposed legislation is currently available—Australian National Code of Practice for the Preparation of MSDS–NOSHC: 2011 (2003), 2nd edition. It is our understanding that the new legislation will be approved in November 2003, with the anticipated enforcement date being 2006. The SDS format needs to follow the Australian National Code of Practice for the Preparation of Material Safety Data Sheets. Table 3.19 presents the contents of an Australian SDS.

Section 2 declarations must conform to Australian rules. Section 8 must show Australian Occupational Exposure Standards (OESs) defaulting to ACGIH Treshold Limit Value. Section 14 must show the Australian Dangerous Goods (ADG) legislation, IMDG, and IATA information (Chapter 5 contains all of the Transport acronyms). Section 15 shows only health-related classifications. Support for schedules is added, for example, poisons schedule, carcinogenic substances, and schedule NZ Toxic Substances Schedule.

TABLE 3.19. Contents of Current Requirements for an Australian MSDS

Area/ Section	Title	Content
	MSDS no.	Australian Registration Number
1	Statement of hazardous nature	Statement of hazardous nature
2	Col 4 (Health-Symbol)	HSE hazards
	Col 5 (R Phrases)	HSE R phrases
3	UN no.	ADG UN no.
	Proper shipping name	ADG PSN
	Class	ADG Class—primary
	Sub-risk	14 ADG Class—subsidiary
	Packing group	ADG packing group
	Hazchem code	ADG hazchem code
	Initial emergency response guide	ADG initial ER guide
	Combustible liquid	Combustible liquid
	Poisons schedule (Australia)	Poisons schedule
	Toxic substance schedule (NZ)	Toxic substance schedule
4	First aid facilities	First aid facilities
7	Combustible liquid	Combustible liquid
8	Table	Hazardous ingredients HL
	Col 1	Ingredient name
	Col 2—Year	Year
	Col 3—8 hr, ppm	OES—8 hr, ppm
	Col 4—8 hr, mg/m^3	OES—8 hr, mg/m^3
	Col 5—15 min, ppm	OES—15 min, ppm
	Col 6—15 min, mg/m^3	OES—15 min, mg/m^3
	Col 7—peak ppm	OES—peak ppm
	Col 8—peak mg/m^3	OES—peak ppm
	Col 9—Carc. cat.	AU—carc.
14	ADG—UN no.	ADG—UN no.
	ADG—proper shipping name (PSN)	ADG PSN
	ADG—class	ADG—class, primary
	ADG—Subrisk	ADG—class, subsidiary
	ADG—packing group	ADG—packing group
	ADG—additional info.	ADG—notes
15	Hazard—health	HSE hazards
	Risk phrases—health	HSE R phrases
15	Safety phrases	HSE S phrases
15	Carcinogenic substance schedule (NOHSC)	
15	Australian inventory status	AICS Status

In the following section, additional information on key requirements of the current legislation are presented.

Statement of Hazardous Nature. This checks the health-related risk phrases and the ADG (UN) code and returns one of four sentences summarizing the hazard present.

- If there is an R phrase and a UN number, the following sentence must appear: "Classified as hazardous according to the criteria of NOHSC and classified as dangerous goods according to the ADG Code."
- If there is an R phrase but no UN number, then the following sentence must appear: "classified as hazardous according to the criteria of NOHSC and not classified as dangerous goods according to the ADG Code."
- If there is no R phrase but there is a UN number, then the following sentence must appear: "Not classified as hazardous according to the criteria of NOHSC but classified as dangerous goods according to the ADG Code."
- If there is no R phrase and no UN number, then the following sentence must appear: "Not classified as hazardous according to the criteria of NOHSC nor classified as dangerous goods according to the ADG Code."

Poisons List. Provides a list containing two types of data. The first one is whether the substance is on the list or not and the second one is a schedule number, if listed. The poison list is contained in the Australia Poisons Code; refer to Appendix 3 for the Australian government Web sites.

OES. A list of components with Australian OES. If Australian values are not available for a substance, then the US-ACGIH values should be taken into account. Refer to Appendix 5 for additional information on OELs. OES is the Australian definition for Occupational Exposure Standard.

Transportation Regulation. The Australian Dangerous Goods Regulation (ADG) defines the transportation information and is based on UN regulations, with some minor differences. For the ADG, the requirement is also to display the Hazchem Code.

Carcinogenic Substances Schedule. The carcinogen substances schedule is another list where substances are listed or not listed. If the substance is listed, then there is a schedule number that is available.

Inventory List Status. The values for the inventory list status are as follows:

1) Listed on the Australian Inventory of Chemical Substances (AICS)
2) Not listed on Australian Inventory of Chemical Substances (AICS)
3) Exempt from the requirements of the Industrial Chemicals (Notification and Assessment) Act 1989
4) This material is new and has been introduced under an Assessment Certificate granted under Section 23 of the Industrial Chemicals (Notification and Assessment) Act 1989
5) This material is being introduced under a Commercial Evaluation Permit granted under Section 21G of the Industrial Chemicals (Notification and Assessment) Act
6) This material is being introduced under a Low Volume Chemical Permit granted under Section 21U(2) of the Industrial Chemicals (Notification and Assessment) Act

7) This material has been introduced under an Early Introduction Permit granted under Section 30A of the Industrial Chemicals (Notification and Assessment) Act 1989
8) This material has been introduced under a permit granted under Section 30 of the Industrial Chemicals (Notification and Assessment) Act 1989

Insert the appropriate statement 1 or 2. If statement 2 is true, include additional statement 3, 4, 5, 6, 7, or 8, as applicable:

SDS Layout. The content that differs from the European SDS to comply with the Australian MSDS is presented in Table 3.19.

New Zealand legislation is outside the scope of this book, however, it is important to note that New Zealand is in the process of adopting the draft GHS legislation (refer to Section 3.7), whereas Australia has a modified version of EU legislation. Appendix 3 contains a list of New Zealand government Web sites that contain information on local requirements pertinent to material compliance issues.

3.5.5 SDS for Malaysia

The Malaysian regulation identifies their SDS also by the term Chemical Safety Data Sheet (CSDS). Occupational Safety and Health Regulations address the classification, packaging and labeling of hazardous chemicals and were last revised in 1999. Regulation 4 stipulates the duty of a supplier of hazardous chemicals to classify each hazardous chemical according to the specific nature of the risk involved during use and handling of the chemical at work.

Classification. The classification of chemicals based on physicochemical properties must be done using methods specified in Annex V (A) to Directive 67/548/EEC (hereafter referred to as "the Directive") and as amended in the subsequent Directives. A chemical is considered as hazardous and should be classified as either explosive, oxidizing, extremely flammable, highly flammable, or flammable when the results of tests carried out according to the Directive satisfy one or more of the specific nature of the risk definitions in Part A of Schedule 1 of the Regulations.

Table 3.20 define the chemical classification according to health effects criteria as stipulated in Part B of Schedule 1 of the regulation.

The references stipulated in all documentation refer to the EU legislation and the adaptation done by Australia. The following are a few examples of references

1) National Occupational Health and Safety Commission—List of Designated Hazardous Substances—NOHSC: 10005(1999).
2) National Occupational Health and Safety Commission—Approved Criteria For Classifying Hazardous Substances—NOHSC: 1008(2000).
3) Official Journal of the European Community—Council Directive 79/831/EEC.

TABLE 3.20. Health Effect Criteria

Classification	Health Effects	Toxicity Data
Very toxic	Substances and preparations that, if inhaled, ingested, or penetrated into the skin, may involve extremely serious acute or chronic health risks or even death	LD_{50} < 25 mg/kg oral absorption in rat LD_{50} < 50 mg/kg skin absorption in rat or rabbit LC_{50} < 0.5 mg/L (4-hour) inhalation in rat
Toxic	Substances and preparations that, if inhaled, ingested, or penetrated into the skin, may involve serious acute or chronic health risks or even death Substances and preparations that are defined as carcinogenic, tetratogenic, or mutagenic	LD_{50} between 25 and 200 mg/kg oral absorption in rat LD_{50} between 50 and 400 mg/kg skin absorption in rat or rabbit LC_{50} between 0.5 and 2 mg/L (4-hour) inhalation in rat
Corrosive	Substances and preparations that may, on contact with living tissues, destroy them	
Harmful	Substances and preparations that, if inhaled, ingested, or penetrated into the skin, may involve limited health risk	LD_{50} between 200 and 500 mg/L oral absorption in rat LD_{50} between 400 and 2000 mg/kg skin absorption in rat or rabbit LC_{50} between 2 and 20 mg/L (4-hour) in rat
Irritant	Noncorrosive substances and preparations that, through immediate, prolonged, or repeated contact with the skin or mucous membrane, can cause inflammation	

4) Official Journal of the European Community—Council Directive 67/548/EEC.
5) Official Journal of the European Community—Council Directive 91/325/EEC.
6) Occupational Safety and Health (Classification, Packaging and Labeling of Hazardous Chemicals) Regulations 1997.

Format and Content. The Malaysian CSDS is divided into 16 sections. Appendices I to XVI describe the relevant and additional information to be included on the CSDS. Table 3.21 illustrates how the information is to be presented.

TABLE 3.21. Content of Malaysian SDS

Chemical Safety Data Sheet

Introductory Details
Page x of total y:
Date of preparation:

Section 1: Chemical Product and Company Identification

1.1. Product Details
Product name, trade name, chemical name, chemical formula, molar mass, chemical family, manufacturer's code, and use

1.2. Company Identification
Manufacturer's name, importer's/distributer's name and address, emergency telephone number, and telephone number

1.3. Contact Point
Designation, telephone number
Note: The contact point given should direct a caller to someone who can clarify information or provide further information and/or a bibliography of the product. The titles of a position or section should be inserted.

Section 2: Composition/Information on Ingredient

Chemical name, CAS no., proportion, exposure limit, and toxicity data

Section 3: Physical and Chemical Properties

Appearance, odor, solubility, boiling point, melting point (°C), vapor pressure (mm Hg at 25 °C), percentage volatiles, evaporation rate, vapor density, specific gravity, flash point, auto ignition, temperature, flammable limit (%), and other properties if applicable

Section 4: Hazard Identification

Most important hazards

Section 5: First Aid Measures

Ingestion, eye contact, skin contact, inhalation, and notes to physician

Section 6: Fire-Fighting Measures

Extinguishing media, fire-fighting instruction, and special hazards (e.g., explosion properties and explosion hazards in the presence of various chemicals)

Section 7: Accidental Release Measure

Leak/spill

Section 8: Handling and Storage

Handling and storage

TABLE 3.21. ***Continued***

Section 9: Exposure Control and Personal Protection
Exposure limits, engineering measures, and personal protection
Section 10: Stability and Reactivity
Conditions to avoid, incompatibles, decomposition products, and hazardous polymerization
Section 11: Toxicological Information
Toxicity data, carcinogenicity, reproductive effect, effects of overexposure, chronic effects, target organs, and medical conditions generally aggravated by exposure
Section 12: Ecological Information
Mobility, bioaccumulation, biodegradability, and aquatic toxicity
Section 13: Disposal Information
Disposal method in accordance with all applicable national environment laws and regulations
Sectoin 14: Transport Information
Any international and national regulatory requirements, packaging information, and any other special requirements
Section 15: Regulatory Information
This section should contain information on proposed classification, risk phrase, and safety phrase
Section 16: Other Information
This category contains any information not specified in other sections that the manufacturer could provide

The regulations require that the information be written in the national language and English. Both versions should be in a single document rather than in two separate documents. An important note to remember is that the translation of the CSDS needs not to be done line-by-line but a translator certified by Dewan Bahasa & Pustaka or Institut Terjemahan Negara should do the translation of the CSDS.

3.5.6 SDS for Thailand

Most relevant to the control of industrial chemicals in Thailand is the Hazardous Substance Act B.E. 2535 (1992). B.E. 2535 is under the direct

authority of the ministry of Industry, with the cooperation of the ministers of Defense, Agriculture, Public Health, and Science, Technology, and Environment. The Hazardous Chemicals Act lists chemicals, uses and the ministries having jurisdiction over those chemicals. Hazard communication in the form of classification, labeling, and MSDS are stipulated.

MSDS are required under Act B.E. 2535 for all companies that produce, use, or store dangerous substances as defined by B.E. 2535. Thailand has recently adopted a format similar to the ISO-11014 standard. Table 3.22 presents the required content of a Thailand SDS.

Classification. Ten hazard groups are identified: explosives, flammable, oxidizing, radioactive, toxic, mutagenic, corrosive, irritating, causing disease, and causing injury to humans, animals, plants, property, or the environment.

3.6 GLOBAL HARMONIZED SYSTEM (GHS)

Extensive international trade in chemicals and the need to ensure the safe use of chemicals is the background for the development by the UN of an International Recommendation for Globally Harmonized Classification and Labeling System (GHS). The recommendations have been available since December 2002. The GHS is a nonmandatory recommendation available to countries to implement.

The issue with the different systems available in the world is their definition of dangers that are not unified. As an example, the same product can be classified as flammable in one country but not in another one. The same schema may apply for carcinogenicity, where a chemical would be considered to cause cancer in one country but not in another. This means that decisions on when or how to communicate hazards on a label or SDS vary around the world, and companies wishing to be involved in international trade must have large staffs of experts who can follow the changes in these laws and regulations and prepare different labels and SDS.

The target audience for the system ranges from professional users and consumers to transport/freight handlers and emergency responders. With this in mind, the criteria for classification, use of symbols, signal words, and hazard statements for the communication have been carefully selected.

The UN GHS can be compared with the existing UN system for transport classification and labeling, which has been implemented in many countries all over the world. The implementation of the GHS will require changes in all the existing systems including the EU classification and labeling system.

The goals of the UN GHS are to enhance protection of mankind and the environment by the following measures:

- Providing an internationally comprehensible system for hazard communication

TABLE 3.22. Content of a Thailand SDS

Thailand Material Safety Data Sheet

Product/chemical name:
Company name:
Address:

1. Product and Company Identification

Chemical/product name, chemical formula, CAS number, other names, manufacturer/dealer, address, telephone, fax, and emergency telephone

2. Composition/Information on Ingredients

3. Physical and Chemical Properties

Melting point (°C), boiling point (°C), density (g/mL at °C), vapor pressure (kPa at °C), viscosity (m^2/sec at °C), water solubility (g/100 mL at °C state solid liquid gas at °C, color and odor, flash point (°C), test method, ignition temperature (°C), exposure limits, LEL (%), UEL (%), and others physical properties

4. Hazards Identification

Main hazards (e.g., flammable, explosive material, corrosion, and health hazard data)

5. First-Aid Measures

Eye contact, skin contact, inhalation, swallowed, and other medical advice

6. Fire-Fighting Measures

Extinguishing media, not recommended media, unusual fire and explosion hazards, fire-fighting procedure, and protective equipment

7. Accidental Release Measures

Human protection, environmental protection, and disposal procedure

8. Handling and Storage

Use—precautions, warnings, ventilation, safe usage, storage condition, and incompatible chemicals

9. Exposure Controls/Personal Protection

Exposure limits (TLV-TWA), special engineering controlling, respiratory protection, skin protection, hand protection, and eye protection

10. Stability and Reactivity

Is inhibitor needed for stabilization—No/Yes
If yes, specify inhibitor/stabilizer/phlegmatization

TABLE 3.22. ***Continued***

Material/condition to avoid
Is explosive material—No/Yes
If yes, specify
Can react with water—No/Yes
If yes, specify
Is oxidizing material—No/Yes
If yes, specify
Is hazardous decomposition product—No/Yes
Hazardous decomposition product
Disposal of decomposition product

11. Toxicological Information

Oral LD_{50} (mg/kg) animal, skin LD_{50} (mg/kg) animal, inhalation LC_{50} (mg/kg) animal, exposure time, eye contact, skin contact, chronic adverse, allergic adverse, irritation, carcinogenic, adverse reproductive development, genotoxicity, mutagencity, and neurogical effect

12. Ecological Information

Mobility, persistence/degradation, bioaccumulation, and ecotoxicity

13. Disposal Considerations

Product disposal procedure, packaging disposal procedure, and waste disposal

14. Transportation Information

UN number, UN class, UN packing group
ADR/RID substance identification number, ADR/RID—Class
ADR/RID—item number
ADR-RID—hazard identification number
IMDG—packing group, IMDG—class
IMDG—marine pollutant, IMDG—EMS number
IMDG—MFAG table number, IATA—packing group
IATA—class, TREMcard Number TEC (R)

15. Precautionary Label

16. Other Information References

- Providing a recognized framework for those countries without an existing system
- Facilitating international trade in chemicals whose hazards have been properly assessed and identified on an international basis
- Reducing the need for testing and evaluation of chemicals

The major references that were used as the basis of the GHS are the following:

- U.S. legislation for the workplace, consumers, and pesticides
- Canadian legislation for the workplace, consumers, and pesticides
- EU directives for classification and labeling of substances and preparations
- UN recommendations on the transport of dangerous goods

The co-ordination of the harmonization work was addressed to a Co-ordinating Group for the Harmonization of Chemical Classification Systems (CG/HCCS) under the umbrella of the Interorganization Programme on the Sound Management of Chemicals, IOMC.

CG/HCCS developed a set of principles for the GHS (CG/HCCS, 1996):

a. The overall level of protection should not be reduced.
b. The hazard classification process should refer only to the intrinsic properties of the chemicals.
c. The appropriate elements relevant to means of transport, consumer, worker and environment protection should be selected from a common and coherent basis for chemical hazard classification and communication.
d. Harmonization should include both hazard classification criteria and hazard communication tools, e.g. labeling and chemical safety data sheets.
e. Changes in all existing systems will be required.
f. The involvement and contributions of international organizations of employers, workers, consumers, and other relevant associations should be encouraged.
g. The comprehensibility of chemical hazard communication tools should be addressed.
h. Current test data for the classification of chemicals under existing systems should be accepted under a new harmonized approach.
i. A new harmonized classification system might require adaptation of existing methods for testing of chemical substances and mixtures.
j. Hazard communication programs should be designed to protect, the health safety and environment for operators, consumers and the general public, while respecting suppliers confidentiality.

The permanent "home" for the GHS will be the UN Economic and Social Council (ECOSOC). The GHS Subcommittee of ECOSOC will be responsible for implementation and capacity building issues, and any maintenance/update of the technical work that is required. The Transport

Subcommittee of ECOSOC will maintain the existing UN Transport System, and the two subcommittees will share a secretariat and a parent committee, which reports to the ECOSOC.

The system uses a building block approach that can be tailored to suit the particular needs of each of the target groups. This will provide consistency of information for transport, consumer, operators, and emergency responders, but with the added flexibility of being tailored to meet all their requirements.

The GHS is not intended to harmonize risk assessment procedures or risk management decisions (such establishment of a permissible exposure limit for employee exposure), which generally require some risk assessment in addition to hazard classification. In addition, chemical inventory requirements in various countries are not related to GHS. You can refer to the IOMC Description and Further Clarification of the Anticipated Application of the GHS, IFCS/ISC3/98.32B.

The GHS applies to pure chemical substances, their dilute solutions, and to mixtures of chemical substances. "Articles," as defined in the Hazard Communication Standard (29 C.F.R. 1910.1200) of the U.S. Occupational Safety and Health Administration, or by similar definition, are outside the scope of the system. One objective of the GHS is for it to be simple and transparent with a clear distinction between classes and categories in order to allow for "self-classification" as far as possible. For many hazard classes the criteria are semi-quantitative or qualitative and expert judgment is required to interpret the data for classification purposes. Furthermore, for some hazard classes (e.g., eye irritation, explosives, or self-reactive substances) a decision tree approach is provided to enhance ease of use.

Concept of "Classification" The GHS uses the term *hazard classification* to indicate that only the intrinsic hazardous properties of substances or mixtures are considered. The hazard classification incorporates only three steps:

a. Identification of relevant data regarding the hazards of a substance or mixture
b. Subsequent review of those data to ascertain the hazards associated with the substance or mixture
c. Decision on whether the substance or mixture will be classified as a hazardous substance or mixture and the degree of hazard, where appropriate, by comparison of the data with agreed hazard classification criteria

Hazard Communication The harmonized hazard communication system includes labeling, SDS, and easily understandable symbols. The hazard communication is based on the classification criteria for physical, health, and environment hazards.

The harmonized system for labeling of hazardous chemicals uses the following key points to achieve its GHS objectives:

- Signal words
- Symbols
- Pictograms
- Hazard statements
- Precautionary information
- Product identifiers
- Suppliers Information
- Ingredients (in the case of mixtures)
- Color

A signal word indicates the severity of the hazard and alerts the reader to its potential. Two signal words are used: *Danger* (to describe the more severe hazard categories) and *Warning* (to describe the less severe hazard categories).

Nine symbols, presented in Table 3.23, will be used by the GHS and they will be the same for all target groups. The pictograms are diamond shaped (a square set at a point). The border and background color may vary for different targeted groups. For multiple hazards there will be an order of precedence allocating appropriate symbols, signal words, and hazard statements.

The GHS has agreed to use a 16-section-format SDS and agreement has been reached on the use of headings and subheadings. Information relevant to the countries or regions for which the SDS is intended should be included. The intended target audience of the GHS hazard communication system is far reaching and will cover operators at the workplace, consumers, emergency responders, and transport operators. The needs of each target group may influence the extent to which the different elements of the GHS hazard communication system are used, but it is emphasized that the use of symbols, signal words, or hazard statements other than those that have been assigned to each of the GHS hazard classes and categories would be contrary to harmonization.

Further information may be required, for example, by the competent authorities, and this will be in addition to information required by the GHS system. It is emphasized that such information should provide further details without contradicting or doubting the validity of the standard harmonized hazard information.

Health and Environmental Hazards, Substances, and Mixtures Harmonized criteria have been included in the Globally Harmonized System (GHS) for the following end points:

- Aquatic toxicity (environment)
- Acute toxicity
- Skin irritation/corrosion
- Serious eye damage/eye irritation

TABLE 3.23. New GHS Symbols

Flame	Flame over Circle	Exploding Bomb	Corrosion	Gas Cylinder
Exclamation Mark	**Health Hazard**	**Environment**	**Skull and Crossbones**	

- Respiratory and skin sensitization
- Germ cell mutagenicity
- Carcinogenicity
- Toxic to reproduction
- Target organ systemic toxicity (single exposure and repeated exposure)
- Work has been started on further endpoints that are currently covered in existing systems. These are as follows:
  —Narcotic effects (work started in November 2000)
  —Aspiration hazard (work started in November 2000)
  —Respiratory irritation (work started in November 2000)
  —Water-activated toxicity/corrosion (work started in November 2000)
- Local dermal effects after repeated exposure
- Immunotoxicity
- Hazardous to the terrestrial environment

Existing classification systems have been analyzed and the key elements have been used for the harmonized classification system and criteria. Some hazards (endpoints) have been subdivided into classes to be able to accommodate the needs of existing systems. The harmonized system would allow existing systems to pick up the elements needed (the building block principle) and implement them in accordance with the GHS.

For example, the system for transportation of dangerous goods would only take up the most hazardous class of acute toxicity, and not use the milder classes covering acute toxicity and the long-term health hazards covering chronic toxicity. The cut-offs used would, however, be as specified in the harmonized system.

The GHS for health and environmental classification deals with five hazard categories, category 1 being the most severe, and category 5 the least. Note that not all hazard categories are used for every endpoint

The classification of mixtures can be decided by using the same criteria as for substances. The bridging principle is introduced in order to provide the possibility of using data from other similar mixtures. For acute toxicity, the acute toxicity estimate (ATE) for the ingredients may be used for calculating the classification of the mixture. For skin or respiratory sanitizers, mutagens, carcinogens, substances toxic for reproduction, and target organ systemic toxicants (TOST) cut-off values are used for the classification of a mixture.

Table 3.24 presents the various cut-off values/concentration limits for various hazard classes.

For each endpoint, the symbol, the signal word (Danger or Warning), and the hazard statements to be applied for each of the hazard categories are detailed by the system. An example of the allocation of label elements is presented in Table 3.25.

The GHS for classification of mixtures includes the physical, health, and

TABLE 3.24. Cut-off Values for Hazard Classes

Hazard Class	Cut-off Value/Concentration Limit
Acute toxicity	≥1.0%
Skin corrosion/irritation	≥1.0%
Serious damage to eyes/eye irritation	≥1.0%
Respiratory/skin sensitization	≥1.0%
Mutagenicity: category 1	≥0.1%
Mutagenicity: category 2	≥1.0%
Carcinogenicity	≥0.1%
Reproductive toxicity	≥0.1%
Target organ systemic toxicity (single exposure)	≥1.0%
Target organ systemic toxicity (repeat exposure)	≥1.0%
Hazardous to the aquatic environment	≥1.0%

TABLE 3.25. Labels for Acute Toxicity Inhalation

Category 1	Category 2	Category 3	Category 4	Category 5
				No symbol
Danger	**Danger**	**Danger**	**Warning**	**Warning**
Fatal if inhaled	**Fatal if inhaled**	**Toxic if inhaled**	**Harmful if inhaled**	**May be harmful if inhaled**
			NOT REQUIRED UNDER THE DG/MR *Notes*: For gases and aerosols under the TDG/MR, replace the number 6 in the bottom corner of the pictogram by 2. For TDG pictogram colours: see table above on acute toxicity-oral.	

environmental hazards. Alloys are considered to be mixtures for the purpose of classification under the GHS.

Physical Hazards The following classes of physical hazards have been identified: flammable liquids, flammable solids, flammable gases, flammable aerosols, pyrophoric liquids, pyrophoric solids, self-heating substances, substances that, in contact with water, emit flammable gases, oxidizing liquids, oxidizing solids, oxidizing gases, organic peroxides, self-reactive substances, explosives, corrosive to metals, and gases under pressure.

The criteria agreed upon are very similar to those adopted in the transport regulation and only very few changes will be necessary in order to align transport regulation with the GHS system. All criteria refer to the UN Manual of Tests and Criteria. Regarding the health effects in transport only acute toxicity and corrosivity to skin are now considered as relevant hazards.

The building block approach of the GHS system will allow the current transport system to be implemented relatively easily by discounting the effects not relevant for transport. It has though been considered to introduce some additional health effects, which might occur after single-dose exposure as a new class or division within the transport regulations. The most significant impact of the GHS on transport is related to the criteria for acute toxicity, which implies changes in the reference values for LD_{50} and LC_{50} for classification.

The purpose of a GHS has been to establish a basis for hazard communication, to enhance protection of man and the environment. The key factor governing the success of a worldwide GHS is the ease at which countries can implement such a system. Due consideration on how to facilitate the transposition and implementation process is of the utmost importance. Countries already having a system for classification and hazard communication will have to adjust their existing regulations and enforcing activities in line with the GHS.

The United Nations Institute for Training and Research (UNITAR) and the International Labour Organization (ILO) have developed a "Training and Capacity Building Program" assisting countries to develop and implement chemical hazard communication and GHS action plans. The program includes existing knowledge and experience from, for example, the work with National Chemical Management Profiles and will offer a three-step strategy for the countries implementing the GHS. The program mainly focuses on the countries not already having systems for classifying chemicals and for hazard communication and is available at www.unitar.org/cwm.

Knowledge and experience gained from the implementation of the EU chemicals management regulations within EU applicant countries will prove invaluable when implementing GHS. The experiences that have been achieved by this process will hopefully prove useful in the process of implementing the GHS in other regions of the world.

Table 3.26 presents the minimum information required for a GHS SDS.

TABLE 3.26. Minimum Information for an SDS

1.	Identification of the substance or mixture and of the supplier	• GHS product identifier • Other means of identification • Recommended use of the chemical and restrictions on use • Supplier's details (including name, address, phone number, etc.) • Emergency phone number
2.	Hazards identification	• GHS classification of the substance/mixture and any national or regional information • GHS label elements, including precautionary statements. (Hazard symbols may be provided as a graphical reproduction of the symbols in black and white or the name of the symbol, e.g., flame, skull and crossbones.) • Other hazards that do not result in classification (e.g., dust explosion hazard) or are not covered by the GHS
3.	Composition/information on ingredients	Substance: • Chemical identity • Common name, synonyms, etc. • CAS number, EC number, etc. • Impurities and stabilizing additives that are themselves classified and which contribute to the classification of the substance Mixture: • The chemical identity and concentration or concentration ranges of all ingredients that are hazardous within the meaning of the GHS and are present above their cut-off levels
4.	First aid measures	• Description of necessary measures, subdivided according to the different routes of exposure, i.e., inhalation, skin and eye contact, and ingestion • Most important symptoms/effects, acute and delayed • Indication of immediate medical attention and special treatment needed, if necessary
5.	Fire-fighting measures	• Suitable (and unsuitable) extinguishing media

TABLE 3.26. ***Continued***

		• Specific hazards arising from the chemical (e.g., nature of any hazardous combustion products) • Special protective equipment and precautions for firefighters
6.	Accidental release measures	• Personal precautions, protective equipment, and emergency procedures • Environmental precautions • Methods and materials for containment and and cleaning up
7.	Handling and storage	• Precautions for safe handling • Conditions for safe storage, including any incompatibilities
8.	Exposure controls/personal protection	• Control parameters (e.g., occupational exposure limit values or biological limit values) • Appropriate engineering controls • Individual protection measures, such as personal protective equipment
9.	Physical and chemical properties	• Appearance (physical state, color, etc.) • Odor • Odor threshold • pH • Melting point/freezing point • Initial boiling point and boiling range • Flash point • Evaporation rate • Flammability (solid, gas) • Upper/lower flammability or explosive limits • Vapor pressure • Vapor density • Relative density • Solubility(ies) • Partition coefficient: n-octanol/water • Autoignition temperature • Decomposition temperature
10.	Stability and reactivity	• Chemical stability • Possibility of hazardous reactions • Conditions to avoid (e.g., static discharge, shock or vibration) • Incompatible materials • Hazardous decomposition products

TABLE 3.26. ***Continued***

11.	Toxicological information	Concise but complete and comprehensible description of the various toxicological (health) effects and the available data used to identify those effects, including: • information on the likely routes of exposure (inhalation, ingestion, skin and eye contact) • Symptoms related to the physical, chemical, and toxicological characteristics • Delayed and immediate effects and also chronic effects from short- and long-term exposure • Numerical measures of toxicity (such as acute toxicity estimates)
12.	Ecological information	• Ecotoxicity (aquatic and terrestrial, where available) • Persistence and degradability • Bioaccumulative potential • Mobility in soil • Other adverse effects
13.	Disposal considerations	• Description of waste residues and information on their safe handling and methods of disposal, including the disposal of any contaminated packaging
14.	Transport information	• UN number • UN proper shipping name • Transport hazard class(es) • Packing group, if applicable • Marine pollutant (yes/no) • Special precautions that a user needs to be aware of or needs to comply with in connection with transport or conveyance either within or outside their premises
15.	Regulatory information	• Safety, health, and environmental regulations specific for the product in question
16.	Other information including information on preparation and revision of the SDS	

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4

PRODUCT LABEL REQUIREMENTS

4.1 INTRODUCTION

In this chapter, regulatory requirements related to labeling of products are presented. Labels serve as the first alert that there may be hazards associated with using a product and indicate what precautions to take when using the product. In many countries they also inform the person reading the label that a MSDS is available.

Suppliers are typically responsible for labeling controlled products that they provide to customers. Employers and sometimes employees are also responsible for labeling or relabeling products in the workplace as directed by local occupational health and safety legislation.

Typically, three types of labels are regulated by government agencies:

- Chemical product label that provides information to workers on how to properly handle the material
- Consumer label that provides information, usually using less technical jargon, to consumers on the proper handling of the material
- Specialized labels that address types of products (medical, pesticides) and are sometimes a combination of the chemical product and consumer label requirements

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This chapter deals primarily with precautionary labels. Information on legislation pertinent to precautionary labeling of products and shipments is presented in the following sections according to region, for example, North America and, subsequently, country requirements.

Under the proposed Global Harmonization System (GHS) the following issues pertinent to labeling are addressed:

- Labeling in general—Target audiences, comprehensibility, translation, standardization, supplemental information, updating, confidential business information, and training
- Labeling procedure—symbols, pictograms, shape and color, signal words, hazard and precautionary statements, product and supplier identification, precedence of hazard, presentation of GHS label elements, and special labeling arrangements

The proposed GHS pictogram, unlike the stand-alone transportation logo, will be part of a rectangular label that also contains text (such as product identification, signal wording, hazard and precautionary statements, and the manufacturer's contact information). Refer to Section 3.1 of this book for additional information on GHS.

4.2 NORTH AMERICA

The key regulatory bodies for precautionary label requirements in North America include:

- United States—OSHA's Hazard Communication (HAZCOM) Standard (29 CFR 1910.1200) with the substance specific standards (29 CFR 1910.1001-1052)
- Canada—Workplace Hazardous Management Information System (WHMIS)
- Mexico—The Official Mexican Standards (referred to as Normas or NOMs)

4.2.1 United States

The OSHA HAZCOM has 12 major requirements:

- Identification of the chemical product (and may also include its hazardous component(s))
- Signal word
- Statement(s) of hazard(s)
- Precautionary measures

- Instructions in case of contact or exposure (first aid)
- Antidotes
- Notes to physician
- Instructions in case of fire
- Instructions in case of spill or leak
- Instructions for container handling and storage
- Reference(s)
- Name, address, and telephone number

The OSHA required elements of a label are:

- identity of the hazardous chemicals
- appropriate hazard warnings
- the name and address of the chemical manufacturer, importer, or other responsible party

See 29 CFR 1910.1200(f)(1) for additional information on the OSHA required elements; see 29 CFR 1910.1001-1052 for substance specific OSHA requirements. The following is an overview of these requirements.

Chemical manufacturers, importers, or distributors shall ensure that each container of hazardous chemicals leaving the workplace is labeled, tagged, or marked in accordance with this section in a manner that does not conflict with the requirements of the Hazardous Materials Transportation Act (49 U.S.C. 1801 et seq.) and regulations issued under that act by the Department of Transportation.

If the hazardous chemical is regulated by OSHA in a substance-specific health standard, the chemical manufacturer, importer, distributor, or employer shall ensure that the labels or other forms of warning used are in accordance with the requirements of that standard.

Except as provided in paragraphs (f)(6) and (f)(7) of this legislation, the employer shall ensure that each container of hazardous chemicals in the workplace is labeled, tagged or marked with the following information:

- Identity of the hazardous chemical(s) contained therein
- Appropriate hazard warnings or, alternatively, words, pictures, symbols, or combination thereof, which provide at least general information regarding the hazards of the chemicals, and which, in conjunction with the other information immediately available to employees under the hazard communication program, will provide employees with the specific information regarding the physical and health hazards of the hazardous chemical

The employer may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to indi-

vidual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys the information required by paragraph (f)(5) of this legislation to be on a label. The written materials shall be readily accessible to the employees in their work area throughout each work shift.

The employer is not required to label portable containers into which hazardous chemicals are transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer. For purposes of this section, drugs that are dispensed by a pharmacy to a health care provider for direct administration to a patient are exempted from labeling.

The employer shall not remove or deface existing labels on incoming containers of hazardous chemicals, unless the container is immediately marked with the required information.

The employer shall ensure that labels or other forms of warning are legible, in English, and prominently displayed on the container, or readily available in the work area throughout each work shift. Employers having employees who speak other languages may add the information in their language to the material presented, as long as the information is presented in English as well.

The chemical manufacturer, importer, distributor, or employer need not affix new labels to comply with this section if existing labels already convey the required information.

Chemical manufacturers, importers, distributors, or employers who become newly aware of any significant information regarding the hazards of a chemical shall revise the labels for the chemical within three months of becoming aware of the new information. Labels on containers of hazardous chemicals shipped after that time shall contain the new information. If the chemical is not currently produced or imported, the chemical manufacturer, importers, distributor, or employer shall add the information to the label before the chemical is shipped or introduced into the workplace again.

For solid metal (such as a steel beam or a metal casting), solid wood, or plastic items that are not exempted as articles due to their downstream use, or shipments of whole grain, the required label may be transmitted to the customer at the time of the initial shipment, and need not be included with subsequent shipments to the same employer unless the information on the label changes. The label may be transmitted with the initial shipment itself, or with the material safety data sheet that is to be provided prior to or at the time of the first shipment, this exception to requiring labels on every container of hazardous chemicals is only for the solid material itself, and does not apply to hazardous chemicals used in conjunction with, or known to be present with, the material and to which employees handling the items in transit may be exposed (e.g., cutting fluids or pesticides in grains).

In order to assist companies interpret the OSHA HAZCOM requirements, the United States Chemical Manufacturer Association (CMA) prepared an interpretation guideline that was approved by the American National Stan-

dards Institute (ANSI). The ANSI guidelines give an interpretation of each section of the legislation and how to measure each of the different criteria. Examples of sentences to use in each area are proposed according to the different criteria of the sections. Different types of labels are designed according to the type of container. There are examples for small containers, drum labels, bulk tag labeling, and solid bag labeling. Figures 4.1–4.3 present a few examples of labels as presented in the ANSI Z129.1-2000.

4.2.2 Canada

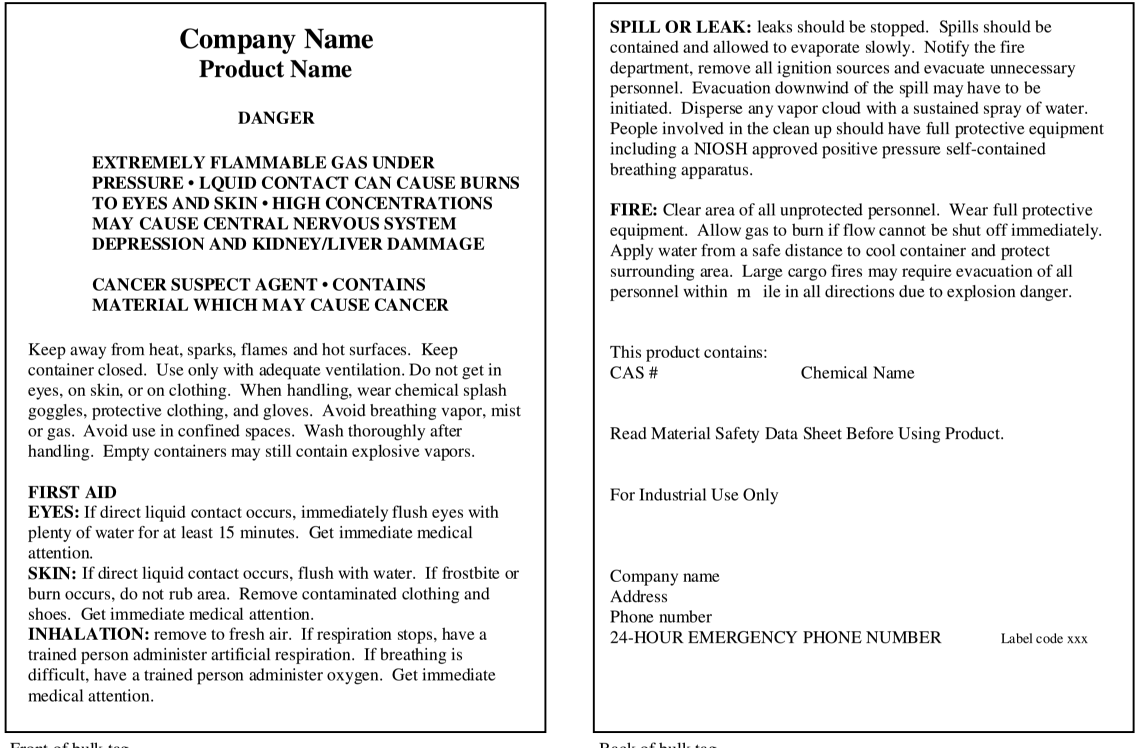
The Workplace Hazardous Material Information System (WHMIS) legislation dictates the requirements for labels in Canada. Labels are deemed important, as they are the first alert there may be hazards associated with using a product covered by WHMIS legislation. The labels must tell what precautions to take when using the product and inform the person that there is a Material Safety Data Sheet (MSDS) available that contains more detailed information on the product (CCOHS, 2001).

Suppliers are responsible for labeling WHMIS-controlled products that they provide to customers. Employers and sometimes employees are all responsible for labeling or relabeling products in the workplace, as directed in occupational health and safety legislation. This includes labeling controlled products with workplace labels, decanted products, laboratory chemicals or piping, and bulk containers where a controlled product is being held or is flowing (CCOHS, 2001).

A WHMIS label can be a mark, sign, stamp, sticker, seal, ticket, tag, or wrapper. It can be attached, imprinted, stenciled, or embossed on the controlled product or its container. However, there are two different types that are used most often: the supplier label and the workplace label. There are slightly different requirements for what must be on the label depending on who is required to put the label on the product. If a supplier label is not attached to a controlled product you are not to use the material until the supplier gives you an MSDS and a supplier label. The Canadian specific hatched border must be used as soon as the product is controlled under the WHMIS regulation (CCOHS, 2001).

A supplier label must:

- appear on all controlled products received at workplaces in Canada
- contain the following information:
  - —product identifier (name of product)
  - —supplier identifier (name of company that sold it)
  - —a statement that an MSDS is available
  - —hazard symbols (the pictures of the classification(s))
  - —risk phrases (words that describe the main hazards of the product)
  - —precautionary measures (how to work with the product safely)



Company Name
Product Name

DANGER

EXTREMELY FLAMMABLE GAS UNDER PRESSURE • LQUID CONTACT CAN CAUSE BURNS TO EYES AND SKIN • HIGH CONCENTRATIONS MAY CAUSE CENTRAL NERVOUS SYSTEM DEPRESSION AND KIDNEY/LIVER DAMMAGE

CANCER SUSPECT AGENT • CONTAINS MATERIAL WHICH MAY CAUSE CANCER

Keep away from heat, sparks, flames and hot surfaces. Keep container closed. Use only with adequate ventilation. Do not get in eyes, on skin, or on clothing. When handling, wear chemical splash goggles, protective clothing, and gloves. Avoid breathing vapor, mist or gas. Avoid use in confined spaces. Wash thoroughly after handling. Empty containers may still contain explosive vapors.

FIRST AID
EYES: If direct liquid contact occurs, immediately flush eyes with plenty of water for at least 15 minutes. Get immediate medical attention.
SKIN: If direct liquid contact occurs, flush with water. If frostbite or burn occurs, do not rub area. Remove contaminated clothing and shoes. Get immediate medical attention.
INHALATION: remove to fresh air. If respiration stops, have a trained person administer artificial respiration. If breathing is difficult, have a trained person administer oxygen. Get immediate medical attention.

Front of bulk tag

SPILL OR LEAK: leaks should be stopped. Spills should be contained and allowed to evaporate slowly. Notify the fire department, remove all ignition sources and evacuate unnecessary personnel. Evacuation downwind of the spill may have to be initiated. Disperse any vapor cloud with a sustained spray of water. People involved in the clean up should have full protective equipment including a NIOSH approved positive pressure self-contained breathing apparatus.

FIRE: Clear area of all unprotected personnel. Wear full protective equipment. Allow gas to burn if flow cannot be shut off immediately. Apply water from a safe distance to cool container and protect surrounding area. Large cargo fires may require evacuation of all personnel within m ile in all directions due to explosion danger.

This product contains:
CAS # Chemical Name

Read Material Safety Data Sheet Before Using Product.

For Industrial Use Only

Company name
Address
Phone number
24-HOUR EMERGENCY PHONE NUMBER Label code xxx

Back of bulk tag

Figure 4.1. Bulk tag.

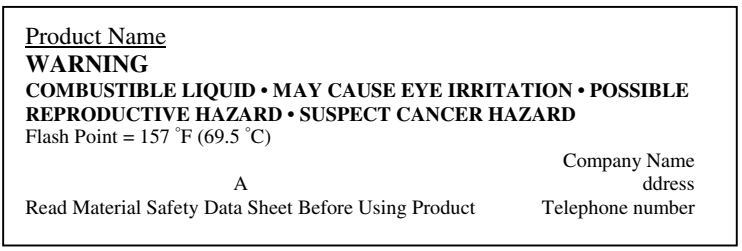


Figure 4.2. Small container label.

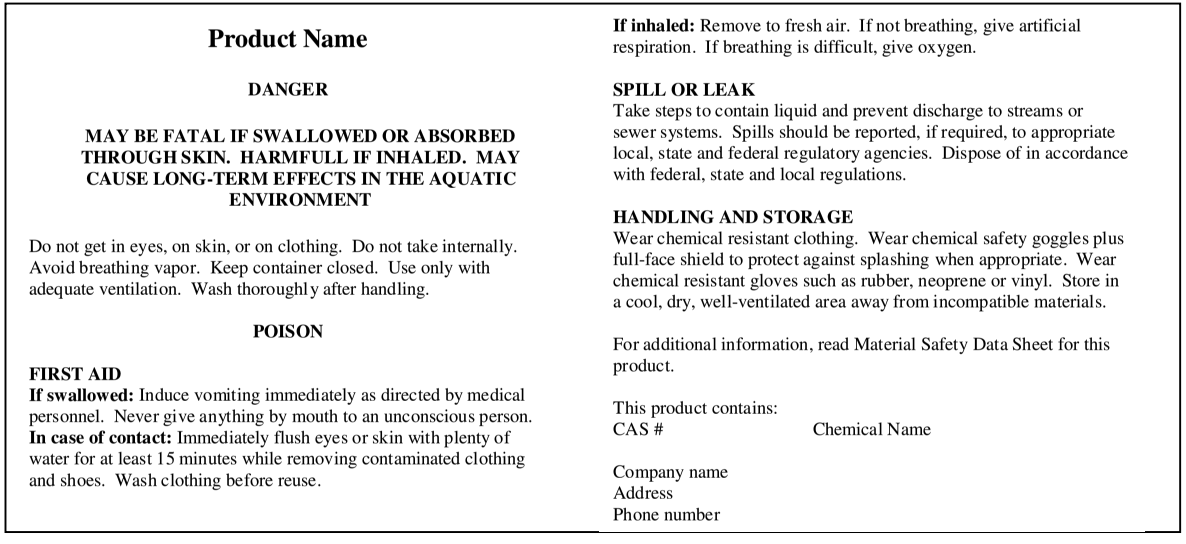
—first aid measures (what to do in an emergency)
—have all text in English and French
—have the WHMIS hatched border (Figure 4.4)

Supplier labels for materials from a laboratory supply house that are intended for use in a laboratory in amount less than 10 kg and any controlled product sold in a container with less than 100 mL may contain less information than listed above. If the product is always used in the container with the supplier label, no other label is required (unless the supplier label falls off or becomes unreadable). However, sometimes you will want to put some of the material into another container for use in the workplace. This new container does require a workplace WHMIS label (CCOHS, 2001).

A workplace label must:

- appear on all controlled products produced in a workplace or transferred to other containers by the employer
- may appear in placard form on controlled products received in bulk from a supplier
- have the following information:
  —product identifier (product name)
  —information for the safe handling of the product
  —statement that the MSDS is available
  —may contain the WHMIS hazard symbols or other pictograms

These are the minimum requirements for workplace labels. The employer may wish to put more information on the labels but it is not required under the law. Supplier labels must have a hatched border around the information on the label but labels prepared in the workplace do not necessarily have to have hatched borders. The Hazardous Products Act and the Controlled Products Regulations specify, among other things, what suppliers and importers are required to do with respect to MSDSs and labels. Section 20 of the Controlled Products Regulations prescribes label design requirements for supplier labels and Schedule III has a picture of how the label should look. It



Product Name

DANGER

MAY BE FATAL IF SWALLOWED OR ABSORBED THROUGH SKIN. HARMFULL IF INHALED. MAY CAUSE LONG-TERM EFFECTS IN THE AQUATIC ENVIRONMENT

Do not get in eyes, on skin, or on clothing. Do not take internally. Avoid breathing vapor. Keep container closed. Use only with adequate ventilation. Wash thoroughly after handling.

POISON

FIRST AID
If swallowed: Induce vomiting immediately as directed by medical personnel. Never give anything by mouth to an unconscious person.
In case of contact: Immediately flush eyes or skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Wash clothing before reuse.

If inhaled: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

SPILL OR LEAK
Take steps to contain liquid and prevent discharge to streams or sewer systems. Spills should be reported, if required, to appropriate local, state and federal regulatory agencies. Dispose of in accordance with federal, state and local regulations.

HANDLING AND STORAGE
Wear chemical resistant clothing. Wear chemical safety goggles plus full-face shield to protect against splashing when appropriate. Wear chemical resistant gloves such as rubber, neoprene or vinyl. Store in a cool, dry, well-ventilated area away from incompatible materials.

For additional information, read Material Safety Data Sheet for this product.

This product contains:
CAS # Chemical Name

Company name
Address
Phone number

Figure 4.3. Drum label.

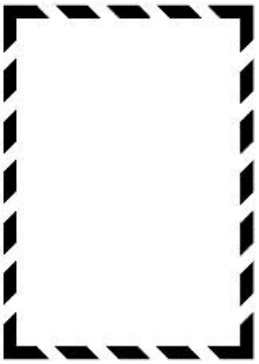


Figure 4.4. WHMIS hatched border.

is occupational health and safety legislation, not the Controlled Products Regulations, which describe what employer must do when preparing workplace labels. For example, Section 10.41 on "Replacing Labels" in the Canada Occupational Safety and Health Regulations states (CCOHS, 2001):

> Where, in a work place, a label applied to a controlled product or a container of a controlled product becomes illegible or is removed from the controlled product or the container, the employer shall replace the label with a work place label that discloses the following information in respect of the controlled product
>
> (a) the product identifier;
>
> (b) the hazard information; and
>
> (c) a statement indicating that a material safety data sheet is available in the work place.

This section does not require employers to use WHMIS symbols and a hatched border when preparing workplace labels. However, nothing in the regulations prevents an employer from using the WHMIS requirements for designing supplier labels when prepare workplace labels. Provincial occupational health and safety legislation have similar provisions (CCOHS, 2001).

A workplace label must be on the container except for two special cases. When a controlled material is poured into a container and it is going to be used immediately, no label is required. Also, if the material is "under the control of the person who decanted it" (which means if the person who poured it will be the only one using it) and if the material is all used during one shift, just the product identifier (name) is required. However, if the material is not used right away or if more than one person will be in control of the material,

a workplace label is required. Your company may have special rules about labeling containers so you should ask about labeling policies (CCOHS, 2001).

Material that is shipped in bulk also follows special rules. The tank or container that the bulk material is transferred into must be labeled with either a supplier label or a workplace label. When the material is moved into containers for resale or delivery out of your workplace, you must put a supplier label on each container. When the bulk material is used in your workplace (usually transferred into smaller containers), a workplace label is required on the containers (CCOHS, 2001).

Laboratory samples of controlled products that are less than 10 kg do not have to have a WHMIS label as long as there is a label, which states the following in both English and French:

- the product identifier (name),
- the chemical identity or generic chemical identity of an ingredient of the controlled product, if known,
- the supplier identification
- the statement "Hazardous Laboratory Sample. For hazard information or in an emergency, call . . ." and an emergency telephone number must be provided.

Table 4.1 presents examples of the WHMIS symbols that can be use on a label and also the MSDS with their description.

4.2.3 Mexico

Mexican labels rely on the assumption that workers will be instructed in the interpretation of the minimal information contained thereon. Container labels may be one of two designs. One design is the so-called "vertical rectangle" design. This label design closely resembles the design format of the Hazardous Material Information System (HMIS) initiated by the U.S. National Paint and Coatings Association as described in Chapter 3. In this design, the "vertical rectangle" label is divided into horizontal segments, each devoted to providing a numeric evaluation of the severity of the hazards of the chemical. From top to bottom, the segments are as follows:

- health
- flammability
- reactivity
- special hazards
- personal protective equipment

The Mexican variant of this basic style is the inclusion of the product identification at the very top. Each segment (hazard category) has a color

TABLE 4.1. WHMIS symbols

Symbol	Definition	Description
	Class A—Compressed Gas	Contents under high pressure. Cylinder may explode or burst when heated, dropped, or damaged
	Class B—Flammable and Combustible Material	May catch fire when exposed to heat, spark, or flame. May burst into flames
	Class C—Oxidizing Material	May cause fire or explosion when in contact with wood, fuels, or other combustible material
	Class D, Division 1—Poisonous and Infectious Material: Immediate and serious toxic effects	Poisonous substance. A single exposure may be fatal or cause serious or permanent damage to health
	Class D, Division 2—Poisonous and Infectious Material: Other toxic effects	Poisonous substance. May cause irritation. Repeated exposure may cause cancer, birth defects, or other permanent damage

TABLE 4.1. ***Continued***

Symbol	Definition	Description
	Class D, Division 3—Poisonous and Infectious Material: Biohazardous infectious materials	May cause disease or serious illness. Drastic exposures may result in death
	Class E—Corrosive Material	Can cause burns to eyes, skin, or respiratory system
	Class F—Dangerously Reactive Material	May react violently causing explosion, fire, or release of toxic gases, when exposed to light, heat, vibration, or extreme temperatures

Source: CCOHS, 2001.

associated with it, paralleling the HMIS convention. The numeric evaluation that is inserted into each hazard category is that derived from the Mexican hazard classification scheme. These values range from 0 for minimal risk to 4 for severe risk. Refer to Chapter 3 for additional information on Mexican risk criteria.

The second permissible label style is the rhombus (a square placed on point). This style resembles the label style that is part of the National Fire Prevention Association (NFPA) system of warning. The rhombus is divided into four quadrants, each corresponding to the category of hazard. The left-most quadrant is the health risk, the top, fire risk, right, reactivity, and the bottom, special risks. In this design, the name of the product must be placed above the rhombus, and the personnel protective equipment recommendations below. As in the vertical rectangle style, the same color assignment applies, and numerical value of the severity of each risk category is noted within each quadrant. The risk severity ratings for the rhombus design use the same criteria as for the rectangular design.

4.3 EUROPE

In the 1960s, each European country provisions on chemicals differed widely and thus hindered community trade. In addition, it was recognized that there was a need to ensure the protection of public health, in particular the health of workers handling dangerous substances. This resulted in the development of European Union (EU) legislation on chemicals applicable to products manufactured in or imported into the territory of the EU. Directive 67/548/EEC outlines the procedures for the classification, packaging, and labeling of dangerous substances. The objective was and is to protect the public health as well as the environment. The EU sought to eliminate the disparity among national laws that could pose barriers to the free movement of goods, a hallowed principle, enshrined in the European Community's founding Treaty of Rome. EU law prevails over national laws.

This 1967 legislation has been amended directly eight times to date and adapted to technical progress 28 times, with future change anticipated as warranted. It has also spawned some siblings, among which is legislation dealing with various aspects of dangerous preparations, handling, marketing and use. Comparable but distinct legislation exists for products such as cosmetics, detergents, pesticides, and pharmaceuticals, which are accordingly excluded from the provisions of the dangerous substances legislation.

As described in the North America section, only the dangerous substance legislation will be looked at without any mention of the other requirements (cosmetics, detergents, pesticides, and pharmaceuticals).

The directive introduced common provisions on three main areas:

- Classification of dangerous substances, since placing a substance into one or several defined classes of danger characterizes the type and severity of the adverse effects that the substance can cause.
- Packaging of dangerous substances, since adequate packaging protects from the known danger(s) of a substance.
- Labeling of dangerous substances, since the label on the packaging informs about the nature of the danger(s) of the substance inside and about the safety measures to apply during handling and use.

The combined standardized provisions should ensure the establishment of a common market in the field of dangerous chemical substances and a high level of protection of human health. Protecting the environment from the dangerous effects of substances was only introduced with the 6th amendment of the directive, adopted in 1979. The 6th amendment also introduced the notification system for "new" substances and, consequently, required the establishment of the list of "existing" substances. The European Inventory of Existing Commercial Chemical Substances (EINECS) lists all substances that were reported to be on the market on or before 18 September 1981. Substances,

placed on the market for the first time after this target date, are designated as "new."

The 7th amendment, of 1992, essentially required that the principles of risk assessment for "new" substances be laid down. It further introduced the "sole representative" in the notification system, and added the SDS as a hazard communication facility for the professional user. Finally, the 8th amendment replaced the term "European Economic Community" with "European Community" in the Directive, to take account of the modification of the Treaty.

In the following section, information derived from Annex 6 of the directive is provided to guide readers on how to ensure a label contains appropriate information. When a substance or preparation has been classified (refer to Chapter 3—EU SDS), the appropriate label is determined with reference to the requirements of Article 23 of Directive 67/548/EC and Article 10 of Directive 1999/45/EC for substances and preparations, respectively.

4.3.1 Information Contained on a European Label

The following information is required for a EU label:

- Preparations—trade name or designation
- Substances—name of the substance and for preparations the names of the substances present in the preparations in accordance with the rules set out in Article 10.2.3. of Directive 1999/45/EC
- Name, full address, and telephone number of the person responsible for placing the substance or preparation on the market, whether manufacturer, importer, or distributor
- Symbol(s) and indication(s) of danger
- Phrases indicating particular hazards (R-phrases)
- Phrases indicating safety advice (S-phrases)
- Substances—EC number, and in addition for substances appearing in Annex I, the words "EC label"
- Preparations—if offered or sold to the general public, the nominal quantity of the contents unless specified elsewhere on the package

Note: For certain preparations there are additional labeling requirements set out in Article 10.1.2 and Annex V of Directive 1999/45/EC and in Article 20 of Directive 98/8/EC.

4.3.2 Final Choice of Risk and Safety Phrases

Although the final choice of the most appropriate risk and safety phrases is primarily governed by the need to give all necessary information, consideration should also be given in the clarity and impact of the label. With clarity in

mind, the necessary information should be expressed in a minimum number of phrases.

In the case of substances that are irritants, highly flammable, flammable and oxidizing, an indication of R-phrases and S-phrases need not be given where the package does not contain more than 125 mL. This shall also apply in the case of the same volume of harmful substances not retailed to the general public.

For preparations, if the contents of the package do not exceed 125 mL, the following requirements must be complied with:

- If classified as highly flammable, oxidizing, irritant, with the exception of those assigned R41, or dangerous for the environment and assigned the "N" symbol it shall not be necessary to indicate the R-phrases or the S-phrases.
- If classified as flammable or dangerous to the environment and not assigned the "N" symbol it shall be necessary to indicate the R-phrases but it shall not be necessary to indicate the S-phrases.

Without prejudice to Article 16.4 of Directive 91/414/EEC and to Directive 98/8/EC, indications such as "nontoxic," "nonharmful," "nonpolluting," "ecological" or any other statement indicating that the substance or preparation is not dangerous or likely to lead to underestimation of the dangers of the substance or preparation in question shall not appear on the label or packaging of substances or preparations subject to this directive or to Directive 1999/45/EC.

4.3.3 Chemical Name(s) to Be Displayed on the Label

For substances listed in Annex I the label shall show the name of the substances under one of the designations given in Annex I. For substances not listed in Annex I, the name is established according to an internationally recognized chemical nomenclature as define earlier. For preparations, the choice of names to be displayed on the label follows the rules of Article 10.2.3 of Directive 1999/45/EC.

Under Subject to Annex V, B. 9. of Directive 1999/45/EC the following is required:

- Name of the sensitizing substance must be chosen in accordance with Section 7.2.1 of Annex 6.
- In the case of concentrate preparations that are intended for the perfume industry:
  —persons responsible for placing them on the market may identify merely the one sensitizing substance judged by him to be primarily responsible for the sensitization hazard.

—in the case of a natural substance, the chemical name may be of the type: "essential oil of . . . ," "extract of . . . ," rather than the name of the constituents of that essential oil or extract.

4.3.4 Choice of Danger Symbols

The design of the danger symbols and the wording of the indications of danger shall comply with those laid down in Annex II. The symbol shall be printed in black on an orange-yellow background. For substances appearing in Annex I the danger symbols and indications of danger shall be those shown in the Annex. For dangerous substances not yet appearing in Annex I and for preparations, the danger symbols and indications of danger shall be assigned according to the rules laid down in this Annex.

Where more than one danger symbol is assigned to a substance or preparation, the following rules apply:

1. Obligation to indicate the symbol "E" makes the symbols "F+," "F," and "O" optional.
2. Obligation to indicate the symbol "T+" or "T" makes the symbols "Xn," "Xi," and "C" optional.
3. Obligation to indicate the symbol "C" makes the symbols "Xn" and "Xi" optional.
4. If the symbol "Xn" is assigned, the symbol "Xi" is optional.

4.3.5 Choice of Risk Phrases

The wording of the R-phrases shall comply with that laid down in Annex III and the combined R-phrases in Annex III shall be used where applicable. For additional information on specific R-Phrases refer to Chapter 3 of this book.

Substances For substances appearing in Annex I, the R-phrases shall be those shown in the Annex. For substances not appearing in Annex I, R-phrases will be selected according to the following criteria and priorities:

1. In the case of dangers that give rise to health effects:
   1.1. R-phrases corresponding to the category of danger illustrated by a symbol must appear on the label.
   1.2. R-phrases corresponding to other categories of danger that are not illustrated by a symbol by virtue of Article 23.
2. In the case of dangers arising from physicochemical properties:
   2.1. R-phrases corresponding to the category of danger illustrated by a symbol must appear on the label.

3. In the case of dangers for the environment
   3.1. the R-phrase(s) corresponding to the classification category "dangerous for the environment" must appear on the label.

Preparations For preparations, R-phrases will be selected according to the following criteria and priorities:

1. In the case of dangers that give rise to health effects:
   1.1. R-phrases that correspond to the category of danger illustrated by a symbol. In certain cases the R-phrases must be adopted according to the tables of Annex II, Part B of Directive 1999/45/EC. More specifically, the R-phrases of the constituent(s) that are responsible for the assignment of the preparation to a danger category must appear on the label.
   1.2. R-phrases that correspond to other categories of danger that have been attributed to the constituents but that are not illustrated by a symbol by virtue of Article 10.2.4. of Directive 1999/45/EC.
2. In the case of dangers arising from physicochemical properties:
   2.1. The criteria described under 7.4.3 (a) are applicable, except that the risk phrases "extremely flammable" or "highly flammable" need not be indicated where they repeat the wording of the indication of danger used with a symbol.
3. In the case of dangers for the environment
   3.1. The R-phrase(s) corresponding to the classification category "dangerous for the environment" must appear on the label.
   3.2. Where the R-phrase R50 has been assigned in addition to a combined R-phrase R51/53 or R52/53 or to the R-phrase 53 alone, the combined R-phrase R50/53 shall be used.

As a general rule, for preparations a maximum of six R-phrases shall suffice to describe the risk; for this purpose the combined phrases listed in Annex III shall be regarded as single phrase. However, if the preparation falls within more than one danger category, those standard phrases shall cover all the principal hazards associated with the preparation. In some cases, more than six R-phrases may be necessary.

4.3.6 Choice of Safety Phrases

The wording of S-phrases shall comply with that laid down in Annex IV. The combined S-phrases in Annex IV shall be used where applicable. Refer to Chapter 3 for additional information on S-phrases.

For substances appearing in Annex I, the S-phrases shall be those shown in the Annex. Where no S-phrases are shown, the manufacturer/importer may include any appropriate S-phrase(s). For substances not in Annex I and for

preparations, the manufacturer shall include S-phrases in accordance with the criteria given in Chapter 6 of the Annex.

The following rules should be employed to select the appropriate safety phrases:

- The final choice of safety phrases must have regard to the risk phrases indicated on the label and to the intended use of the substance or preparation.
- As a general rule, a maximum of six S-phrases shall suffice to formulate the most appropriate safety advice; for this purpose the combined phrases listed in Annex IV shall be regarded as single phrases.
- In the case of S-phrases concerning disposal, one S-phrase shall be used, unless it is clear that disposal of the material and its container does not present a danger for human health or the environment. In particular, advice on safe disposal is important for substances and preparations sold to the general public.
- Some R-phrases become superfluous if a careful selection is made of S-phrases and vice versa; S-phrases that obviously correspond to R phrases will appear on the label only if it intended to emphasize a specific warning.
- Particular attention must be given, in the choice of safety phrases, to the foreseen conditions of use of certain substances and preparations, for example, spraying or other aerosol effects. Phrases should be chosen with the intended use in view.
- The safety phrases S1, S2, and S45 are obligatory for all very toxic, toxic, and corrosive substances and preparations sold to the general public.
- The safety phrases S2 and S46 are obligatory for all other dangerous substances and preparations (except those only classified as dangerous for the environment) sold to the general public.

Where the phrases selected according to the strict criteria in 6.2 results in redundancy or ambiguity or are clearly unnecessary given the specific product/package then some phrases may be deleted.

4.3.7 The EC Number

If a substance named on the label is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) or in the European List of Notified Substances (ELINCS), the EINECS or ELINCS number of the substances shall be shown on the label. This requirement does not apply to preparations.

4.3.8 The Dimensions of the Label for Preparations

Table 4.2 represents the dimensions of the label that must be adhered to. Each symbol shall cover at least one-tenth of the surface area of the label but shall

TABLE 4.2. Dimensions of European Label

Capacity of the Package	Dimensions (in mm)
Not exceeding 3 L	If possible, at least 52 × 74
Greater than 3 L but not exceeding 50 L	At least 74 × 105
Greater than 50 L but not exceeding 500 L	At least 105 × 148
Greater than 500 L	At least 148 × 210

not be less than 1 cm^2. The label shall be firmly affixed to one or more surfaces of the packaging immediately containing the preparation. The information required on the label shall stand out clearly from its background and shall be of such size and spacing as to be easily read.

4.3.9 Special Cases: Substances

There are special cases laid down properly in Annex 6 of the directive concerning mobile gas cylinders, gas containers intended for propane, butane, or liquefied petroleum gas (LPG), metals in massive form, and substances classified with R65.

4.3.10 Special Cases: Preparations

Same as for the substances, there are special cases for preparation concerning gaseous preparations (gas mixtures), gas containers intended for preparations containing stenched propane, butane, or LPG, alloys, preparations containing polymers, preparations containing elastomers, preparations classified with R65, and organic peroxides.

For certain preparations there are additional labeling requirements set out in Article 10.1.2 and Annex V of Directive 1999/45/EC and Article 20 of Directive 98/8/EC.

4.4 PACIFIC RIM

4.4.1 Japan

The Industrial Safety and Health Law (ISHL) requires the labeling of 91 types of chemical substances. Their ingredients, precautions for their use, and other necessary information for proper handling should be provided on their labels. The Guidelines on Labeling Dangers and Toxicity of Chemical Substances (issued to conform to ILO Convention No. 170, Safety in the use of Chemicals at Work) apply to all chemical substances used at workplaces, and require information necessary for their proper management and handling.

These guidelines also require labels on dangerous and toxic chemical substances including:

Figure 4.5. Japanese drum label.

1. Name
2. Contents and their amounts
3. Type of dangers or toxicity
4. Effects on human body
5. Precautions on storage and handling
6. Name of person providing the label
7. Other chemical substances than dangerous and toxic substances should be labeled with the names of the chemicals.

Figure 4.5 presents an example of a drum label.

4.4.2 Korea

The Korean labels requirements are very well defined. The following is a summary of the requirements:

Article 11 (Obligation to Attach Labels)

1. Any manufacturer or importer of the Regulated Chemical Substances (RCS) shall attach warning labels in Korean (including the case where Korean and foreign languages are written in the same warning labels) on containers or packages of such chemicals; provided, however, in the case of a reagent being used in a laboratory for the purpose of test and research, or finished products that are under storage or transportation

for export, warning labels in Korean language may not be attached thereon.

2. Any business owner who uses, transports, or stores chemicals shall check the existence of warning labels, and, if there are none, shall attach ones.
3. A business owner falling within Paragraph (2) above shall be entitled to request the manufacturer or the importer in question to attach a warning label.

Article 12 (Contents and Method of Attachment)

1. The matters to be included in a warning label shall be as follows:
   1.1. Name of the chemical substance or product (which must be the same as the name used in the MSDS).
   1.2. However, the name of the chemical substance or product must be the same as the name used in the MSDS; if the name of the chemical substance or product in a warning label is overlapping with the name of the trademark of the product, the word "separately marked" or the word "marked on the front side" may be attached on the warning label.
   1.3. Hazard mark in the form prescribed in Appendix 2 hereto in accordance with hazardous level of the RCSs.
   1.4. Hazard of the RCSs and the measures to take.
   1.5. A phrase advising that details are available from the MSDS.
   1.6. A phrase to the effect that it is based on Article 41 of the ISHL.
2. In principle, the warning label shall be attached as prints or indicated on a container or package of the RCSs or products containing RCSs.
3. When it is difficult to attach a warning label or to indicate it, a tag may be attached.
4. When a warning label is prepared, all of the concerned hazard marks under the standards for classification as described in the Appendix 1 shall be presented. However, if a chemical substance falls under three (3) or more hazard marks, up to three (3) hazard marks may be attached on the warning label in accordance with the priority in the degree of hazard or danger to health of the employees.
5. When a warning label is prepared on the container of half-finished RCSs for self-use within the concerned business place, only warning words indicating toxicity and danger thereof may be attached. However, in such case, the contents of warning label shall be attached on the place where employees working at the storing or warehousing place can see such warning label easily.

Article 13 (Exception from Application) The requirement of warning label hereunder shall be deemed satisfied if any of the following indications is made:

1. Indication of noxious material in accordance with Article 39 of the ISHL
2. Indication of toxic material in accordance with the Toxic Chemicals Control Law
3. Indication of transportation containers for dangerous materials in excess of designated quantity in accordance with the Fire-Fighting Law
4. Indication of tested container in accordance with the High-Pressure Gas Safety Control Law
5. However, the indication in accordance with International Maritime Dangerous Goods Code (IMDG Code) shall apply only until imported products are brought into the business place for first use
6. However, the indication in accordance with Dangerous Goods Regulations (DGR) shall apply only until imported products are brought into the business place for first use.

Article 14 (Form and Size of Warning Label) A warning label shall be in the form and size as prescribed in Appendix 3 of the legislation (Tables 4.3–4.5); provided, however, that the products falling under the provision of Item 2, Paragraph (3), Article 3 shall be in accordance with Appendix 4.

Article 15 (Color and Location of a Warning Label)

1. The whole ground of the warning label shall be in white, and writings and borders in black.
2. Notwithstanding the above Paragraph (1), in case when it is difficult to make the ground in white such as vinyl bags, the cover of the packaging

TABLE 4.3. Form of a Warning Label

[Warning Label in accordance with Article 41 of ISHL]

Chemical Name or Product Name

ooosubstance ooosubstance ooosubstance

Precautions for hazard · risk

As for other details, refer to the MSDS

TABLE 4.4. Size of a Warning Label

Capacity Volume of Containers or Package of Which the Name, etc. Is to be Marked.	Size of Print or Tag
Volume ≥ 500 L	450 cm^2 (a × b) or more $0.25b \le a \le 4b$ $0.1(a \times b) \le c \times d$
200 L ≤ volume ≤ 500 L	300 cm^2 (a × b) or more $0.25b \le a \le 4b$ $0.1(a \times b) \le c \times d$
50 L ≤ volume ≤ 200 L	180 cm^2 (a × b) or more $0.25b \le a \le 4b$ $0.1(a \times b) \le c \times d$
5 L ≤ volume ≤ 50 L	90 cm^2 (a × b) or more $0.25b \le a \le 4b$ $0.1(a \times b) \le c \times d$
Volume ≥ 5 L	5% or more of the entire surface area, except the top and bottom areas of containers or package $0.25b \le a \le 4b$ $0.1(a \times b) \le c \times d$

* "a" is width of the warning label, "b" is length of the warning label, "c" is width of the hazard marks, and "d" is length of the hazard marks.

TABLE 4.5. Form of a Warning Label of a Finished Product with Carcinogenic Substances

[Warning Label in accordance with Article 41 of ISHL]

Product containing:

- Content (%) of carcinogenic substance in the product:

- Indication of hazard/risk to the worker, including occupational cancer caused by the carcinogenic substance contained:

- Indication of precautions and measures in handling the product to prevent damage to health:

For other details, refer to the MSDS.

Fill in the blanks with the name of the carcinogenic substance contained in the product.

or container may be used as the ground color; provided, however, that if the ground is the container or packaging similar to black, the writings and borders shall be made in contrasting color.

3. The ground of a hazard mark shall be in yellow or orange; and borders and picture in black. However, if he/she wishes to directly print warning label on the small-sized case or package with a volume of less than 1 L, the ground of hazard mark may be in a color (except of black) which is mainly used in the case or package, provided that the color of the surface of the case or package is two (2) colors or less.
4. Warning labels shall be firmly attached on the place where they can be easily seen during the handling of the substance by the employees.

The form and size of warning labels are presented in Tables 4.3 and 4.4, respectively. All the hazard marks must be included if they fall within the classification of hazardous materials. Table 4.5 presents the form and size of the warning labels of finished products that contain carcinogenic substances.

4.4.3 China

The General Rules to Drafting Safety Labels (GB15258-1999) for dangerous goods are well defined. The latest version came after China ratified the convention No. 170 in 1994, and issued the first edition of this standard at the same time. In the following section, the content and general requirements for the Chinese precautionary label is presented. The hazards of chemicals and precautionary warnings are displayed in the combined form of characters, layouts, and numerals.

The following subject matter shall be considered for inclusion on precautionary labels:

- Identification of the chemicals or its hazardous component(s)
- Signal word
- Statement(s) of hazard(s)
- Safety measures
- Fire-fighting measures
- Reference(s)
- Emergency telephone number

Identification of the chemicals or its hazardous component(s) shall be adequate to allow selection of proper action in case of exposure. For a single chemical substance, the chemical name shall be used. For mixtures, the chemical names of the components contributing substantially to the hazard of the mixture shall be included as part of the label. The name on labels should be expressed strikingly and be clearly presented in Chinese and English. The molecular formula may be provided.

For the chemical components and ingredients, the main components of

chemicals and the hazardous ingredients and their concentration or concentration range should be given. The UN number and CN number are used to represent the United Nations dangerous goods code and China dangerous goods code separately. The pictograms for commonly used chemicals are all included in the UN's "Recommendations on the Transport of Dangerous Goods" and China's "Classification and Marks of Dangerous Chemical Substances Commonly Used, GB13690-92." Each chemical may have at most two pictograms, which are located on the right side of a label.

The signal words *Danger*, *Warning*, and *Caution* are used to indicate the relative degree of severity of an immediate hazard of chemicals (Table 4.6 shows the specific principles). When a chemical has more than one hazard, only the signal word corresponding to the class of greatest immediate hazard shall be used. The signal words, which should be striking and clear, are located under the name of the chemicals. The statements of hazards should be below the signal words and shall give a brief description of the fire and explosion hazards of chemicals and their harmful effects to health and environment.

For the safety measures, appropriate technical measures and precautions for safely handling, transporting, storing, and using the chemicals should be described. It should be simple but contain the main points of information. Fire-fighting measures must state which extinguishing media are suitable, which are not, and to what one should pay much attention in fire-fighting.

Other miscellaneous information like the lot number shall state the production date and order of the chemicals. The production date is showed in the form of •• year •• month •• day, and the shift order in ••. Also, this subsection shall prompt a recipient to ask for the chemical safety data sheet from the manufacturer or supplier. Finally, the name, address, post code, telephone number, and emergency telephone number of the manufacturer, and the emergency phone number must be listed.

Text on a label should be written in Chinese (simple) characters, in a clear and understandable manner. If any other language is present, its meaning must

TABLE 4.6. Corresponding Relations Between Signal Words and the Classification of Chemical Hazards

Signal Words	Classification of Chemicals' Hazards
Danger	Explosives, flammable gases, toxic gases, low-flashpoint liquids, first-class spontaneous combustion chemicals, first-class chemicals flammable when wet, first-class oxides, organic peroxides, extremely toxic chemicals, first-class acid corrosives
Warning	Nonflammable gases, mid-flashpoint liquids, first-class flammable solids, second-class spontaneous combustion chemicals, second-class chemicals flammable when wet, second-class oxides, toxic chemicals, second-class acid corrosives, first-class alkaline corrosives
Caution	High-flashpoint liquids, second-class flammable solids, toxic chemicals, second-class alkaline corrosives, other corrosives

be in correspondence with that of the Chinese characters and the type size must be smaller than the Chinese characters used. The same meaning shall be expressed in the same language and with the same layouts. Annex A and B of the guidelines list the main phrases for your reference.

The pictogram on a label should be colored according to the standard of GB13690-92 and the color of the text and its background should be in sharp contrast (white and black are the two most often used colors).

It is important to note that an enterprise cannot sell its products without the registration certificates and safety labels (one label for each certificate). Examples of their labels are in compliance with the ILO and have the same look and feel as the one used as an example for Japan.

4.4.4 Australia

The National Occupational Health and Safety Commission has declared a National Code of Practice for the Labelling of Workplace Substances. National codes of practice declared by the National Commission under s.38(1) of the National Occupational Health and Safety Commission Act 1985 are documents prepared for the purpose of advising employers and workers of acceptable preventive action for averting occupational deaths, injuries, and diseases in relation to workplace hazards.

Workplace hazardous substances that are imported from overseas may be labeled in accordance with overseas requirements. Provided that these overseas labels contain equivalent information to that advised in this national code of practice, it should not be necessary to relabel an imported substance.

Information on the label should be:

1. Located on an outside face of the container
2. In English
3. In durable print
4. In lettering of a size and style that is easily legible
5. The label should be firmly secured and printed in a color or colors that provide a distinct contrast to the background color.

Labels on workplace hazardous substance containers of more than 500 mL(g) capacity should include the following:

1. Signal word(s) and/or dangerous goods class and subsidiary risk label(s) (where applicable)
2. Identification information
3. Product name
4. Chemical name
5. United Nations (UN) number (where required by the ADG Code 1)
6. Ingredients and formulation details (where relevant)

7. Risk phrase(s)
8. Directions for use (where appropriate)
9. Safety phrase(s)
10. First aid procedures
11. Emergency procedures
12. Details of manufacturer or importer
13. Expiry date (where relevant)
14. Reference to the MSDS

Labels on workplace hazardous substance containers of 500 mL(g) capacity or less should include the following:

1. Signal word(s) and/or dangerous goods class and subsidiary risk label(s) (where applicable)
2. Product name
3. Chemical name
4. Risk phrase(s) (at least the most significant phrase(s))
5. Safety phrase(s) (at least the most significant phrase(s))
6. First aid procedures
7. Details of manufacturer or importer
8. Reference to the MSDS

Where a container of a hazardous substance is so small that this information cannot be provided on the actual container, the container should be labeled with at least:

1. Signal word(s) and/or the dangerous goods class and subsidiary risk label(s) (where applicable)
2. Product name
3. Details of manufacturer or importer

In these circumstances, consideration should be given to other methods of providing additional information, such as on outer packaging or on leaflets. Alternative packaging can be used to give maximum clarity to the information and allow the full set of information to be supplied.

4.4.5 Malaysia

The duty to label any packaging containing a hazardous chemical is on the supplier and this duty is stipulated under Regulation 7 of the Occupational Safety and Health (Classification, Packaging and Labelling of Hazardous Chemicals) Regulations 1997, hereinafter referred to as "the Regulations."

For purpose of these guidelines, the duty to label hazardous chemicals or preparations produced locally lies with the manufacturer or formulator while the duty to label imported chemicals or preparations lies with the importer.

Name of the Hazardous Chemical The prescribed internationally recognized nomenclature is the nomenclature that has been devised by the International Union of Pure and Applied Chemistry (IUPAC) to name chemical substances. The name of a single-ingredient hazardous chemical on a label, besides following the IUPAC system, should also include its common name or CAS name. For example, methyl benzene is the name for toluene in accordance with the IUPAC system. In labeling, both names should appear on the label with the common name or CAS name written in parentheses or in smaller lettering (1 font size smaller) located below the IUPAC name.

The name of a hazardous preparation or mixture should use the product name or the trade name. However, the hazardous ingredients should be listed using the IUPAC name in descending order of proportion. The hazardous ingredients are to be disclosed in terms of their percentage weight (for solids or liquids) or percentage volume (for gases).

If the name of the chemical, the name of the ingredients in a preparation, and the concentration of the ingredients constitute confidential information, the information may be omitted if one of the following is true:

1. The chemical or the ingredient is determined to be nonhazardous according to the Guidelines on the Classification of Hazardous Chemical.
2. The chemical or the ingredients are classified as irritant or harmful.
3. The proportion of the ingredient in the preparation is at a concentration below the lowest cut-off level for the ingredient as listed in the List of Hazardous Chemicals contained in the Guidelines on the Classification of Hazardous Chemical.

However, the generic name of the chemical or the ingredients should be disclosed on the label and the concentration of each hazardous ingredient should be disclosed in the appropriate concentration range, that is, **>60%** or **30–60%** or **10–30%** or **<10%**.

The name of a complex mixture should give as much information as possible on each hazardous ingredient, giving the concentration within the appropriate range as mentioned earlier. Chemical classes of the complex mixture should be identified such as aliphatic or aromatic hydrocarbon, aliphatic alcohol, or phenol, and so on.

Name Address, and Telephone Number of Supplier The name and address of the manufacturer, whether foreign or local, must be stated on the label. The name and address of the local supplier of the hazardous chemical must be stated also on the label. The supplier here refers to the importer (for imported

products) or the principal distributor. The address is the full postal address of the company's marketing office in Malaysia, including the postcode number.

The telephone number is the local telephone number of the supplier in Malaysia (including area code) where advice can be obtained, especially in an emergency. However, if the chemical is an imported chemical, the foreign manufacturer's contact number (24 hours) may be included for advice during an emergency.

Danger Symbol and Indication of Danger The danger symbol and corresponding indication of danger used must be in accordance with Regulation 7(2) of the Regulations. Danger symbol(s) assigned to a hazardous chemical must take into consideration its physicochemical properties and the adverse health effects.

A maximum of only two danger symbols is suggested. One to represent the hazard solely due to its physicochemical properties (Part A of Schedule I of the Regulations) and the other the hazard solely due to its adverse health effects (Part B of Schedule I of the Regulations).

The indication of danger is the hazard classification determined using the Guidelines on the Classification of Hazardous Chemicals. This indication of danger has already been included together with the danger symbol in the diamond-shaped figure as depicted in Schedule II of the Regulations.

If there are two danger symbols, they should be placed together and located either

1. top and bottom on the right hand portion,
2. side by side at the top portion, or
3. diagonally positioned on the right hand portion of the label.

Each danger symbol should cover at least one-tenth of the surface area of the label and should not be less than one square centimeter (the danger symbol is a diamond-shaped figure with the sides tilted at 45 degrees to the horizontal).

Nature of the Special Risk The nature of the special risk associated with the use of the hazardous chemical is described by the risk phrase also known as the R-phrase. This phrase should give notice of the hazards present with the normal or reasonably foreseeable handling or use of the hazardous chemical and should include effects of overexposure or any likely chronic effects following multiple low level exposure.

Where a chemical has been determined to be a hazardous chemical, the provision of risk phrase(s) should be in accordance with the hazard classification that has been determined using the Guidelines on the Classification of Hazardous Chemical. The guidelines spell out the criteria for choosing the appropriate risk phrase(s) for the hazardous chemical.

Where a chemical poses more than one hazard, an appropriate risk phrase for each hazard should be included, with the most significant being placed first. The most appropriate risk phrases should be selected from Appendix 7 of the Regulation. In general, no more than four phrases should be necessary. Additional risk phrases may be used for risks not identified in Appendix 7.

When more than four phrases apply, it may be possible to eliminate phrases that refer to the lowest degree of hazard, provided that the overall effectiveness of the warning is not reduced. The uses of suitable safety phrases (S-phrases) may also make certain risk phrases superfluous.

Safety Precautionary Measures The safety precautionary measures are described by the safety phrase, otherwise known as the S-phrase. When choosing the safety phrase, the risks indicated by the risk phrase chosen for the label should be considered together with the intended use of the hazardous chemical.

Generally, a safety phrase that gives obvious advice in relation to a related risk, which has been taken care of by the R-phrase, should be omitted from the label unless it is used to give particular emphasis to a specific warning. For example, the risk phrase, "*Contact with water liberates toxic gas*," need not be supplemented with the safety phrase, "*Never add water to this product*."

When a safety phrase refers to personal protective equipment, the safety phrase should, where appropriate, specify the type of protective equipment needed. For example, "*Wear suitable gloves*" becomes "*Wear gloves—neoprene*."

The most appropriate safety phrases should be selected from Appendix 8 (reproduced from Schedule IV to the Regulations and in dual languages) and, in general, no more than four phrases should be necessary. The criteria for selecting safety phrase(s) is given in Appendix 9.

First aid instructions should be included where contact or exposure to the chemical substance warrants immediate treatment. The most appropriate first aid phrases should be selected from Appendix 10. Additional first aid phrase(s) may be used for situations not identified in Appendix 10. It is important to note the following:

a. The risk and safety phrases need not be given in the case of irritant, highly flammable, flammable, and oxidizing chemicals where the package contain 125 mL or less of the hazardous chemical.
b. For labeling of certain classes of hazardous chemical, as mentioned in paragraph (b), the danger symbols may be positioned in the middle of the label.

Languages The labels should be written in both the national language (Bahasa Malaysia) and English. The lettering in English should not be bigger than that in Bahasa Malaysia. Refer to Section 3 of the guidelines for the lettering sizes. Where no translation of a particular word or phrase is available

in the national language, the English word or phrase may be used and the word or phrase should be in parentheses.

Background Colors for Label The background color for a label is either white or a light color that will not camouflage the symbol. The background color for the danger symbols, as stipulated in Schedule II to the Regulations, are given in Table 4.7.

Letters and Numerals The letters and numerals are to be in print and should be in a font size not smaller than 7 points (example of font size 7). The letters and numerals should be in black.

Revision of Label If a hazardous preparation changes, for example, a new ingredient is introduced, or if new information about the health hazards of a chemical becomes known, then the existing label must be revised to take into consideration the new information. This revision of a label should be in line with the mandatory review of the Chemical Safety Data Sheet (CSDS).

TABLE 4.7. Color for Malaysian Label

Color	BS381C*	AS2700**	PMS***
Light orange	No. 557	X15 (orange)	Pantone 151
Signal red	No. 537	R13 (signal red)	Pantone 192
Canary yellow	No. 309	Y11 (canary)	Pantone 109

* British standards; ** Australian standards; *** Pantone Matching System published by Pantone Inc, USA.

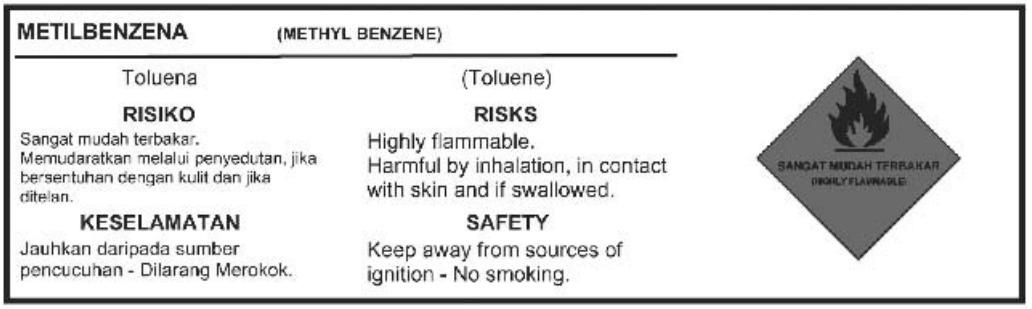


Figure 4.6. Sample label for single hazardous ingredient.

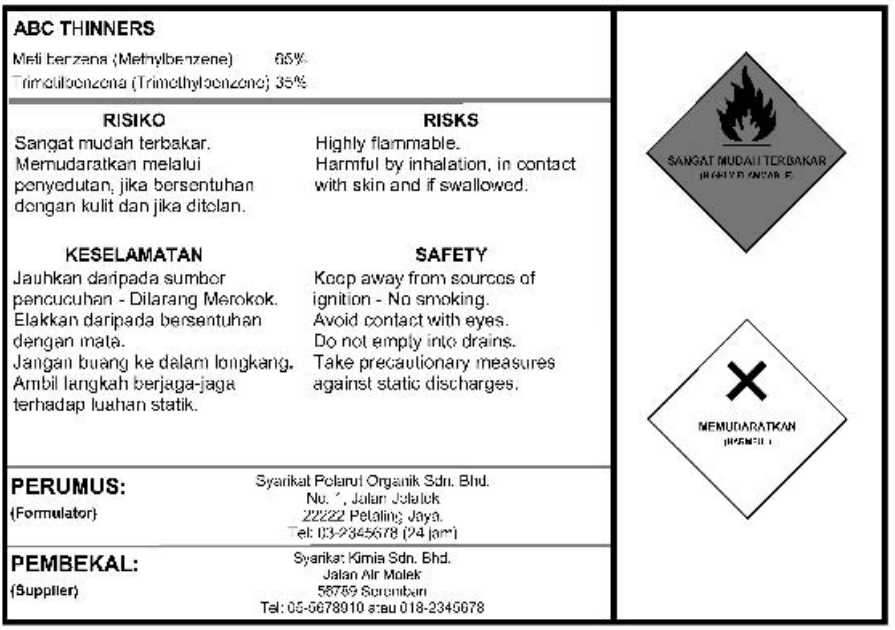


Figure 4.7. Sample label for all categories of hazardous chemical preparations.

Figure 4.6 presents a sample label for all categories of chemical products containing a single hazardous ingredient. Figure 4.7 presents a sample label for all categories of hazardous chemical preparations.

REFERENCE

CCOHS 2001. Canadian Center for Occupational Health & Safety, July 25, 2001. Available at www.ccohs.ca.

5

TRANSPORT REQUIREMENTS

5.1 OVERVIEW OF TRANSPORT LEGISLATION

Transportation legislation has been in effect since the 1800. In the 1950s the legislation was adapted to also cover the transport of dangerous goods. Table 5.1 presents a list of key regulatory bodies and the associated legislation that govern the majority of transportation activities in the world. Unique, local legislation may exist, however, most is derived from one of the documents shown in Table 5.1.

The United Nations Economic and Social Council's Committee issued their first recommendation regarding the transport of dangerous goods in 1956. The current Model Regulation on the Transport of Dangerous Goods was published in 1996. The last adaptation of the Model Regulation was made in December 2000. The principle of the UN Model Regulations has been adopted in most countries with minor local adaptations and interpretations.

The United Nations (UN) Committee of Experts on the Transport of Dangerous Goods has been reconfigured (renamed) into a "UN Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labeling of Chemicals." This committee has set up two subcommittees: a new "Sub-Committee of Experts on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS Sub-Committee)" and the previous "Sub-Committee of Experts on the Transport of Dangerous Goods (TDG Sub-Committee)."

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TABLE 5.1. Key Regulatory Bodies and Legislation Government Transportation

Region	Transport Medium	Regulatory Bodies	Legislation
Global	All	United Nations	United Nations Recommendations on Model Regulation
	Air	International Civil Aviation Organization (ICAO) International Air Transport Association (IATA)	ICAO Technical Instructions
	Shipping	Inter-Governmental Maritime Consultative Organization (IMCO and also IMO)	International Maritime Dangerous Good (IMDG) Code
Europe	Road	United Nations and European Union	United Nations Economic Commission for Europe (UNECE) European Agreement concerning the International Carriage of Dangerous Goods by Road (also referred to as ADR)
	Rail	European Union	Regulations governing the International Carriage of Dangerous Goods by Rail (also referred to as RID)
	Inland Waters	European Union and the Central Commission for the Navigation of the Rhine (CCNR)	European Inland Waterways regulation (also referred to as ADNR)
United States	All	The Office of Hazardous Materials Safety and the U.S. Department of Transportation (DOT)	Hazardous materials regulations and procedures (49 CFR Parts 100-185)
Canada	All	Canadian Department of Transportation and Provincial transportation departments/agencies (roadways within province)	Federal Transportation of Dangerous Goods (TDG) Acts and Regulations and provincial legislation for roadways within province
Australia	All	Australian Department of Transport and Regional Services and the Dangerous Goods	Transportation of Dangerous Goods (TDG) Acts and regulations

TABLE 5.1. ***Continued***

Region	Transport Medium	Regulatory Bodies	Legislation
China	All	Ministry of Labor and Ministry of Chemical Industry, State Environmental Protection Agency, State Economic and Trade Commission (SETC)	GB 15098-94 "The principle of classification of transport packaging groups of dangerous goods"

The "UN Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labeling of Chemicals" and the "TDG Sub-Committee" will still publish the "United Nations Recommendations on the Transport of Dangerous Goods Model Regulations (UNRTDG)" taking into account the Globally Harmonized System. The criteria and labeling under the Globally Harmonized System regarding physical hazards/labeling was basically taken from the already established "UN Recommendations on the Transport of Dangerous Goods Model Regulations." Any new regulations affecting transportation not presently in the UNRTDG will still follow the procedure of adoption into the UNRTDG. After adoption into the UNRTDG the procedure follows as a decision for each international mode of transportation and country governmental transportation agency to either adopt or not adopt the new model. The UNRTDG also forms the basis for international modal regulations on the transport of dangerous goods prepared by the International Maritime Organization (IMO) and the International Civil Aviation Organization (ICAO) and is also used as a basis for the development of regional (e.g., NAFTA and European Road and Rail regulations) and national transport regulations in the United States, Canada, and so on. The international modal regulations run on a two-year update cycle for adoption of new or modified regulations therefore any new requirements affecting transportation will span at least a two-year period.

The ICAO, which secures international co-operation and uniformity in regulations and standards, procedures, and organization regarding civil aviation, also manages legislation regarding the transportation of dangerous goods by air. ICAO follows the UN model with its own adaptation regarding products that have more stringent requirements and, in some cases, cannot be transported by air at all. The International Air Transport Association (IATA) was founded in 1945. It is the prime vehicle for interairline cooperation in promoting safe, reliable, secure, and economical air services for the benefit of the world's consumers. IATA also assists airlines in adopting and interpreting the ICAO legislation.

The International Maritime Organization (IMO) was created in 1948 under the name Inter-Governmental Maritime Consultative Organization (IMCO).

Once the United Nations was formed officially, IMCO was recognized as the international agency to promote and enforce maritime safety. This was achieved in 1948 at the International Conference in Geneva. The International Maritime Dangerous Good (IMDG) Code was developed by IMO as a uniform international code for the transport of dangerous goods by sea.

The only downside of this international legislation is that it is not available to the general public and each organization sells its own. As they are under copyright, they can only be reproduced in part or be obtained for a predetermined fee.

In North America, transport legislation also follows the UN Model Regulation. In the United States, the Department of Transport (DOT) in cooperation with the Office of Hazardous Materials Safety enforces legislation governing the transport of dangerous goods. The latter is part of the U.S. Department of Transportation's Research and Special Programs Administration (RSPA) and is responsible for coordinating a national safety program for the transportation of hazardous materials by air, rail, highway, and water in the United States. In Canada, the Department of Transport monitors the implementation of the Transportation of Dangerous Goods (TDG) legislation. In Mexico, transport is covered by the Official Mexican Standards (referred to as Normas or NOMs) and is enforced by the pertinent Mexican authorities. This legislation augments the Mexican Hazardous Materials Land Transportation Regulation.

In Europe, multiple organizations are in place to control the transportation of dangerous goods. The ADR is the common abbreviation for the United Nations Economic Commission for Europe (UNECE) European Agreement concerning the International Carriage of Dangerous Goods by Road. Its provisions set out how producers/consignors and carriers should classify, package, label, and transport dangerous goods.

In the last amended version, applicable from 1 July 2001, Annexes A and B are presented under a new format ("Restructured ADR"). The new structure is consistent with that of the United Nations Recommendations on the Transport of Dangerous Goods, Model Regulations. The European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) came into force in 1968. The agreement itself was amended by the Protocol amending article 14 (3) in 1975, which entered into force in 1985.

The RID is the common abbreviation for the set of regulations governing the International Carriage of Dangerous Goods by Rail. The regulations are published in French and German by OCTI, the body responsible for administering RID, and are updated every two years. Any amendments to the regulations are discussed and agreed by the RID Committee of Experts (sometimes known as the Fachausschuss, from its German name).

The European Inland Waterways regulation, known as ADN, was adopted in May 2000 and consists of main legal text and regulations ensuring a high level of safety of the international carriage of dangerous goods by inland waterways and should be the same as those applicable to the Rhine. The nav-

igation on the Rhine brought the first Act of the Congress of Vienna to adopt rules and regulation for general international waterways transportation. This was adopted the first time in 1815 and then became the ADN later on.

In the Pacific Rim, the Australian dangerous goods legislation is seen as the leading edge regulatory framework. The Department of Transport and Regional Services of Australia is the legal entity ensuring that the legislation for the land transport of dangerous goods and explosives are met. They are closely aligned with the International Standard contained in the "UN Recommendations on the Transport of Dangerous Goods."

China is still using an old version of the UN Model Regulation as they still have Classification 3.1, 3.2, and 3.3. GB 15098-94—"The Principle of Classification of Transport Packaging Groups of Dangerous Goods" is the official transport documentation.

5.2 INTERNATIONAL REQUIREMENTS

5.2.1 United Nations (UN)

Overview The United Nations normally creates recommendations on the transport of dangerous goods. These are addressed to governments and to the international organizations concerned with safety in the Transport of Dangerous Goods. The recommendations have been prepared by the United Nations Economic and Social Council's Committee of Experts on the Transportation of Dangerous Goods and were first published in 1956 (ST/ECA/43-E/CN.2/170). At its nineteenth session of December 2–10, 1996, the Committee adopted the first version of the Model Regulations on the Transport of Dangerous Goods, which were annexed to the tenth revised edition of the Recommendations on the Transport of Dangerous Goods.

This model regulation was put in place to facilitate the harmonization of transportation of dangerous goods into all modal, national, and international regulations. Subsequent modifications were done in December 1998 and December 2000. These recommendations do not apply to the transport of dangerous goods in bulk, which, in most countries, is subject to special regulations (UN, 2003).

The model regulations presents a basic scheme of provisions that will allow uniform development of national and international regulations governing the various modes of transport. These model regulations are flexible enough to accommodate any special requirements that might have to be met by a particular country. The UNECE expects governments, intergovernmental organizations, and other international organization, when revising or developing regulations for which they are responsible, will conform to the principles laid down in these model regulations, thus contributing to worldwide harmonization (UN, 2003).

The model regulations cover principles of classification and definition of

classes, listing of the principal dangerous goods, general packing requirements, testing procedures, marking, labeling or placarding, and transport documents. The UNECE believes that with this system (model regulations), carriers, consignors, and inspecting authorities will benefit from the simplified transport, handling, and control and from a reduction in time-consuming formalities (UN, 2003).

These model regulations also cover the marking and labeling of packages to indicate the hazards of a consignment and through the inclusion of relevant information in the transport documents. The placarding of the transport units is also well defined. The labels need to be affixed on goods or packages according to Section 5.2.2.2 of the UN "Recommendations on the Transport of Dangerous Goods Model Regulation, twelfth revised edition" ST/SG/AC.10/1/Rev.12. The labeling system is based on the classification of dangerous goods and was establish with two main criteria:

- To make dangerous goods easily recognizable from a distance by the general appearance (symbol, color and shape) of the labels they bear
- To provide, by means of color on the labels, a useful first guide for handling, stowage, and segregation

Wastes, deemed to be dangerous goods, are also addressed in these regulations. They must be classified according to the nine classes. If a waste is not classified into the first eight classes, then it will go under the general class 9 for waste that are covered under the Basel Convention (Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (1989)).

In the following section, detailed information on the key requirements pertaining to the transport of dangerous goods is presented.

Scope and Application These regulations prescribe detailed requirements applicable to the transportation of dangerous goods. Except as otherwise provided in these regulations, no person may offer or accept dangerous goods for transport unless those goods are properly classified, packaged, marked, labeled, placarded, described, and certified on a transport document.

These regulations do not apply to the transport of bulk dangerous goods, dangerous goods that are required for the propulsion of the means of transport or the operation of its specialized equipment, and, finally, dangerous goods that are packaged for retail sale.

Certain dangerous goods packed in limited quantities are exempted from certain requirements of these regulations subject to the conditions laid down in Chapter 3.4 of the regulation.

Radioactive materials are also covered under these regulations.

Finally, as mentioned earlier, some dangerous goods are forbidden from transport and includes any substance that is liable to explode, dangerously react, produce a flame or dangerous evolution of heat or dangerous emission

of toxic, corrosive, or flammable gases or vapors under normal conditions, are encountered during normal transport conditions.

Training Individuals that are implicated in any of the steps for transporting dangerous goods shall receive the following training:

- General awareness and familiarization training
- Detailed training according to their function and implication with the dangerous goods
- Safety training commensurate with the risk of exposure in the event of a release and the functions performed

Transport Classification There are nine different classes that describe the different hazards (Table 5.2). Some of these classes have divisions. The class number is not attributed by the order of danger, that is, a class 1 product is not more dangerous then a class 3.

It is important to remember that, normally, when a product is assigned one of these classes, these products are also considered as being environmentally hazardous.

For packing purposes, certain substances may be assigned to packing groups in accordance with their degree of danger. The packing groups have the following meanings:

- Packing group I: Substances presenting high danger
- Packing group II: Substances presenting medium danger
- Packing group III: Substances presenting low danger

The dangerous goods that are presenting a danger of a single class and division are assigned to that class and division and the degree of danger (packing group). When an article or substance is specifically listed by name in the dangerous goods list (specific table defined and supplied by this regulation) in Chapter 3.2 of the legislation, its class or division, its subsidiary risk(s), and, when applicable, its packing group is taken from this list.

Dangerous goods meeting the defining criteria of more than one hazard class or division and which are not listed by name in the dangerous goods list in Chapter 3.2 are assigned to a class and division and subsidiary risk on the basis of the precedence of hazards in Chapter 2.0.3 of the legislation.

Table 5.3 presents the precedence for classification as per Chapter 2.0.3 of the legislation.

Each product needs to have a UN number and proper shipping name. Dangerous goods are assigned UN numbers and proper shipping names according to their hazard classification and their composition. The dangerous goods that are commonly carried are listed in the Dangerous Goods List in Chapter 3.2 of the Recommendation. For dangerous goods that are not specifically

TABLE 5.2. Transport Classes

Class	Division	Description
Class 1		Explosive
	Division 1.1	Substances and articles that have a mass explosion hazard
	Division 1.2	Substances and articles that have a projection hazard but not a mass explosion hazard
	Division 1.3	Substances and articles that have a fire hazard and either a minor blast hazard or a minor projection hazard or both, but not a mass explosion hazard
	Division 1.4	Substances and articles that present no significant hazard
	Division 1.5	Very insensitive substances that have a mass explosion hazard
	Division 1.6	Extremely insensitive articles that do not have a mass explosion hazard
Class 2		Gases
	Division 2.1	Flammable gases
	Division 2.2	Nonflammable, nontoxic gases
	Division 2.3	Toxic gases
Class 3		Flammable liquids
Class 4		Flammable solids; substance liable to spontaneous combustion; substances that, on contact with water, emit flammable gases
	Division 4.1	Flammable solids, self-reactive substances, and solid desensitized explosives
	Division 4.2	Substances liable to spontaneous combustion
	Division 4.3	Substances that, in contact with water, emit flammable gases
Class 5		Oxidizing substances and organic peroxides
	Division 5.1	Oxidizing substances
	Division 5.2	Organic peroxides
Class 6		Toxic and infectious substances
	Division 6.1	Toxic substances
	Division 6.2	Infectious substances
Class 7		Radioactive material
Class 8		Corrosive substances
Class 9		Miscellaneous dangerous substances and articles

listed by name "generic" or "not otherwise specified (NOS)" entries are provided to identify the article or substance in transport.

A UN number characterizes each entry in the Dangerous Goods List. This list also contains the hazard class, subsidiary risk(s), packing group, and others. Entries in the list are of four types:

- Single entries
- Generic entries for group

TABLE 5.3. Precedence of Hazards

	4.2	4.3	5.1 I	5.1 II	5.1 III	6.1,I Dermal	6.1,I Oral	6.1 II	6.1 III	8, I Liquid	8, I Solid	8, II Liquid	8, II Solid	8, III Liquid	8, III Solid
3, I		4.3				3	3	3	3	3	—	3	—	3	—
3, II		4.3				3	3	3	3	8	—	3	—	3	—
3, III		4.3			6.1	6.1	6.1	3	8	—	8	—	3	—	
4.1, II	4.2	4.3	5.1	4.1	4.1	6.1	6.1	4.1	4.1	—	8	—	4.1	—	4.1
4.1, III	4.2	4.3	5.1	4.1	4.1	6.1	6.1	6.1	4.1	—	8	—	8	—	4.1
4.2, II		4.3	5.1	4.2	4.2	6.1	6.1	4.2	4.2	8	8	4.2	4.2	4.2	4.2
4.2, III		4.3	5.1	5.1	4.2	6.1	6.1	6.1	4.2	8	8	8	8	4.2	4.2
4.3, I			5.1	4.3	4.3	6.1	4.3	4.3	4.3	4.3	4.3	4.3	4.3	4.3	4.3
4.3, II			5.1	4.3	4.3	6.1	4.3	4.3	4.3	8	8	4.3	4.3	4.3	4.3
4.3, III			5.1	5.1	4.3	6.1	6.1	6.1	4.3	8	8	8	8	4.3	4.3
5.1, I						5.1	5.1	5.1	5.1	5.1	5.1	5.1	5.1	5.1	5.1
5.1, II						6.1	5.1	5.1	5.1	8	8	5.1	5.1	5.1	5.1
5.1, III						6.1	6.1	6.1	5.1	8	8	8	8	5.1	5.1
6.1, I Dermal										8	6.1	6.1	6.1	6.1	6.1
6.1, I Oral											8	6.1	6.1	6.1	6.1
6.1, II Inhalation											8	6.1	6.1	6.1	6.1
6.1, II Dermal											8	6.1	8	6.1	6.1
6.1, II Oral											8	8	8	6.1	6.1
6.1, III											8	8	8	8	8

- Specific NOS entries covering a group of substance of a particular chemical or technical nature
- General NOS entries covering a group of substances or articles meeting the criteria of one or more classes or division

A mixture or solution containing a single dangerous substance specifically listed by name in the Dangerous Goods List and one or more substances not subject to these regulations shall be assigned the UN number and proper shipping name of the dangerous substance. This is true unless the hazards of the mixture or solution are different and changes the classification.

A mixture or solution containing one or more substances identified by name in the regulations or classified under NOS entry and one or more substances is not subject to these regulations if the hazard characteristics of the mixture or solution are such that they do not meet the criteria for any class. If a mixture contains multiple listed substances the precedence table identified before needs to be followed.

The most stringent packing group denoted to the respective hazards of the goods takes precedence over other packaging groups, irrespective of the precedence of hazard table. The following hazard characteristics are not in the table because they always take precedence:

- Substances and articles of Class 1
- Gases of Class 2
- Liquid desensitized explosives of Class 3
- Self-reactive substances and solid desensitized explosives of Division 4.1
- Pyrophoric substances of Division 4.2
- Substances of Division 5.2
- Substances of Division 6.1 with packing group I inhalation toxicity
- Substances of Division 6.2
- Material of class 7

Definition of Each Class *Class 1, Explosives*. Explosive substances are defined as solid or liquid substances (or mixtures of substances) capable by chemical reaction of producing gases at such a temperature and pressure and at such a speed as to cause damage to the surroundings.

Pyrotechnic substances are defined as substances or mixtures of substances designed to produce an effect by heat, light, sound, gas, or smoke or a combination of these as the result of nondetonating, self-sustaining exothermic chemical reactions.

Class 2, Gases. A gas is a substance that:

(a) at 50 °C has a vapor pressure greater than 300 kPa (3 bar); or
(b) is completely gaseous at 20 °C at the standard pressure of 101.3 kPa.

The following are additional definitions:

- compressed gas: a gas that when packaged under pressure for transport is entirely gaseous at –50 °C
- liquefied gas: a gas that when packaged under pressure for transport is partially liquid at temperature above –50 °C
- refrigerated liquefied gas: a gas that when packaged for transport is made partially liquid because of its low temperature
- dissolved gas: a gas that when packaged under pressure for transport is dissolved in a liquid phase solvent

Class 3, Flammable Liquids. Flammable liquids are liquids, or mixtures of liquids, or liquids containing solids in solution or suspension, which give off a flammable vapor at temperatures of not more than 60.5 °C, closed-cup test, or not more than 65.6 °C, open-cup test, normally referred to as the flash point. The packing group here changes according to their flash point.

Class 4, Flammable Solids; Substance Liable to Spontaneous Combustion; Substances That, on Contact with Water, Emit Flammable Gases. Flammable solids are solids that, under conditions encountered in transport, are readily combustible or may cause or contribute to fire through friction; self-reactive substances, which are liable to undergo a strongly exothermic reaction; solid desensitized explosives, which may explode if not diluted sufficiently.

Substances liable to spontaneous combustion are substances that are liable to spontaneous heating under normal conditions encountered in transport; or to heating up in contact with air, and being then liable to catch fire.

The substances that will react with water and become spontaneously flammable are substances, which, by interaction with water, are liable to become spontaneously flammable or to give off flammable gases in dangerous quantities.

Class 5, Oxidizing Substances and Organic Peroxides. An oxidizing substance is a substance that, in itself, will not necessarily be combustible, may generally by yielding oxygen, cause, or contribute to, the combustion of other material.

An organic peroxide is a substance that contains bivalent—O—O—structure and may be considered derivatives of hydrogen peroxide, where one or both

TABLE 5.4. Packing Group According to Their Flash Point and Boiling Point

Packing Group	Flash Point CC (°C)	Initial Boiling Point (°C)
I	—	≤35
II	< 23	>35
III	≥ 23 ≤ 60.5	>35

of the hydrogen atoms have been replaced by organic radicals. Organic peroxides are thermally unstable substances, which may undergo exothermic self-accelerating decomposition. In addition, they may have one or more of the following:

- Be liable to explosive decomposition
- Burn rapidly
- Be sensitive to impact or friction
- React dangerously with other substances
- Cause damage to the eyes

Class 6, Toxic and Infectious Substances. A toxic substance is a substance liable to either cause death or serious injury or to harm human health if swallowed or inhaled or by skin contact.

An infectious substance is a substance known or reasonably expected to contain pathogens. Pathogens are defined as micro-organism or recombinant micro-organisms, which are known or reasonably expected to cause infectious disease in animals or human.

Class 7, Radioactive Material. Radioactive materials means any material containing radionuclides where both the activity concentration and the total activity in the consignment exceed the values specified in the UN definition.

Class 8, Corrosive Substances. Corrosive substances are substances that, by chemical action, will cause severe damage when in contact with living tissue, or, in the case of leakage, will materially damage, or even destroy, other goods or the mean of transport.

Class 9, Miscellaneous Dangerous Substances and Articles. This class includes all substances that present a danger during transport and are not covered by any of the previous classes.

Proper Shipping Name The proper shipping name is that portion of the entry most accurately describing the goods in Chapter 3.2 of the regulation, which is shown in uppercase characters (plus any numbers, Greek letters, "sec," "tert," and the letters "m," "n," "o," "p," which form an integral part of the name). An alternative proper shipping name may be shown in brackets following the main proper shipping name [e.g., ETHANOL (ETHYL ALCOHOL)]. Portions of an entry appearing in lowercase need not be considered as part of the proper shipping name.

When conjunctions such as "and" or "or" are in lowercase or when segments of the name are punctuated by commas, the entire name of the entry need not necessarily be shown in the transport document or package markings. This is the case particularly when combinations of several distinct entries are listed under a single UN number. Examples illustrating the selection of the proper shipping name for such entries are:

- UN 1057 LIGHTERS or LIGHTER REFILLS—The proper shipping name is the most appropriate of the following possible combinations:
  —LIGHTERS
  —LIGHTER REFILLS;
- UN 3207 ORGANOMETALLIC COMPOUND or COMPOUND SOLUTION or COMPOUND DISPERSION, WATER-REACTIVE, FLAMMABLE, N.O.S. The proper shipping name is the most appropriate of the following possible combinations:
  —ORGANOMETALLIC COMPOUND, WATER-REACTIVE, FLAMMABLE, N.O.S.
  —ORGANOMETALLIC COMPOUND SOLUTION, WATER-REACTIVE, FLAMMABLE, N.O.S.
  —ORGANOMETALLIC COMPOUND DISPERSION, WATER-REACTIVE, FLAMMABLE, N.O.S.

Each is supplemented with the technical name of the goods.

Proper shipping names may be used in the singular or plural as appropriate. In addition, when qualifying words are used as part of the proper shipping name, their sequence on documentation or package markings is optional. For instance, "DIMETHYLAMINE AQUEOUS SOLUTION" may alternatively be shown "AQUEOUS SOLUTION OF DIMETHYLAMINE." Commercial or military names for goods of Class 1 that contain the proper shipping name supplemented by additional descriptive text may be used.

Unless it is already included in capital letters in the name indicated in Chapter 3.2 of the regulation, the qualifying word "LIQUID" or "SOLID," as appropriate, shall be added as part of the proper shipping name when a substance mentioned by name may, due to the differing physical states of the various isomers of the substance, be either a liquid or a solid (e.g., DINITROTOLUENES, LIQUID; DINITROTOLUENES, SOLID). Unless it is already included in capital letters in the name indicated in Chapter 3.2, the qualifying word "MOLTEN" shall be added as part of the proper shipping name when a substance, which is a solid in accordance with the definition in 1.2.1, is offered for carriage in the molten state (e.g., ALKYLPHENOL, SOLID, NOS., MOLTEN).

For the purposes of documentation and marking of packages, when an "NOS." or "generic" proper shipping name is used, the proper shipping name shall be supplemented with the technical name of the goods, unless a national law or international convention prohibits its disclosure if it is a controlled substance.

The technical name shall be shown in parentheses immediately following the proper shipping name. It shall be a recognized chemical or other name currently used in scientific and technical handbooks, journals, and texts. Trade names shall not be used for this purpose. In the case of pesticides, only ISO common name(s), other name(s) in the World Health Organization (WHO)

Recommended Classification of Pesticides by Hazard and Guidelines to Classification, or the name(s) of the active substance(s) may be used.

When a mixture of dangerous goods is described by one of the "NOS." or "generic" entries to which special provision 274 has been allocated in the Dangerous Goods List in Chapter 3.2 of the regulation, not more than the two constituents which most predominantly contribute to the hazard or hazards of a mixture need to be shown, excluding controlled substances when their disclosure is prohibited by national law or international convention. If a package containing a mixture is labeled with any subsidiary risk label, one of the two technical names shown in parentheses shall be the name of the constituent that compels the use of the subsidiary risk label.

Examples illustrating the selection of the proper shipping name supplemented with the technical name of goods for such NOS. entries are:

— *UN 2003 METAL ALKYL, WATER-REACTIVE, N.O.S. (trimethylgallium)*
— UN 2902 PESTICIDE, LIQUID, TOXIC, N.O.S. (drazoxolon)

When mixtures and solutions have to be regarded as the dangerous substance mentioned by name in accordance with the classification requirements of 2.1.3.3 of the regulation, the qualifying word "SOLUTION" or "MIXTURE," as appropriate, shall be added as part of the proper shipping name, for example, "ACETONE SOLUTION." In addition, the concentration of the solution or mixture may also be indicated, for example, "ACETONE 75% SOLUTION."

Limited Quantities The limited quantities provide the maximum quantity per inner packaging authorized for transport of the substance concerned according to the provision for limited quantities. Dangerous goods in small packages are considered as presenting a minor risk in transport. For these reasons they are exempted from many requirements. More detailed information is given in the recommendations in Chapter 3.4 of the regulation.

Labeling Requirements Section 5.2.2 of the recommendations define very clearly the requirements. Here is an overview without any of the specificity required according to their class.

Each label shall:

- be affixed to the same surface of the package, if the dimensions of the package allow; for packages of Class 1 and 7, near the mark indicating the proper shipping name
- be so placed on the package that it is not covered or obscured by any part or attachment to the packaging or any other label or marking
- be displayed next to each other when more than one label is required

Where a package is of such an irregular shape or small size that a label cannot be satisfactorily affixed, the label may be attached to the package by a securely affixed tag or other suitable means.

Labels shall be in the form of a square set at an angle of 45° (diamond-shaped) with minimum dimensions of 100 mm by 100 mm. They have a line of the same color as the symbol, 5 mm inside the edge and running parallel with it. If the size of the package so requires, the dimensions of the labels may be reduced, provided that they remain clearly visible.

Gas cylinders for Class 2 may, on account of their shape, orientation, and securing mechanisms for carriage, bear labels representative of those specified in this section, which have been reduced in size, according to the dimensions outlined in ISO 7225:1994, "Gas cylinders—Precautionary labels," for display on the noncylindrical part (shoulder) of such cylinders.

Labels are divided into halves. With the exception of Divisions 1.4, 1.5, and 1.6, the upper half of the label is reserved for the pictorial symbol and the lower half for texts and the class number and the compatibility group letter as appropriate.

Except for Divisions 1.4, 1.5, and 1.6, labels for Class 1 show in the lower half the division number and compatibility group letter for the substance or article. Labels for Divisions 1.4, 1.5, and 1.6 show in the upper half the division number and in the lower half the compatibility group letter.

On labels other than those for material of Class 7, the optional insertion of any text (other than the class number) in the space below the symbol shall be confined to particulars indicating the nature of the risk and precautions to be taken in handling.

The symbols, text, and numbers shall be clearly legible and indelible and shall be shown in black on all labels except for:

- Class 8 label where the text (if any) and class number shall appear in white
- Labels with entirely green, red, or blue backgrounds where they may be shown in white

All labels shall be able to withstand open weather exposure without a substantial reduction in effectiveness.

Placards Placard shall be affixed to the exterior surface of transport units to provide a warning that the content of the unit are dangerous goods and present risk. Placard shall correspond to the primary risk and, if applicable, subsidiary risks of the goods contained in the transport unit. This is valid for road transport tank and freight vehicles, railway transport tank and freight wagons, and multimodal freight containers and portable tanks.

Except as provided in 5.3.1.7.2 of the Recommendation for the Class 7 placard, a placard shall:

- Be not less than 250 mm by 250 mm, with a line of the same color as the symbol running 12.5 mm inside the edge and parallel with it.
- Correspond to the label required for the dangerous goods in question with respect to color and symbol (see 5.2.2.2).
- Display the numbers (and for goods of Class 1, the compatibility group letter) prescribed for the dangerous goods in question in 5.2.2.2 for the corresponding label, in digits not less than 25 mm high.

5.2.2 ICAO and IATA

Dangerous goods can be transported safely by air transport provided certain principles are strictly followed. The International Civil Aviation Organization (ICAO) secures international co-operation and uniformity in regulations and standards, procedures, and organization regarding civil aviation matters. The International Air Transport Association (IATA) Dangerous Goods Regulations designed an easy-to-use manual based on the ICAO Technical Instructions. Transporters must comply with IATA due to the required specifications as adopted by the association of airline transporters. It incorporates additional operational requirements, which provide a harmonized system for airlines to accept and transport dangerous goods safely and efficiently. Users of the IATA Dangerous Goods Regulations are assured that they are meeting all legal requirements for shipping dangerous goods by air internationally. The regulations include a detailed list of individual articles and substances specifying the United Nations classification of each article or substance and their acceptability for air transport as well as the conditions for their transport. Because no listing can be complete, the list also includes many generic or "not otherwise specified" entries to assist in the classification of those articles or substances not listed by name. Some dangerous goods have been identified as being too dangerous to be carried on any aircraft under any circumstances; others are forbidden under normal circumstances but may be carried with specific approvals from the states concerned; some are restricted to carriage on all cargo aircraft; most, however, can be safely carried on passenger aircraft as well, provided certain requirements are met. The proper declaration of dangerous goods by the shipper ensures that all in the transportation chain know what dangerous goods they are transporting. The pilot-in-command must know what is on board the aircraft in order to properly deal with any emergencies, which may occur. The pilot must also convey this information if possible to air traffic services to aid in the response to any aircraft incident or accident.

IATA was founded in April 1945. It is the prime vehicle for interairline cooperation in promoting safe, reliable, secure, and economical air services for the benefit of the world's consumers (IATA, 2003).

The most important tasks of IATA during its earliest days were technical, because safety and reliability are fundamental to airline operations. These

require the highest standards in air navigation, airport infrastructure, and flight operations. IATA's airline members provided vital input to the work of ICAO, as that organization drafted its standards and commended practices. By 1949, the drafting process was largely complete and was reflected in the "Annexes" to the Chicago convention, the treaty that still governs the conduct of international civil aviation (IATA, 2003).

In those early days, ICAO coordinated regional air navigation and support for airports and operational aids in countries that could not themselves afford such services. IATA provided airline input to ICAO and to sessions of the International Telecommunications Union on wavelength allocation (IATA, 2003).

Until 1955, there was a complete embargo on the air transport of toxic, flammable, or corrosive materials. Then IATA developed the Dangerous Goods Regulations for their safe carriage (IATA, 2003).

Packaging is the essential component in the safe transport of dangerous goods by air. The IATA Dangerous Goods Regulations provide packing instructions for all dangerous goods acceptable for air transport with a wide range of options for inner, outer, and single packaging. The packing instructions normally require the use of UN performance-tested specification packaging, however, these are not required when dangerous goods are shipped in limited quantities under the provisions of Limited Quantity "Y" Packing Instructions. The quantity of dangerous goods permitted within these packaging is strictly limited so as to minimize the inherent risk presented by the dangerous goods should an incident occur (IATA, 2003).

Training is also an essential element in maintaining a safe regulatory regime. It is necessary for all individuals involved in the preparation or transport of dangerous goods to be properly trained to carry out their responsibilities. Depending on the job function, this may entail only familiarization training or may also include more detailed training in the intricacies of the regulations. It is important to remember that dangerous goods are very unlikely to cause a problem when they are prepared and handled in compliance with the IATA Dangerous Goods Regulations (IATA, 2003).

Lastly, dangerous goods accidents or incidents must be reported, so that an investigation by the relevant authorities can establish the cause and take corrective action. Also, if as a result of these investigations changes are required in the regulations, appropriate regulatory action can be taken without delay (IATA, 2003).

5.2.3 IMO

Shipping is perhaps the most international of all the world's great industries and one of the most dangerous. It has always been recognized that the best way of improving safety at sea is by developing international regulations that are followed by all shipping nations and from the mid-19th century onwards a number of such treaties were adopted. Several countries proposed that a

permanent international body should be established to promote maritime safety more effectively, but it was not until the establishment of the United Nations itself that these hopes were realized. In 1948 an international conference in Geneva adopted a convention formally establishing IMO (the original name was the Inter-Governmental Maritime Consultative Organization, or IMCO, but the name was changed in 1982 to IMO) as the official organization for maritime safety. The IMO Convention entered into force in 1958 and the new organization met for the first time the following year (IMO, 2003).

The purposes of the organization, as summarized by Article 1(a) of the Convention, are "to provide machinery for cooperation among Governments in the field of governmental regulation and practices relating to technical matters of all kinds affecting shipping engaged in international trade; to encourage and facilitate the general adoption of the highest practicable standards in matters concerning maritime safety, efficiency of navigation and prevention and control of marine pollution from ships." The organization is also empowered to deal with administrative and legal matters related to these purposes. IMO's first task was to adopt a new version of the International Convention for the Safety of Life at Sea (SOLAS), the most important of all treaties dealing with maritime safety. This was achieved in 1960 and IMO then turned its attention to such matters as the facilitation of international maritime traffic, load lines, and the carriage of dangerous goods, while the system of measuring the tonnage of ships was revised (IMO, 2003).

But although safety was and remains IMO's most important responsibility, a new problem began to emerge—pollution. The growth in the amount of oil being transported by sea and in the size of oil tankers was of particular concern and the Torrey Canyon disaster of 1967, in which 120,000 tons of oil was spilled, demonstrated the scale of the problem (IMO, 2003).

During the next few years IMO introduced a series of measures designed to prevent tanker accidents and to minimize their consequences. It also tackled the environmental threat caused by routine operations such as the cleaning of oil cargo tanks and the disposal of engine room wastes—in tonnage terms a bigger menace than accidental pollution (IMO, 2003).

The most important of all these measures was the International Convention for the Prevention of Pollution from Ships, 1973, as modified by the Protocol of 1978 relating thereto (MARPOL 73/78). It covers not only accidental and operational oil pollution but also pollution by chemicals, goods in packaged form, sewage, garbage, and air pollution (IMO, 2003).

Other measures introduced by IMO have concerned the safety of containers, bulk cargoes, liquefied gas tankers, and other ship types. Special attention has been paid to crew standards, including the adoption of a special convention on standards of training, certification, and watch keeping (IMO, 2003).

The adoption of maritime legislation is still IMO's most important concern. Around 40 conventions and protocols have been adopted by the organization and most of them have been amended on several occasions to ensure that

they are kept up to date with changes taking place in world shipping (IMO, 2003).

IMO has introduced measures to improve the way legislation is implemented by assisting flag states (the countries whose flag a ship flies) and by encouraging the establishment of regional port state control systems. When ships go to foreign ports they can be inspected to ensure that they meet IMO standards. By organizing these inspections on a regional rather than a purely national basis resources can be used more efficiently (IMO, 2003).

Two initiatives in recent years are especially important. On 1 July 1998 the International Safety Management Code entered into force and became applicable to passenger ships, oil and chemical tankers, bulk carriers, gas carriers, and cargo high-speed craft of 500 gross tonnage and above. It became applicable to other cargo ships and mobile offshore drilling units of 500 gross tonnage and above on 1 July 2002 (IMO, 2003).

On 1 February 1997, the 1995 amendments to the International Convention on Standards of Training, Certification and Watchkeeping for Seafarers, 1978 entered into force. They greatly improve seafarer standards and, for the first time, give IMO itself powers to check government actions (IMO, 2003).

It is expected that these two measures, by raising standards of management and shipboard personnel, will greatly improve safety and pollution prevention in the years to come (IMO, 2003).

International Maritime Dangerous Goods (IMDG) Code. The International Maritime Dangerous Goods (IMDG) Code was developed as a uniform international code for the transport of dangerous goods by sea covering such matters as packing, container traffic, and stowage, with particular reference to the segregation of incompatible substances.

Development of the IMDG Code. The development of the IMDG Code dates back to the 1960 Safety of Life at Sea (SOLAS) Conference, which recommended that governments should adopt a uniform international code for the transport of dangerous goods by sea to supplement the regulations contained in the 1960 International Convention for the Safety of Life at Sea (SOLAS).

A resolution adopted by the 1960 Conference said the proposed code should cover such matters as packing, container traffic and stowage, with particular reference to the segregation of incompatible substances. A working group of IMO's Maritime Safety Committee began preparing the Code in 1961, in close co-operation with the United Nations Committee of Experts on the Transport of Dangerous Goods, which in a 1956 report had established minimum requirements for the transport of dangerous goods by all modes of transport.

Since its adoption by the fourth IMO Assembly in 1965, the IMDG Code has undergone many changes, both in appearance and content to keep pace with the ever-changing needs of industry. Amendments, which do not affect the principles upon which the code is based, may be adopted by the Maritime Safety Committee, allowing IMO to respond to transport developments in reasonable time.

Amendments to the IMDG Code originate from two sources: proposals submitted directly to IMO by member states and amendments required to take account of changes to the United Nations Recommendations on the Transport of Dangerous Goods which sets the basic requirements for all the transport modes. Amendments to the provisions of the United Nations Recommendations are made on a two-year cycle and approximately two years after their adoption they are adopted by the authorities responsible for regulating the various transport modes. In that way a basic set of requirements applicable to all modes of transport is established and implemented, thus ensuring that difficulties are not encountered at inter-modal interfaces.

Amendment 30. The Maritime Safety Committee (MSC) at its 72nd session in May 2000 adopted a revised and reformatted International Maritime Dangerous Goods (IMDG) Code, which is intended to be more user-friendly and understandable.

"Amendment 30" to the IMDG Code involves the complete reformatting of the IMDG Code as well as revisions to various sections of the code and to transport requirements for specific substances. The reformatted IMDG Code did enter into force on January 1, 2001, with a 12-month transitional period ending December 31, 2001.

- The reformatted IMDG Code includes seven parts, two appendices and an index
- General provisions, definitions and training (Part 1)
- Classification (Part 2)
- Dangerous goods list (DGL) and limited quantities exceptions (Part 3)
- Packing and tank provisions (Part 4)
- Consignment Procedures (Part 5)
- Construction and testing of packaging, intermediate bulk containers (IBCs), large packaging, portable tanks and road tank vehicles (Part 6)
- Requirements concerning transport operations (Part 7)
- Appendix A—List of Generic and NOS (Not Otherwise Specified) Proper Shipping Names
- Appendix B—glossary of terms
- Index

The present code appears in four volumes, but the reformatted code will appear in two volumes: one covering Parts 1, 2, 4, 5, 6, and 7 and the second incorporating Part 3, the two Appendices and the Index.

IMDG Amendment 31 as been released officially and can be use on a voluntary basis as of January 1, 2003. Amendment 31 will be made mandatory on January 1, 2004. The code lays down basic principles; detailed recommendations for individual substances, materials and articles, and a number of recommendations for good operational practice including advice on terminology,

packing, labeling, stowage, segregation and handling, and emergency response action. The two-volume code (instead of four for Amendment 30) is divided into seven parts.

IMDG Code to Be Made Mandatory. The MSC at its 73rd session in November–December 2000 decided, in principle, to make sections of the IMDG Code mandatory, aiming at an entry-into-force date of 1 January 2004, and instructed the Sub-Committee on Dangerous Goods, Solid Cargoes and Containers at its sixth session in July 2001 and the Secretariat to prepare relevant documents such as draft amendments to SOLAS.

The MSC agreed that some chapters of the IMDG Code would remain recommendatory in nature. These include the following:

- Chapter 1.3 (Training)
- Chapter 2.1 (Explosives—Notes 1 to 4)
- Section 2.3.3 of Chapter 2.3 (Determination of Flashpoint)
- Chapter 3.2 (Columns 15 and 17 of the Dangerous Goods List)
- Chapter 3.5 (Transport Schedules)
- Section 5.4.5 of Chapter 5.4 (Multimodal dangerous goods form)
- Chapter 7.3 (Special provisions in the event of an incident and fire precautions involving dangerous goods)

5.3 NORTH AMERICAN REQUIREMENTS

5.3.1 U.S. DOT

The Office of Hazardous Materials Safety, which is within the United States Department of Transportation's Research and Special Programs Administration (RSPA), is responsible for coordinating a national safety program for the transportation of hazardous materials by air, rail, highway, and water. The work of the RID/ADR Joint Meeting has increasingly stimulated proposals for revisions to the UN Recommendations. RSPA represents the United States at these meetings, where the U.S. has full voting status. RSPA participates in the Joint Meeting to advise U.S. shippers on applicable European requirements, and also to ensure U.S. input into the development of those requirements, which, once adopted, are likely to be proposed for adoption in the UN Recommendations.

Hazardous Materials Regulations and Procedures These regulations represent the October 1, 2001, 49 CFR Parts 100–185 and all amendments through June 30, 2002. In the following section an overview of key parts of the transportation of dangerous goods legislation are presented. For information on other sections please consult Appendix 3 of this book for a list of government web sites where access to the legislation is available free of charge.

Table 5.5 presents the U.S. DOT requirements related to transportation of dangerous goods. According to Part 171.11, the ICAO technical instruction can be used if the general provision of Part 174 is followed. Part 172 contains a similar table as the requirements published in UN documentation.

TABLE 5.5. DOT CFR References

Part	Subpart Section	Description
Part 105		Hazardous Materials Program Definitions and General Procedures (Sections 105.5–105.55)
Part 106		Rulemaking Procedures . . .
106 Subpart A		Definitions (Section 105.5)
106 Subpart B		General Procedures (Section 105.15–105.55)
Part 107		Hazardous Materials Program Procedures
Part 110		Hazardous Materials Public Sector Training and Planning Grants
Part 130		Oil Spill Prevention and Response Plans
Part 171		General information, regulations, and definitions
	171.1	Purpose and scope
	171.2	General requirements
	171.3	Hazardous waste
	171.4	Marine pollutants
	171.6	Control numbers under the Paperwork Reduction Act
	171.7	Reference material
	171.8	Definitions and abbreviations
	171.9	Rules of construction
	171.10	Units of measure
	171.11	Use of ICAO Technical Instructions
	171.12	Import and export shipments
	171.12a	Canadian shipments and packaging
	171.14	Transitional provisions for implementing certain requirements
	171.15	Immediate notice of certain hazardous materials incidents
	171.16	Detailed hazardous materials incident reports
	171.19	Approvals or authorizations issued by the Bureau of Explosives
	171.20	Submission of Examination Reports
	171.21	Assistance in investigations and special studies
Part 172		Hazardous materials tables and hazardous materials communications regulations
Part 173		Shippers—General requirements for shipments and packaging
Part 174		Carriage by rail
Part 175		Carriage by aircraft
Part 176		Carriage by vessel
Part 177		Carriage by public highway
Part 178		Specifications for packaging
Part 179		Specifications for tank cars
Part 180		Continuing qualification and maintenance of packaging

172.407 Label specifications

1. *Durability.* Each label, whether printed on or affixed to a package, must be durable and weather resistant. A label on a package must be able to withstand, without deterioration or a substantial change in color, a 30-day exposure to conditions incident to transportation that reasonably could be expected to be encountered by the labeled package.
2. *Design.*
   (a) Except for size and color, the printing, inner border, and symbol on each label must be as shown in §§**172.411** through **172.448** of this subpart, as appropriate.
   (b) The dotted line border shown on each label is not part of the label specification, except when used as an alternative for the solid line outer border to meet the requirements of §**172.406(d)** of this subpart.
3. *Size.*
   (a) Each diamond (square-on-point) label prescribed in this subpart must be at least 100 mm (3.9 inches) on each side with each side having a solid line inner border 5.0 to 6.3 mm (0.2 to 0.25 inches) from the edge.
   (b) The CARGO AIRCRAFT ONLY label must be a rectangle measuring at least 110 mm (4.3 inches) in height by 120 mm (4.7 inches) in width. The word "DANGER" must be shown in letters measuring at least 12.7 mm (0.5 inches) in height.
   (c) Except as otherwise provided in this subpart, the hazard class number, or division number, as appropriate, must be at least 6.3 mm (0.25 inches) and not greater than 12.7 mm (0.5 inches).
   (d) When text indicating a hazard is displayed on a label, the label name must be shown in letters measuring at least 7.6 mm (0.3 inches) in height. For SPONTANEOUSLY COMBUSTIBLE or DANGEROUS WHEN WET labels, the words "Spontaneously" and "When Wet" must be shown in letters measuring at least 5.1 mm (0.2 inches) in height.
   (e) The symbol on each label must be proportionate in size to that shown in the appropriate section of this subpart.
4. *Color.*
   (a) The background color on each label must be as prescribed in §§**172.411** through **172.448** of this subpart, as appropriate.
   (b) The symbol, text, numbers, and border must be shown in black on a label except that—
      i. White may be used on a label with a one color background of green, red or blue; and
      ii. White must be used for the text and class number for the CORROSIVE label.

(c) Black and any color on a label must be able to withstand, without substantial change, a 72-hour fadeometer test (for a description of equipment designed for this purpose, see ASTM G 23–69 (1975) or ASTM G 26–70).

(d) (i) A color on a label, upon visual examination, must fall within the color tolerances—

i. Displayed on color charts conforming to the technical specifications for charts set forth in Table 1 or 2 in appendix A to this part; or

ii. For labels printed on packaging surfaces, specified in Table 3 in appendix A to this part.

(ii) Color charts conforming to Appendix A to this part are on display in Room 8421, Nassif Building, 400 Seventh Street, SW., Washington DC 20590-0001.

(e) A color on a label, upon visual examination, must fall within the color. The specified label color must extend to the edge of the label in the area designated on each label except the CORROSIVE, RADIOACTIVE YELLOW-II AND RADIOACTIVE YELLOW-III labels on which the color must extend only to the inner border.

5. *Form identification.* A label may contain form identification information, including the name of its maker, provided that information is printed outside the solid line inner border in no larger than 10-point type.
6. *Exceptions.* Except for materials poisonous by inhalation (see § 171.8 of this subchapter), a label conforming to specifications in the UN recommendations may be used in place of a corresponding label that conforms to the requirements of this subpart.
7. *Trefoil symbol.* The trefoil symbol on the RADIOACTIVE WHITE-I, RADIOACTIVE YELLOW-II, and RADIOACTIVE YELLOW-III labels must meet the appropriate specifications in Appendix B of this part.

General Labeling Requirements

1. Except as specified in §**172.400a**, each person who offers for transportation or transports a hazardous material in any of the following packages or containment devices, shall label the package or containment device with labels specified for the material in the §**172.101** Table and in this subpart:

(a) A non-bulk package; a bulk packaging, other than a cargo tank, portable tank, or tank car, with a volumetric capacity of less than 18 m^3 (640 cubic feet), unless placarded in accordance with subpart F of this part;

(b) A portable tank of less than 3785 L (1000 gallons) capacity, unless placarded in accordance with subpart F of this part;

(c) A DOT Specification 106 or 110 multi-unit tank car tank, unless placarded in accordance with subpart F of this part; and

(d) An overpack, freight container or unit load device, of less than 18 m^3 (640 cubic feet), which contains a package for which labels are required, unless placarded or marked in accordance with §**172.512** of this part.

2. Except as specified in §**172.400a**, each person who offers for transportation or labeling is required for a hazardous material which meets one or more hazard class definitions, in accordance with Column 6 of the §**172.101** Table and Table 5.6.

TABLE 5.6. Hazard Classes and Their Label Names

Hazard Class or Division	Label Name	Label Design or Section Reference
1.1	EXPLOSIVES 1.1	172.411
1.2	EXPLOSIVES 1.2	172.411
1.3	EXPLOSIVES 1.3	172.411
1.4	EXPLOSIVES 1.4	172.411
1.5	EXPLOSIVES 1.5	172.411
1.6	EXPLOSIVES 1.6	172.411
2.1	FLAMMABLE GAS	172.417
2.2	NONFLAMMABLE GAS	172.415
2.3	POISON GAS	172.416
3 (Flammable Liquid) Combustible Liquid	FLAMMABLE LIQUID (none)	172.419
4.1	FLAMMABLE SOLID	172.420
4.2	SPONTANEOUSLY COMBUSTIBLE	172.422
4.3	DANGEROUS WHEN WET	172.423
5.1	OXIDIZER	172.426
5.2	ORGANIC PEROXIDE	172.427
6.1 (Inhalation Hazard, Zone A or B)	POISON INHALATION HAZARD	172.429
6.1 (Other than Inhalation Hazard)	POISON	172.430
6.2	INFECTIOUS SUBSTANCE	172.432
7 (see § **172.403**)	RADIOACTIVE WHITE-I	172.436
7	RADIOACTIVE YELLOW-II	172.438
7	RADIOACTIVE YELLOW-III	172.440
7 (Empty Packages, see § **173.428**)	EMPTY	172.450
8	CORROSIVE	172.442
9	CLASS 9	172.446

172.400a Exceptions from Labeling

1. Notwithstanding the provisions of §172.400, a label is not required on—
   (a) A cylinder, or a Dewar flask conforming to §173.320 of this subchapter containing a Division 2.1 or Division 2.2 gas that is
      (i) Not poisonous;
      (ii) Carried by a private or contract motor carrier;
      (iii) Not over packed; and
      (iv) Durably and legibly marked in accordance with CGA Pamphlet C-7, appendix A.
2. A package or unit of military explosives (including ammunition) shipped by or on behalf of the DOD when in—
   (a) Freight container load, carload or truckload shipments, if loaded and unloaded by the shipper or DOD; or
   (b) Unitized or palletized break-bulk shipments by cargo vessel under charter to DOD if at least one required label is displayed on each unitized or palletized load.
3. A package containing a hazardous material other than ammunition that is—
   (a) Loaded and unloaded under the supervision of DOD personnel, and
   (b) Escorted by DOD personnel in a separate vehicle.
4. A compressed gas cylinder permanently mounted in or on a transport vehicle.
5. A freight container, aircraft unit load device or portable tank, which—
   (a) Is placarded in accordance with subpart F of this part, or
   (b) Conforms to paragraph (a)(3) or (b)(3) of §172.512.
6. An over pack or unit load device in or on which labels representative of each hazardous material in the over pack or unit load device are visible.
7. A package of low specific activity radioactive material and surface contaminated objects, when transported under § 173.427(a)(6)(vi) of this subchapter.

Certain exceptions to labeling requirements are provided for small quantities and limited quantities in applicable sections in part 173 of this subchapter.

Notwithstanding the provisions of §172.402(a), a subsidiary hazard label is not required on a package containing a Class 8 (corrosive) material which has a subsidiary hazard of Division 6.1 (poisonous) if the toxicity of the material is based solely on the corrosive destruction of tissue rather than systemic poisoning.

A package containing a material poisonous by inhalation (see § 171.8 of this subchapter) in a closed transport vehicle or freight container may be

excepted from the POISON INHALATION HAZARD or POISON GAS label or placard, under the conditions set forth in §§ 171.12 and 171.12a of this subchapter.

5.3.2 Canadian TDG

The regulation related to transport of dangerous goods in Canada was completely restructured over the last few years. The new regulation, published in the Canada Gazette August 15, 2001 (SOR/DORS/2001-286) became effective on August 15, 2002. It is readily available on the Internet—refer to Appendix 3 of this book for government Web sites. The revised definitions, formatting as well as the large numbers of examples makes this one of the easiest regulatory document to consult. The Initial Act may be cited as the Transportation of Dangerous Goods Act, 1992. As there is no transition period, the old TDG regulation (SOR/DORS/85-77) has been repealed.

It should be noted that even though SOR/2001-286 is a new regulation, its material is very similar to the old SOR/85-77 regulation. The primary goal of this new regulation is to make the language used easier to understand to facilitate compliance. Its second goal was to level the Canadian TDG regulation with the 11th edition of the UN model regulation.

Scope of Regulatory Changes

- Hazard class 2.4 no longer exists; no more specific class for corrosive class
- Hazard Class 9 does no longer has divisions 9.1, 9.2, and 9.3
- The pictogram for Hazard Class 9 changed
- Subsidiary pictograms are now the same as primary pictograms
- The Limited Quantity index of Schedule 1 is used to replace the former Limited Quantity and Consumer Commodity exemptions
- More chemicals will require Emergency Response Assistance Plans, ERAP (tied to the new ERAP index of Schedule 1)
- The way to express quantities allowed to be carried on passenger carrying ship or on passenger carrying road/rail is now using an index instead of a quantity
- The number of the Emergency Response Guide associated with a UN Number is now part of Schedule 1
- In the hazardous material table (Schedule 1), there are now some entries indicated as "•" for marine pollutant (only collective entries appear to have this indicator). It means that it must be established if the substance is a marine pollutant or not

A consignor may use the appropriate classification in the ICAO Technical Instructions, the IMDG Code or the UN Recommendations to transport

dangerous goods within Canada by a road vehicle, a railway vehicle or a ship on a domestic voyage if these Regulations or the document from which the classification is taken does not forbid their transport.

Table 5.7 and 5.8 present the different sections of the legislation.

Classifying Substances That Are Listed by Name in Schedule 1. If the name of a dangerous good is shown as a shipping name in column 2 of Schedule 1, that name must be used as the shipping name. That shipping name and the corresponding data for that shipping name in columns 1, 3, and 4 of Schedule 1 must be used as the classification of the dangerous goods.

Classifying Substances That Are Included in Only One Class and One Packing Group. If, in accordance with the criteria and tests in this part, a substance is included in only one class and one packing group, the substance is dangerous goods and the shipping name in column 2 of Schedule 1 that most precisely describes the dangerous goods and that is most consistent with the class and the packing group determined by the criteria and tests must be

TABLE 5.7. Canadian Regulations and Their Appropriate Regulatory Text

Coming into Force, Repeal, Interpretation, General Provisions and Special Cases	Part 1
Classification	Part 2
Documentation	Part 3
Dangerous Goods Safety Marks	Part 4
Means of Containment	Part 5
Training	Part 6
Emergency Response Assistance Plan	Part 7
Accidental release and Imminent accidental release Report Requirements	Part 8
Road	Part 9
Rail	Part 10
Marine	Part 11
Air	Part 12
Protective Direction	Part 13
Permit for Equivalent Level of Safety	Part 14
Court Order	Part 15
Inspectors	Part 16

TABLE 5.8. Canadian Schedule

Schedule 1	Classes 1 to 9
Schedule 2	Special Provisions
Schedule 3	Alphabetical Index

selected as the shipping name. That shipping name and the corresponding data for that shipping name in columns 1, 3, and 4 of Schedule 1 must be used as the classification of the dangerous goods.

Classifying Substances That Are Included in More Than One Class or Packing Group. The word "potential" is used in paragraphs (a), (b), and (c) of this section because the final subsidiary class or classes and the final packing group are determined in accordance with paragraph (d).

If, in accordance with the criteria and tests in this part, a substance meets the criteria for inclusion in more than one class or packing group, the substance is a dangerous goods and its classification is determined in the following manner:

a. Classes in which the dangerous goods are included are ranked in order of precedence in accordance with Section 2.8 to determine the primary class and the potential subsidiary class or classes.
b. Potential packing group is the one with the lowest Roman numeral.
c. Shipping name in column 2 of Schedule 1 that most precisely describes the dangerous goods and for which the corresponding data in columns 1, 3, and 4 are the most consistent with the primary class, the potential subsidiary class or classes and the potential packing group are selected.
d. Shipping name and the corresponding data in columns 1, 3, and 4 of Schedule 1 are used as the classification of the dangerous goods.

Classifying a Mixture or Solution. A mixture or solution of substances that are not dangerous goods and one substance that is dangerous goods and that is listed by name in Schedule 1 has the classification shown for the dangerous

TABLE 5.9. Canadian TDG Classes and Their Section Reference

Class with Description	Section Reference
Class 1, Explosives	
General	2.9
Divisions	2.10
Compatibility Groups	2.11
Packing Groups	2.12
Class 2, Gases	
General	2.13
Divisions	2.14
Packing Groups	2.15
Determination of LC_{50}	2.16
Determination of LC_{50} of a Mixture of Gases	2.17

TABLE 5.9. Continued

Class with Description	Section Reference
Class 3, Flammable Liquids	
General	2.18
Packing Groups	2.19
Class 4, Flammable Solids; Substances Liable to Spontaneous Combustion; Substances That on Contact with Water Emit Flammable Gases (Water-reactive Substances)	
General	2.20
Divisions	2.21
Packing Groups	2.22
Class 5, Oxidizing Substances and Organic Peroxides	
General	2.23
Divisions	2.24
Packing Groups	2.25
Class 6, Toxic and Infectious Substances	
General	2.26
Divisions	2.27
Criteria for Inclusion in Class 6.1, Toxic Substances	2.28
Packing Groups	2.29
Determination of LD_{50} (oral or dermal)	2.30
Determination of LD_{50} (oral or dermal) of a Mixture of Substances	2.31
Determination of LC_{50} (dust, mist or vapour)	2.32
Determination of LC_{50} (dust, mist or vapour) of a Mixture of Substances	2.33
Determination of the Packing Group of a Mixture of Liquids with an Inhalation Toxicity by Vapor	2.34
Determination of the Packing Group of a Mixture of Liquids with an Inhalation Toxicity and an Unknown LC_{50}	2.35
Risk Groups	2.36
Class 7, Radioactive Materials	
General	2.37
Divisions	2.38
Packing Groups	2.39
Class 8, Corrosives	
General	2.40
Divisions	2.41
Packing Groups	2.42
Class 9, Miscellaneous Products, Substances or Organisms	
General	2.43
Divisions	2.44
Packing Groupsz	2.45

goods in that Schedule if the mixture or solution is still dangerous goods in accordance with paragraph 2.1(a) and the mixture or solution is not identified by a shipping name in Schedule 1. However, if the classification for the dangerous goods does not precisely describe the mixture or solution but the mixture or solution meets the criteria in this part for inclusion in at least one of the nine classes of dangerous goods, then sections 2.4 and 2.5 must be used to determine its classification.

Information on a Shipping Document. The following information must be included on a shipping document:

(a) Name and address of the place of business in Canada of the consignor
(b) Date the shipping document or an electronic copy of it was prepared or was first given to a carrier
(c) Description of each of the dangerous goods, in the following order:
    i. the shipping name and, immediately after the shipping name unless it is already part of it,
        1. for dangerous goods that are subject to special provision 16 in Schedule 2, the technical name, in parentheses, of the most dangerous substance related to the primary class, and
        2. for a liquefied petroleum gas that has not been odorized, the words "Not Odorized" or "Not Odourized" or "Sans odorisant,"
    ii. the primary class, which may be shown as a number only or under the heading "Class" or "Classe" or following the word "Class" or "Classe,"
    iii. for dangerous goods with a primary class of Class 1, Explosives, the compatibility group letter following the primary class,
    iv. the subsidiary class or classes, in parentheses, which may follow the words "subsidiary class" or "classe subsidiaire" except that for transport by aircraft or by ship the subsidiary class or classes may be shown after the information required by this paragraph,
    v. the UN number,
    vi. the packing group roman numeral, which may be preceded by the letters "PG" or "GE" or the words "Packing Group" or "Groupe d'emballage", and
    vii. for infectious substances, the risk group number, which may be preceded by the letters "RG" or "GR" or the words "Risk Group" or "Groupe de risque";

Examples of the description of dangerous goods are:

- GASOLINE, 3, UN1203, II
- GASOLINE, Class 3, UN1203, PG II
- ISOBUTYLAMINE, Class 3, Subsidiary Class (8), UN1214, II
- ISOBUTYLAMINE, Class 3(8), UN1214, Packing Group II
- INFECTIOUS SUBSTANCE, AFFECTING HUMANS, 6.2, UN2814, 3
- INFECTIOUS SUBSTANCE, AFFECTING HUMANS, Class 6.2, UN2814, RG 3

(d) for each shipping name, the quantity of dangerous goods and the unit of measure used to express the quantity, which must be in the International System of Units (SI) on shipping documents prepared in Canada, but for dangerous goods included in Class 1, Explosives, the quantity must be expressed in net explosives quantity;

i. *Examples of descriptions of units of measure include "net mass, 30 kg" or "gross mass, 200 kg."*

(e) for dangerous goods included in any of Classes 2 to 9 that are in small means of containment that require a label to be displayed on them in accordance with Part 4, Dangerous Goods Safety Marks, the number of small means of containment for each shipping name; and

(f) the words "24-Hour Number" or "Numéro 24 heures," or an abbreviation of these words, followed by a telephone number, including the area code, at which the consignor can be reached immediately for technical information about the dangerous goods in transport, without breaking the telephone connection made by the caller.

i. *The terms "24-Hour Number" and "Numéro 24 heures" used in this paragraph refer to the telephone number that must be available when the dangerous goods are in transport. The terms were chosen to emphasize that the requirement is applicable not only during office hours but must also be satisfied at any hour of the day when the dangerous goods are in transport.*

ii. *An example of the type of technical information referred to in paragraph (1)(f) is the information contained in ANSI Standard Z400.1-1998, Material Safety Data Sheet.*

(g) The telephone number of a person who is not the consignor, such as CANUTEC, but who is competent to give the technical information required by paragraph (1)(f) in English or in French may be used. However, to use CANUTEC's telephone number, the consignor must receive permission, in writing, from CANUTEC. A consignor who uses the telephone number of an organization or agency other than CANUTEC must ensure that the organization or agency has current, accurate information on the dangerous goods the consignor offers for transport and, if the organization or agency is located outside Canada, the telephone number must include the country code and, if required, the city code.

(h) A means of containment, or the contents of a means of containment, that is being fumigated with dangerous goods and that is in transport must be accompanied by a shipping document that, despite subsections (1) and (5) and Section 3.6, includes the following information if the fumigant is the only dangerous goods in transport in the means of containment:

(i) Shipping name, "FUMIGATED UNIT" or "ENGIN SOUS FUMIGATION"

(ii) Class, Class 9

(iii) UN number, UN3359

(iv) Quantity of the fumigant

(v) Date of fumigation

(vi) Instructions for the disposal of residues of the fumigant or fumigation device

Visibility, Legibility and Color. Dangerous goods safety marks must be

(a) Visible, legible and displayed against a background of contrasting color.

(b) Made of durable and weather-resistant material that will withstand the conditions to which they will be exposed without substantial detachment or deterioration of their color, symbols, letters, text or numbers; and

i. For example, deterioration is considered substantial if the color of the safety mark fades or darkens so that it is no longer the color that represents the class of dangerous goods associated with it.

(c) Displayed in the colors specified in

i. the appendix to this Part, which colors must conform to the following standards in the PANTONE® "Formula Guide," published by Pantone Inc., 590 Commerce Boulevard, Carlstadt, New Jersey 07072-3098, United States:

1. for blue, PANTONE 285,
2. for green, PANTONE 335,
3. for orange, PANTONE 151,
4. for red, PANTONE 186, and
5. for yellow, PANTONE 109,

ii. Part 172 of 49 CFR, or

iii. Chapters 5.2 and 5.3 of the UN Recommendations.

Labels and Placards: Size and Orientation. Labels and placards must be displayed on a means of containment as they are illustrated in the appendix to this Part, that is, a square on a point.

1. Each side of a label must be at least 100 mm in length with a line running 5 mm inside the edge. However, except for dangerous goods included in Class 7, Radioactive Materials, if that size label, together with the shipping name, technical name and UN number, cannot be displayed because of the irregular shape or size of the small means of containment, each

side of the label may be reduced in length by the same amount to the point where the label, together with the shipping name, technical name and UN number, will fit that small means of containment, but must not be reduced to less than 30 mm.

(a) If 30 mm will not fit, subsection 4.10(4) allows the label to be displayed on a tag attached to the means of containment.

2. Each side of a placard must be at least 250 mm in length and, except for the DANGER placard, have a line running 12.5 mm inside the edge. However, except for dangerous goods included in Class 7, Radioactive Materials, if that size placard cannot be displayed because of the irregular shape or size of the large means of containment, each side of the placard may be reduced in length by the same amount to the point where the placard will fit that large means of containment, but must not be reduced to less than 100 mm.
3. If the size of a label or a placard is reduced, every symbol, letter and number required on that label or placard must be reduced proportionately.
4. If a large means of containment contains dangerous goods included in Class 7, Radioactive Materials, and a placard is required to be displayed in accordance with this Part, the means of containment must have displayed on it the placard required for the dangerous goods or the appropriate optional placard illustrated in the appendix to this Part.

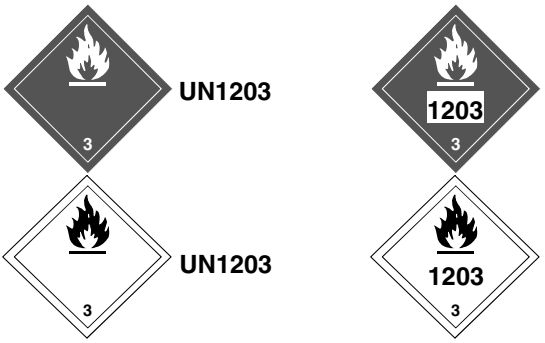
Ways to Display a UN Number.

1. A UN number that is required by this Part to be displayed on a small means of containment or on a tag attached to it must be displayed in one of the following ways:

(a) Next to the primary class label for the dangerous goods.

(b) Within a white rectangle located on the primary class label for the dangerous goods, without the prefix "UN," but it must not obscure the symbol, class number, compatibility group letter, or text on the label.

The examples supplied show the original red pictograms but black and white samples have been provided for charity.



The illustration showing the UN number to the right of the placard is an example only and does not indicate a mandatory position. For example, a wrap-around label may be used on a cylinder.

2. A UN number that is required by this Part to be displayed on a large means of containment must be displayed in one of the following ways:
   (a) On an orange panel placed next to the primary class placard for the dangerous goods, without the prefix "UN."
   (b) Within a white rectangle located on the primary class placard for the dangerous goods, without the prefix "UN," but it must not obscure the symbol, class number, compatibility group letter or text on the placard.

Dangerous Goods Safety Marks on a Small Means of Containment: Labels

1. One label must be displayed on a small means of containment for the primary class and one for each subsidiary class set out in column 3 of Schedule 1 for each of the dangerous goods in transport in the small means of containment, except that:
   (a) A label is not required to be displayed on a small means of containment that is inside another small means of containment if the other small means of containment has a label displayed on it and is not opened during loading or unloading or while the dangerous goods are in transport.
   (b) The oxidizing gas label, illustrated in the appendix to this Part, must be displayed on a small means of containment for the following dangerous goods:
      i. UN1072, OXYGEN, COMPRESSED;
      ii. UN1073, OXYGEN, REFRIGERATED LIQUID;
      iii. UN3156, COMPRESSED GAS, OXIDIZING, N.O.S.; and
      iv. UN3157, LIQUEFIED GAS, OXIDIZING, N.O.S.; and
   (c) If the dangerous goods are included in Class 7, Radioactive Materials, two labels must be displayed on the small means of containment for the primary class.

2. For the subsidiary class of Class 1, the label to be displayed is the label for Class 1.1, 1.2, or 1.3 illustrated in the appendix to this Part:
   i. The dangerous goods that have a subsidiary class of Class 1 are listed in paragraph 2.8(1)(a) in Part 2, Classification, and have "(1)" shown in column 3 of Schedule 1.
3. When a label is required to be displayed, it must be displayed by one of the following:
   (a) On any side of the outer surface of a small means of containment other than the side on which it is intended to rest or to be stacked during transport.
   (b) On or near the shoulder of a cylinder containing dangerous goods.
   (c) In the case of a label for dangerous goods included in Class 7, Radioactive Materials, on two opposite sides of the outer surface of a small means of containment, other than the side on which it is intended to rest or to be stacked during transport.
4. Despite subsection (3), a label with sides that are reduced to 30 mm in length in accordance with subsection 4.7(2) may be displayed on a tag that is securely attached to a small means of containment.

5.3.3 Mexican

The regulation related to transport of dangerous goods in Mexico refers to the "Project for the OFFICIAL MEXICAN STANDARD (PROY-NOM-003-SCT/1999) on the Characteristics of the Labels of Packages and Packaging Destined to Transport of Hazardous Substances, Materials and Wastes."

The Official Mexican Standard Project sets forth the characteristics, dimensions, symbols, and colors of labels to be displayed by all packages and packaging. Such labels identify the risks presented by the hazardous substances, materials and wastes during their transport and handling. This Official Mexican Standard Project applies compulsorily to the shippers, carriers, and consignees of hazardous substances, materials, and waste transported trough the general ways of communication by land, sea, and air.

Classification. The symbols utilized for risk identification in the transport of hazardous substances, materials, and wastes indicated in this Standard are within the classification established by:

- Articles 7 to 16, Chapter I, Title First, of the Regulations for the Land Transport of Hazardous Materials and Wastes—Part 2 of Classification.
- List of Dangerous Goods of DOC 9284-AN/905 of the Technical Instructions for the Safe Transport of Dangerous Goods by Air from ICAO.
- General Introduction of the IMDG Code.

Principles. All packages and packaging destined to transport hazardous materials or wastes whose net mass or capacity does not exceed 400 kg or

450 L, respectively, must display an adhesive label or labels, (primary or subsidiary, depending on the case) either printed or painted, to allow easy visual identification, of the associated risks of their contents. Packages and packaging containing hazardous substances, materials, or waste that are transported in "limited quantities" or "exempt quantities" are exempted to the obligation to display labels for transport purposes. All packages or packaging destined to the transport of hazardous materials and wastes whose net mass or capacity exceeds 400 kg or 450 L must display identification placards as established on the corresponding standard.

In the case of transporting packages or packaging with various compatible hazardous materials or wastes but having different risks, the package and the outside packaging, must display the labels for the principal risk and when required, also secondary risk labels.

According to the legislation, labels have the following purposes:

1. Recognize by its general appearance in terms of color, form and symbol, the packages and packaging containing hazardous materials and wastes;
2. Identify the nature of potential risk of the hazardous material or waste through symbols.
3. Prevent dangerous situations in the handling and storage of materials.

The five basic label symbols and the four complementary ones, with their corresponding meaning are as follows:

Basic Symbols

- Exploding bomb (danger of explosion)
- Flame (danger of fire)
- Skull and crossbones (danger of poisoning)
- Trefoil (danger of radioactivity)
- Liquids spilling from two glass vessels and attacking a hand and a metal (danger of corrosion)

Complementary Symbols

- Flame over circle (oxidizing substances and organic peroxides)
- Gas cylinder (nonflammable, nontoxic compressed gases)
- Three crescents superimposed on a circle (infectious substances)
- Seven vertical stripes (miscellaneous hazardous substances)

Labeling Criteria

1. They must be square with minimum dimension of 100 mm × 100 mm per side, except in the case of packages of such dimensions that they can only bear smaller labels with opposite vertices in vertical position in the form

of a diamond or romboidal, with a line of the same color as the symbol, 5 mm. inside the edge and parallel with it.

2. The labels are divided into halves. With the exception of Divisions 1.4, 1.5, and 1.6, the upper half of the label is reserved for the pictorial symbol and the lower half for texts and the class or division number and the compatibility group letter as appropriate. Text corresponding to risk is optative. However, when specific regulations for a determined mode of transport establishes so, labels must show the required texts.
3. Except for Divisions 1.4, 1.5, and 1.6, labels for Class 1 show in the lower half the division number and compatibility group letter for the substance. Labels for Divisions 1.4, 1.5, and 1.6 show in the upper half the division number and in the lower half the compatibility group letter. For Division 1.4, Compatibility Group "S," no label is recommended.
4. In the case of primary risk labels for Class 5, the division number of the substance should be shown in the bottom corner of the label. For all other primary risk labels, the class number of the substance should be shown in the bottom corner of the label.
5. Blanks in the text appearing in the lower half of the labels for substances of Class 7 must be filled with the required data, before the products are transported. In the case of existence of levels of radioactive contamination, once the container has been emptied, radiological safety measures will be applied to the effect have been established by the Nuclear Safety and Safeguard National Commission from the Secretariat of Energy. On the romboid labels not corresponding to Class 7 substances, the insertion of any text other than than the class or division number any other text than indications relative to to the nature of risk in its case and particular cautions to be followed for the specific mode of transportation handling.
6. The symbols, texts and numbers should be shown in black on all labels except:
   i. On labels for Class 8, the text "corrosive" and class number should appear in white and;
   ii. Labels with entirely green, red, or blue backgrounds where they may be shown in white.

In the following section the requirements for the shipment of individual products and several products within the same chemical family are presented.

Hazardous Materials and Wastes Labeling Criteria The standard stipulates that the label must contain the following:

1. Company name/address; must write down company name and address of the shipping company along with its activity, for example, manufac-

turer, importer, consumer, or distributor of the transported product. In the case of a waste, name of the generator of it.

2. Shipper's emergency phone and fax numbers; telephone number of the company within national boundaries where either authorities or any person may call to report in case of emergency.
3. Name of the product; official designation of the material, or waste being transported must be written down, according to the Official Mexican Standard NOM-002-SCT2/1994, or the lists of hazardous materials for the air and sea transport.
4. Classification; write down risk class and division number of the substance or waste as it appears on NOM-002-SCT2/1994.
5. Material number; write down the assigned number of the United Nations Organization, as indicated on NOM-002-SCT2/1994
6. Transporting company; write down the name or company name or owner's name of the carrier.
7. Emergency telephones; write down the transporting company phone and fax numbers, for emergency cases.
8. Physical state; must indicate the physical state, its color and odor of the substance, material, or waste being transported.
9. Physical-chemical properties; must describe briefly the most relevant ones according to the material or waste and the means of transportation:
   - density
   - specific gravity
   - temperature (boiling point, fusion, flammability, self-ignition)
   - pH
   - water solubility
   - flammability or explosivity limits
   - vapor pressure
   - maximum exposition limits value
10. National Emergency System Telephone; write down the telephone number of the national emergency system shown here. In case of accident or incident must report it immediately.
    - CECOM: 01-800-00-413-00 in the Mexican Republic
    - For calls from Mexico City and Metropolitan area: 55-50-14-96; 55-50-15-52; or 55-50-14-85 Fax: 56-16-55-60 or 56-16-55-61
    - For calls from any other area of the Republic, dial: 52-55-50-14-96; 52-55-50-15-52; 52-55-50-14-85 or 52-55-50-48-85
    - SETIQ: 01-800-00-214-00 in the Mexican Republic
    - For calls from Mexico City and Metropolitan Area: 55-59-15-88
    - For calls from any other area of the Republic, dial: 52-55-59-15-88

Where radioactive materials are concerned, report it to competent authority:

- National Nuclear Safety and Safeguards Commission: 55-79-41-99; 55-79-47-79 and 55-79-46-60

In case of an accident on airport zones or within their jurisdictional area the Airport Authority must be properly notified.

11. Equipment and means of personal protection: must write down the equipment for personal protection, specific for the material being transported. Such equipment must be carried by the driver of the transporting unit for hazardous materials or wastes, as well as the means that allow the emergency teams to take the initial protective actions such as safety goggles, rubber gloves, leather gloves, rubber aprons, rubber boots, dust masks, gases masks, shovel, brush, sand, and so on; or any other type of equipment or material required to minimize accidents. In the case of radioactive materials, it is necessary to carry ionizing radiation detection equipment.
12. Risks; must indicate possible risks that may be present in an accident during transportation, as pointed out on paragraphs 14 to 22 of the legislation.
13. Actions; it refers to actions to be taken immediately, such as stopping the transport unit at the safest possible place, set up alert signals to prevent accidents to other drivers, referring also to actions pointed out on paragraphs 15, 17, 19, 21 and 23 in order to face the risks indicated on numbers 14, 16, 18, 20 and 22 of the "emergency sheet."
14. Intoxication (poisoning)/ exposure; refers to damages or injuries that may be suffered by a person who ingests, inhales, or has physical contact with the hazardous materials or wastes, emphasizing actions to avoid for safety reasons. Write down initial actions to be taken to protect injured or harmed personnel due to exposure, inhalation, physical contact, or ingestion of the hazardous materials or wastes, emphasizing actions to avoid for safety reasons.
15. Pollution; refers to alteration of the environment caused by accidental release of hazardous substances, materials, or wastes. Write down actions to be taken to minimize damages to population and the environment.
16. Medical information; point out initial attention measures in case of intoxication (poisoning) and exposure, when these are not within other sections of this information. Also in its case, specific antidotes will be pointed out. Point out medical indications about special measures to be applied in case of intoxication (poisoning) suffered by the personnel through exposure, inhalation, physical contact, ionizing radiation, or

ingestion of the substances, materials or wastes, antidotes if any and countermeasures, as well as data on possible after effects or complications or warnings to the medical staff and recommendations for hospital treatment.

17. Drippings, leakages, and spills; Refers to risks represented by accidental liberation of hazardous substances, materials, or wastes in any physical state of the material; solid, liquid, or gaseous. Write down actions to be taken to minimize the effects of such spills and isolation distances and initial isolation of the zone near the accident, as well as procedures for the disposal of the spilled material, emphasizing actions to avoid for safety reasons.
18. Fire/explosion; briefly describe conditions and risks that may occur when the substance or material catches fire and its behavior under fire conditions, as well as emphasizing actions to avoid for safety reasons and indicating isolation and evacuation area. Write down actions to be taken to prevent the hazardous substance, material or waste from coming in contact with fire or heat sources, as well as the required protective equipment and the special procedures and caution for fighting fire, emphasizing actions to avoid for safety reasons.
19. At the end of the form must bear the name and signature of the person responsible of gathering the information (shipper), that person's position in the company and telephone numbers.
20. It is required that the emergency sheet for the transport of hazardous substances, materials, and wastes, to be filled out in full, in order to make use of it if needed. Its adequate completion and filling out is the responsibility of the company that owns the material being transported.

Shipment of Several Products Within the Same Chemical Family If a shipment consists of several products belonging to the same chemical family, an emergency sheet is not required for each product. It will suffice with one sheet per chemical family.

To complement the information contained in the form specified on several product of the same chemical family, the North American Emergency Response Guidebook, 1996 Edition, must be carried. It contains:

1. Safety cautions
2. Who to call for assistance in Canada, the United States, and Mexico
3. Table of placards and initial response guides to be used on the site
4. United Nations Organization numbers index
5. Alphabetical index, indicating the guide number and the United Nations Organization assigned number for the hazardous substance or material

6. Response guides:
   a) Potential dangers, fire, explosion, and health hazards
   b) Public safety, protecting clothing, and isolation
   c) Emergency response, fire, spills or leakage, and first aid
7. Table of initial isolation and protective action distances
8. List of hazardous materials that are water reactive and the corresponding number of response guide
9. Glossary

For the harmonization with the United States and Canada, the Official Mexican Standard is equivalent to the Emergency Response Guidebook for first responders during the initial phase of a hazardous materials incident, United States Department of Transport, Research and Special Projects Administration, 1993 Edition and Dangerous Goods Initial Emergency Response Guide 1992 (CANUTEC), of Canada.

5.4 EUROPEAN REQUIREMENTS

5.4.1 ADR

The European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) was done at Geneva on 30 September 1957 under the auspices of the United Nations Economic Commission for Europe, and it entered into force on 29 January 1968. The agreement itself was amended by the Protocol amending article 14(3) done at New York on 21 August 1975, which entered into force on 19 April 1985. The agreement itself is short and simple. The key article is the second, which say that apart from some excessively dangerous goods, other dangerous goods may be carried internationally in road vehicles subject to compliance with:

- Conditions laid down in Annex A for the goods in question, in particular as regards their packaging and labeling
- Conditions laid down in Annex B, in particular as regards the construction, equipment, and operation of the vehicle carrying the goods in question

Annexes A and B have been regularly amended and updated since the entry into force of ADR. In the last amended version, applicable from 1 July 2001, Annexes A and B are presented under a new format ("Restructured ADR").

Even though the legislation went into force on July 1, 2001, there was an 18-month period in which the old and the new editions of ADR could be used. In case of radioactive materials, the transition period was only six months, meaning that the new regulation entered into effect on January 1, 2002.

The entire regulation was changed (this is why it is referred to as "restructured" ADR). The vast majority of the changes were cosmetics; the regulation is now much easier to understand. The following are examples of key differences in the old and new version of ADR:

1. Marginal, submarginal, and item numbers no longer exist.
2. The ADR Classification Code replaces the item numbers (there is no direct correspondence between the former Item numbers and the ADR Classification Code).
3. The bottom of the labels now shows the number of the class.
4. The HazMat table now lists the following items:
   (a) UN no.
   (b) Name and description
   (c) Class
   (d) Classification code
   (e) Packing group
   (f) Labels
   (g) Special provisions
   (h) Limited quantities
   (i) *Packaging*: Packing instructions/special packing provisions/mixed packing provisions
   (j) *UN Portable tank*: Instructions/special provisions
   (k) *ADR tank*: Tank code/special provisions
   (l) Vehicle for tank carriage
   (m) Transport category
   (n) *Special provisions for carriage*: Packages/bulk/loading, unloading and handling/operation
   (o) Hazard identification no.
5. The proper shipping names used throughout ADR 2001 are in capital letters instead of lowercase.
6. (a), (b), and (c) substance qualifiers have been replaced with I, II, and III packing groups.
7. Types of packaging and IBCs (intermediate bulk containers) must be selected from ADR Packing Instructions, as in the IMDG Code.
8. Load limit for exemption changed for PGII.
9. Vehicles carrying explosives no longer need a second person to accompany the driver.
10. Decision trees are now used to help find the ADR Classification Code, and the best collective entry for UN Number and Proper Shipping Name.

TABLE 5.10. European General Provisions Concerning Dangerous Articles and Substances

Part	Description
Part 1	General provisions
Part 2	Classification
Part 3	Dangerous goods list, special provisions, and exemptions related to dangerous goods packed in limited quantities
Part 4	Packing and tank provisions
Part 5	Consignment procedures
Part 6	Requirements for the construction and testing of packaging, intermediate bulk containers (IBCs), large packaging and tanks
Part 7	Provisions concerning the conditions of carriage, loading, unloading, and handling

The new structure is consistent with that of the United Nations Recommendations on the Transport of Dangerous Goods, Model Regulations, the International Maritime Dangerous Goods Code (of the International Maritime Organization), the Technical Instructions for the Safe Transport of Dangerous Goods by Air (of the International Civil Aviation Organization) and the Regulations concerning the International Carriage of Dangerous Goods by Rail (of the Intergovernmental Organisation for International Carriage by Rail). The layout is presented in Table 5.10.

There are some minor differences from these models but are beyond the scope of this book, for example, some definition and values that differ for Class 2 and Class 3.

Regarding labeling, it is exactly the same as defined earlier in the UN model.

5.4.2 EU Inland Waterways

The ADN was adopted on 25 May 2000 on the occasion of the Diplomatic Conference organized jointly by the Economic Commission for Europe (UNECE) and the Central Commission for the Navigation of the Rhine (CCNR). ADN consists of a main legal text and regulations annexed thereto and aims at (UN, 2003):

- Ensure a high level of the safety of the international carriage of dangerous goods by inland waterways.
- Contribute effectively to the protection of the environment, by preventing any pollution resulting from accidents or incidents during such carriage.
- Facilitate transport operations and promoting international trade of chemicals.

The annexed regulations contain provisions concerning dangerous substances and articles, provisions concerning their carriage in packages and in bulk on board inland navigation vessels and tank vessels, as well as provisions concerning the construction and operation of such vessels. They also address requirements and procedures for inspections, issue of certificates of approval, recognition of classification societies, monitoring, and training and examination of experts (UN, 2003).

These regulations, at the time of adoption of the agreement, are the same as those applicable on the Rhine, and the agreement is therefore intended to set up the same high level of safety on the entire European Inland Waterways Network (UN, 2003).

5.4.3 Navigation on the Rhine

In 1815, the Final Act of the Congress of Vienna established the principle of freedom of navigation on international waterways. Among the provisions that followed, the ones concerning the river Rhine held the creation of a Central Commission "in order to ensure a precise control of the enforcement of common rules as well as to provide an authority used as a means of communication between riparian States with regard to all aspects of navigation" (annex to the Final Act of the Congress of Vienna) (Rhine, 2003).

The first meeting was held on August 15, 1816, in Mainz. On March 31, 1831, the Convention of Mainz was signed, providing a set of statutory provisions concerning navigation on the Rhine (Rhine, 2003).

On 17 October 1868, the Convention of Mannheim brought about an update of the main regulations, taking into account the evolution of the Rhine navigation in the fields of technique, economy and politics. On 17 October 1963, the Convention was again amended in Strasbourg and integrated into the Revised Convention for Rhine Navigation (Rhine, 2003).

Among later amendments, the most important is the additional Protocol number 2, which adapts the principle of free navigation by setting up conditions for the transport of goods and passengers on the Rhine giving a content to the criteria of membership to the Rhine navigation (Rhine, 2003).

The CCNR, international organization (the oldest of governmental organizations) settles the technical and operational safety requirements for the license and the operation of inland navigation vessels carrying on board dangerous goods. Dangerous goods include the following examples:

- explosive substances and articles
- gases
- flammable liquids and solids
- toxic and infectious substances
- radioactive and corrosive substances

Structure of the ADNR

ADNR
(Basic provision)
- 8 Articles -

Annexes A
Prescriptions concerning substances

Annexes B1 **Bulk vessels**	**Annexes B2** **Tank vessels**
I. General II. Special provisions for the carriage of substances III. Rules for construction	
0) General 1) Mode of carriage 2) Requirements applicable to vessels 3) Operating rules 4) Loading / unloading 5) Navigation	
Appendices 1. Certificate of approval, certificate of special knowledge of ADNR, danger labels 2. ADNR check list 3. Discharge of residual quantities 4. List of substances 5. Transitional provisions	

CCNR

The ADNR provisions have settled the requirements and apply additionally to the police regulation, inspection regulation for vessels, and the boatmaster license regulation. The ADNR provisions apply to all vessels intended to carry dangerous goods on the Rhine. The vessel has to have in addition to the ship's certificate (ship's attest) a special certificate of approval (Rhine, 2003).

5.4.4 RID-OTIF

The Intergovernmental Organisation for International Carriage by Rail (OTIF) was set up on 1 May 1985 as a consequence of the Convention of 9 May 1980 (COTIF). Its predecessor was the Central Office for International Carriage by Rail that was set up in 1893. Until the signature of the Protocol of 3 June 1999, (Protocol of Vilnius) for the amendment of COTIF, the objective of this governmental organization was principally to develop the uniform systems of law that apply to the carriage of passengers, luggage, and freight in international through traffic by rail. These legal rules, which have been in operation for many years, are the CIV and CIM Uniform Rules (OTIF, 2003).

Forty-one states are members of OTIF at the present time: all the European states, excluding the successor states of the former Soviet Union, but including Lithuania and Latvia, four Near Eastern states and three North African states. The CIV/CIM Uniform Rules apply over about 240,000 km of rail routes and about 25,000 km of road and sea routes (OTIF, 2003).

The headquarters of the organization are in Bern. The work of the organization is carried out by the following bodies: the General Assembly, the Administrative Committee (12 members), which exercises both administrative and financial control, the Revision Committee, the Committee of Experts for the Carriage of Dangerous Goods, and the Central Office for International Carriage by Rail, which provides the permanent secretariat of the organization (OTIF, 2003).

5.5 OTHER COUNTRY REQUIREMENTS

5.5.1 Australia National Dangerous Goods Policy

The Department of Transport and Regional Services has had a long commitment to promoting best practice and harmonized legislation for the land transport of dangerous goods and explosives in Australia. The Australian government is strongly committed to ensuring that Australian legislative requirements for the transport of dangerous goods are closely aligned with international standards contained in the UN Recommendations on the Transport of Dangerous Goods.

The Dangerous Goods Policy Unit of Land Division provides policy advice on national and international dangerous goods matters, administers the Commonwealth Explosives Act, and provides secretariat support to the

Advisory Committee on the Transport of Dangerous Goods (ACTDG) and the Competent Authorities Panel (CAP).

The policy unit also works with the National Road Transport Commission (NRTC) on the maintenance of the nationally harmonized regulatory framework that is underpinned by the Road Transport Reform (Dangerous Goods) Act 1995 and Regulations 1997(Commonwealth). This unit has responsibility for the publication of the main technical advisory document referenced by the regulations, the "Australian Code of Practice for the Transport of Dangerous Goods by Road and Rail" and its supplements. Also published by this unit are the "Australian Code of Practice for the Transport of Explosives by Road and Rail" and the "Notes for the Guidance of Supervisors, Drivers & Attendants Transporting Commonwealth Explosives."

The Manager, Dangerous Goods Policy attends the United Nations Committee of Experts on the Transport of Dangerous Goods (UNCETDG), accompanied by appropriate technical experts from industry and state governments. Australia is a voting member of this committee and therefore can contribute to the development of uniform international safety requirements for the transport of dangerous goods and ensure that Australia's interests are represented at this level.

Harmonizing Australian Dangerous Goods Legislation In 1970 the Australian Transport Advisory Council established the Advisory Committee on the Transport of Dangerous Goods (ACTDG) to develop and co-ordinate uniform national requirements for the safe land transport of dangerous goods. The ACTDG has been responsible for six editions of the Australian Dangerous Goods Code and two editions of the Australian Explosives Code, documents that ensured a high level of uniformity in transport practices for dangerous goods around Australia. These codes were adopted under each state and territory's individual dangerous goods legislation and were administered by eight competent authorities around Australia.

In the early 1990s it was agreed by transport ministers that a national process should be established to develop nationally uniform dangerous goods transport legislation. Although the Dangerous Goods Code was adopted under each state and territory's dangerous goods legislation, this legislation varied widely in the duties and obligations placed on persons handling dangerous goods. There was also no mechanism for mutual recognition of decisions made by the eight state and territory competent authorities.

The reform of dangerous goods legislation was placed on the Road Transport Reform agenda and included in the key reforms of the National Competition Policy. The National Road Transport Commission, in consultation with this department, ACTDG, regulatory authorities, and industry set about to produce model legislation that could be adopted into state and territory law.

In 1995, the Commonwealth Government made the Road Transport Reform (Dangerous Goods) Act followed closely by the Road Transport Reform (Dangerous Goods) Regulations 1997. These are both enacted for the

ACT and Jervis Bay, with the agreement by all states and territories that the regulations would be referenced in all jurisdictions, achieving uniform legislation around Australia.

Industry now has the same rules applying to the transport of dangerous goods around Australia as well as a mechanism for mutual recognition of Competent Authority decisions.

Australian Dangerous Goods Code (ADG Code) The ADG Code (6th Edition) was prepared by the National Road Transport Commission in conjunction with the Advisory Committee on the Transport of Dangerous Goods and the Federal Office of Road Safety. It was approved by the Ministerial Council for Road Transport and endorsed by the Australian Transport Council, and replaces the Fifth Edition. The code sets out technical requirements and guidelines for the transport of dangerous goods by road and rail and is adopted under all state and territory legislation implementing the Road Transport Reform (Dangerous Goods) Regulations 1997 (Cwlth).

One important difference in the sixth edition of the code and regulations is that many of the requirements for transporting dangerous goods are performance based rather than explicitly fixed by regulation. Thus, a person who can demonstrate an equivalent or better way of safely transporting a commodity than is required in the regulations may seek approval to do so (see "Competent Authorities," below).

The code does not contain all requirements and guidelines relating to the transport of explosives, infectious substances, radioactive materials, waste products, and other environmentally hazardous substances. Provisions of the code dealing with those substances should be read subject to S10 of the Road Transport Reform (Dangerous Goods) Act 1995 of the Commonwealth and the following:

- The requirements in ADG 6 relating to the transport of explosives are in addition to the requirements of any other law of a state or territory or the commonwealth relating to the transport of explosives. Rules for the transport of explosives are to be found predominantly in the Australian Explosives Code, as it is applied by state, territory, and commonwealth legislation.
- The requirements relating to the transport of infectious substances are in addition to the requirements of any other law of a state or territory or the commonwealth relating to the transport of infectious substances.
- The requirements relating to the transport of radioactive substances are in addition to any other law of a state or territory or the commonwealth relating to the transport of those substances, including the Code of Practice for the Safe Transport of Radioactive Substances.
- The requirements of this code do not apply to waste products and other environmentally hazardous substances unless those products or substances are also dangerous goods within the meaning of the code.

Enquiries concerning the transport of waste and other environmentally hazardous substances should be directed to the relevant state or territory authority responsible for administering environment protection legislation. The Australian Dangerous Goods Classes are described in Table 5.11.

Australian Explosives Code In 1991, the Department of Transport and Regional Services published the Australian Explosives Code (Edition 1). This code sets out the requirements for transport of explosives by road and rail in Australia and is adopted under explosives legislation in most states and territories. This code was prepared with the advice of ACTDG. The second edition of the code was published in March 2000 and brings Australian requirements up to date with the 11th edition of the UN Recommendations on the Transport of Dangerous Goods. This code will not be adopted under the Road Transport Reform (Dangerous Goods) legal framework but adopted under explosives legislation in each state and territory.

Competent Authorities for Land Transport If advice is needed on the application of the ADG Code or AE Code, or a variation from the requirements of a code is sought, the competent authority appointed in the relevant state or territory should be approached first. If the matter covers more than one state or is for an extended period, it will normally be referred to the Competent Authorities Panel (excluding explosives matters).

The competent authority for road transport in each state and territory is the authority appointed by the minister in that state or territory. The transport

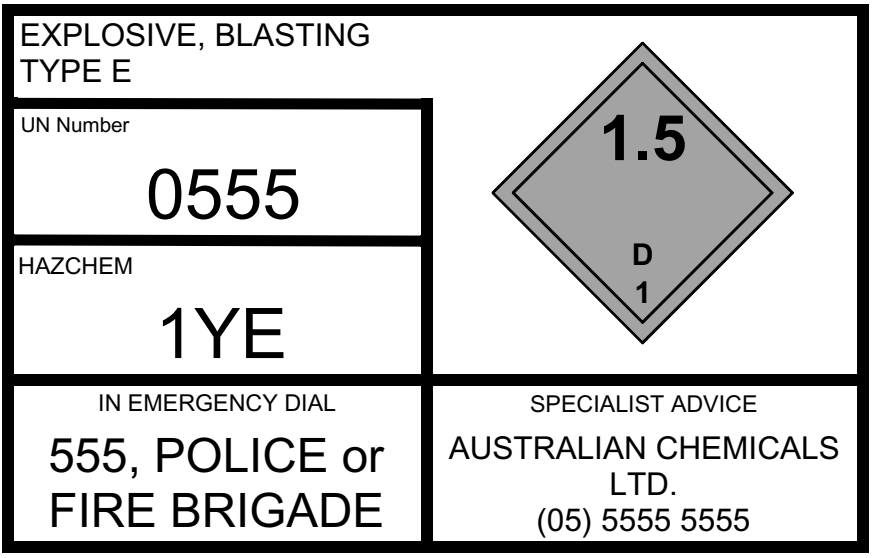


Figure 5.1. Example of an Australian Transport Label.

TABLE 5.11. Australian Dangerous Goods Classes

Class	Description	Example
1	Explosives	Gelignite, fireworks, ammunition, marine flares
2.1	Flammable gas	LPG, acetylene
2.2	Nonflammable/nontoxic gas	Carbon dioxide, refrigerant gas
2.3	Toxic gas	Chlorine (gas), ammonia
3	Flammable liquids	Paint thinners, kerosene, petrol
4.1	Flammable solids	Matches, sulfur
4.2	Spontaneously combustible	White phosphorus, activated carbon
4.3	Dangerous when wet	Calcium carbide, sodium metal
5.1	Oxidizing substances	Sodium peroxide, calcium hypochlorite (pool chlorine), ammonium nitrate
5.2	Organic peroxides	Methyl ethyl ketone peroxide (MEKP)
6.1	Toxic substances	Sodium cyanide
6.2	Infectious substances	Clinical or medical waste
7	Radioactive substances	Uranium
8	Corrosives	Sodium hydroxide (caustic soda), hydrochloric acid
9	Miscellaneous dangerous goods	Asbestos, dry ice

portfolio also contains the competent authorities for air and sea transport of dangerous goods.

Standard Marking for Packages. A standard marking of a package includes (TDGQT, 1998):

- proper shipping name
- UN number (prefaced with either "UN" or "UN no.")
- class label
- at least one of each subsidiary risk label (if applicable)
- name and address in Australia of the manufacturer or consignor of the dangerous goods, or their agent

Inner Packaging. Inner packaging containing 20 mL/g or more of Packing Group I substances, and any inner packaging containing other dangerous goods in quantities requiring marking as specified in Table 5.12, must be clearly marked with all of the following (TDGQT, 1998):

- proper shipping or technical name
- appropriate class label
- subsidiary risk label (if applicable)

Marking of Packages and Unit Loads. When packages are required to be marked, the label size must be at least the size specified in Table 5.13. Lettering sizes are desirable but not mandatory (TDGQT, 1998).

TABLE 5.12. Class with Respective Minimum Quantity

Class	Minimum Quantity
2.1	30 mL
2.2	100 mL
2.3	30 mL
3*	150 mL
3**	300 mL
3***	2 L
4.1	2 kg
4.2	500 g
4.3	150 g
5.1	1 kg/L
5.2	150 g/mL
6.1	500 g/mL
8	500 g/mL
9	2 kg/L

* PG II, ** PG III—Not a manufactured product; *** PG III—A manufactured product, which is a mixture of Class 3 Dangerous Goods of PG II or III with at least 10% of non-volatile materials such as resins, waxes, and pigments.

TABLE 5.13. Australian Labeling Size

Package Capacity/Content	Minimum Label Size (in mm)	Minimum Size of Lettering (in mm)
	Class 2 (not aerosols)	
up to .5 L	15 × 15	2.5
up to 5 L	20 × 20	3
up to 150 L	30 × 30	5
more than 150 L	100 × 100	7
	Class 2 (aerosols)	
up to 25 g	10 × 10	2
up to .5 kg	15 × 15	2.5
up to 5 kg	20 × 20	3
up to 25 kg	50 × 50	5
more than 25 kg	100 × 100	7
	Classes 3, 4, 5, 6, 8, and 9	
up to .5 L/kg	15 × 15	2.5
up to 5 L/kg	20 × 20	3
up to 25 L/kg	50 × 50	5
more than 25 L/kg	100 × 100	7

5.5.2 China Transport Packaging of Dangerous Goods

For China, the main transport legislation is governed by a document entitle GB 15098-94 "The Principle of Classification of Transport Packaging Groups of Dangerous Goods" (PCTPGDD). It is the same regulatory bodies as the import, export and MSDS regulation that enforced these rules.

The PCTPGDD standard regulates the principle of classification of transportation packaging groups of dangerous goods in China. This standard is applicable for departments that manufacture, store, transport, and inspect dangerous goods to test and examine properties of transportation package and for determining what the package group is. This standard is not applicable to the following:

- Pressured container contains compressed gases and liquefied gases
- Transportation package contains infectious goods
- Transportation package contains radioactive substances
- Transportation package contains miscellaneous dangerous substances
- Package weight >400 kg
- Package volume >450 L

Other standards need to be looked at to complete this standard:

- GB 6944 Classification and code of dangerous goods
- GB11806 Regulation for safety transportation of radioactive substances
- GB 12268 List of dangerous goods
- GB 12463 General specifications for transport packages of dangerous goods

The following are the specific requirements of PCTPGDD standard.

Packaging Group. They are divided to three packaging groups based on the degree of hazard of dangerous goods.

- Packaging group I: Goods have great danger. Higher packaging intensity is required.
- Packaging group II: Goods have median danger. High packaging intensity is required.
- Packaging group III: Goods have minor danger. Normal packaging intensity is required.

Classification of Packaging Group. Classify the packaging group according to the different classes and divisions of dangerous goods in GB6944 and related quantity value. If the goods have a special property its packaging group can be regulated by other standards. The following are the classes:

Class 1 Explosives—The intensity of packaging container for explosives should be packaging group II except if it is regulated by another standard.

Class 2 Compressed gases and liquefied gases—Steel gas cylinders contain compressed gases and liquefied gases. The designing, manufacturing, injecting, transporting, and storing of steel gas cylinders must be in accordance with the regulation of "Rule for Cylinder Safety Inspect Procedure" promulgated by China's Ministry of Labor (MOL).

The steel cylinder contains ethylene should be in accordance with the related regulation of "Rule for Soluted Ethylene Cylinder Safety Inspect Procedure" promulgated by China's MOL.

External package is wooden trunk or paper trunk, internal container is a glass bottle or the container contains compressed or liquefied gases.

a. Class 2.1 Flammable gases (CN No.21001-21999): Packaging group II
b. Class 2.2 Non-flammable gases (CN No.22001-22999): Packaging group III
c. Class 2.3 Poisonous gases (CN No.23001-23999): Packaging group II

Class 3 Flammable liquids—Class 3.1, Low flashpoint liquids (flash point < –18 °C)(CN No.31001-31999): Packaging group I.

Class 3.2, Median flashpoint liquids (–18 °C ≤ flash point < 23 °C) (CN No.32001-32999):

- Initial boiling point ≤35 °C: Packaging group I
- Initial boiling point >35 °C: Packaging group II

Class 3.3, High flashpoint liquids (23 °C ≤ flash point ≤ 61 °C) (CN No.33001-33999): Packaging group III.

Class 4 Flammable solids, substances liable to spontaneous combustion and substances emitting flammable gases when wet—The following are the various Class 4 subcategories:

Class 4.1 Flammable Solids

a. First grade flammable solids (CN No.41001-41500): Packaging group II
b. Second grade flammable solids (CN No.41501-41999): Packaging group III

*In class 4.1, Desensitized explosives: Packaging group I or II; Self-reactive substances: Packaging group II

Class 4.2 Pyrophoric Goods

a. First grade pyrophoric goods (CN No.42001-42500): Packaging group I
b. Second grade pyrophoric goods (CN No.42501-42999): Packaging group II

c. Second grade pyrophoric goods among which the goods contain oil and water fiber or scraps : Packaging group III

*In class 4.2, Self-heating substances: Packaging group II or III

Class 4.3 Substances Emitting Flammable Gases When Wet

a. First grade substances emitting flammable gases when wet (CN No.43001-43500): Packaging group I or II
b. Second grade substances emitting flammable gases when wet (CN No.43501-43999): Packaging group II

*Among Second grade substances emitting flammable gases when wet, if the goods' danger is minor: Packaging group III

Class 5 Oxidizer and Organic peroxides—The following are the Class 5 subcategories:

Class 5.1 Oxidizer

a. First grade oxidizer (CN No.51001-51500): Packaging group I
b. Second grade oxidizer (CN No.51501-51999): Packaging group II

*Among second grade oxidizers, if the goods' danger is minor: Packaging group III

Class 5.2 Organic Peroxides

a. Organic peroxides: Packaging group II

Class 6 Toxic and infectious substances—The following are the Class 6 subcategories.

Class 6.1 Toxic Substances

a. First grade toxic substances(very toxic)(CN No.61001-61500) (Table 5.14)
b. Second grade toxic substances (toxic)(CN No.61501-61999) See Table 5.15
c. First grade toxic liquid with flashpoint <23 °C: Packaging group I. Second grade toxic liquid with flashpoint <23 °C: Packaging group II

Class 6.2 Infectious substances—The packaging container and packaging group of this kind of substances, the testing items, testing requirements, and qualification standard for the container of this kind of substances should be determined by consulting with the responsible Department of Transportation.

Class 7 Radioactive Substances—The materials, designing, manufacturing, testing items and test methods, periodical examination of the packaging container for radioactive substances should be in accordance with GB11806 and be determined by consulting with the responsible Department of Transportation.

TABLE 5.14. First Grade Toxic Substance for Classification of Packaging Group

Packaging Group	Oral LD_{50} (mg/kg)	Dermal LD_{50} (mg/kg)	Inhalation Dust/Mist LC_{50} (mg/L)
I	⩽5	⩽40	⩽0.5
II	>5–50	>40–200	>0.5–2

TABLE 5.15. Second Grade Toxic Substance for Classification of Packaging Group

Packaging Group	Oral LD_{50} (mg/kg)	Dermal LD_{50} (mg/kg)	Inhalation Dust/Mist LC_{50} (mg/L)
III	solid: >50–500 liquid: >50–2000	>200–1000	>2–10

Class 8 Corrosives—The following are the class subcategories:

Class 8.1 Acid Corrosives

a. First grade acid corrosives (CN No.81001-81500): Packaging group I
b. Second grade acid corrosives (CN No.81501-81999): Packaging group II

Class 8.2 Alkaline Corrosive

a. First grade alkaline corrosive (CN No.82001-82500): Packaging group II
b. Second grade alkaline corrosive (CN No.82501-82999): Packaging group III

Class 8.3 Other Corrosives: Packaging Group III

Class 9 Miscellaneous—The packaging container, packaging group, the testing items, testing requirements, and qualification standard of the container for this kind of substances should be determined by consulting with the responsible Department of Transportation.

REFERENCES

UN 2003—United Nations UN (www.unece.org/trans/danger/danger.htm).

IATA 2003—International Air Transport Association (www.iata.org).

ICAO 2003—International Civil Aviation Organization (www.icao.int).

IMO 2003—International Maritime Organization (www.imo.org).

Rhine 2003—Central Commission for Navigation on the Rhine (www.ccr-zkr.org).

OTIF 2003—Intergovernmental Organisation for International Carriage by Rail (www.otif.org).

TDGRT 1998—Transporting Dangerous Goods, Guide to new requirements, Queensland Transport. September 1998.

6

IMPORT COMPLIANCE

6.1 CHANGE IN STRATEGY AT THE BORDER

6.1.1 Overview of Content

Globalization becomes more widespread with each passing year. World economies merge and become more interdependent as transportation systems improve and become increasingly automated. Factories rely on "just-in-time" parts deliveries and products assembled with "foreign" parts or assemblies abound. Isolation and protectionism begin to evaporate as free trade agreements proliferate throughout the world and vast new markets emerge. Each year, an unprecedented amount of goods and materials pass in and out the countries.

This chapter describes changes in compliance strategies for imported goods, the transition to automation, and the legal and practical requirements for importing into the largest markets of the global economy. An explanation of the import requirements of individual countries and economic unions, as well as common operating principles of individual customs services, is also provided.

6.1.2 Historical Perspective

Beginning in the 1970s, developing nations customs services were unable to cope with increasingly large volumes of imported goods brought about by bur-

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geoning economies and improvements in transportation (e.g., containerization and the express courier industry). In many countries, the enormity of foreign trade soon overwhelmed the static workforce of customs inspectors and other border agents. Many customs services, limited by nonautomated entry control systems, could simply not keep pace. In some instances, customs services were so overwhelmed that they could only offer token examinations and get the duty deposited. Overwhelmed by foreign trade, the shipment-to-shipment "eye-balling" scrutiny of customs slowly dissolved with the passing years; the number of shipments examined remained constant despite an exponential growth in trade. At the same time, narcotics smuggling and money laundering swallowed their resources. Eventually, government legal mandates for examination numbers or percentages were ignored or annulled.

In the 1980s, the governments introduced the first automated import execution systems. Although these systems greatly reduced the government's clerical burdens, they were not terribly innovative—many systems "paved the cow path" by following previous manual procedures. In order to avoid data entry nightmares, the customs services of the world persuaded their trade partners (e.g., customs brokers and freight forwarders) to provide an automated feed of import data.

In the 1990s, Australian Customs began the first efforts at statistical customs compliance, the next evolutionary phase for border cargo management after automation. Soon other countries like the United States followed suit. Using random sampling, the border agencies measured whole categories of goods (textiles, footwear, auto parts, etc.) for compliance. The level of effort, although considerable, was doable. In a year, only 400 examinations are necessary to statistically sample and to compute a compliance rate on over 150,000 shipments of cotton shirts. The examinations would have to be inclusive of all customs considerations of material and manufacturing descriptions as well customs issues as marking and fiber content. The results were tallied and used to figure an overall compliance rate.

This philosophy was a significant change in traditional customs thinking. Instead of trying to find violations in individual shipments passing through border checkpoints, the Customs services began to focus on an individual company's overall performance through measuring actual compliance rates. Companies are typically measured on the accuracy of their tariff classification (HSUSA), ability to back up their special trade program claims (such as NAFTA), transaction value, quantities, etc. Companies that have no system in place to ensure compliance or blindly rely on vendors such as customs brokers or freight forwarders to handle their formalities can no longer and avoid detection in the vast flow of goods crossing the border.

Malcolm K. Sparrow, in his 1994 book *Imposing Duties*, defined compliance as "the purpose or the method of government agencies, whose principal business involves encouraging, and sometimes forcing, citizens to meet their public obligations." Customs import compliance also follows this principle, and objective measurement and self-policing are the keynotes of the current direction.

CBP methods for this strategic change in direction were simple. Customs decided which verticals to concentrate on based upon risk or political interest. Risk is the degree of exposure to the chance of noncompliance that would result in loss or injury to the public or industry while paying due political consideration to sensitive verticals such as steel, textiles and soft wood lumber.

As the next step in the compliance process, Customs did a full "soup to nuts" audit of the top 400 companies in each of the vertical, finding wide variations in compliance among the companies audited. Some verticals were excellent, some were satisfactory, and others were abysmal. Customs also had some big surprises. For example, U.S. Customs' traditional mindset was that new cars and auto parts from the original manufacturer were perfect in terms of compliance. Not so. Customs was correct about the cars, but the parts review showed disastrous results, auto parts only scored an unsatisfactory 71% accuracy figure in the statistically valid sample.

Deficient companies were put on improvement plans with U.S. Customs' newly created "account managers" to track the firm's progress. These account managers were a new position for U.S. CBP, instituted to monitor the larger importers, either compliant or "compliance challenged." Another job for these officers is making sure there is no backsliding as companies change personnel, change corporate structure, or add and drop products. Most significant is the change of Customs' focus from the "import stream" itself to the importing company itself. Accountability is firmly fixed. Clearly, companies need to pay attention to their import operations or face the consequences. In addition, a central pillar of U.S. CBP's new modernization effort, the Automated Commercial Environment (ACE) System, bases its central principle upon treating importers, brokers and other international trade entities as accounts, measuring compliance and results against industry-wide levels.

In March 1, 2003, the most massive reorganization since World War II, U.S. Customs, U.S. Immigration (INS) and the border inspection agencies for agriculture and Border Patrol reorganized were unified under the U.S. Customs and Border Protection (CBP). This action placed the major border agencies under the new Department of Homeland Security—a direct response to the attacks of September 11, 2001). Chapter 8, "Impact of Terrorism on the Supply Chain" discusses coping with this change of strategy.

6.2 IMPORT COMPLIANCE ISSUES

Corporate compliance managers are about as pleased with a customs notice of an impending international trade audit as we ordinary humans are when our friends at the tax authority ask about the details of individual income tax returns.

In 2001, U.S. Customs upped the audit ante when they announced focused assessments, a major change in regulatory audit direction. Instead of devoting

considerable staff time to one company over a year or more, Customs is now instituting a "hit-and-run" philosophy. Basing focused assessments upon Customs risk analysis of companies and their import pattern, they are very similar to the U.S. Internal Revenue Service technique where tax auditors zero in on the most suspicious records. Customs, for instance, may only wish to check a company's preferential trade program claims such as NAFTA or the classification of products that are either problematic or politically sensitive. Customs likes focused assessments because they act as a force multiplier: Customs has thus extended their range to companies outside their verticals and to smaller companies, thereby undertaking more audits.

In June 2002, Customs announced a new program, the Importer Self-Assessment Program (ISA). ISA is Customs' newest compliance program. Importers with records of accomplishment for compliance with import laws and regulations will assess their own compliance program (as described above) without intervention from Customs auditors.

To participate, importers must also comply with the following:

- participants in the Customs-Trade Partnership Against Terrorism (C-TPAT) (refer to Chapter 8 for details on C-TPAT)
- based or reside in the U.S. with at least two years' importing experience
- prove that sufficient internal controls and business systems exist and are used for Customs compliance; and sign a memorandum of understanding with Customs.

The audit approach is efficient for agencies like CBP who are not all that interested in penalizing importers with seizures and penalty cases. Rather, Customs wants firms to have the processes and systems in place to do a competent job complying with a complex set of continually changing import requirements. Companies also have their own needs such as import planning and the ability to measure the performance of their logistics vendors, such as carriers and brokers. Considering the huge volume of imported goods that traverse borders daily, programs like C-TPAT and ISA that take known, documented, and compliant importers out of the suspect category, is a huge advantage to the border agency.

For private import companies, joining a program like C-TPAT and ISA may be advantageous for several reasons. Certainly, anything that removes imported cargo from scrutiny for drugs or terrorism is a significant help to U.S. CBP and worthwhile from the desire to be good corporate citizens. However, companies whose commodities are noncontroversial and already have a good compliance program may not wish to join these programs, especially if they have a very low examination rate. (See Section 8.4.2 for more information on C-TPAT.)

Additional information on importing through these programs is found on the U.S. Customs Web site at *www.cbp.gov*.

6.3 SELF-ASSESSMENTS?

In a U.S. CBP transaction, the importer of record is responsible for using reasonable care to enter, classify and value imported merchandise, and to provide any other information necessary to enable the correct entry of goods. Reasonable care is defined as the degree of care that a reasonably prudent person would use under like circumstances. Self-assessments are the cornerstone of reasonable care. A copy of the U.S. Customs and Border Protection "Reasonable Care Checklist" is included in Appendix 2 of this book.

Since the introduction of audits, the self-assessment has become the most effective and efficient means for ensuring import-export compliance. A self-assessment is an independent review of a company's importing and exporting activities designed to determine how well a company conducts its international trade transactions, its compliance practices and procedures, and its successes and failures in implementing those practices and procedures.

The following seven-step process to a self-assessment was adapted from a speech by Melvin S. Schwechter (2002).

Step 1—Prepare the "Inventory." Create and complete a diagnostic questionnaire that identifies all of the company's importing actions for the most recent year (including products, volumes, values, duties paid, sourcing, tariff preference programs used, destinations and customers, and visas obtained) as well as the possible issues implicated by these activities.

Step 2—Collect the Data. Using the importing actions listed in Step 1, a representative sample of transactions should be chosen to review. For each action, the company should pull every related document. A review of all of the company's import/export compliance procedures manuals and other forms of written procedures should take place concurrently.

Step 3—Prepare for the Assessment. Begin the assessment with a "kick off" meeting with all participants. Senior management should be represented and stay involved throughout the assessment. The meeting agenda should include reasons for conducting the assessment; an explanation of "reasonable care" concepts; a decision on how the assessment will be conducted; who will be involved; and any follow-up actions. A report with recommendations can follow. In addition, the consequences for both negative and positive findings can be discussed. Because some of the members may be responsible for some of the problems encountered, an "amnesty" may be useful for encouraging objectivity.

Step 4—Conduct the Assessment. The import assessment should begin with an oral review of purchasing/importing processes and procedures to use as reference materials during the assessment. Interviews can often elicit more accurate information than questionnaires. At this point, discussion should focus on specific details of how communications occur, how transactions are processed and how entries are made. Most importantly, any high volume or repetitive types of transactions and the computer systems/software used to prepare import declarations should be reviewed in detail. The processes

related to each customs broker, freight forwarder, and express consignment operator that the company deals with should be reviewed.

Specifically, the following processes and issues should be reviewed:

- classification (manufacturing/purchasing/sales)
- transfer pricing/valuation (tax/accounting)
- consignments/buy-resale transactions
- additions to invoice value for such items as assists purchasing/manufacturing), royalties and license fees (finance/accounting)
- freight charges (logistics)
- marking (logistics/receiving/sales)
- quantity declarations (receiving)
- eligibility for tariff preference programs—(In the U.S. 9801, 9802, NAFTA, GSP, CBI, TIB)
- products subject to anti-dumping/countervailing duty orders or their equivalent.

Step 5—Sharpen the Assessment. The differences between total payments to foreign vendors and the total value of imports need to be reconciled and compared with the entered value reported to Customs. All documentation connected with the preselected imports also needs to be reviewed at this point (e.g., begin by reviewing the entry summary, then check against commercial invoice, bill of lading/air waybill, packing slip, dock receipts, applicable tariff preference documents and proof of payment). The results should be recorded and compliance rates computed.

Step 6—Final Review. Conduct a closeout meeting with the executive sponsor present. Both large and small issues should be addressed along with possible remedial actions, duty management, and cost saving alternatives. A timetable and action plan that will address the findings and implement the recommendations should be devised. A written report may be prepared at this point.

Step 7—Call for Action. Areas of improvements will likely be unearthed during this process because Customs compliance has not been a priority for most corporations. However, since the advent of government compliance programs, the position of compliance manager was created and given Director or Vice-President status to reflect this change in importance.

6.4 IMPORT REQUIREMENTS OF INDIVIDUAL COUNTRIES AND ECONOMIC UNIONS

Individual countries and economic unions vary greatly in their import requirements. In this section, the legal and practical requirements for importing into the largest markets of the global economy are discussed. The following areas

are described in detail: North America (United States, Canada, and Mexico), the European Union, and the Pacific Rim (Australia, Canada, Japan, Korea, and Taiwan). For additional information, refer to pertinent Web sites provided in Appendix 4.

When importing to unfamiliar economies, thorough research and preparation with complete attention to details will prove very helpful. Additionally, hiring good overseas representatives to handle the shipment is imperative. For the cautious, sending a preliminary shipment through is very helpful to test its treatment in the country of destination.

6.4.1 United States

U.S. Import Requirements An individual or company may make his or her own Customs clearance of goods imported for personal use or business. Most companies use intermediaries such as customhouse brokers (CHBs) to handle formalities, although increasing numbers of importers have decided to take on the task themselves. All merchandise coming into the United States must clear Customs and is subject to a Customs duty unless specifically exempted by law. Some examples of duty exemption are goods from Mexico and Canada that are "free" of duty under the North American Free Trade Agreement (NAFTA). Clearance involves a number of steps: entry, inspection, appraisement, classification, and liquidation.

Although the United States does not require an importer to have a license or permit, other agencies requiring border clearance may require a permit, license, or other certification depending on what is being imported. For example, the U.S. Fish and Wildlife service requires permits for certain species of imported plants and animals.

Key Information for Customs Clearance *Importer Number.* Customs entry forms ask for an importer number. This can be either a business registration number (EIN) or a social security number if the business is not registered with the IRS or if there is not a business.

Value. The importer must declare the dutiable value of merchandise. The final appraisement is fixed by Customs. Several appraisement methods are used to arrive at this value. Most commonly, the transaction value serves as the primary basis of appraisement. Transaction value is the price actually paid or payable by the buyer to the seller for the goods imported. Other factors may also add to the dutiable value of merchandise, such as packing costs, selling commissions, royalty or licensing fees, and so on.

When the transaction value cannot be determined, then the value of the imported goods being appraised is the transaction value of identical merchandise. If merchandise identical to the imported goods cannot be found or an acceptable transaction value for such merchandise does not exist, then the value is the transaction value of similar merchandise. Similar merchandise refers to merchandise that is produced in the same country and by the same

person as the merchandise being appraised. It must be commercially interchangeable with the merchandise being appraised. The identical or similar merchandise must have been exported to the United States at or about the same time the merchandise being appraised is exported to the United States.

Classification. The importer must determine the classification number of the merchandise being imported. The Harmonized Tariff Schedule of the United States (HSUSA), issued by the United States International Trade Commission, prescribes the classification of merchandise by type of product; for example, animal and vegetable products, textile fibers and textile products. All goods that enter the United States are categorized according to the Harmonized Tariff Schedule. The act of placing goods into the correct category is called classification. Classification determines how much duty will be collected. Classification is more than simply looking up an item in an index. It is a very complicated process requiring the application of the General Rules of Interpretation; the section, chapter, and subheading notes and the Explanatory Notes. The importer is responsible for properly classifying his merchandise before entry.

If not sure how to properly classify an item, an importer can submit a request, in writing, for a binding classification ruling to the: Director, National Commodity Specialist Division, Bureau of Customs and Border Protection, Attn: CIE/Ruling Request, One Penn Plaza-10th Floor, New York, NY 10119 *or* to any service port office of the CBP.

The rulings will be binding at all ports of entry unless revoked by the Headquarters' Office of Regulations and Rulings. If an importer is not satisfied with the binding ruling received from New York, he or she can appeal it to the Headquarters' Office of Regulations and Rulings, Washington, DC 20229. The CBP will not issue binding rulings in response to oral requests. Import specialists can give oral advisory rulings but the classification-related opinions or advice of CBP personnel at one port are not binding on the Customs ports elsewhere. Oral inquiries may be made to Customs offices regarding existing binding rulings that might cover your importation. Binding rulings may also be researched on the Customs Web site at *www.cbp.gov*.

Admissibility. It is the importers' responsibility to ensure that goods being imported meet admissibility requirements—such as proper marking, safety standards, etc.—and that the proper permits, if required, have been obtained in advance of the goods arriving in the United States. For example, many importers of hats and t-shirts are surprised to discover that these items fall under textile quotas requiring permits on visas and which are very difficult to obtain once the goods are in the United States. A prominent feature of Customs law is a relationship between CBP and importers characterized by "informed compliance." A key component of informed compliance is the shared responsibility between Customs and the import community, wherein Customs communicates its requirements to the importer, and the importer, in turn, uses reasonable care to assure that Customs is provided accurate and timely data pertaining to his or her importations.

U.S. Customs and Border Protection and the Examination of Goods All merchandise entering the United States is subject to examination by Customs in order to determine its compliance with U.S. federal laws and regulations. Merchandise selected for examination is usually examined at the place of arrival or a designated Centralized Examination Station (CES); however, Customs may, at its discretion, require or authorize that examination take place at another location. In special cases, examinations may be authorized at the importer's premises. Regardless of where Customs examinations occur, the importer is responsible for all expenses involved with preparing merchandise for a Customs examination.

Once the merchandise has been examined and found to be compliant with all federal laws and regulations, it may be released to the importer. In some instances, sample packages of the merchandise may be retained by Customs for appraisal or classification purposes and the remainder of the shipment released. These sample packages will also be released to the importer once a final determination is made.

Examination of goods is necessary to determine:

- The value of the goods for Customs purposes and their dutiable status.
- Ensure goods are properly marked with the country of their origin. Special marking or labeling may apply. Generally, imported merchandise must be legibly marked in a conspicuous place and with the English name of the country of origin. Certain specific articles are exempt from this requirement.
- Ensure goods have been correctly invoiced.
- Whether the shipment contains prohibited articles to determine if the requirements of other federal agencies have been met.
- That the amount/quantity of the goods listed on the invoice is correct.

If necessary, goods may be analyzed by a Customs laboratory to determine proper classification and appraisal, to see if the goods meet safety requirements, or to ensure that they are not counterfeit or otherwise in violation of U.S. laws.

An increase in duties may be assessed if Customs determines that the goods are different from the entered descriptions in quantity or value, that the classification of the goods is incorrect, or that a duty rate is different than the one indicated by the importer applies. If Customs determines that the importer has deliberately failed to properly classify and value his goods, they may be liable for a fine or other penalty.

A final determination of duty is made and the entry is liquidated after all the information has been acquired, including the report of the Customs import specialist as to the customs value of the goods and the laboratory report, if required. At this time, any overpayment of duty is returned or under-payments billed.

Filing—Automated Reporting Currently, over 99% of U.S. Customs and Border Protection entries are automated. To speed customs clearance, the import community and the Customs Service have created the Automated Commercial Systems (ACS), which electronically receives and processes entry documentation and provides cargo disposition information. Cargo carriers, customs brokers, and importers may use the system, which reduces clearance time from days to hours or even minutes. Persons entering into the importing trade who intend to file their own entry documentation with Customs are encouraged to explore this method of transacting business. Also, those importing merchandise either for their own use or for commercial transactions may use a customs broker who transacts customs business using the Automated Broker Interface (ABI) in combination with ACS. Although ACS is an adequate system, it has experienced numerous operating failures in recent years.

Customs is currently replacing the legacy system with a new multimillion dollar system known as ACE or the Automated Commercial Environment. The new system will be phased from 2003 to 2008. Importers are cautioned against joining the legacy ACS system since it will be replaced in the near future. Automation can be achieved in the interim by using the services of a Customhouse Broker (CHB) or a software vendor.

Payment The importer must pay estimated duties and processing fees if applicable. Customs makes the final determination of the correct rate of duty. Informed compliance is a shared responsibility between Customs and the import community where Customs effectively communicates its requirements to the trade, and the people and businesses subject to those requirements conduct their regulated activities in accordance with U.S. laws and regulations. A key component of informed compliance is that the importer is expected to exercise reasonable care in his or her importing operations.

The duty rate of an item is tied to its classification number. The HSUSA provides several rates of duty for each item: general rates for countries with which the United States maintains normal trade relations (NTR); special rates for special programs (free, or lower than the rates currently accorded NTR countries); and column 2 rates for imports not eligible for either general or special rates. Customs duties are generally assessed at *ad valorem* rates, a percentage of which is applied to the dutiable value of the imported goods. Some articles, however, are dutiable at a specific rate (so much per piece, liter, kilo, etc.). Other articles are dutiable at a compound rate of duty (i.e., combination of both *ad valorem* and specific rates).

U.S. Regulatory Procedures *Arrival of Goods.* Imported goods may not legally enter U.S. commerce until the shipment has arrived within the port of entry and Customs has authorized delivery of the merchandise. This is normally accomplished by filing the appropriate documents, either by the importer or by the importer's agent. To expedite this process, Customs entry

papers may be presented before the merchandise arrives, but entry will not take place until the merchandise arrives within the port limits.

The carrier of the goods usually makes notification of arrival. Since 9/11, these documents have become more accurate and are presented at least 24 hours prior to arrival. Arrangements should be made to ensure that the importer or their agent is informed immediately of arrival so that the entry can be filed and delays in obtaining the goods avoided.

The Customs Service defines "entry" not merely as the arrival of goods at a port, but as the process of presenting documentation for clearing goods through Customs. Imported merchandise not entered through Customs in a timely manner (within 15 calendar days of arrival) is sent by Customs to a general order warehouse to be held as unclaimed. The importer is responsible for paying storage charges (which may be exorbitant) while unclaimed merchandise is held at the warehouse. If this merchandise remains unclaimed at the end of six months it is sold at auction.

Entry. Some type of Customs entry must be made at the first port of arrival. Ordinarily, entry is made at this port for consumption, for entry into a bonded warehouse or foreign trade zone, or for transportation in bond to another port where a consumption or warehouse entry will be made. If an importer is unable to be there to prepare and file the entry, CHB's (customs broker that is licensed by the Customs Service) may act as an agent for the importer. These brokers charge a fee for their services. A list of customs brokers may be obtained from the local Customs office or found in the yellow pages of the local telephone directory.

In the case of a single noncommercial shipment, a relative or other individual may act as the importer's agent for customs purposes. This person must know the facts pertaining to the shipment and must be authorized in writing to act for the importer.

Formal vs. Informal Entry. Informal entries cover personal shipments, commercial shipments and mail shipments that are being entered for consumption, that is, for use or sale. In most cases informal entry can be used if the merchandise is valued at $2000 or less. There are some exceptions such as textiles, certain types of footwear and other goods subject to quota/visa restrictions. Personal shipments valued over $2000 will also require a formal entry. The difference between an informal entry and a formal entry is the bond requirement and the liquidation process. Liquidation is the final computation of duties or drawback accruing to an entry and is the final step in the entry process. Also, liquidation marks the point where the entry is "fixed and final" and not subject to rate advances and other disheartening surprises.

Formal entries are generally commercial shipments supported by a surety bond to ensure payment of duties and compliance with Customs requirements. A bond is like an insurance policy that is payable to Customs in the event that the importer does not comply with import requirements. Having a bond on file allows an importer to take possession of his merchandise before the payment of duties, taxes, and fees. Bonds can be obtained from a surety, which

is an insurance company that has been authorized by the U.S. Treasury Department to write Customs bonds.

A port director can require a formal entry for any importation regardless of value if he or she deems it necessary for the protection of the revenue or for admissibility or enforcement issues.

Goods admitted as informal entries do not require the posting of a bond and goods are liquidated on the spot. After the importer receives notification of the arrival of merchandise from the carrier and it is determined that all shipping charges are satisfied, an invoice is presented to Customs. When an informal entry is being made, the inspector, not the importer, is responsible for determining the classification number of the goods being imported. The inspector also completes the Customs forms used for informal entry. Breaking shipments into smaller portions to avoid formal entry is frowned upon by Customs. Besides penalties, this dishonest behavior virtually guarantees increased and expensive delays in your subsequent shipments.

Required Documents. To make or file a consumption entry, for imported goods going directly into the commerce of the United States without any time or use restrictions placed on them, the following documents are generally required:

- A bill of lading, airway bill, or carrier's certificate (naming the consignee for customs purposes) is accepted as evidence of ownership and of the consignee's right to make entry.
- A commercial invoice obtained from the seller, which shows the value and description of the merchandise.
- Entry manifest (Customs Form 7533) or Entry/Immediate Delivery (Customs Form 3461)
- Packing lists, if appropriate.
- Other documents necessary to determine whether the merchandise may be admitted, can be helpful.

When a consumption entry is filed, the importer indicates the tariff classification and pays any estimated duty and processing fee. A surety bond containing various conditions, including a provision for paying any increased duty is required. Cash in lieu of surety is also possible.

Other Types of Entry. Imported goods may be sent in-bond from the first port of arrival to another Customs port. In-bond entries postpone final Customs formalities including payment of duty and processing fees, until the goods arrive at the final port. Arrangements for in-bond shipments should be made before the goods leave the country of export.

Imported merchandise may also be sent to a bonded warehouse under a warehouse entry. Duties and processing fees are not paid on warehoused merchandise until the goods are withdrawn for consumption. Storage fees are paid to the warehouse proprietor by the importer.

Protest. Within 90 days after the date of liquidation or other decision, an importer or consignee may protest the decision and receive an administrative review. The protest is filed with the port director whose decision is being protested. At the time the initial protest is filed, the importer or consignee must make a request for further review if one is desired. Review of the port director's decision by the Customs Service Center or Headquarters is then automatic. Notice of the denial of all or part of the protest will be mailed to the person filing the protest or to his agent. Any person whose protest has been denied may contest the denial by filing a civil action in the United States Court of International Trade.

Mail Shipments. Shipments by mail that do not exceed $2000 in value, whether commercial or noncommercial importations (except for commercial shipments of textiles from all countries and made-to-measure suits from Hong Kong, regardless of value), are entered under a mail entry prepared by a Customs officer after the Postal Service submits the package for Customs examination. The parcel is delivered to the addressee by the Postal Service and is released upon the payment of duty, which is shown on the mail entry accompanying the package. A postal handling fee will also be collected from the addressee at the time the package is delivered. This handling fee is not charged on packages sent through military mail channels.

A formal entry is required for any mail shipment exceeding $2000 in value. Formal entry is also required, regardless of value, for commercial shipments of textiles from all countries and made-to-measure suits from Hong Kong. Certain other articles valued over $250 require a formal entry (billfolds, footwear, fur, gloves, handbags, leather, luggage, plastics, rubber, textiles, toys, games and sports equipment, etc.) If formal entry is required on a parcel, the parcel is held at the Customs international mail branch and notice is sent to the addressee of the package's arrival. The addressee can then go to the nearest Customs office to file the formal entry on the package. An entry must be filed in the same manner as for shipments arriving by vessel or airfreight. Once the mail branch has been notified that entry has been filed, the package will be released to the Postal Service and forwarded to its final destination.

Restricted Merchandise. A license or permit from the responsible agency may be necessary to import:

1) alcoholic beverages
2) animal and animal products
3) certain drugs
4) firearms and ammunition
5) fruits, nuts
6) meat and meat products
7) milk, dairy, and cheese products
8) plants and plant products
9) poultry and poultry products

10) petroleum and petroleum products
11) vegetables
12) trademarks and copyrights

Prohibited Merchandise. Certain items in the preceding categories may also be prohibited:

1) cultural property
2) hazardous/toxic/flammable materials
3) household appliances
4) some electronics products
5) toys and children's articles

Embargoed Countries. Generally, you may not bring in any goods from the following countries: Cuba, Iran, Iraq, Libya, Serbia, and Sudan. The Office of Foreign Assets Control of the U.S. Treasury Department enforces this ban. Importers may, however, import informational materials—pamphlets, books, tapes, films or recordings—from these countries, except for Iraq. If you want to import merchandise from any of these countries, you will first need a specific license from the Office of Foreign Assets Control, Department of the Treasury, Washington, DC 20220, before you make your plans (note that such licenses are rarely granted). The embargo on goods from Iran and Iraq may be revised. Please check with your local port to find out when the new regulations are scheduled to take effect. Until the new regulations are published, the complete embargo is still in force.

Requirements related to the importing of goods, pertinent to environmental health and safety legislation, are presented in Chapter 2 of this book.

6.4.2 Canada

Canada Customs import process is closely aligned with that of the United States because of the shared border and because each country is the other's largest trade partner. The following is a summary of Canada's Trade Compliance function.

Business Registration Commercial importers must have a business number for their import/export account. The business number (BN) has 15 digits: nine numbers to identify the business, plus two letters and four numbers to identify the program and each account. The system includes major types of Canada Customs and Revenue Agency (CCRA) programs, including tax programs, which businesses may be registered for:

- Goods and Service Tax (GST)
- payroll deductions

- Corporate income tax
- import/export (identified by the letters "RM").

AN example of the latter is a company's import/export account that may look like 123456789RM0002.

Importers can register for a business number, or add an import/export account to an existing business number, by notifying CCRA. A business number may also be obtained by registering online at *www.businessregistration.gc.ca* or by completing Form RC1, Request for a Business Number (BN0).

Businesses must enter their import/export account on their customs documents. This applies to most shipments that enter Canada. Import/export accounts are only for importing or exporting. If you do not use it, your account will expire after two years. Contacting any customs office can reactivate it. If there is any change in your status (e.g., name or address change), you must report these changes to CCRA as soon as possible.

Reporting Your Shipment In most cases, the carrier reports a shipment to the CCRA when it arrives at the international border entry point. Carriers must either report all commercial goods imported into Canada on an approved Cargo Control Document (CCD), or, in the case of rail and marine shipments, electronically transmit the cargo information using electronic data interchange (EDI) before arriving at the Canadian border.

A CCD is not required in the following cases:

- The importer has line release privileges.
- The importer personally transports the shipment, accounts for the goods and pays any duties at the customs office where the goods arrived.

Customs Release To obtain release of goods, importers can use one of two methods:

- Release with full accounting and payment.
- Release on Minimum Documentation (RMD). By using RMD, you can fast track the release of your goods by accounting for and paying for your shipments after Customs releases them. To take advantage of this privilege, you have to post an approved amount of security with CCRA. Release information is provided to Canada Customs using EDI. To take advantage of RMD, which includes uncertified check privileges, a security is required. Importers can post security either locally or nationally, depending on whether or not you need your shipments released at various CCRA offices across the country.

The following are used as security: cash, certified check, transferable Government of Canada bonds, or CCRA customs bonds, that a registered Canadian bank or approved financial institution has issued.

Transaction Number Each Canadian import shipment has a unique 14-digit transaction number. The transaction number is used to identify shipments at various times throughout the customs process. Under the cash option, CCRA assigns a transaction number to the documents in the accounting package when they are presented for release of goods.

If the importer has RMD privileges, a unique five-digit account security number is assigned. This number will always appear as the first five digits of the transaction number. After the account security number is received, the transaction number in bar-coded format is attached to your release and accounting documents for all later shipments.

Canada Customs Examinations Canada Customs has the authority to randomly select shipments for examination to verify compliance or to take samples in reasonable amounts. The frequency of examinations will depend on an importer's compliance record and that of other persons or organizations involved with the shipment as well as the type of goods being importing. The rate of examination is very low.

CCRA examines goods for various reasons:

- To detect prohibited or restricted items (e.g., pornography, narcotics) or smuggled goods;
- To fulfill other government departments' legislative requirements (e.g., meat inspection, import permits);
- To ensure the goods comply with customs requirements (i.e., to verify their description, value, quantity, and origin marking against the invoice information)
- To intercept terrorist originated shipments.

Because carriers are responsible for making shipments available to Canada Customs for examination, importers ultimately have to pay for the examination costs associated with unloading and loading cargo. Additionally, importers also have to pay special service charges for a Canada customs officer's time and travel costs when the officer conducts examinations and releases goods at locations other than designated customs facilities, or when after-hours service is needed.

Entry Forms and Accounting A final documentation/accounting package is necessary for shipments imported into Canada. In most cases, a complete package consists of:

- Two copies of the cargo control document (CCD)
- Two copies of the invoice
- Two copies of a completed Form B3, Canada Customs Coding Form

- Any import permits, health certificates, or forms that other federal government departments require
- A Form A, Certificate of Origin (when necessary)
- Other Government Departments (OGD) Single Window Interface

The OGD Single Window Interface is a joint initiative between CCRA and other Government Departments and Agencies wishing to receive release information on commercial import data electronically. The objective of this project is to develop a common electronic commerce-based interface between participating departments and the CCRA.

Prohibitions and Restrictions Imported merchandise is subject to a variety of controls by the Canadian federal government and even individual provinces. The following categories of goods have restrictions and prohibitions.

Goods Prohibited Absolutely. This covers a narrow range of goods prohibited under annex VII of the Customs Tariff such as hate literature and pornography. It also covers goods that are subject to international sanctions.

Permitted Goods. Under the Export and Import Permits Act, Canada controls imports of primarily textiles and clothing, steel, wheat, barley and their products, supply-managed farm products (dairy, chicken, eggs, turkey), and firearms. These are all found on the Import Control List. If you wish to import a textile or clothing article, call (613) 996-3711 for information about how to get an import permit. If you wish to import an agricultural good on the Import Control List, call (613) 995-8104. For steel, call CCRA to get a permit on request, or call any customs broker. For endangered species and their products, call the Canadian Wildlife Service (613) 997-1840. For information about firearms, call (613) 992-0478.

Controlled Products. For example, goods for retail sale have to comply with labeling laws; motor vehicles have to meet emission control standards; food and agricultural products have to pass the necessary health and sanitary checks. Checking with CCRA before your first importation can prevent unnecessary delays and unexpected costs.

Canadian Standards. For example, the Canadian Standards Association International must certify all electrical appliances and equipment before they can be sold in Canada. Call the CSA International at (416) 747-4000 (or toll-free 1-800-463-6727) for information on electrical and other standards.

Provincial Restrictions. Imports of liquor, wine and beer require prior authorization from the appropriate liquor commission before Customs will clear them.

Import Permits. Import Permits are issued under the authority of the Export and Import Permits Act. The Export and Import Controls Bureau (EICB) of the Department of Foreign Affairs and International Trade (DFAIT) is responsible for assisting importers to determine if import permits are required. Importing goods, which are on the Import Control List to Canada

for commercial or personal purposes, is controlled by a series of quotas and import licenses. Because the list is quite extensive, please refer to the following Canadian government Web site: *http://laws.justice.gc.ca/en/E-19/C.R.C.-c.604/index.html*.

Requirements related to the importing of goods, pertinent to environmental health and safety legislation, are presented in Chapter 2 of this book.

Canada Customs Compliance Measurement: Postrelease Verification A number of key industries in Canada operate in a highly competitive and political marketplace. For these industries, noncompliance with trade requirements by foreign or domestic competitors, and the resulting loss for both Canadian producers and legitimate Canadian importers can have a significant impact on their bottom line and ultimately on Canada's economy. As a result, when selecting priorities for the postrelease verification component of the first Compliance Improvement Plan, the CCRA has chosen to focus initially on the commodities within some of these industries, where there are historical issues related to noncompliance or where the consequences of noncompliance may be significant.

For example, CCRA has emphasized compliance in key industries—steel, textiles/apparel, footwear—and tariff rate quotas (e.g., for milk protein and certain chickens).

Random selections, based on sectors, importers, or programs are continuing to be made for postrelease verification purposes, as will monitoring of those where past verification activities have identified the need for improvement. In addition, the CCRA responds to any significant compliance issues that may arise throughout the year and will review and adjust its priorities annually based on results. Priority areas will also include all imports subject to the Special Import Measures Act. These imports are important because of the possible damage that dumped or subsidized imports could cause to Canadian producers.

6.4.3 Mexico

Key Import Requirements for Mexico The Government of Mexico has struggled with a variety of problems that has inhibited their entry to the world arena as a first-world economic power. These include corruption within the government's customs service and transportation infrastructure problems. However, Mexico has been making great progress in recent years with automation, making the Customs process less prone to corruption as well as improving the bridges and roadways.

Tariffs and Fees *Duties.* With entry into the North American Free Trade Agreement (NAFTA) on January 1, 1994, Mexico embarked on a progressive, scheduled reduction of tariffs on U.S. and Canadian goods. Mexican tariffs on U.S. goods currently are between 0 and 10 percent *ad valorem*, with an average

of 2 percent. At present, more than 80 percent of U.S. goods enter Mexico duty-free. Under the NAFTA, tariffs on U.S. goods will be phased out over a 10-year period with a few exceptions on selective products, mostly agricultural commodities, which will be phased out over a 15-year period. Prior to NAFTA, the average tariff facing U.S. goods entering Mexico was 10 percent; the average tariff on Mexican goods entering the United States was 2 percent.

Mexico has negotiated free trade agreements with many other countries, including the European Union, European Free Trade Area, Israel, and 10 countries in Latin America. The agreement with the European Union was modeled after the NAFTA and provides EU goods with rough NAFTA parity from 2003 onwards. Mexico is holding free trade discussions with additional Latin American and Far Eastern trading partners. Mexico's other trading partners will soon enjoy duty free treatment as with Canada and the United States.

Mexico also has implemented what are called "Sectoral Promotion Programs (PROSEC)" which will reduce MFN (Most Favored Nation) tariffs to 0 or 5 percent on a wide range of important goods and materials needed by Mexico's export manufacturing sector. This program includes some 20 different industry sectors and affects 16,000 tariff line items. Mexican companies must be registered under this program to participate, thus giving Far East exporters the ability to enter Mexico duty free or pay only 5 percent tariff, which diminishes the relative advantage enjoyed under NAFTA.

Under NAFTA, the import duty is calculated on the U.S./Canadian plant value of the product(s) (invoice) plus the inland freight charges to the border and any other costs listed separately on the invoice and paid by the importer such as export packing. All products imported definitively into Mexico no longer need to pay the customs processing fee (CPF). Products temporarily imported for processing and re-export may be subject to the CPF since the imports are not considered "definitive."

VAT. Mexico has, in addition, a value-added tax (IVA) on most sales transactions, including sales of foreign products. The IVA is 10 percent for products staying in the Mexican border region and 15 percent for products going to the interior of Mexico. Basic products such as food and drugs (but not processed foods) are exempt from the IVA. The 10–15 percent VAT is assessed on the cumulative value of the transaction as listed above, plus the duty. The importer pays other IVA fees for such services as the inland Mexico freight and warehousing. The IVA typically is recovered at the point of sale. The IVA may be waived for imports by a manufacturing plant registered under an approved Mexican government program (e.g., maquiladora plant).

Valuation. Where an "arms length" transaction does not exist between seller and importer, such as in intracompany sales or transfers, Mexico applies valuation rules that are compatible with the Brussels Customs Valuation Code. Goods for which the NAFTA preferential tariff treatment is not requested are valued on a C.I.F. basis. In November 1992, Mexico published a list of goods (with several subsequent updates and expansions) previously susceptible to fraudulent customs under-valuation and established a "minimum estimated

price" for such goods. Undervaluation is a rampant problem for emerging economies. Importers of some 200 subject goods (including categories of liquor, apparel, chemicals, footwear, steel, hand tools, appliances, plywood, apples, rice, and poultry, among others) must post a guarantee representing any difference in duties and taxes if the declared customs value is less than the established reference price. This guarantee usually is in the form of a cash deposit, trust, or line of credit established with an authorized bank, which charge high fees to open, manage, and close the accounts. Mexican government authorities then have up to six months to decide whether to start a formal investigation or to release the guarantee. U.S. exporters may expedite this review by providing an invoice certified by their local chamber of commerce. Exemptions from this regulation exist for active or highly capitalized importers. This policy is subject of negotiations between the U.S. and Mexican governments, with the United States claiming it to be a violation of World Trade Organization (WTO) rules.

Import Licenses The Secretariat of Economy requires import licenses for a number of sensitive products, including endangered species and weapons. Also, the Secretariat of Agriculture requires prior import authorization for fresh/chilled and frozen meat. For the importation of certain foods, the Secretariat of Health requires either an "advance sanitary import authorization" or "notification of sanitary import."

To be eligible to import well over 400 different items, including agricultural products, textiles, chemicals, electronics, and auto parts, Mexican importers must apply to the Secretariat of Finance and Public Credit (Hacienda) and be listed on a special industry sector registry. Problems are encountered when products are added to the list without notice or importers are summarily dropped from the registry without prior notice or subsequent explanation.

Import Documentation The basic Mexican import document is the "pedimiento de importacion" or more simply the "pedimento." This document must be accompanied by a commercial invoice (in Spanish), a bill of lading, documents demonstrating guarantee of payment of additional duties for undervalued goods (see "Customs Valuation") if applicable, and documents demonstrating compliance with Mexican product safety and performance regulations (see "Standards"), if applicable. The import documentation may be prepared and submitted by a licensed Mexican customs house broker or by an importer with sufficient experience in completing the documents.

Products qualifying as North American must use the NAFTA Certificate of Origin in order to receive preferential treatment. This must be issued by the exporter (not the seller!) and does not have to be validated or formalized.

According to the Mexican customs law, the long-standing rule mandating participation of a customs broker is no longer required. However, use of a customs broker is recommended unless the importer is very familiar with Mexico's customs regulations. Mexican customs law is very strict regarding

proper submission and preparation of customs documentation. Errors in paperwork can result in fines and even confiscation of merchandise as contraband. Exporters are advised to ensure that Mexican clients employ competent, reputable Mexican importers or customs house brokers. Because customs brokers are subject to sanctions if they violate customs laws, some have been known to be overly restrictive in their interpretation of Mexican regulations and standards.

Temporary Importations Demonstration equipment may be imported under a temporary importation bond (TIP), provided the following basic requirements are followed:

- The equipment must be declared to Mexican Customs at the time of entry into the country, by completing a request to temporarily import equipment (Pedimento de Importacion Temporal).
- The importer must provide a letter from the foreign owner of the equipment, affirming that the demonstration equipment is for temporary entry into Mexico and will not be sold.
- The importer must provide a letter from the Mexican business (recipient of the equipment, if not the same as the foreign owner) indicating that they take full responsibility for ensuring that the demonstration equipment is returned to the United States within the period allowed. The letter also should indicate that there is a business relationship between the Mexican party and the importer.
- A fee must be paid in cash to Mexican Customs (currently $135 pesos).

If the shipment is from the United States, the list of equipment being taken into Mexico must also be presented to U.S. Customs before entering Mexico to ensure its duty-free return to the United States.

Failure to declare demonstration equipment upon entry entails stiff penalties including confiscation of equipment and/or costly fines.

Standards Under Chapter IX of the NAFTA, Mexico, the United States, and Canada agreed to provide national treatment in standards related issues. National treatment simply means that locally manufactured products will have to comply with the same requirements as imported ones. Mexico has also affirmed its WTO (GATT) obligations to adopt international standards whenever possible. The extent to which these international standards are compatible with North American standards varies by industry sector. Even if Mexican standards are compatible with those of the United States and Canada, companies must show compliance with mandatory Mexican standards, known as Normas Oficiales Mexicanas (NOMs). The Mexican government generally recognizes as international standards those issued by the ISO/IEC. These standards tend to favor European manufacturers.

The cornerstone of conformity assessment in Mexico is the 1992 Federal Law of Metrology and Standardization (as amended on December 24, 1996, and May 20, 1997), which provides for greater transparency and access by the public and interested parties to the mandatory standard formulation process. Another key document is the regulations to the Federal Law of Metrology published on January 14, 1999. Poorly drafted regulations and inadequate communication between enforcement agencies have occasionally led to trade disruptions. Over the past 6 years, the number of trade disruptions over standard matters has gradually decreased; however, some serious disruptions still occur.

Further to a 1992 law, all mandatory standards had to be reissued as NOMs. As of July 2001, there are over 690 NOMs in effect and the number goes up weekly. A certificate of compliance with mandatory standards is required for the importation into Mexico of many goods and different types of merchandise. Harmonized tariff system (HTS or HS) code numbers lists specific NOM requirements. Not all HTS code numbers have mandatory standards assigned. The Mexican government publishes lists and updates of HTS code numbers with the corresponding NOMs. The Ministry of the Economy publishes the main list. The same lists describe the situations under which products and merchandise do not have to comply with mandatory standards. These circumstances are described under Article 10 of the document and include shipments valued at less than US $1000, goods intended for use in maquila and other industrial operations, samples, and others.

In addition to mandatory standards (NOMs), there are numerous voluntary standards known as Normas Mexicanas or NMXs. As of July 2001 there are over 6000 valid NMXs in Mexico. NMXs become mandatory for importation purposes when they are referred to in a NOM. The current trend in Mexico is to update and develop new NOMs using and quoting existing NMXs. This practice is consistent with the WTO agreements on standard related measures.

The common feature of most labeling requirements is that package labels must carry commercial information in Spanish. If the required information appears in a language other than Spanish, then this information must appear in Spanish in the same size font, format, and clarity as it appears in the other language. Consequently, many of the labels added to packages in the past for the Mexican market are no longer acceptable. However, placing stickers over information preprinted on a package or label is permitted as long as the resulting label complies with the labeling requirements. Additionally, labels can be applied or modified in Mexico provided that the process complies with Mexico's verification procedures.

Additionally, a comma must be used as a decimal point in the quantity declaration on packages. Imported products using a period as a decimal point are likely to be rejected by Mexican Customs officials. Accredited verification units exist in Mexico, where companies can obtain an evaluation of their labels prior to export to Mexico for a small fee.

Examples of commercial information follow below. Not all products are required to have all of the information. The applicable NOM for a specific product must be referenced to determine what is required.

- Name or business name, address and fax number of the importer
- Name or business name of the producer of an imported product
- Trademark or commercial name brand of the product
- Net contents (note that a comma must be used as the decimal point)
- Expiration date (required for prepackaged foods and nonalcoholic beverages) or date of recommended consumption
- Use, handling, and care instructions for the product as required
- Warnings or precautions on hazardous products
- Country of origin
- List of ingredients

This information must be on the packages or the products as presented for retail sale. Listing this information on the container in which a good is packed for shipment will not satisfy the labeling requirement.

Mexican Customs brokers and agents generally have the information about NOMs to import into Mexico as well as other regulatory requirements for importation. Importers may find that the research and language skills necessary for accurate and compliant shipments to be overwhelming. Hiring a good broker who has familiarity with the very complex requirements is recommended.

6.4.4 European Union

The European Union is a single market, which means that goods, capital, services, and people can move freely among its 15 member countries. Member countries currently include Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, and the United Kingdom. Countries that are candidates for the EU include Bulgaria, Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Macedonia, Poland, Romania, Slovak Republic, Slovenia, and Turkey.

Compliance regulations and market requirements of international standards, marking, label and certifications are shared among the members. The European Union is currently operating under a unified customs system and member countries must adhere to EU import procedures and rules. Each country has some flexibility to impose its own processes and restrictions according to individual needs and desires. Therefore, individual countries within the EU may have slight variations in regulations and requirements. The value of research and due diligence due to these variations as well as revisions to the EU laws and regulations cannot be emphasized enough. See Appendix 4 for links to Customs Web sites for European Union member countries.

Documents Required The official model for written declarations to customs under "normal procedure" is the Single Administrative Document (SAD). Other forms may be used for this purpose where the provisions of the customs procedure in question permit.

Additional information on import/export documentation can be found in Title III, of Council Regulation (EEC) No. 2913/92 of October 12, 1992, establishing the Community Customs Code (Articles 37 through 57).

Goods brought into the customs territory of the Community are, from the time of their entry, subject to customs supervision until customs formalities are completed.

Goods presented to customs are covered by a summary declaration that is lodged once the goods have been presented to customs. The customs authorities may, however, allow a period for lodging the declaration that cannot be extended beyond the first working day following the day on which the goods are presented to customs. The summary declaration can be made on a form corresponding to the model prescribed by the customs authorities. However, the customs authorities may permit the use, as a summary declaration, of any commercial or official document that contains the particulars necessary for identification of the goods. The summary declaration may also be in computerized form.

The main documents that the importers/exporters are required for the compliance of Customs regulations in the European Union are following:

Commercial Invoice. For the customs clearance in EU, a commercial invoice is to be provided to the officials and it should contain a clear and precise description of the product, terms of sale and all details necessary to establish the full cost, insurance and freight price. The commercial invoice should include:

- Date and place of shipment
- Name (firm's name) and address of the seller and buyer
- Method of shipment
- Number, markings of the packages, and their numerical order
- Description of the goods using the usual commercial description according to kind, quality, grade, and the weight (gross and net in metric units), along with any factors increasing or decreasing the value
- Agreed price of goods; unit cost; total cost FOB factory plus shipping; insurance charges; delivery and payment terms
- The signature of a responsible official of the shipper's firm

Bill of Lading. One copy of bill of lading (or airway bill) is required for the customs clearance in the EU. Bills of lading should bear the name of the party to be notified. The consignee usually needs the original bill of lading to take possession of the goods.

Certificate of Origin. This certificate is to be provided in case of few goods

such as textile products subject to quota restrictions. The need for a certificate of origin should be verified directly from the importer or from the appropriate customs authority. Sometimes, it is specified in terms of letter-of-credit terms that a certificate of origin be provided.

Origin rules are either preferential or nonpreferential in nature. Nonpreferential rules of origin, which are contained in the Customs Code (Council Regulation No. 2913/92/EEC, Articles 22–26 and Commission Regulation No. 2454/93/EEC Articles 35–65), apply when no tariff preferences are involved and when other trade measures—such as antidumping duties—need to specify a particular nontariff treatment for goods from a given country.

Specific rules of origin for textiles and textile articles are found in the section on nonpreferential origin (Commission Regulation No. 2454/93/EEC, Articles 36–38).

There are many rules that determine the origin of products made from nonoriginating components, but perhaps the most recognizable definition pertaining to nonpreferential origin is Article 24 of the Customs Code, Council Regulation No. 2913/92/EEC:

> *Goods whose production involved more than one country shall be deemed to originate in the country where they underwent their last, substantial, economically justified processing or working in an undertaking equipped for that purpose and resulting in the manufacture of a new product or representing an important stage of manufacture.*

Preferential rules of origin vary according to the legislation granting preference. Each bilateral or multilateral trade agreement with the EU has its own specific rules of origin.

Origin marking (e.g., "Made in the EU" or "Made in USA") should not be confused with Rules of Origin for customs purposes. There is no EU requirement for goods to bear marks indicating their origin, nor is there anything to prevent voluntary origin marking where traders wish to do so (European Union, 2003).

Export/Import License. The import license is needed mostly for agriculture and food items, coal and lignite fuel, a few specified base metal products such as steel products, various apparel and textile products (under the rules of MFA), and controlled items such as arms and ammunitions. The import licenses are mostly non-transferable and they may be used to cover several shipments within the total quantity authorized. The goods are identified on the license using the harmonized system classification number and the corresponding wording of the tariff position.

Licenses are usually issued up to a set quota limit each year and can be either export-administered or import-administered. The Department of Trade and Industry issues these licenses. If the product falls under MFA and it is subject to import quota, the exporter has to give the importer an export license so that importer may obtain an import license. The delay in the issuance of

license is generally due to lack of proper documentation or information provided in the requisite form.

Summary Declaration. The summary declaration is to be filed by a person who brought the goods into the customs territory of the Community or by any person who assumes responsibility for carriage of the goods following entry. Non-EU goods presented to customs must be assigned a customs-approved treatment or use authorized for such non-community goods. Goods that are either carried by sea or other than by sea are required to get customs-approval for treatment or use with in 45 days or 20 days, respectively, from the date on which the summary declaration is filed. In some cases, the customs authorities may set a shorter period or authorize an extension of the period.

Phytosanitary Certificates. When products like fresh fruits, vegetables, and other plant materials are to be exported than the EU countries require phytosanitary certificates. This certificate verifies that the product left the exporting country in a healthy condition. The authorized (food) inspection department of the country of origin has to inspect the product to ensure that it is free of insects and disease.

Customs Valuation The primary basis for determining customs value set out in EU regulations is "the transaction value, that is, the price actually paid or payable for the goods when sold for export to the customs territory of the Community."

The following conditions must be met in determining customs value:

- That there are no restrictions as to the disposal or use of the goods by the buyer, other than restrictions which are imposed or required by a law or by the public authorities in the community, that limit the geographical area in which the goods may be resold, or do not substantially affect the value of the goods.
- That the sale or price is not subject to some conditional consideration for which a value cannot be determined with respect to the goods being valued.
- That no part of the proceeds of any subsequent resale disposal or use of the goods by the buyer will accrue directly or indirectly to the seller.
- That the buyer and seller are not related or where the buyer and seller are related, that the transaction value is acceptable for customs purposes.

The "price actually paid or payable" in the regulation refers to the price for the imported goods. Thus the flow of rebates or other payments from the buyer to the seller that do not relate to the imported goods are not part of the customs value.

Adjustments to the value for customs purposes are charges that are added to the customs value, such as, commissions and brokerage, costs of containers, packing, royalties and license fees, and the value of goods and services sup-

plied directly or indirectly by the buyer in connection with the production and sale for export of the imported goods. However, some charges are not included in the customs value, such as, charges for transport, charges incurred after importation, charges for interest under a financing arrangement for the purchase of the goods, charges for the right to reproduce imported goods in the European Community, and buying commissions.

Customs Duty Customs duty is a pan-European tax levied on goods produced outside the EU when they are imported into the EU for consumption. The law on EU customs matters generally is enacted by the EC, but administered by the various EU states' customs authorities. As a result of this, for example, the rate of duty for any given product should be the same no matter which EU state the goods are imported. Duty rates are set annually by the EC, effective from January 1 to December 31 each year and are published in a Customs Tariff issued by each EU member state. The EU rate of duty applicable to any given product is determined by its classification (description) for customs purposes. The EU Customs Tariff contains some 14,000 classifications in the form of 10-digit Customs Commodity Codes (CCCs), with duty rates of between 0 percent and 85 percent, with an average of between 3 percent and 13 percent. Duty once paid is not usually recoverable by the importer and, therefore, constitutes a bottom line cost to importing businesses. Any reduction or increase in duty will therefore increase or decrease profit to the same extent.

Classification The correct classification for any product may need reference to a number of EC regulations and guidelines. In addition to the full rate of duty, a classification indicates any preferential rates available (if goods originate in certain countries) or any additional (antidumping) duties that may apply. Any particular duty relief or restrictions such as import licensing will also be indicated via the classification.

An incorrect classification may result in too much or too little duty being paid with recovery by a business, or Customs, normally limited to three years in retrospect. Either situation could affect the competitiveness or profitability of the product concerned. Where there is a possible doubt concerning the correct classification of a product, importers can apply to the EC Customs authorities for a written classification decision, known as Binding Tariff Information (BTI).

A BTI is legally binding on the customs administrations of all EC member states and provides certainty regarding a product's classification for a period of up to six years. Once such a BTI is issued, however, it is extremely difficult to effect a change in that ruling (involving a formal review and appeal process). Businesses would be well advised, therefore, to investigate possible alternative classifications, together with the attendant duty implications before embarking on a BTI application.

The cautionary note above applies to imports into any EU state. With

increasing co-operation between the EU Customs authorities, a problem or difficulty with an import into one EU state may quickly become a problem at import into any other EU state (Grant Thornton, 2003).

Prohibited Items These bans are mainly applicable on trade of dangerous products such as chemical waste. In some of member countries of EU such as Austria, Denmark, Greece, and Sweden, the import of toys and accessories (for children under three years of age) made from the plastic, polyvinyl chloride is banned.

There are some other items, which are banned in EU due to safety and health considerations, such as medicines, pesticides, plants and foodstuff, electrical products and exotic animals and plants. The European Commission for Norms (CEN) and European Committee for Norms for Electrotechnical goods (CITES) are the regulatory bodies for movement of these items in the EU.

Restricted Items The foreign trade of the EU can be considered as principally liberalized. There are, however, exceptions and restrictions in the form of import quotas, surveillance measures, and safeguard measures against dumping and illegal subsidies.

Imports of products originating in countries where the cost of production is unusually low can be subjected to import quantity limitations. Quantitative restrictions in terms of amount of products allowed into the Community are limited and normal customs duties are paid.

All these restrictions are based on a double control system. The national authorities in the EU member states issue the import license upon presentation of the export license of the respective exporting country. Certain iron and steel products require an import document or license. Once issued this document is valid throughout the EU. Some agricultural products such as wine, milk, wheat, meat, rice and products thereof require import licenses.

In case of exports of textile and clothing the customs authority may ask for the import license. Sometimes, at the point of entry documentary proof of origin may be required.

There are three categories of origin proof required: textile certificate of origin, certificate of origin, or evidence of origin (including invoice declaration).

Additional information regarding environmental health and safety requirements related to import of goods is presented in Chapter 2—Chemical Registration, Notification, and Listing.

Import Tariff Quotas In the following section, examples of quota restrictions levied in the EU are presented.

Frozen beef import quota. An amount of frozen beef and veal is imported with no levies every year. This quota is allocated on the basis of past trading patterns. Each quarter the Commission allows some traders to import frozen

beef for processing, either levy-free or at reduced rates. To qualify, traders must have been involved in manufacturing eligible products for the last 12 months.

Bananas. There is a quota restriction on imports of bananas. Licenses are allocated to established traders and based on earlier banana import patterns, but some quota is set-aside for newcomers based on imports of fresh fruit and vegetables.

Chinese garlic. Imports are limited to a monthly quota allocated to established traders.

Mushrooms. Certain mushrooms can be imported at a reduced tariff. There is a quota that is allocated to established traders according to earlier trade patterns, but some new traders can join.

Pork, eggs, and poultry. There are a number of preferential import quota schemes available if certain qualifying conditions are met. Each quarter, the Commission grants either levy-free or reduced levy import licenses.

Wine. A license is required to import wines from non-EU countries.

6.4.5 Australia

Documentation The minimum documentation required to be submitted with customs import entries or Informal Clearance Documents includes an air way-bill or bill of lading, invoices, and any other papers (including packing lists, insurance documents, etc.) relating to the shipment.

Australian law requires importers to retain commercial documents relating to a transaction for five years from the date of entry. These documents may be required for Customs audit purposes. Failure to meet the requirement may cause a penalty of Australia $2000.

The customs audit is the primary tool in Customs' Commercial Compliance program which aims, through a partnership with industry, at improving overall compliance levels.

Valuation While there are several methods of valuing goods for Customs purposes, the method most applied (transaction value) is based on the price actually paid (or payable) for the imported goods subject to certain adjustments. A major condition for using the transaction value is that there is no relationship between the buyer and seller which may influence the price. Valuation of imported goods can be complex and importers are urged to seek advice from a customs broker, agent, or to contact Australian Customs.

Duty Rates Rates of duty payable by an importer are determined by the classification of goods within the Australian Customs Tariff. Because the tariff contains more than 5000 headings and subheadings, it is impossible to list specific rates here. In some circumstances, antidumping or countervailing measures, which result in the imposition of additional rates of duty, may also apply. Advice on general duty rates can be obtained from every Australian

Customs Information Centre, and this is best done before goods are ordered from overseas.

Indirect Taxes Imported goods may be subjected to one or more indirest taxes. These indirect taxes comprise the goods and services tax, the wine equalization tax and the luxury car tax.

Goods and Services Tax (GST). GST applies to most imported goods. There are few exemptions from the GST, the main ones being certain basic foodstuffs, some medical aids and appliances, and imports that qualify for certain customs duty concessions. GST is applied at 10 percent of the value of the taxable importation. The value of the taxable importation is the sum of:

- customs value of the imported goods
- any customs duty payable
- amount paid or payable to transport the goods to Australia and to insure the goods for that transport
- any wine tax payable

Wine Equalization Tax (WET). WET applies to the following alcoholic beverages:

- grape wine products such as marsala, vermouth, wine cocktails, and creams
- other fruit wines and vegetable wines, including fortified fruit wines and vegetable wines
- cider and perry
- mead and sake, including fortified mead.
- grape wine, including sparkling wine and fortified wine

Luxury Car Tax (LCT). LCT applies to motor vehicles (except motor cycles or similar vehicles) that are designed to carry a load of less than two tons and fewer than nine passengers and those which are above a certain value. The definition of a car for LCT purposes includes limousines regardless of the passenger carrying capacity.

The Australian Business Number If importers have an Australian Business Number (ABN) they will need to supply it to Customs when formally entering goods. Importers need to be registered for GST purposes and have an ABN in order to claim input tax credits or access the GST deferral scheme.

Commerce Trade Descriptions Importers are required to ensure that goods entering the commerce of Australia are correctly marked. Australian Customs administers truth in labeling provisions that make it an offence to knowingly apply, or for imported goods to carry, false trade descriptions.

A false trade description means any description that by addition, deletion,

or any other treatment is likely to mislead on matters such as weight, origin, manufacturer, preparation, contents, copyright, etc. Trade description markings must be in English; in prominent and legible characters; on a principal label or brand attached to the goods in a prominent position in a manner as permanent as is practicable; and in certain circumstances include the country of origin.

Goods Subject to Import Controls Table 6.1 presents a partial list of categories of goods subject to import control and the names of the relevant authorities to contact.

TABLE 6.1. Partial List of Categories Subject to Import Control

Category of Goods	Relevant Authority
Certain drugs and goods containing those drugs—hazardous and health related manufactured articles and substances	Department of Health and Aged Care
Animals and animal products—food and plant imports	Australian Quarantine and Inspection Service, Imported Food Inspection Service
Firearms—other weapons	Australian Federal Police (Capital Cities), Local (State) Police Authorities, Australian Customs Service
Protected wildlife (animals) and related products	Environment Australia
Protected cultural heritage items	Department of Communications, Information Technology and the Arts
Motor vehicles	Department of Transport and Regional Services
Restricted trading (certain countries)	Department of Foreign Affairs and Trade
Labelling of goods	Consumer Affairs Division, Department of the Treasure
Intellectual property	IP Australia, Attorney General's Department, Australian Customs Service
Currency	Australian Transaction Reports and Analysis Centre
Woolpacks	IP Australia, Australian Wool Exchange, Department of Agriculture, Fisheries and Forestry

Hazardous/Dangerous Goods Goods subject to prohibition or restriction are many and varied and sometimes bizarre. They may include items, goods, and substances as diverse as the following:

- certain breeds of dogs
- toys and other articles containing quantities of lead, mercury, arsenic or their compounds which exceed prescribed limits
- explosives
- flamethrowers
- daggers capable of being concealed
- hand-held battery-operated devices designed to administer an electric shock
- blowpipes
- pistol crossbows
- nunchakus
- shuriken throwing irons or stars
- protective jackets and vests
- erasers resembling food
- firearms, parts, and ammunition including replicas
- disposable cigarette lighters that do not meet the construction and performance standards, including child-resistant features.

Import Permit Controls Where goods are subject to import controls under the Australian Customs (Prohibited Imports) regulations, the importers must apply to the appropriate department or agency for a permission to import.

The permission to import must be obtained prior to the goods arriving in Australia. Failure to obtain the permission to import prior to the arrival of the goods may result in the forfeiture of the goods.

Intellectual Property Rights Australian Customs is tasked with administering certain provisions of the Copyright Act 1968, the Trade Marks Act 1995, and the Sydney 2000 Games (Indicia and Images) Protection Act 1996 to protect the intellectual property rights of individuals, companies, and corporations.

The owner or authorized licensee of copyrightable goods or a trademark can object to the importation of goods that allegedly infringe their intellectual property rights. This is done through lodging a Notice of Objection with Customs listing the trademarks or goods in which they can claim copyright.

Once a Notice of Objection has been accepted, Customs has the power to seize imported goods that may infringe the intellectual property rights of the objector and to hold them for a specified period during which the objector must commence action against the importer in the Federal Court. Importers may, if they wish, forfeit infringing goods to Customs before legal action has commenced. Customs' role in the enforcement of intellectual property legislation is limited to imported goods that have not been released from Customs' control.

The issue of intellectual property rights enforcement at the Customs "border"

is complex because trademarks and copyright may exist in labels, logos, and images as well as in more traditionally recognized works such as books, sound recordings, films, designs, computer software, etc. These goods may also subject to the truth in labeling provisions.

Copyright and trademark owners whose rights are infringed have options once goods are in the market place. These include both civil remedies and criminal prosecution. Civil litigation is the most common form of intellectual property rights enforcement. Effective criminal prosecution invariably requires police involvement, usually with the Australian Federal Police, although the relevant acts do not name a specific enforcement agency. Customs has no role in enforcing intellectual property rights in the market place.

Customs is not responsible for the formulation of government policy relating to intellectual property rights. Policy in relation to the Copyright Act 1968 rests with the Attorney General's Department and the Department of Communications, Information Technology and the Arts. IP Australia, a specialized division of the Department of Industry, Science and Resources is the agency responsible for the Trade Marks Act 1995 and the Sydney 2000 Games (Indicia and Images) Protection Act 1996.

Assistance Importers are able to clear their own goods and should contact the nearest Customs Information Centre for advice on Customs requirements and operating hours. However, the Australian Customs Service does not complete customs import entries on behalf of importers.

Customs import entry procedures are based on self assessment by importers who should be aware of all their obligations. Penalties may be imposed for the submission of incorrect or misleading information or for the omission of information to mislead. Therefore, while it is not a requirement, it is recommended that importers use the services of a customs broker to complete customs import entries and related clearance formalities.

Brokers specialize in the clearance of imported goods and are licensed by Customs. They may be contacted by reference to the yellow pages of local telephone directories under "customs brokers" or by contacting the local branch of the Customs Brokers Council of Australia.

Clearance For at least 15 hours per day (excluding national public holidays) Customs electronic systems provide an almost instantaneous service for import entries without impediment (approximately 98 percent of all entries). All but a small percentage of brokers are connected to Customs electronic systems.

Individual importers are also able to connect to Customs electronic system, COMPILE, via the Internet utilizing a VPN (Virtual Private Network) facility. Importers electing to complete their own customs import entries for goods arriving by air, sea, or post can also lodge documentary (manual) entries at an Australian Customs Service Entry Processing Section in their state. A time-

frame for documentary entries cannot be guaranteed—at least one full working day should be anticipated. In a small number of cases, cargo is selected for physical examination. While these checks are conducted as expeditiously as possible, delays may be caused in the release of goods.

6.4.6 China

Import Licensing Since the early 1990s, China has eliminated many import license requirements, a process that is likely to continue as preparations are made for China's WTO accession. However, many products subject to import quotas also require import licenses, including some wool, grains, oilseeds and oilseed products, cotton, iron and steel products, commercial aircraft, passenger vehicles, fertilizer, hauling trucks, and rubber products. MOFTEC administers the licensing system, but as of late 1999 had given primary authority for approval and import of some agricultural items to the State Administration for Entry-exit Inspection and Quarantine (SAIQ). Import licenses are not easy to come by. The applicant must prove that the import is "necessary" and that there is sufficient foreign exchange available to pay for the transaction.

Documentation Normally, the Chinese importer (agent, distributor, or joint-venture partner) handles the documentation requirements. Necessary documents include the bill of lading, invoice, shipping list, sales contract, an import quota certificate for general commodities (where applicable), import license (where applicable), inspection certificate issued by the State Administration for Import and Export Commodity Inspection (SACI) or its local bureau (where applicable), insurance policy, and customs declaration form.

Prohibited Imports The following items are prohibited from entering China:

- Counterfeit currencies and counterfeit negotiable securities
- Printed matter, magnetic media, films, or photographs, which are deemed to be detrimental to the political, economic, cultural, and moral interests of China
- Lethal poisons
- Illicit drugs
- Disease-carrying animals and plants
- Foods, medicines, and other articles coming from disease-stricken areas
- Old/used garments
- Food containing certain food colorings and additives deemed harmful to human health by the Ministry of Health

In addition, new rules went into effect in June 1999, which further restrict or prohibit the importation of certain commodities related to the processing trade. Jointly issued by MOFTEC and the State Economic and Trade

Commission, the "Catalogue of Commodities Which Are Restricted or Prohibited from Importing for Use in the Processing Trade" is designed to shift the direction of China's processing trade toward handling commodities with higher technological content and greater value-added potential.

The catalog identifies the following "prohibited commodities": used garments; used publications with licentious content; radioactive or harmful industrial waste; junk cars, used automobiles, or components; seeds, seedlings, fertilizers, feed, additives, or antibiotics used in the cultivation or breeding of any export commodity. The catalog also lists seven general types of "restricted commodities": raw materials for plastics, polyester sections, raw materials for chemical fibers, cotton, cotton yarn, cotton cloth, and some steel products. Companies should contact the China General Administration of Customs for guidance regarding the import of any of these types of products.

Customs Information and Import Documentation *Valuation.* Problems at the port of entry most commonly result from misclassification of the import or an insufficient understanding by the local customs inspector of customs regulations or policies. For this reason, cases are often referred to customs headquarters for review, a process that can often take several months. In cases where the foreign company's investment in China is substantial, the Ministry of Foreign Trade and Economic Cooperation (MOFTEC) has sometimes becomes involved in these appeals.

Labeling and Marking Requirements. Under Chinese law governing safety and product-quality standards, certain imported commodities must be inspected and certified to be in compliance with compulsory national, domestic trade or contractually stipulated standards. Once a quality certificate for a product is issued, a safety label can be affixed.

All products sold in China must be marked—in the Chinese language—with relevant information. The National Health and Quarantine Administration require imported (but not domestic) food items such as candy, wine, nuts, canned food, and cheese to be affixed with a laser sticker evidencing the product's safety. Importers are charged US$ five to seven cents per sticker, and the stickers must be affixed under State Administration.

Food Labeling Law. As of October 1, 1995, a national Chinese regulation was put into effect for the implementation of food label standards. This Chinese law requires that all packaged food products (except bulk) must have Chinese labels clearly stating the type of food, brand name, trademark, manufacturer's name and address, country of origin, ingredients, date of production, and sell-by date. This law applies to imported as well as locally packaged products. English-language versions of the new regulations and other rules about food additives, such as Food Laws, Labeling Requirements, Food Additives Regulations, Pesticides and other Contaminants, Organic "Green" Food Standards, and Copyright/Trademark can be obtained in the Food and Agricultural Import Regulations and Standards Report (FAIRS). This report can be accessed via http://www.fas.usda.gov, report number CH9010.

6.4.7 Japan

Japanese Import Procedure Any person wishing to import goods must declare them to the Director-General of Customs and obtain an import permit after necessary examination of the goods concerned. The formalities start with the lodging of an import declaration and end with the receipt of an import permit after the necessary examination and payment of Customs duty and excise tax. In this way, measures are taken to ensure compliance of the requirements for the control of foreign exchange and other regulations concerning the importation of goods.

The procedure for submitting declaration documents to Customs—a basic procedure of import clearance—is explained below. More than 90 percent of import clearance is currently computerized.

Completion and Submission of Import Declarations Lodging an import declaration that describes the quantity and value of goods as well as any other required particulars constitutes a declaration. This import declaration must be made, in general, after the goods have been taken into a Hozei area or other specially designated place. A Hozei is a designated Customs examination area/warehouse that adds to the overall costs associated with importing to Japan. However, in the case of specific items, which need the approval of the Director-General of Customs, the declaration may be made while they are located aboard a ship or barge or before they are taken into a Hozei area.

Reporting Requirements. The person who is importing the goods must make import declarations, in principle. Usually, a customhouse broker files the declaration as a proxy for importers.

Documentation. An import (Customs duty payment) declaration form (Customs form C-5020) must be prepared in triplicate and submitted to Customs with the following documents:

- invoice
- bill of lading or air waybill
- certificate of origin (where a WTO rate is applicable)
- generalized system of preferences, certificates of origin (Form A) (where a preferential rate is applicable)
- packing lists, freight accounts, insurance certificates, etc. (where deemed necessary)
- licenses, certificates, etc. required by laws and regulations other than the Customs Law (when the importation of certain goods is restricted under such laws and regulations)
- detailed statement on reductions of, or exemption from Customs duty and excise tax (when such reduction or exemption is applicable to the goods)
- customs duty payment slips (when goods are dutiable)

In principle, Customs requires only those additional documents necessary to determine details of those documents listed above.

Prohibited Articles Japanese law prohibits the following articles:

- Opium, other narcotic drugs, utensils for opium smoking, stimulants, and psychotropic substances (excluding those designated by an ordinance of the Ministry of Health and Welfare)
- Firearms (pistols, rifles, machine guns, etc.), ammunition (bullets) for such articles, and pistol parts
- Counterfeit, altered or imitation coins, paper money, bank notes, or securities
- Books, drawings, carvings, or any other articles which harm public security or morals (obscene or immoral materials, such as pornography)
- Articles which infringe upon rights in patent, utility models, designs, trademarks, copyrights, neighboring rights, or layout designs of integrated circuits

Some goods imported from abroad are considered to have potential negative affects on Japanese industry, economy, health, hygiene, or on public safety and morals. Such goods fall under "import restrictions" as provided by various domestic laws and regulations.

In the case of restricted imports for which the importer must have a permit and approval relating to the importation of goods under the Customs Law, which stipulates conditions for a permit, approval, or disposal to be taken by administrative bodies, requirements for inspection or other requisites (hereinafter referred to as a permit and approval) must be met.

Therefore, when goods for import require a permit and approval under laws and regulations other than the Customs Law (called other laws and regulations), a certificate of application for a permit and approval under other laws and regulations must be submitted (Article 70 of the Customs Law):

1) Foreign Exchange and Foreign Trade Control Law
2) Laws and Regulations Related to Banned Goods:
   - Firearms and Swords Possession Control Law
   - Poisonous and Harmful Substance Control Law
   - Pharmaceutical Affairs Law
   - Silk Farming Law
   - Fertilizer Control Law
   - Explosive Control Law
   - Law Concerning Screening of Chemical Substances and Regulation on their Manufacture, etc.
   - High-Pressure Gas Safety Law
   - Law Concerning Wildlife Protection and Hunting

3) Laws and Regulations Concerning Government Monopoly:
   - Alcohol Monopoly Law
4) Laws and Regulations Concerning Quarantine:
   - Food Sanitation Law
   - Plant Quarantine Law
   - Domestic Animal Infectious Control Law
   - Rabies Prevention Law
5) Laws and Regulations Concerning Narcotics:
   - Cannabis Control Law
   - Stimulant Drug Control Law
   - Narcotics and Psychotropic Control Law
   - Opium Law

Prearrival Examination System *1. Outline of the Pre-Arrival Examination System.* Importers are required to declare their imports to Customs after the cargo arrives from foreign countries and bring them into a Hozei area (Customs Law, Article 67-2).

Generally, Customs inspects the content of each import declaration. The inspection can start only after the cargo is brought into a Hozei area. The pre-arrival examination system was established to flexibly manage these requirements and allow an import permit to be issued immediately after the import declaration is presented as long as physical examination is not required. Under this system, examinations are conducted before cargo is brought into a Hozei area.

2. Specific Procedures. The specific procedures of the pre-arrival examination system are as follows:

Cargo Covered by the System. The pre-arrival examination system can be applied to all types of imported cargo. The cargo which benefit from the pre-arrival examination system are, needless to say, those in need of quick processing, namely:

1) Those shipments that require speedy clearance due to the nature of the content, such as fresh food.
2) Those under strict delivery terms.
3) Those with a seasonally limited selling market, such as Christmas and New Year's goods, etc.
4) Those requiring procedures under other laws and regulations.
5) Those requiring extensive examination of import declarations, such as items requiring various documents.
6) Those on which the required documents are available in advance.
7) Those requiring long-distance sea transport or to be transported with approval of Customs transit.
8) Cargo imported on a regular basis.

Document to Be Submitted. A pre-arrival declaration is completed through the submission of a pre-arrival declaration form, and a general import (duty payment) declaration form is used. Document to be attached to the pre-arrival declaration form are the same as the documents attached to the declaration (duty payment) form of regular imports.

Customs Office for the Submission of Documents. A pre-arrival declaration form should be submitted to the Customs office that controls a certain Hozei area where cargo is expected to be brought in. However, if the Director-General of Customs approves the submission of a preliminary declaration from to other Customs office, regional Customs can utilize a different procedure upon consultation with the Customs and Tariff Bureau.

Submission Time. A pre-arrival declaration can be made at any time after the bill of lading (airway bill in the case of air cargo) related to the pre-arrival declaration is issued, and after the foreign exchange rate for the scheduled date of import declaration is announced.

Current exchange rates against the U.S. dollar, the Sterling Pound and other major foreign currencies are normally announced around Tuesday of the previous week. As soon as the documents to be submitted are ready, and declared items are understood, the pre-arrival declaration can be made as early as 11 days before the arrival of the cargo.

Import Declaration. When cargo is brought into a Hozei area for preliminary declaration Customs can then treat the pre-arrival declaration as an import declaration if all requirements are met for the import declaration under the Customs Law, such as the completion of the procedures required under other laws and regulations and the importer informs Customs of the import declaration.

Customs Duties The Japanese Customs Tariff is based on the Harmonized System (HS) of classification. Exceptions are in place for certain raw materials, (essential items of industrial equipment and antiques as well as agricultural tractors, machine tools, cars, home appliances, books, etc) and imports are liable to Customs duties. On most dutiable items there is a WTO rate and some items have temporary reduced rates of duty. Most goods are subject to *ad valorem* Customs duty based on the CIF value.

Additional Taxes From 1 April 1989 the commodity tax, which was levied mainly on luxury goods, was abolished and the consumption tax (5% on all goods sold in Japan) was introduced. The consumption tax is levied at every stage in the distribution chain and is payable on imports at the same time as import duty. The government is currently looking into proposals for exemption from the tax for certain goods, for example, food and children's clothes, but nothing has been finalized.

AntiDumping and Countervailing Duties Most goods enter Japan unrestricted. However, some goods are subject to Import Quota (IQ) and Tariff

Quota (TQ) Systems. The IQ system mainly covers items that are controlled for public safety such as narcotics, weapons, and dangerous chemicals. However, imports of rice and some fish are also covered by the system. To import goods covered by the system, the importer must first obtain and an IQ Allocation Certificate from the Ministry of International Trade and Industry (MITI), which entitles him/her to receive an import license on application to an authorized foreign exchange bank. An import license is valid for six months.

The TQ system covers a wide range of products. These milk and milk-based products, dried beans, corn and products made from corn, peanuts, some cocoa-based products, leather goods, and leather footwear. The controls on the import of leather and leather footwear were provided for in a 1986 EC/Japan agreement, which was renewed in 1992.

There are certain other cases where the separate approval of the MITI is required. These are called "special type payment" cases where payment is to be made more than two years of Customs clearance. The procedure involves the filing of an import declaration to the Customs. Machinery imports are an exception for which this advance payment rule does not apply up to 50% of its value.

Drawback and Bounties The customs duty refund system allows for the partial or complete refund of customs duty paid in advance on imported cargo if the cargo is later found to meet certain legal requirements. The current refund system applies to duties paid on cargo that is spoiled or damaged, to raw materials used in the manufacture of exports, to imported raw materials used in the production of exported goods at bonded manufacturing warehouses, and to certain other claimed merchandise.

Commercial Samples and Temporary Imports There are three methods of importing samples into Japan:

1) Import with no limitation on the place, time or period of use of the samples. In certain cases commodity tax must be paid. Import duty must be paid, except where total value is under ¥10,000 or where the samples are individually of little value. In these cases samples are to be clearly identified as such, for example, dye-marked samples or in other ways defaced so that they cannot be sold. No import license is required for gift imports of IQ items not exceeding ¥180,000 in total value.
2) Import by ATA Carnet Note. No import duty and commodity tax will be required, provided that samples are not for sale and are to be re-exported within one year, for example, for demonstration or exhibition use. For details of ATA Carnet Notes, non-Japanese firms should contact a major Chamber of Commerce. ATA Carnet Notes have to be arranged before the goods have left the country of origin.

3) Where such articles do not have an ATA Carnet Note they may be imported duty and tax-free, provided that a bank guarantee equal to the duty payable is presented to Customs. It is essential to have a Customs broker in Japan to carry out these formalities.

6.4.8 Korea

Trade Barriers, Customer Regulations, Tariffs, and Import Taxes The most up to-date Korean tariff rates are published online by the Korean Customs Administration (KCA) at http://www.customs.go.kr/eng/. Korea revised 92 percent of its tariff-line items as a result of the Uruguay Round negotiations. Korea's average basic tariff in 2000 is about 7.9 percent. Duties still remain very high on a large number of high-value agricultural and fisheries products. Korea imposes tariff rates of 30–100 percent on many agricultural and horticultural products of interest to U.S. suppliers. Under WTO "Zero for Zero" initiatives, Korea is in the process of reducing tariffs to zero on most or all products in the following sectors: paper, toys, steel, furniture, semiconductors and farm equipment.

Korea also maintains a tariff quota system designed to stabilize domestic commodity markets. Customs duties can be adjusted every six months within the limit of the basic rate plus or minus 40 percent. As of July 1, 2001, 70 items were selected, up from 60 items as of year-end 2000 and 55 items as of July 1, 2000. Among the 70 items, 20 items are agricultural, forestry and fishery related. In operating the quota rate system, the government has agreed to notify foreign business associations like AmCham (American Chamber of Commerce) when local industry recommends items for quota rate designation to the government. Korea also uses "adjustment tariffs" at the four-digit H.S. code level to respond to import surges and to protect domestic producers. The system is adjusted on an annual basis. Effective January 1, 2001, Korea reduced the number of items subject to adjustment tariffs from 27 items to 26 items, 20 of which are agriculture, forestry, and fishery related.

In accordance with the Information Technology Agreement (ITA), Korea is reducing to zero tariffs on 203 types of telecommunication and information related equipment. The tariff reduction was completed for most tariffs in 2000, but implementation will be phased in for 10 categories (six by 2002 and four by 2004). Korea has also participated in the ITA—two negotiations aimed at eliminating tariffs on 108 other items with a target year of 2002.

Korea has a flat 10 percent Value Added Tax on all imports and domestically manufactured goods. A special excise tax of 10–20 percent is also levied on the import of certain luxury items and durable consumer goods. Tariffs and taxes must be paid in Korean won within 15 days after goods have cleared customs.

Customs Valuation Most duties are assessed on an *ad valorem* basis. Specific rates apply to some goods, while both *ad valorem* and specific rates apply

on a few others. The dutiable value of imported goods is the cost, insurance, and freight (C.I.F.) price at the time of import declaration.

Import duties are not assessed on capital goods and raw materials imported in connection with foreign investment projects. Authorization to import on a duty-free basis those items and supplies designated in a foreign investment application usually accompanies the Ministry of Finance and Economy's approval of a foreign investment project. In addition, raw materials used in the production of export goods are often exempt from duty, and certain machinery, materials, and parts used in designated industries such as high technology and aerospace may enter Korea either duty free or at reduced rates. Tariffs are zero on materials used for educational purposes and on computer software.

Import License and Special Import/Export Requirements Following a revision of the Customs Act and its Enforcement Decree, import procedures and the required documentation were simplified effective January 1, 1997. Goods entering Korea no longer require an import license (I/L) issued by a foreign exchange bank. Separate approval for payment in foreign currency is also no longer required. All commodities can be freely imported, subject to special registrations and import approvals for categories like pharmaceuticals and medical devices, unless they are included on the Negative List, which includes commodities that are either prohibited or restricted.

The Negative List is officially known as the Export and Import Notice. Fifty-four individual laws stipulate requirements and procedures for importing certain products (1074 items, or 1 percent of all items) to ensure the protection of public health and sanitation, national security, safety, and the environment.

Applications for licenses to import items on the Negative List are approved on a case-by-case basis after screening and approval by the government agencies concerned, or by the relevant manufacturer's association. Typically, health- or safety-related products, such as pharmaceutical and medicines, require additional testing or certification by recommended organizations before clearing customs. In addition, special items defined by the Ministry of Commerce, Industry and Energy (MOCIE) in its Annual Trade Plan (firearms, illicit drugs, endangered species, etc.) require approval by the Minister of MOCIE. In most cases, the supplier's qualified local agent completes the registration process. In accordance with the amendment of the Foreign Trade Act, all restrictions on trading companies were eliminated by changing from the previous approval system to a new system under which firms simply file import notifications with MOCIE.

The IMF program called on Korea to improve the transparency of its import certification procedures. The government has reviewed 54 laws and regulations to identify necessary improvements in transparency. Amendment of the relevant laws and regulations was completed in 2000. Streamlining efforts on import certification continues through amendment of the Export

and Import Notice. Whether or not these changes are liberalizing trade remains to be seen.

Import/Export Documentation Customs clearance procedures were simplified by the revision of the Customs Act and its Enforcement Decree in December 1995. The import license system was replaced by the import declaration system so that an import declaration filed without defect is immediately accepted for release of goods. With the exception of high-risk items related to public health and sanitation, national security, and the environment, which often require additional documentation and technical tests, goods imported by companies with no record of trade law violations are to be released upon the acceptance of the import declaration, without customs inspection. The KCA's Electronic Data Interchange (EDI) system for paperless import clearance came on line in July 1999 and allows importers to make an import declaration by computer, without visiting the customs house. Another noteworthy change in customs clearance effective January 1, 1999, is that goods can be released even before the filing of an import declaration and payment of tariffs. In 1999, the KCA linked its computer database with all the agencies dealing with exports and imports, allowing all exchanges of documents (approval, issuing recommendation, inspection and quarantine) to be done electronically.

Import declarations may be filed at the Customs House before a vessel enters the ports, or before the goods are unloaded into bonded areas. In both cases, goods are released directly from the port without being stored in a bonded area if the import declaration is accepted.

Along with import procedures, export procedures and documentation were also simplified effective January 1, 1997. Exported goods no longer require an export license (E/L) issued by a foreign exchange bank. Exporters can file their export notices to Korean Customs by computer based on their shipping documents at the time of export clearance. All commodities can be freely exported unless they are included on the negative list.

Import License Requirements/Special Import-Export Requirements Following a revision of the Customs Act and its Enforcement Decree, import procedures and the required documentation were simplified effective January 1, 1997. Goods entering Korea no longer require an import license (I/L) issued by a foreign exchange bank. Separate approval for payment in foreign currency is also no longer required. All commodities can be freely imported, subject to special registrations and import approvals for categories like pharmaceuticals and medical devices, unless they are included on the Negative List, which includes commodities that are either prohibited or restricted.

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The IMF program called on Korea to improve the transparency of its import certification procedures. The government has reviewed 54 laws and regulations to identify necessary improvements in transparency. Amendment of the relevant laws and regulations was completed in 26 of the cases. The remaining cases are to be finalized with amendment of the relevant laws and regulations. Among the cases still pending at the National Assembly are eliminating the requirements for obtaining permission on a category basis for importing cosmetics and for an importer to designate a local manager.

6.4.9 Taiwan

Taiwan Customs has a Web site in both Chinese and English (www.eng.dgoc.gov.tw) that provides information on import requirements. To access pertinent information, click on the English tab at the top enter the customs website, click on "tariff database search," and enter the six-digit HS code *without* periods between the numbers.

Dutiable Value The dutiable value of an import into Taiwan is based on the transaction value between a foreign manufacturer and a Taiwan importer or the transaction value between a foreign intermediary and a Taiwan importer. The dutiable value is defined as its cost, insurance, and freight (C.I.F.). If customs officials consider an invoice's transaction value to be too low, they will value the item based on the actual transaction value.

Should a foreign supplier desire further information or a binding ruling on the dutiable status of its products, it is suggested that companies fully describe the articles and address the inquiry to the Director General of Customs, Directorate General of Customs, MOF, 13 Ta Cheng Street, Taipei, Taiwan, Tel: 886-2-2550-8166, Fax: 886-2-2550-8124.

Tariffs and Taxes In May 1998, Taiwan began implementing tariff cuts on 1130 items, including buses, agricultural products, and camera film. In Febru-

ary 1999, Taiwan waived tariffs on 15 aircraft components as part of plans to accede to the WTO Agreement on Trade in Civil Aircraft. An additional 777 items are slated for tariff cuts pending legislative approval. Taiwan's current average nominal tariff rate is 8.2 percent; the trade-weighted rate is 3.1 percent, both down slightly from 1998. Taiwan is a participant in the Information Technology Agreement (ITA). Under the ITA, Taiwan has agreed to phase out tariffs on information technology products. The first set of ITA-related cuts was implemented on a temporary basis on July 1, 1997, under administrative order. A second set of cuts went into effect on January 1, 1998. While the vast majority of tariffs on these products were phased out as of the year 2000, for some products reductions were not completed until 2002. The administrative order must be renewed annually until Taiwan enacts permanent reductions in connection with its accession to the WTO.

In addition to the import duty, importers must also pay a 0.3 percent harbor due and a 5 percent value-added tax. Goods entering Taiwan by airfreight or parcel post are exempt from harbor fees. A commodity tax must be paid if an imported product falls into one of seven commodity categories. The rates range from 2 to 60 percent. The tax is assessed on the C.I.F. and duty-paid value of affected imports. The seven commodity categories include rubber tires, cement, beverages, oil and gas, electric appliances, flat glass, and automotive products.

Customs Valuation Taiwan revised its Customs Law in July 1986 in order to implement procedures consistent with the "Agreement on Implementation of Article VII of the GATT." This article refers to the valuation of all imports for the assessment of duties. The Taiwan authorities have stated that upon its accession to WTO, it will fully adhere to the Customs Valuation Code.

The dutiable value of an import into Taiwan is defined as its C.I.F. value. Taiwan generally assesses the *ad valorem* duty on the invoice price a stated on the import document. If customs officials consider an invoice's transaction value to be too low, they will value the item based on the actual transaction price of the same or similar goods sold to Taiwan at approximately the same time of exporting the said products.

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7

EXPORT COMPLIANCE

7.1 OVERVIEW

Export compliance is becoming more complex due to globalization, the proliferation of free trade agreements, national security concerns, and the increasing number of emerging markets. Legislation governing the export of goods is constantly changing. Export companies that are not fully compliant with current requirements can get into trouble in a variety of ways. Most violations are not deliberate, but rather the result of ineptitude, negligence, or even bad luck. Seizures, penalties, and investigations come from activities such as customs spot inspections, analysis of export data, and shipping patterns as well as intelligence information. In most cases, however, the largest source of enforcement cases comes from informants. Most informants are not from the government, but rather competitors (who, for instance, lost a sale that they previously declined because they determined that the particular shipment was in violation), employees in your company, or even intermediaries. In the United States, 70 percent of the cases taken up by the Bureau of Industrial Security (BIS) are generated from tips from these non-governmental sources.

This chapter provides information on the following key aspects of export legislation:

- General export control requirements
- International agreements on the export of goods

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- Brief descriptions of individual countries export legislation
- Corporate export compliance strategy

The information contained in this chapter should greatly assist companies to avoid common pitfalls and thus delays in shipment of goods and potential government prosecution.

7.2 GENERAL EXPORT CONTROL LEGISLATION

Individual countries and economic unions vary greatly in their requirements for exported goods. In this section, the following key legal and practical requirements for exporting goods out of major markets are presented. Detailed information on particular jurisdictions is presented in Section 7.4:

- classification of goods
- export control regulations
- export reporting and customs clearances
- restricted export parties/denied parties
- export embargoes

Classification of Goods The Harmonized Tariff Schedule (HTS) was developed in the 1980s to provide an international standard for classifying goods. Known typically as the Harmonized Code, most countries today rely on the system to classify goods both entering and leaving their countries. There are some differences between nations, but most of these are based upon the need for specific statistical information for a particular country's trade data needs.

Export Control Regulations An effective export control system is critical to a country's national and economic security. This is particularly true as the nations of the world continue to face threats from terrorists and rogue states developing weapons of mass destruction. An effective export control regime must ensure that adversaries (and potential adversaries) do not obtain goods or technologies that could be used for weapons that might ultimately be directed against civilized countries. It is also important that the export control system affords indigenous exporters the opportunity to compete on an equal footing with foreign competitors in the global marketplace. The challenge for global policy makers is to construct a tough-minded, yet common sense export control regime that enhances legitimate, commercial trade while at the same time prevents the diversion of sensitive goods and technologies that could jeopardize a country's national security.

Export Reporting and Customs Clearances Export data either is collected manually on the forms received from the carriers transporting the goods from

the country or via government sponsored automated systems. Paper reports are usually of poor quality and received late. In most cases, these manual shipments are reported to the carrier by the freight forwarder or the exporter themselves. For example, recently, the United States and Canada have encouraged automated reporting through government reporting systems. Other countries (such as Mexico) mandate automated reporting.

Restricted Export Parties/Denied Parties The United States uses a formal list of names of companies, organizations, and individuals who have lost their export privileges or been debarred for export based upon export infractions. Any export from the United States is required to be checked against the lists that are detailed in Section 7.4.1. Other countries may have informal lists, but typically, they are only given to specific exporters and are not published for general use.

Export Embargoes Governments or the United Nations for a variety of purposes use sanctions and embargoes to:

- Punish a country or group for unacceptable behavior
- Influence the behavior of the target
- Signal disapproval of a government or group's behavior
- As a necessary early reaction and as a warning that harsher measurers could follow
- Limit a target's freedom of action
- Deny resources or technology
- Increase the cost of engaging in unacceptable behavior
- Drawing international attention to unacceptable behavior
- Challenge a country's allies to take action that is more forceful themselves in support of common objectives
- Signal to a government or group that violates core values that a business-as-usual approach is not acceptable
- Protect the assets of allies from hostile actions
- Assur that the assets of targets will be available to meet future claims.

In addition, economic sanctions are imposed through various methods such as:

- Limiting exports and re-exports to the targets (including exports to third countries predominantly for use in products for the targets)
- Limiting imports from the targets
- Blocking assets of the targeted country, company, or individual
- Restricting investments in the targets

- Prohibiting private financial transactions
- Restricting government trade financing and investment assistance.

7.3 INTERNATIONAL AGREEMENTS FOR EXPORT CONTROLS

During the 1990s, nonproliferation became a central security objective of nearly every industrialized country. The former adversaries of the Cold War together are working to prevent the spread of weapons of mass destruction and their means of delivery. Vigilance and responsibility in transfers of conventional arms and sensitive technologies related to military capability are essential to non-proliferation efforts.

The Stockholm International Peace Research Institute (SIPRI) developed a list of countries who have signed on to international agreements to enforce export controls on sensitive materials (refer to Table 7.1). The agreements listed cover the following commodities, technology, or technical information:

- Zangger Committee—Nuclear Export Controls
- Nuclear Suppliers Group—also, Nuclear Export Controls
- Australia Group—Nonproliferation of chemical and biological materials and equipment
- Missile Technology Control Regime—Exports of missiles capable of delivering weapons of mass destruction
- Wassenaar Arrangement—Transfers of conventional arms and dual use goods and technology

Exporters of military or dual use items should perform due diligence for the countries listed in Table 7.1.

7.4 NORTH AMERICA

7.4.1 United States

Classification of Goods The United States permits two different classification schemes that are both based on the international Harmonized Tariff System (HTS). The first, the United States *Harmonized Tariff System (HTS)*, is used to classify both imported and exported goods. The HTS is administered by the U.S. International Trade Commission (USITC) and is primarily used to determine import duties. In addition to the six-digit codes that the international HTS assigns for general categories, the United States defines products with four additional numbers to compose 10-digit HTS codes. Countries that use the HTS are allowed to define commodities at a more detailed level than six digits, but all definitions must be within that six-digit framework.

TABLE 7.1. Membership of Multilateral Military-Related Export Control Regimes

State	Zangger Committee	Nuclear Suppliers Group	Australia Group	Missile Technology Control Regime	Wassenaar Arrangement
Argentina	×	×	×	×	×
Australia	×	×	×	×	×
Austria	×	×	×	×	×
Belarus		×			
Belgium	×	×	×	×	×
Brazil		×		×	
Bulgaria	×	×	×		×
Canada	×	×	×	×	×
Cyprus		×	×		
China	×				
Czech Republic	×	×	×	×	×
Denmark	×	×	×	×	×
Estonia					
Finland	×	×	×	×	×
France	×	×	×	×	×
Germany	×	×	×	×	×
Greece	×	×	×	×	×
Hungary	×	×	×	×	×
Iceland			×	×	
Ireland	×	×	×	×	×
Italy	×	×	×	×	×
Japan	×	×	×	×	×
Kazakhstan		×			
Korea, South	×	×	×	×	×
Latvia		×			
Lithuania					
Luxembourg	×	×	×	×	×
Moldova					
Netherlands	×	×	×	×	×
New Zealand		×	×	×	×
Norway	×	×	×	×	×
Poland	×	×	×	×	×
Portugal	×	×	×	×	×
Romania	×	×	×		×
Russia	×	×		×	×
Slovakia	×	×	×		×
Slovenia	×	×			
South Africa	×	×		×	
Spain	×	×	×	×	×
Sweden	×	×	×	×	×
Switzerland	×	×	×	×	×
Turkey	×	×	×	×	×
Ukraine	×	×		×	×
UK	×	×	×	×	×
USA	×	×	×	×	×

Source: http://projects.sipri.se/expcon/natexpcon/country_matrix.html. Information was current as of 1 August 2002.

Worldwide, there are billions of trade transactions occurring each year. In the United States, all exported goods can be categorized under approximately 8000 different product classifications. Every item that is exported is assigned a unique 10-digit identification code that is based on a series of progressively broader product categories. For example, concentrated frozen apple juice is assigned a 10-digit identifier that is aggregated into a broader category, assigned a six-digit identifier described as apple juice. The six-digit identifier described as apple juice is aggregated into a broader category, assigned a four-digit identifier described as fruit juices and vegetable juices, etc. The four-digit identifier is further aggregated into a broader category, assigned a two-digit identifier described as Preparations of Vegetables, Fruit, and Nuts etc.

The second scheme, *Schedule B*, is used only to classify exported goods. It is a separate code from the HTS and is administered by the U.S. Census Bureau at the request of exporters and forwarders. The Census Bureau uses Schedule B to collect trade statistics.

Schedule B is often simpler to use than the HTS because it remains constant throughout the year while HTS import numbers often change weekly or monthly. Because this system does not change as often as HTS, using Schedule B will reduce the number of fatal errors that are generated by users of the U.S. Automated Export System (AES) due to obsolete or incorrect codes.

Using HTS to classify exports also has its advantages. Most companies use experts to classify their imports. Globally, most corporations import and export the same parts, components, and products. Because the United States HTS is based on the international HTS, identical codes may be used for the same goods no matter which country is exporting or importing the goods. This is synergistic and insures that coding is consistent. This advantage depends largely upon the sophistication of an exporter's IT system and the completeness of the item master (or product master). Item masters are also useful for entering license or document requirements and other restrictions and cautions. If this is the case, then the item master's classification (from a recognized expert) can be used to generate accurate government export messages or forms.

Export Control Regulations The United States also has one other commodity code to control the export of goods—the Export Control Classification Number (ECCN). The Bureau of Industrial Security (BIS) maintains this list to control goods that can be used for both civilian and military purposes. An ECCN is an alphanumeric classification used in the Commerce Control List (CCL) to identify items for export control purposes. It is different from both the Schedule B number (used by the Bureau of Census to collect trade statistics) and the HTS (used to determine import duties).

Three steps need to be taken to initiate the export of goods:

1) assign an ECCN number
2) consult the U.S. Department of Commerce's Country Charts to determine if a license is required

3) If munitions, military goods, spacecraft, or satellites, a U.S. Munitions License must be obtained

Assign an ECCN Number. All ECCNs are composed of a total of five characters (e.g., 1A001, 4B994, or 8D001). The first number of the ECCN identifies the category to which it belongs. Ten categories of goods are listed on the Commerce Control List (e.g., 1 = Nuclear Materials Facilities and Equipment, 4 = Computers, 9 = Propulsion Systems, Space Vehicles and Related Equipment).

There are three ways to determine the ECCN for exported goods:

1) *Determine the classification yourself.* Review the alphabetical index to the Commerce Control List (CCL) (Supplement 1 to Part 774 of the Export Administration Regulations (EAR)). The index will give an ECCN for each item listed. Look in the corresponding CCL category to determine if your item is described by that ECCN. You may need to review more than one ECCN description. Instructions for using the CCL are found in Export Administration Regulations (EAR) Part 738. As mentioned in the preceding section on commodity classification, an item or product master is an excellent means to store and retrieve ECCN, HTS, and/or Schedule B numbers. In a well-designed International Trade Logistics System, this feature will assure consistence and save time wasted on repetitive classification.
2) *Go to the source.* Ask the manufacturer, producer, or developer of the item for the ECCN. If the item has been exported in the past, they may know the ECCN, what countries require a license, and whether a license exception may be used. Information on license exceptions can be found in EAR Part 740.
3) *Get an official classification from the U.S. Bureau of Industry and Security (BIS).* With commodities where you have a doubt or need the reassurance of an official ruling then submit a classification request on the U.S. Multipurpose Application Form BXA-748P or on-line through the *Simplified Network Application Process (SNAP)*. This is the only way to receive an official BIS classification of your item.

For goods not specified in the ten ECCN categories, a "basket" designation can be used as long as they are covered by the Export Administration Regulations (EAR) and not listed on the Commerce Control List. This designation, EAR99, is the category into which most goods and the majority of the commercial exports from the United States fall into. EAR99 items can be shipped without a license to most destinations under most circumstances. A license from BIS is required when shipments of EAR99 are sent to embargoed destinations, denied persons, sanctioned entities, or prohibited end-users or end-uses.

Consult the U.S. Department of Commerce's Country Chart. Once an ECCN number is assigned to goods, then the U.S. Department of Commerce's

Country Charts need to be consulted to determine whether a license is required for that particular ECCN. License requirements vary from country to country for a variety of policy and nonproliferation purposes. For example, titanium tubes can be shipped to Italy but not to Vatican City. Details on ECCNs and the Commodity Control List can be found in the U.S. EAR, part 738. (See *http://w3.access.gpo.gov/bis/ear/txt/738spir.txt* for the Country Chart.)

Obtain a U.S. Munitions Licenses (Department of State—Office of Defense Trade Control). Munitions, military goods, spacecraft, and satellites are controlled by the U.S. Department of State, Office of Defense Trade Controls (ODTC). Export Licenses are required for the following items that are to be exported from the United States (Table 7.2). A validated export license with the license number and the Munitions Control List (MCL) included is required on the Shipper' Export Declaration.

Export Reporting and Customs Clearances The export process begins when the exporter decides to export merchandise. First, the exporter or their authorized forwarding agent makes shipping arrangements with the carrier. Then, the exporter or the authorized forwarding agent transmits the shipper's export

TABLE 7.2. United States Munitions List

Code	Description
I	Firearms
II	Artillery projectors
III	Ammunition
IV	Launch vehicles, guided missiles, ballistic missiles, rockets, torpedoes, bombs, and mines
V	Explosives, propellants, incendiary agents, and their constituents
VI	Vessels of war and special naval equipment
VII	Tanks and military vehicles
VIII	Aircraft and associated equipment
IX	Military training equipment
X	Protective personnel equipment
XI	Military electronics
XII	Fire control, range finder, optical and guidance and control equipment
XIII	Auxiliary military equipment
XIV	Toxicological agents and equipment and radiological equipment
XV	Space systems and associated equipment
XVI	Nuclear weapons design and test equipment
XVII	Classified articles, technical data, and defense services not otherwise enumerated
XVIII	[Reserved]
XIX	[Reserved]
XX	Submersible vessels, oceanographic and associated equipment
XXI	Miscellaneous articles

information using the Automated Export System (AES). AES is one of the better-designed automated systems in the U.S. federal government. This information can come directly from the exporter or the exporter's authorized agent or through a service center or port authority. The AES validates the data against editing tables and U.S. government agency requirement files. If the data is validated, a confirmation message is generated and sent to the filer. If the information submitted is incorrect, then the filer will receive an error message.

The carrier or an authorized forwarding agent then transmits the export manifest data generated by the AES to U.S. Customs. AES validates the transportation data and then generates either a confirmation message or an error message. Any error messages generated by AES must be corrected and the proper data retransmitted to AES.

In the United States, more than 88 percent of Shippers Export Declarations (SED) are submitted electronically through the AES, a relatively new system first developed in the 1990s. Recent legislative changes have made AES mandatory for any goods with an ECCN or Munitions Control List classification and subsequently all exports.

Restricted Export Parties/Denied Parties The U.S. government maintains export exclusion lists that include, but are not limited to, the Treasury Department's Specially Designated Nationals List and Commerce Department's Entity and Denied Persons Lists. No U.S. company or individual is allowed to either physically or electronically export or re-export items or provide services to any party, whether in the United States or abroad, that is on this list.

These lists can consist of companies, organizations, or individual names and addresses. Many of these are similar and can be confusing, resulting in false positives. Any hits should be researched to ensure their validity and so due diligence can be demonstrated if challenged. The lists are:

- Table of Denial Orders and entities lists (Department of Commerce)
- Unverified List (Department of Commerce)
- Debarred list (Department of State)
- Specially designated nationals (Office of Asset Control) including specially designated narcotics agents and terrorists
- Parties excluded from federal procurement (General Services Administration)
- Embargoed and boycotted countries
- Enhanced Proliferation Control Initiatives (EPCI).

Export Embargoes The United States maintains economic and trade sanctions and embargoes against targeted foreign countries, groups, organizations, and individuals. As of August 2001, the United States maintained sanctions and embargoes against the following nations and groups: Cuba, Iran, Iraq, Libya, North Korea, Sudan, the Federal Republic of Yugoslavia (specific

parties), Liberia, Sierra Leone, the Taliban in Afghanistan, the UNITA faction in Angola, Syria, Burma (Myanmar) (new U.S. investments only), narcotics traffickers, named terrorists, foreign terrorist organizations, designated foreign persons who threaten international stabilization efforts in the Western Balkans, and designated foreign persons who have engaged in activities related to the proliferation of weapons of mass destruction.

The office of Foreign Assets of the U.S. Department of the Treasury ("OFAC") administers and enforces over 20 different economic sanctions programs based on U.S. foreign policy and national security objectives. Each program is driven by differing concerns and features a unique set of blocking provisions, trade, or other restrictions. It is also very important to note that OFAC publishes a list of Specially Designated Nationals and Blocked Persons ("SDN list"), which includes over 4500 companies and individuals who are connected with the sanctions targets and are located throughout the world. For example, a number of the named individuals and entities are known to move from country to country and may end up in locations where they would be least expected. OFAC's programs are dynamic and constantly changing. OFAC recommends that U.S. businesses should check OFAC's web site at *http://www.treas.gov/ofac* on a regular basis to ensure that they have a current SDN list and complete information regarding current restrictions affecting countries and parties with which they plan to do business. The countries of residence for SND targets as of August 2001 are provided in Table 7.3.

Americans (including U.S. firms with overseas branches) are generally prohibited from dealing with those listed on the SDN list unless authorized by OFAC. If it is determined that they have dealt with a restricted person or group, all of their assets will be blocked. Several companies offer Restricted Party Screening, which covers every list government agencies maintain. These services can range from simple Web-based look-ups handled on a case-by-case basis, performing sophisticated checks on an enterprise system's customer list, or order entry files. Additionally, these same systems can perform license determination and embargo checks for all shipments.

U.S. Export Compliance Problems: Corrective and Preventive Action

Certain provisions in the U.S. Export Administration Regulations (EAR) require companies to submit a validated license application for every export that they "know" will be used in some way for end-uses involving nuclear, chemical, and biological weapons or related missile delivery systems in certain destinations listed in the regulations, regardless of whether the products themselves are otherwise exempt. BIS has issued the following guidance on how individuals and firms should act under this knowledge standard.

Decide whether there are "red flags." Take into account any abnormal circumstances in a transaction that indicate that the export may be destined for an inappropriate end-use, end-user, or destination. Such circumstances are referred to as "red flags." Included among examples of red flags are orders for items that are inconsistent with the needs of the purchaser, a customer's

TABLE 7.3. Companies and Individuals in the Following Locations Are on the Specially Designated Nationals and Blocked Persons ("SDN list") as of August 2001

Afghanistan	Algeria	Angola
Argentina	Armenia	Australia
Austria	Bahrain	Bangladesh
Barbados	Belgium	Belize
Bosnia-Herzegovina	Brazil	Bulgaria
Burkina Faso	Burma	Canada
Central African Republic	Chad	Channel Islands
Colombia	Croatia	Cuba
Cyprus	Czech Republic	Denmark
Ecuador	Egypt	England
Ethiopia	Federal Republic of Yugoslavia	Finland
France	Germany	Gibraltar
Greece	Guinea	Gulf of Gabes
Guyana	Haiti	Honduras
Hong Kong	Hungary	India
Iran	Iraq	Israel
Italy	Jamaica	Japan
Jordan	Kenya	Kazakhstan
Korea (Peoples Democratic Rep)	Kosovo (Serbia)	Kuwait
Latvia	Lebanon	Liberia
Libya	Liechtenstein	Luxembourg
Macedonia	Mali	Malta
Mauritania	Mexico	Monaco
Mongolia	Montenegro	Morocco
Netherlands	Netherlands Antilles	Nicaragua
Niger	Nigeria	Norway
Pakistan	Panama	People's Republic of China
Peru	Poland	Romania
Russia	Rwanda	Saudi Arabia
Scotland	Serbia	Slovak Republic
Spain	Sri Lanka	St. Kitts and Nevis
St. Vincent and the Grenadines	Sudan	Sweden
Switzerland	Syria	Thailand
Togo	Tunisia	Turkey
Uganda	Ukraine	United Arab Emirates
United Kingdom	U.S.A.	Uzbekistan
Venezuela	Vojvodina (Serbia)	Yemen Arab Republic
Zambia		

declining installation and testing when included in the sales price or when normally requested, or requests for equipment configurations which are incompatible with the stated destination (e.g., 120 volts in a country with a standard of 220 volts). Commerce has developed lists of such "red flags,"

which are not all-inclusive but are intended to illustrate the types of circumstances that should cause reasonable suspicion that a transaction will violate the EAR.

Handling "red flags." If there are no "red flags" in the information that comes to your firm, you should be able to proceed with a transaction in reliance on information you have received. That is, absent "red flags" (or an express requirement in the EAR), there is no affirmative duty upon exporters to inquire, verify, or otherwise "go behind" the customer's representations. However, when "red flags" are raised in the information that comes to your firm, you have a duty to check out the suspicious circumstances and inquire about the end-use, end-user, or ultimate country of destination.

The duty to check out "red flags" is not confined to the use of general licenses affected by the "know" or "reason to know" language in the EAR. Applicants for validated licenses are required by the EAR to obtain documentary evidence concerning the transaction, and misrepresentation or concealment of material facts is prohibited, both in the licensing process and in all export control documents. You can rely upon representations from your customer and repeat them in the documents you file unless "red flags" oblige you to take verification steps.

Do not limit or restrict your employees or information systems. Do not cut off the flow of information (self-blinding) that comes to your firm in the normal course of business. For example, do not instruct the sales force to tell potential customers to refrain from discussing the actual end-use, end-user, and ultimate country of destination for the product your firm is seeking to sell. Do not put on blinders that prevent the learning of relevant information. An affirmative policy of steps to avoid "bad" information would not insulate a company from liability, and it would usually be considered an aggravating factor in an enforcement proceeding.

Employees need to know how to handle "red flags." Knowledge possessed by an employee of a company can be imputed to a firm so as to make it liable for a violation. This makes it important for firms to establish clear policies and effective compliance procedures to ensure that responsible senior officials can evaluate such knowledge about transactions. Failure to do so could be regarded as a form of self-blinding.

Reevaluate all the information after the inquiry. The purpose of this inquiry and reevaluation is to determine whether the "red flags" can be explained or justified. If they can, you may proceed with the transaction. If the "red flags" cannot be explained or justified and you proceed, you run the risk of having had "knowledge" that would make your action a violation of the EAR.

Refrain from the transaction or disclose the information to BIS and wait. If you continue to have reason for concern after your inquiry, then you should either halt the transaction or submit all relevant information to BIS in the form of an application for a validated license. Continuing the transaction at this point is risky as you may be deemed to be in potential violation and

as such may have to hire a law firm, pay a hefty fine, and receive negative press.

7.4.2 Canada

Classification of Goods The Canadian Export Classification is a structured, hierarchical classification system that is called the Harmonized Description and Coding System (HS). Like the United States, Canada is a Contracting Party to the Convention on the Harmonized Commodity Description and Coding System and therefore its statistical nomenclature conforms to the international Harmonized Tariff Schedule.

HS nomenclature is divided into 21 sections, which in general, group goods produced in the same sector of the economy. For example, Section IV includes all kinds of agriculture products (e.g., Prepared Foodstuffs; Beverages, Spirits and Vinegar: Tobacco and Manufactured Tobacco Substitutes), whereas Section VI includes all kinds of chemical products (e.g., Products of the Chemical or Allied Industries).

Statistics Canada maintains an excellent classification tool and extensive background on their Web site *www.statcan.ca/english/tradedata*. This information is also available in French.

Export Control Regulations Canada requires export reporting not only to collect information on Canadian exports and control the outbound movements of goods, but also to control the export of strategic, embargoed, and dangerous goods. Export controls exist in order to fulfill Canada's obligations in bilateral and multilateral agreements. They are designed to prevent or regulate the movement of certain goods by controlling the sources of supply. From 1950 to 1994, Canada was a member of the Coordinating Committee for Multilateral Strategic Export Controls (COCOM). On March 31, 1994, COCOM ceased to exist and the former COCOM members agreed to establish a new multilateral arrangement known as the "Wassanaar Arrangement on Export Controls for Conventional Arms and Dual-use Goods and Technologies." Trade controls are implemented by Canada to:

- regulate trade in military and strategic dual-use goods, and prevent the proliferation of weapons of mass destruction, as we are obliged to do under multilateral agreement
- prevent the supply of military goods to countries that threaten Canada's security, are under UN sanction, are threatened by internal or external conflict, and/or abuse the human rights of their citizens
- protect vulnerable Canadian industries, such as clothing manufacturing
- obtain negotiated benefits from international agreements

- implement trade restrictions in support of Canada's supply management programs
- fulfill other international obligations
- implement UN Security Council trade sanctions

In order to export goods that are (1) destined for a country on Canada's Area Control List (ACL), (2) on Canada's Export Control List (ECL), or (3) of U.S. origin, an exporter must first obtain a federal export permit from the Department of Foreign Affairs and International Trade (DFAIT). Regardless of the product, any goods going to a country on the ACL require a permit before they can be exported. Similarly, any nation that is embargoed by the United Nations (e.g., Iraq) may require additional approvals over and above any export permit that may be required.

The Export Control List (ECL) includes:

- Agricultural products: refined sugar, sugar-containing products, and peanut butter
- Textiles and clothing
- Military, strategic dual-use goods
- Nuclear energy materials and technology
- Missile, chemical, or biological goods of nonproliferation concern
- Softwood lumber, unprocessed logs, and certain other forest products
- Miscellaneous goods, including goods of U.S. origin, roe herring, and certain items with medical value
- All goods destined for countries on the Area Control List: Angola and Myanmar

For these restricted goods, Form B13A, Export Declaration, must be submitted regardless of the value of the goods. It is the exporter's responsibility to ascertain if the goods fall within this category. Other government departments such as Environment Canada and Agriculture and Agri-Food Canada may have additional restrictions on the export of certain goods.

For more details, you can contact the CCRA's Automated Customs Information Service (ACIS) at 1-800-461-9999 from within Canada or (204) 983-3500 or (506) 636-5064 from outside Canada. Additionally, Canada Customs and Revenue Agency (CCRA) provide links to many documents outlining restricted goods at: *http://www.ccra-adrc.gc.ca/customs/business/exporting/ogd-e.html*.

The Export Controls Division of the Department of Foreign Affairs and International Trade can also be contacted at Export Controls Division, Department of Foreign Affairs and International Trade 6th floor, Tower C, 125 Sussex Drive, Ottawa ON K1A 0G2, Telephone: (613) 996-2387, Facsimile: (613) 996-9933, Email: ECL?@dfait-maeci.gc.ca.

Export Reporting and Customs Clearances Shipments to the United States, Puerto Rico, and the U.S. Virgin Islands are regulated differently than shipments to other countries. Under an agreement with the U.S., the Government of Canada gets export information on goods destined for consumption in the U.S. market directly from U.S. import data. Therefore, Canadian shipments of regular goods bound for the United States or its territories do not have to be reported. However, export permits, certificates, and licenses are still required for controlled, prohibited, or regulated goods.

For shipments to countries other than the United States and its territories, export declaration must be filed prior to export when the goods are valued at CAN $2000 or more. All goods that are controlled, prohibited, or regulated by any Act of Parliament must be reported and the required permits, certificates, and licenses submitted. These requirements are summarized in Table 7.4.

Statistics Canada and CCRA launched the national implementation of the Canadian Automated Export Declaration (CAED) program, which gives registered exporters and agents the opportunity to report goods electronically to the Federal Government of Canada. This program was launched on January 1, 1998, and is a fast, inexpensive, and easy way of reporting exported goods. Paper export declarations remain acceptable and are still the dominant means of reporting export data.

Canada also requires export documentation to identify goods and terms of sales, provides title to the goods and evidence of insurance coverage, and certifies that the goods are of a certain quality or standard. Several documents are required for overseas shipping and generally fall into two basic categories: shipping documents and collection documents.

Shipping documents must be prepared before shipments are allowed to pass through Customs, be loaded onto a carrier, and be transported to the destination. Key shipping documents include:

TABLE 7.4. Exporting Goods from Canada: Documents Required from Exporters Prior to Export

Type of Goods	U.S. Destinations (Includes Puerto Rico and U.S. Virgin Islands)	All Other Destinations (Includes Goods Moving Through the U.S. to Foreign Destinations)
Controlled goods (regardless of value)	Permit, certificate, or license documents required by other government departments (if applicable)	Permit, certificate, or license documents required by other government departments (if applicable) Form B13A, Export Declaration
Noncontrolled goods	Export declaration is not required	Export declaration (for goods valued at CAN$2000 or more)

- commercial invoices
- special packing or marking list
- certificate of origin
- certificate of insurance
- bill of lading (for ocean freight), air waybill (for air freight) or rail and truck bills of lading (for land freight)

The most important collection document is the commercial invoice, which describes the goods in detail and lists the amount owed by the foreign buyer. This form is also used for customs records, and must include the date of issue; the names and addresses of the buyer and seller; the contract or invoice number; a description of the goods; the unit price; the total weight and number of packages; shipping marks and numbers; and the terms of delivery and payment. Other documentation may be required to meet specific import restrictions. Collection documents are submitted in advance by the exporter to the buyer or its bank, and trigger payment once the goods have been received.

Collection documents include:

- commercial invoices (the seller's bill of sale)
- consular invoices (required by some foreign countries)
- certificates of origin (attesting to the origin of the exported goods)
- import and export licenses (Importers in some foreign countries are required to obtain these. For example, a NAFTA certificate of origin is used to secure duty-free, or lower duty rate, entry into the United States and Mexico for Canadian exports.)
- inspection certificates (health or sanitary certificates are required by many foreign countries for animals, animal products, plants, and other agricultural products)
- dock and insurance receipts

Export Embargoes Permits are required to export any goods to countries on the Area Control List (ACL). At present only Angola and Burma (Myanmar) are on the ACL.

7.4.3 Mexico

Classification of Goods Mexican law mandates that all exports from Mexico be reported electronically using licensed Mexican Customs brokers. Harmonized Tariff Schedules are used to report exports.

Export Control Regulations Mexico has few export controls. Mexico is a signatory of the International Convention on Trade in Endangered Species

and therefore exceptions include endangered plants and animals (including products from such plants and animals), logs of all species, and archeological pieces and other items considered to be part of the Mexican national heritage.

Export Reporting and Customs Clearances In Mexico, all exports and imports must be submitted to the Mexican government with an application known as a "pedimento." The company must be registered as an exporter (in the case of export) and an importer (in the case of import) with the Federal Taxation authority of Mexico "Hacienda" (Secretariat of Hacienda and Public Credit / "Secretaría de Hacienda y Credito Público").

In addition to the application for import or export, the exporter must determine whether a license is needed to import or export certain goods. This license must be acquired prior to the good being exported or imported. If the good is to be imported, the importer must verify whether there is any duty payable for the import and pay it prior to the good's arrival.

All businesses in Mexico that wish to export goods valued more than $1,000 US must file their goods with a customs broker licensed in Mexico. The United States also has customs brokers that can handle the import/export from the U.S. side.

7.5 EUROPEAN UNION

The European Union (EU) is a single market, and goods, capital, services, and people can move freely among its 15 member countries. The countries of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, and the United Kingdom are currently members of the European Union. Candidate countries that may join the EU in the future include Bulgaria, Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovak Republic, Slovenia, and Turkey.

All countries belonging to the EU operate under a unified custom system and must adhere to EU export procedures and rules. The single market can only function properly when common rules are applied uniformly at its external border. The EU's Customs Union establishes common rules that extend to all aspects of trade policy, such as preferential trade, health and environmental controls, common agricultural and fisheries policies, the protection of our economic interests by nontariff instruments, and external relations policy measures. However, individual countries have some flexibility to impose their own processes and restrictions according to individual needs and desires. Therefore, export regulations and requirements may vary somewhat from country to country within the EU. For exporters, the value of research and due diligence due to these variations as well as revisions to the EU laws and regulations cannot be emphasized enough. See Appendix 4 for links to available Customs Web sites for EU member countries.

Classification of Goods Imported and exported goods that are declared to any EU member customs have to be classified according to the Combined Nomenclature (CN). Goods can fall into numerous subheadings, which determine the rate of customs duty and how the goods are treated for statistical purposes.

The CN designation meets both the requirements of the Common Customs Tariff as well as the external trade statistics of the Community. The CN is comprised of the Harmonized System (HS) nomenclature and is run by the World Customs Organization (WCO).

The Binding Tariff Information (BTI) system is key to implementing the Common Customs Tariff. It is issued to traders by customs authorities of the individual member countries so they will know in advance the tariff classification of the goods they intend to import or export.

Export Control Regulations The EU Dual-Use Export Control System was implemented in July 1995 to harmonize export controls within the 15 member states of the EU. Although the EU is a single market that aims at free movement of goods and services, some products and goods are restricted. The purpose of the dual-use export control system is to help facilitate the internal market for goods and services while at the same time safeguarding the nonproliferation requirements of the EU. It is presently undergoing revision.

The main principle that underlies the dual-use export system is that civilian trade does not undermine the essential security interests of individual member states or their commitment to nonproliferation. Export controls cover technical assistance required to be controlled by international export control regimes (including oral transfers of technology), bodies and treaties for weapons of mass destruction and missiles, and for conventional military goods exported to countries subject to arms embargoes of the above times.

The decisions about whether to approve or deny a given transfer are taken by the member states through their national authorities, which are required to provide enforcement and penalty power. Member states exchange information about license denials to ensure that each licensing authority is aware of potential proliferation risks.

Member states have agreed to respect export licenses issued by EU partners at the point where goods leave EU territory. In cases where aspects of a specific transfer are unclear or in dispute, the responsible national authorities in the country from which the goods are to be exported can contact the responsible national authorities in the country where the license was issued. Alternatively, the EU Commission can act as a clearinghouse to assist in resolving the case.

Export Reporting and Customs Clearances A customs declaration is usually required when goods are exported from a EU member country to countries outside the EU. In some cases, an export license has to be obtained before export.

If goods are dispatched to another EU member, a declaration is not required. However, details of the transaction should be provided to Customs under the intra-EU trade statistics system (Intrastat).

Intrastat is the system for collecting statistics on the physical trade in goods (i.e., the actual movement of goods) between EU member countries. It has been in operation since the beginning of the Single Market on 1 January 1993 and replaced customs declarations as the source of trade statistics within the EC. The requirements of Intrastat are similar for all EU members.

7.6 PACIFIC RIM

7.6.1 Australia

The Australia government prohibits the export of certain goods and to adequately record Australia's international trade via legislation and policy. Part VI of the Customs Act 1901 (the Customs Act) provides the legislative basis for Customs' control over the exportation of goods. The Australian Customs Service Manual (ACSM) outlines government requirements for exporting goods from Australia.

Classification of Goods All goods, before they are approved for export, will be assigned an Export Clearance Number (ECN). A clear ECN (i.e., an ECN without an "incorrect" or embargoed status) is the legal authority to export goods from Australia. An ECN with errors or embargoes must be attended to and the ECN must obtain a clear status before goods can be exported.

The ECN is placed on documentation that accompanies the goods when they are exported. An ECN consists of 14 alphanumeric characters ending in either a "C" (indicating a status of Clear) or an "E" (indicating a status of either Error or Embargo). Each of the 14 alphanumeric characters has a specific meaning. For example, 4A031521498JHC means the following:

4 = State code
A = Port code
03 = year
152 = Day of the year (Julian date)
1498 = Entry number for the day
J = First check character
H = Second check character
C = Clear status

Goods that are exempt from normal Customs export entry requirements are still required to be quoted on export manifests and submanifests. Instead of being an ECN, these goods are quoted using an exemption code, which con-

sists of three data fields: owner name, destination country, and goods description. The following classes of goods can be quoted using an exemption code:

- unaccompanied personal/household effects
- pets
- goods not exceeding A$2000 in value
- military goods belonging to the Australian Defense Forces (ADF) and foreign defense forces
- trans-shipment cargo
- goods temporarily imported under section 162A or temporarily exported under Australian carnet
- part shipped consolidation (air cargo only)
- bags of mail
- Australian domestic (air) or coastal (sea) cargo
- Australian ships and aircraft spares
- Customs use only

In addition to the ECN, exporters and agents must classify goods when providing export declarations to Customs according to the Australian Harmonized Export Commodity Classification (AHECC), which is designed to assist in the compilation and interpretation of export statistics published by the Australian Bureau of Statistics (ABS).

The AHECC is based on more than 5000 six-digit items of the Harmonized Commodity Description and Coding System (HS) and, with a few exceptions, is directly comparable with the six-digit base of the Customs Tariff for statistical purposes. The HS is a broad classification system used for classifying goods involved in international trade. It provides international statistical and administrative comparability of trade information and is updated every five years by the World Customs Organization.

Export Control Regulations All cargo that is received for export is subject to Customs control and therefore may be examined. Customs officers examine cargo for a variety of reasons, such as verifying the goods against entry details and detecting prohibited or restricted exports not covered by an appropriate permit.

Certain goods are completely prohibited from being exported from Australia, and include protected wildlife, some heritage items, selected weapons, and other dangerous goods.

Other goods are conditionally prohibited. For these, the exporter must apply to the appropriate agency for approval to export. This approval, generally in the form of a permit, must then be submitted to a Customs officer.

For those companies who are located in Australia, Customs fosters com-

pliance with export requirements through training and awareness programs, audits and sanctions.

For more information on which goods are both completely or conditionally prohibited, see Appendix 10—Goods Subject to Export Prohibition or Restriction of the Australian Customs Service document *Export Controls*, which is available at *http://www.customs.gov.au/resources/Files/volume12.pdf.*

Export Reporting and Customs Clearances Goods must be reported to Customs before being taken on board the ship or aircraft in which they are to be exported, unless they are exempt from entry. There are three ways to submit an Export Entry to Customs:

1) Manually complete Forms B957 and B957(a), which will then be inputted into the Export Integration (EXIT) system by Customs;
2) Electronically by a registered EXIT user; or
3) Electronically by completed an export entry on the Internet.

The Customs Export Integration (EXIT) system is an automated system that links Customs with exporters or their agents, consolidators and freight forwarders, airline and shipping companies, export permit issuing agencies, and the Australian Bureau of Statistics. Approximately 98 percent of all export entries are entered directly into the EXIT system.

EXIT is based on self-assessment principles. EXIT also uses risk management techniques to identify instances of non-compliance. The majority of entries is accepted as low risk and is cleared for export almost instantaneously. Delays occur when entries fall into a high-risk category and further information is required. Any consignments that match an EXIT profile may be embargoed and given a more detailed examination. This may involve Customs examining in close detail its commercial documentation or even a physical examination of the actual goods. To ensure compliance, Customs applies sanctions to deter carelessness, recklessness, and fraud.

Once goods are entered into EXIT, Customs can give approval for export by means of a "clear" Export Clearance Number (ECN). Ships and aircrafts can leave Australia only after an ECN has been assigned and a Certificate of Clearance acquired. Once an export entry has been submitted to Customs, the owner must export the goods in accordance with the export entry within 30 days of the ECN will be revoked. The export entry must be amended if only some or none of the goods are actually exported.

Export Embargoes Australia, in accordance with resolutions passed by the United Nations Security Council (UNSC), restricts the trade of certain goods to certain countries, which include Iraq, Libya, Angola, Rwanda, Sierra Leone, and Afghanistan.

Permission to export listed goods to these embargoed countries must be obtained from the Department of Foreign Affairs and Trade (DFAT) prior to exportation. If goods to be exported to an embargoed country appear in the Defense and Strategic Goods List (DSGL), a separate permission may be required from the Australian Department of Defense (DOD).

In addition, there may be UNSC arms embargoes on countries that are not specified above. Countries to which this form of embargo applies are listed in the DOD publication, "Australian Controls on the Export of Technology with Civil and Military Applications: A Guide for Exporters and Importers." Currently, this form of embargo is only applied to the Federal Republic of Yugoslavia and Sierra Leone, and restricts the exportation of arms and related materials of all types.

Further information regarding specifically which goods and which countries are embargoed, and the application of those embargoes, contact the Department of Foreign Affairs and Trade (DFAT): RG Casey Building, John McEwen Cr, BARTON ACT 2601, Telephone: 02 6261 1111, Facsimile: 02 6261 3111, Internet: *http://www.dfat.gov.au*

7.6.2 China

The General Customs Administration in China has the power by law to check and examine all exports from the country and detains those in violation of their laws and regulations.

Classification of Goods The China Customs Statistics (CCS) keeps track of all products passing through the territory of Chinese Customs and is the basic information on China's external trade performance. The Commodity Classification for China Customs Statistic (CCCCS) contains more than 6900 eight-digit commodity subdivisions in 22 sections and 98 Chapters. It is based on the Harmonized Commodity Description and Coding Systems. All imports and exports are entered with units of quantity and the value in U.S. dollars. Imports are valued on a CIF basis, whereas exports are valued on a FOB basis.

Export Control Regulations China maintains export bans and restrictive licensing procedures on certain items. Products banned from export include musk, copper, platinum, specified chemical compounds, and products whose export is banned under international treaties. Other items that may not leave China include all items that are prohibited from being imported; manuscripts, printed matter, magnetic media, photographs, films or other articles that involve state secrets; valuable cultural relics; and endangered animals and plants.

Products subject to strict licensing controls include dual-use chemicals, chemical precursors, heavy water, and exports of fish, fresh vegetables and fruits to Hong Kong and Macao. Foreign-invested enterprises are restricted to exporting out of China only the products they manufacture.

The export licensing system is administered by the Ministry of Foreign Trade and Economic Cooperation (MOFTEC) and designated local offices. An export tendering system for a limited but growing number of products has also been introduced. Most licenses are valid for a single use within three months after issuance. For certain items, including 26 categories of agricultural and petroleum products, licenses are granted for six months with multiple use up to 12 times.

On June 10, 1998, China promulgated Regulations on the Administration of the export of dual-use (military and civil) Nuclear Facilities and related technologies of the People's Republic of China. The export licenses required under these regulations are issued by MOFTEC.

Export Reporting and Customs Clearances Export licenses are required for almost every good exported from China (some exemptions apply). For those goods subject to export license control, the export must apply for an export license to the authorized administrative body. Customs in China will not accept the application for exporting of any commodities without an export license. The Ministry of Foreign Trade and Economic cooperation (MOFTEC) is China's administrative body for the issuing and control of most export licenses. Other issuing bodies include local foreign trade departments.

The following goods do not require an export license:

- Export commodities produced by foreign funded enterprises;
- Export commodities related to compensation trade
- Twenty-seven varieties of commodities such as rice, soya beans, corn, live pigs, live cattle, live sheep, live fowls, frozen beef, frozen mutton, frozen pork, frozen suckling pigs, frozen fowls, frozen doves, giant crabs, swimming crabs, chestnuts, Hebei-produced pears, Hami melons, fragrant pears, tea, fireworks, toilet paper, drawn work, carpets, crude oil, refined oil, and coal.

7.6.3 Japan

One of the duties of Japanese Customs is outbound clearance. Under the Customs Law, any person who is to export or import goods must submit a declaration to the Director-General of Customs. Customs checks the legitimacy of the export and/or import declarations and examines the goods, if required. The exporter of goods must declare to the Director-General of Customs the nature of the goods as well as quantity, price, and any other necessary particulars. An export permit must also be obtained after the necessary physical examination of the goods.

Goods to be exported must be brought into the Hozei area or a specially permitted place for storage. The exporter or his proxy, in most cases a cus-

tomhouse broker, prepares an export declaration describing the nature, quantity, value, etc. of the goods to be exported. This declaration is accompanied by supporting documents such as invoices and applicable permits, approvals, or licenses (e.g., exportation of strategically sensitive materials under the control of the Ministry of Economy, Trade and Industry).

The submitted export declaration is checked against the invoices and other supporting documents at Customs. Documents are checked for:

- statistical classification validity (correctly made according to the "Export Statistical Schedule")
- permission or approval is secured in respect to pertinent goods
- a correct application for approved excise tax exemption accompanying goods that are to be exempted

In checking the submitted documents, Customs decides whether the goods have to be physically examined to ascertain the correctness of the classification of goods and to see whether the examinations required by laws and regulations other than the Customs Laws have been completed. In principle, Customs examinations of goods are conducted at a Customs examination corner in the building of the Customhouse. "Examination at a place where the goods are stored" or importer's premises are conducted when it is difficult to bring goods to the Customs examination corner due to their nature. An example would be a very large machine or a delicate artwork.

As Japan is a participating nation in the Wassenaar Arrangement on Export Control for Conventional Arms and Dual-Use Goods and Technologies, it is important to note that in general, export controls to Japan remain one of the least restrictive of any destination country for United States exporters and multinationals based wholly or in part in the United States. Currently, Japan identifies only four countries (Iran, Iraq, Libya, and North Korea) as restricted destinations. Some Japanese companies conduct either direct or indirect trade with countries against which the United States has imposed embargoes. All U.S. exporters must ensure that any shipments to Japan have Japan as the final destination and that trans-shipments through Japan comply with U.S. export control laws.

The Customs Law is the most fundamental export control law concerning exports. In addition, depending on the type of cargo, some shipments require a prior permit or approval for export of the cargo before declaring exports to Customs. These must be obtained from government offices other than Customs, such as the Ministry of Economy, Trade and Industry and the Ministry of Health, Labor and Welfare. According to the stipulations of these other laws and regulations, exporters of cargo, who are required to obtain permits, approvals or passing of examinations, must prove to Customs that these requirements have been met during the Customs clearance procedure, which then needs to be confirmed. Unless these requirements are proven and

confirmed, Customs will not permit the cargo to be exported (Customs Law, Article 70).

The purpose of these laws and regulations that require permits, approvals, completion of examination, or other conditions concerning exports of cargo is to regulate "unrestricted and disorderly exports" and to assist in the general development of foreign trade by either prohibiting or restricting the export of certain cargoes. These laws and regulations were enacted "to achieve administrative objectives through the confirmation of required permits, approvals, completion of inspection, and other conditions in the physical presence of cargo at Customs," which is the final regulatory agency. There are major laws and regulations that regulate exports that are listed below.

Export Trade Control Order. This order is based on the Foreign Exchange Law, which broadly regulates exports and supplements the Customs Law. In order to promote the sound development of trade, depending on the type of cargo, destination or the contents of a commissioned processing trade contract, the order requires a permit or approval from the Minister of Economy Trade and Industry ("METI Minister"). The METI Minister's export permits and other documents of proof are attached to the export declaration when declaring exports at Customs, which must confirm that these requirements have been met.

Cultural Property Protection Law. Important cultural assets of Japan, such as antique arts and crafts, cannot be exported unless permitted by the Director-General of the Cultural Agency. This requirement has been enacted to protect Japan's cultural assets. When a question arises whether a cargo shipment declared for exports is either an important cultural asset or important art piece stipulated in the Cultural Property Protection Law, the exporter must submit an "Antique Art Export Evaluation Certificate." Either the Arts and Crafts Division Director of the Cultural Asset Protection Department of the Cultural Agency or the Curator of the National Museum of Kyoto issues these documents.

Other Japanese laws governing export control include the following:

1. Foreign Exchange Order
2. Export-Import Trading Law
3. Forest Seedling Law
4. Law Concerning Wildlife Protection and Hunting
5. Cannabis Control Law
6. Opium Law
7. Stimulant Drugs Control Law
8. Rabies Prevention Law
9. Plant Quarantine Law
10. Domestic Animal Infections Disease Control Law
11. Narcotic Drugs and Psychotropic Substances Control Law

To summarize, Japanese export reporting and control processes are complex and burdensome. Use of a competent Customs Broker, freight forwarder, or other intermediary is advised.

7.6.4 Korea

Export Control Regulations Korea, although not a member of COCOM, has observed COCOM licensing procedures since 1993. In 1995, the Korean government became a member of the post-COCOM regime, known as the "Wassenaar Arrangement." Korea is also a signatory to the Chemical Weapons Convention (CWC). Under the Foreign Trade Act, if an export control is deemed necessary for the maintenance of international peace and security, national security, or other national interests, an exporter or importer is required to obtain a certificate or permit from the head of the related administrative agency. The list of controlled items is published in Korea, which includes nuclear products, arms, chemical weapons, and missiles.

On its negative export list, Korea also prohibits the export of 13 items by Harmonized System six-digit classification, including whale meat, uncut pieces of stone (granite, etc.), and dog fur or skin products. In the past, any person wishing to export industrial equipment, or technical services together with industrial equipment, had to obtain approval. This mandatory license requirement was abolished in March 1997.

In accordance with the elimination of "gray area measures" under WTO/Safeguards agreement, out of 834 items, which require export licenses, 20 items were eliminated and the list of restricted country was reduced for 52 items. The export license requirement will be eliminated for most of the remaining items by the end of 1998, except for license requirements aimed at protecting natural resources and intellectual property rights.

Import/Export Documentation After the revision of the Customs Act and its Enforcement Decree in December 1995, customs clearance procedures have been simplified. The import license system was replaced by the import declaration system so that an import declaration filed without defect is immediately accepted for release of the goods. With the exception of high-risk items related to public health and sanitation, national security, and the environment, which oftentimes require additional documentation and technical tests, goods imported by companies with no record of trade law violations are to be released upon the acceptance of the import declaration, without customs inspection. The Korean Customs Administration is still working on the Electronic Data Interchange (EDI) system for paperless import clearance that will allow importers to make an import declaration by computer, without visiting the customs house. Although substantial progress has been made on EDI for exports, it will take one or two more years until Customs completes the EDI system both for exports and for imports.

Import declarations may be filed at the Customs House before a vessel enters the ports, or before the goods are unloaded into bonded areas. In both cases, goods are released directly from the port without being stored in a bonded area if the import declaration is accepted.

Along with import procedures, export procedures and documentation were also simplified effective January 1, 1997. Exported goods no longer require an export license (E/L) issued by a foreign exchange bank. Exporters can file their exports notices based on their shipping documents to Korean Customs by computer at the time of export clearance. All commodities can be freely exported unless they are included on the negative list.

Predictability of export procedures in Korea is problematic. Hiring a good customs broker, freight forwarder, or other logistics intermediary is highly recommended.

7.6.5 Taiwan

Of the total 10,616 items in Taiwan's current tariff schedule (HS), 9748 or 91.82 percent may be exported. In the past, most exports required export permits. As of May 2002, 862 items or 8.12 percent require export licenses. Licenses may be required under international treaties and trade agreements, or for purposes of national security, hygiene, and environmental/ecologic protection or policy. The Ministry of Economics Affairs (MOEA) Board of Foreign Trade (BOFT) maintains a Web site at *www.moeaboft.gov.tw* with information on export control regulations.

Some of the cooperative export control measures that Taiwan has implemented in recent years include the following:

- Implementation of quantitative restriction arrangements on exports of textile and garment products to the United States, Canada, Brazil, Argentina, Turkey, and the European Community
- National security, that is, the secure supply of certain daily necessities and important industrial materials, including rice, salt, coal, and uranium
- Implementation of strategic trade and nonproliferation agreements, that is, the export of munitions and armaments, strategic high-tech commodities, and technical data
- Protection of intellectual properties and commodities containing intellectual works through implementation of the Trademark Export Monitoring System
- Protection of endangered plants and animals and preservation of the natural ecological balance in accordance with the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)
- Concern over hygiene and health effects of certain products, such as toxic waste and chemicals

Taiwanese Customs administration is efficient, well trained, and organized. Despite this government professionalism, use of a highly regarded freight forwarder is recommended.

7.7 CORPORATE EXPORT COMPLIANCE PROGRAMS

Although many companies have excellent export control programs, others rely substantially on the contracted freight forwarders, a potentially dangerous situation, and in some cases, believe that that they will not be assessed. For example, the following U.S. government press release illustrates how much trouble a company, identified as "X," may find themselves in if they do not have a proper procedure in place:

California Company Penalized for Exporting Fingerprint Identification Systems and Encryption Software

Assistant Secretary of Commerce for Export Enforcement Michael J. Garcia announced that the Department of Commerce has imposed a $135,000 civil penalty on *Company X* to resolve allegations that the company exported automated fingerprint identification systems, associated fingerprint identification software, and encryption software to numerous destinations in violation of U.S. export control laws.

The Commerce Department's Bureau of Industry and Security (BIS) alleged that, on 37 occasions between January 1997 and October 2000, *Company X* exported or re-exported automated fingerprint identification systems, associated fingerprint identification software, and encryption software to numerous destinations without the required export licenses. In eight of these shipments, BIS further alleged that *Company X* made false statements on Shipper's Export Declarations, the forms used to report export data to the U.S. Government. *Company X* voluntarily disclosed these alleged violations to BIS and cooperated fully in the investigation.

BIS administers and enforces export controls for reasons of national security, foreign policy, nonproliferation, anti-terrorism, and short supply. Criminal penalties and administrative sanctions can be imposed for violations of the Export Administration Regulations.

—[Source: Press Releases—July, 25, 2000 *www.bxa.doc.gov/press/2002*.]

If a company violates exporting regulations or restrictions, a hefty fine, negative press, and costly lawyer fees may result. Most country's customs services concentrate their resources on inbound or import operations rather than on exported shipments. In the United States, for instance, Customs examines between 2 and 4% of import shipments and far less than 1% of export shipments. Table 7.5 provides U.S. government audit questions that can be used to determine the strength of your export compliance program. A poor program or negative audit can lead to dire consequences. A more detailed checklist is

TABLE 7.5. Self-Assessment

How Good Is Your Company's Export Compliance Program?

1) Was management commitment demonstrated throughout the system? Does the organizational placement of the compliance department ensure that their compliance concerns are heeded?
2) Does the company have adequate resources to do the necessary tasks?
3) Does the company have a written export management program document and policy statement?
4) Is ongoing export control communication and training demonstrated throughout the organization?
5) Are the written procedures current?
6) Are the written procedures consistent with operational procedures? If not, which procedures need to be amended?
7) Were there designated responsible persons (and are names current)? Are they well trained in export control tasks?
8) Were there gaps in performance of export management procedures? Is a well-designed process, either automated or manual, in place?
9) Was adequate documentation in place to verify performance of all export control tasks?
10) Assess the stability of the environment of any recent company-wide changes, mergers, or acquisitions? What is the impact of inexperienced export control personnel on the operation?

provided in Appendix 2 while information on material compliance systems is presented in Chapter 9.

If a company discovers a violation, the appropriate government agency should be alerted as soon as possible. The resulting enforcement action will be less harsh if the company initiates the disclosure rather than having the enforcement agencies discover the violation. A thorough internal investigation should be conducted and corporate or outside counsel should be consulted.

The following sections provide specific guidance for complying with individual country export reporting and export control procedures. Readers are advised that the information provided is of a general nature of advice and practical applications. Conducting further research or engaging in expert consultation for individual transactions is important since national export laws are complex and subject to change frequently.

The majority of exporters rely on brokers, freight forwarders, and other intermediaries to handle the logistical and legal requirements for exported goods. Exporters trust their goods to freight forwarders who, even though not licensed by the government, are thought to be experts at export control. However, some of these intermediaries often lack even rudimentary knowledge of export requirements and their implications. Hiring a knowledgeable and experienced intermediary is therefore one of the most critical things an exporter can do to ensure their shipments are fully compliant with current reg-

TABLE 7.6. How to Identify an Excellent Freight Forwarder

1) Are the freight forwarder's (FF's) personnel experienced in all things "export" or do they appear to be new hires?
2) Do they have a formal Export Compliance Program?
3) Does the FF have a written policy affirming the importance of export compliance backed by top management?
4) Does the FF require you to sign a broad "Power of Attorney" or agreement that absolves them from all blame if something goes wrong and makes you 100 percent responsible for all errors?
5) Does the FF have a very large client that will absorb all the FF's energy/resources, leaving you as an "also ran"?
6) Are the FF's branches located in all the ports of exit that your goods traverse?
7) Are they certified for your country's automated export reporting system?
8) Do they maintain a compliance department that oversees export compliance for their entire organization?
9) Does the FF conduct regular compliance training for their employees and customers?
10) In the event of an export hold or examination/penalty/seizure notice, does the FF have the means to know that the shipment is held and has the means and desire to resolve the issue?
11) Finally, do you have your own measurements in place to monitor your FF's performance? If service is poor or slipping, you need to take action!

ulations and policies. Exporters are legally responsible and should be knowledgeable of the export control requirements for the countries that they encounter in the course of business. At the very least, intermediaries should have a point person within their organization for all aspects of exporting goods, a thorough training program, and knowledgeable employees. Table 7.6 presents questions that can be used to assess freight forwarders. If, for example, U.S. freight forwarder tells you that "NLR" (a common term used in documentation that means "No License Required") indicates, "No Shipper's Export Declaration (SED) is required," another agent should be chosen.

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PART II

MATERIAL COMPLIANCE SYSTEMS

8

IMPACT OF TERRORISM ON THE SUPPLY CHAIN

8.1 INTRODUCTION

The horrific attacks of September 11, 2001, on the World Trade Center towers in New York City and the Pentagon in Arlington, Virginia, will not soon be forgotten. The attacks had an immediate impact on the movement of goods across U.S. borders and at U.S. seaports and airports. All flights, both cargo and passenger, were grounded immediately and international flights already in the air were diverted to Canada and less critical airports in the United States. Land border crossings came to a halt. U.S. seaports were closed, container movements stopped, and arriving vessels, were held outside of U.S. ports by the Coast Guard.

The effects of the halt in commerce were immediate and profound as U.S. Bureau of Customs and Border Protection (CBP) strove to avoid further terrorist attacks. The CBP issued a "Severe Alert," the highest alert level possible, as illustrated in Figure 8.1, at all border entry points. A Severe Alert requires sustained, intensive antiterrorist questioning and includes increased inspections of travelers and goods at every port of entry. In the days and weeks following September 11, the United States began to open up border crossings but at a snail's pace as the incessant volume of traffic overwhelmed the CBP Service, the National Guard, and state and local police officers assigned to the border antiterrorism surveillance.

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Figure 8.1. Homeland Security Advisory System.

8.2 EFFECT ON CARGO MOVEMENTS

The effect of CBP actions on delivery schedules of imported merchandise was severe and lasting. Safety stocks were depleted rapidly and companies' attempts to replenish their shelves were thwarted as the goods sat in CBP holding areas. The effect on manufacturing plants relying on imported parts and materials from their suppliers was especially profound.

The Ambassador Bridge in Detroit is a particularly unwieldy chokepoint for U.S.–Canada transborder traffic, even in the best of times. On September 11, the usual hours-long queuing and processing of trucks came to a complete halt. Over the next few days, very few trucks were able to complete the transit of the Ambassador Bridge from Canada to the United States.

Many of the thousands of trucks in line had the parts and assemblies needed immediately for the U.S. vehicle assembly plants of the big three U.S. auto companies: Daimler-Chrysler, Ford, and General Motors (GM). Most of the U.S. auto plants were shut down for some period of time lasting from hours to weeks. The longer a plant is closed, the worse its effect on company sales and profits.

Ford and Daimler-Chrysler plants were closed for several weeks. General Motors, however, had a contingency plan in place for general bridge congestion. Tugboats and barges were already under contract to bring 12 of the most critical tractor-trailers across the river in case of long delays and mile-long lines on the bridge and in Canada.

Hours after the tragedy of September 11, the compliance department of GM swung into action and GM customs brokers and compliance staff drove up and down the long lines of trucks to find those containing the key components needed for GM's manufacturing plants. They pulled them out of the line

and directed the vehicles to the Windsor, Ontario, docks. They were loaded immediately onto barges for the short trip across the river to Detroit and then on to the GM plants. Round-the-clock operations were mounted and GM was able to weather the immediate aftermath of the attack while their competition suffered. As GM logistics caught up with their shipment backlog, the competition was allowed to use the excess barge capacity. Weeks later, border operations returned to more normal processing times.

8.3 DANGEROUS TIMES: NEXT ATTACK?

The U.S. government has intelligence that sea containers and other cargo shipments in general are a source of vulnerability as dangerous as the jumbo jets that destroyed the World Trade Center towers and crippled the Pentagon. "Dirty" bombs (conventional explosives laced with radioactive materials) could wreak widespread devastation, panic, and disruption. Any number of other, possible scenarios are capable of being unleashed by terrorists. Most terrorism experts expect that another attack at a scale similar to or perhaps even exceeding the New York/Pentagon tragedy is not only possible, but also imminent. Because the threshold from "conventional" low-impact terrorist warfare has been crossed, the new types of terrorist attacks will likely involve not only weapons of mass destruction but conventional means to attack critical infrastructure targets such as ports and airports, nuclear and chemical plants, water treatment and power plants, and the financial and commodity centers in New York and Chicago with catastrophic economic and human consequences. Osama bin Laden's al Qaeda terrorist network and its satellite affiliates are the most likely groups to carry out such catastrophic attacks.

As leaders, cells, and operatives of these groups are being rounded up or killed in Afghanistan or arrested in the United States, Western Europe, and elsewhere, there reportedly are dozens or hundreds of "sleeper cells" left, armed with plans for the next wave of terrorist operations. The devastating military defeat of these groups in the military campaigns in Afghanistan and Iraq are likely to serve as the trigger for their remaining operatives to seek catastrophic revenge on behalf of their fallen and retreating comrades.

Security and supply chain directors must adopt active measures to defend against new types of terrorist threats while maintaining a strategic view. Additionally, experts expect past trends to reveal future attack patterns because terrorists, especially al-Qaeda planners, seek to exploit new vulnerabilities and new modes of warfare in order to inflict maximum damage. Therefore, instead of such catastrophic attacks' taking place "beyond the imagination" of those responsible for security, we need to begin thinking like the enemy—always anticipating and preparing to counteract new types of attacks and targeting. Above all, antiterrorism emphasis must be placed on intelligence tracking of suspected terrorist networks, cells, and operatives; detection; and pre-emption during the earliest possible preattack phases.

8.4 COUNTERMEASURES

In the wake of this intelligence and the high-level alert, U.S. CBP and the federal government embarked on a comprehensive and long-term series of changes to prevent terrorist attacks from leveraging vulnerability in organization's supply chain. The purpose of these changes is to combat international terrorism while improving the flow of trade.

In the largest and most sweeping U.S. government reorganization since the 1950s, the Homeland Security Department was created. Combining emergency response capabilities with law enforcement and border security the new department are a formidable weapon in the fight against international terrorism. Of particular note is a reorganization of all three U.S. border inspection agencies into a single entity. It is anticipated that a single unified organization with a single chain of command will achieve substantial gains in efficiency and effectiveness.

The best way (outside of specific intelligence) to detect and interrupt terrorist-related shipments is to separate "high-risk" or potential targets from the vast bulk of legitimate shipments in the international trade logistical pipeline. The following section presents U.S. CBP programs that address the separation of shipment.

8.4.1 Tightening Legal Requirements

Laws and regulations requiring automated and advanced shipment reporting have been changed. Carriers, for example, must report shipments to U.S. CBP 24 hours in advance of arrival and terms of convenience such as "FREIGHT ALL KIND (FAK)," "MISCELLANEOUS," and "SAID TO CONTAIN" are prohibited. CBP will issue "DO NOT LOAD" messages to the carriers if such nondescriptive terms are used. In addition, if the parties in interest (shipper, manufacturer, and consignee) are not listed, the shipments will be held.

As another segment of its multifaceted legal anti-terrorism precautions, CBP now requires all ocean carriers and non-vessel operating common carriers (NVOCCs) to file a manifest 24 hours before shipments are loaded at the foreign port. In addition, the CBP is in the process of planning to expand the notification to 8 hours for all airfreight cargo that has its destination in or transits through the United States. This allows border officers time to profile inbound shipments. If a cargo is perceived as a risk, CBP will do one of two things depending on degree of suspicion: Instruct the carrier not to accept it on the vessel, or allow it to sail but upon arrival subject it to inspection. It is important to note that the CBP will hold a shipment as long as they think is necessary. If you goods are part of this shipment, this may translate into late deliveries and cancellations of orders.

Clearly in the program, CBP issued approximately 170 no-load orders, delaying U.S.-bound shiploads on docks worldwide since the start of the program in February 2003. Clearly, any company shipping products, parts, and

materials should ensure that all documentation and CBP formalities are complete, accurate, and consistent with legal international business practices. Table 8.1 provides examples of activities that companies can take to improve security and minimize opportunities for terrorist to leverage a company's supply chain.

TABLE 8.1. Border Security Measures for Companies Involved in International Trade

Develop and implement a sound plan to enhance security procedures. The following are general recommendations that will help insure that goods and commodities in the supply chain do not become susceptible to tampering or use by terrorists:

- *Procedural Security:* Companies should notify your Customs authority and other law enforcement agencies whenever anomalies or illegal activities related to security issues are detected or suspected.
- *Documentation Processing:* Intermediaries should make their best efforts to ensure that all information provided by the importer/exporter, freight forwarder, consolidator, etc., and used in the clearing of merchandise/cargo, is legible and protected against the exchange, loss, or introduction of erroneous or misleading information. Documentation controls should include, where applicable, procedures for:
  - —Maintaining the accuracy of information received, including the shipper and consignee name and address, first and second notify parties, description, weight, quantity, and unit of measure (i.e. boxes, cartons, etc.) of the cargo being cleared.
  - —Recording, reporting, and/or investigating shortages and overages of merchandise/cargo.
  - —Safeguard your computer access and information.
  - —Reporting any unusual shipper's instructions and routings.
- *Manifest Procedures:* Manifests should be complete, legible, and accurate and submitted in a timely manner.
- *Personnel Security:* Consistent with federal, state, and local regulations and statutes, companies should establish an internal process to screen prospective employees and verify employment applications. Such an internal process could include background checks and other tests depending on the particular employee function involved.
- *Education and Training Awareness:* A security awareness program should include notification to Customs and other law enforcement agencies whenever anomalies or illegal activities related to security are detected or suspected. This program should become an integral part of your business. These programs should provide:
  - —Recognition for active employee participation in security controls.
  - —Training in documentation fraud and computer security controls.
- Emphasizing security through words and example by the CEO and other company executives.

Source: http://www.cbp.gov/xp/cgov/import/commercial_enforcement/.

8.4.2 Private Sector Partnerships

CBP has initiated a new program called "CBP—Trade Partnership against Terrorism" (C-TPAT). Companies using CBP guidelines insure that every level and step of their supply chain processes are secure, reliable, reputable, and not subject to utilization for destructive purposes by terrorists or their allies. To date, approximately 2000 importers, brokers, carriers, and port authorities have signed on to the program. In return (and after validation by U.S. CBP), C-TPAT participants enjoy lower rates of disruption than nonparticipants. By developing this voluntary program of self-imposed supply chain security measures for companies importing goods, U.S. CBP has greatly eased their burden of scrutiny at the border cargo operations.

In working with importers in the battle against terrorism, the CBP looks at such criteria as where their goods originated; the physical security and integrity of a company's overseas plants and those of their foreign suppliers; the background of their personnel; the means by which they transport goods; and the companies they employ to transport their goods into our country. Also under scrutiny are the security practices of their freight transporters and the routes their shipments travel.

Importers need to understand and stress the importance of "know your customer," and assess the overall vulnerability of their supply chains, from factory floor, to loading dock, to transportation to the border. Every single link in that chain must become more secure against the very real threat of international terrorism.

C-TPAT recognizes that CBP can provide the highest level of security only through close cooperation with the ultimate owners of the supply chain—importers, carriers, brokers, warehouse operators, and manufacturers. Through this initiative, CBP is asking businesses to ensure the integrity of their security practices and communicate their security guidelines to their business partners within the supply chain.

The program offers businesses an opportunity to play an active role in the war against terrorism. By participating in this first worldwide supply chain security initiative, companies will ensure a more secure supply chain for their employees, suppliers, and customers. Beyond these essential security benefits, CBP will offer additional benefits to C-TPAT members, including:

- Potential reduction in the number of inspections (reduced border times)
- If currently a "low-risk importer," an opportunity to expand "low-risk" treatment to all divisions within the company
- Eligibility for account-based processes (instead of transaction-by-transaction payment, bimonthly/monthly payments will be allowed)
- The emphasis on self-policing, not CBP verifications, will add control and predictability to scheduling.

To quote a recent speech about private sector security incentives by Judge Robert C. Bonner, Commissioner of CBP (CBP speech, 2003):

> **I'm talking about initiatives like our Customs-Trade Partnership Against Terrorism, or C-TPAT, which enables companies, that meet or exceed our security requirements to get expedited treatment through our ports of entry. Over 1600 companies have now signed up to participate in C-TPAT.**

Global supply chain and logistic managers who select a C-TPAT integration model will not only minimize disruptions but also realize reductions in direct costs. Prior to applying for C-TPAT, importers should evaluate current supply chain security, assess the cost and timing of implementation, establish value propositions, and assess their organizational readiness to implement and support the new model. Table 8.2 presents the potential activities that should be undertaken prior to C-TPAT submission.

The challenges in the wake of September 11, 2001, are extraordinary, but so may be the benefits for early adopters willing to address global supply chain security requirements in concert with their corporate strategies.

Additional information on C-TPAT can be obtained from the following Web site: *www.customs.ustreas.gov/xp/cgov/import/commercial_enforcement/ctpat/.*

8.4.3 Overseas Targeting of Container Freight

CBP has initiated a program entitled "Container Security Initiatives" (CSI) whereby teams of U.S. inspectors are deployed to major container ports overseas to target suspect cargo. Working jointly with the host country CBP to

TABLE 8.2. Activities to Take Prior to Joining C-TPAT

- Form a team to access and improve your overall supply chain security
- Complete C-TPAT questionnaires
- Update or write their global supply chain security procedures to be C-TPAT compliant
- Update your minimum-security requirements with your transportation service providers (forwarders, brokers, and ocean carriers, rail carriers, trucking companies, air cargo suppliers, third-party logistic providers, such as NVOCC'S, and overseas manufacturers and suppliers)
- Provide education and training programs to your employees, vendors, and overseas transportation suppliers
- Audit your suppliers and manufacturers for C-TPAT security compliance

Source: CBP Web site.

review pre-arrival manifests and bills of loading of vessels destined for the United States, U.S. bound containers that raise suspicions are examined at the foreign port using large X-ray machines and other nonintrusive inspection equipment as well as typical physical examinations.

CBP has a number of ports already in operation, with many more to follow. Containers examined and cleared will be sealed and allowed to proceed without interruption to the United States. Within the first year of the program, 18 of the top 20 ports have agreed to join CSI and are at various stages of implementation. These ports are points of passage for approximately 70 percent of cargo containers shipped to the United States. They include (by container cargo volume): Hong Kong, Shanghai, Singapore, Rotterdam, Pusan, Bremerhaven, Tokyo, Genoa, Yantian, Antwerp, Nagoya, Le Havre, Hamburg, La Spezia, Felixstowe, Algeciras, Kobe, and Yokohama.

CBP offers CSI-participating countries the opportunity to send their CBP officers to U.S. major ports to target cargo that is exported to their country via ocean containers. CBP will also share its intelligence and pre-arrival information on a bilateral basis with its CSI partners. Sharing of information is intended to be a reciprocal process. Both Canada and Japan have taken advantage of this opportunity to station their officers in the United States to prescreen suspect containers heading to their jurisdictions.

8.4.4 U.S./Canadian Border Clearance and Security Enhancements

In another antiterrorism measure, the United States and Canada have initiated an accelerated clearance that is being tested and deployed along their joint border. To be eligible, the importer must be C-TPAT approved and the carrier and driver of the conveyance must have security clearances.

By moving these shipments into the "low-risk" category, CBP and the importers are able to quickly process their import shipments, in some case using transponders, through border formalities with high degrees of integrity. These shipments, however, are subject to spot checks and audits.

Importers and their shipments face an unprecedented amount of scrutiny as their shipments cross international borders. If another major attack occurs, governments will respond with swift and decisive actions. The borders and ports would likely close again and the supply chain would again be frozen. Table 8.3 presents potential actions to be taken to minimize supply chain interruptions in the event of a terrorist attack.

8.5 NEW REALITY

New security measures have forced importers and their agents to rethink processes, in particular to ensure proper documentation accompanies shipped merchandise and that the schedule of shipment (including government inspections/delays) is integrated in supply chain scheduling. The result of

TABLE 8.3. Logistical Contingency Plan for Terrorist Incident

In order to avoid or minimize the disruption to your supply chain, the following actions are recommended:

- Write and promulgate a published contingency plan for continuation of operations
- Make sure that the plan is available, tested, and accepted by participants
- Evaluate safety stock levels and emergency sourcing alternatives
- Rethink your inventory policies; deal with the cost of extra security, including insurance
- Decide how much security is "enough"
- Rethink your procurement policies; avoid "problematic" sources
- Rethink your customer service commitments
- Design a secure IT infrastructure for global supply chain management
- Make sure that your communications and IT will function during and after a major disruption
- Ensure that the best logistics partners (carriers, freight forwarders, and customs brokers) possible have been hired
- Reorganize to meet the challenge: Place your compliance department under the tax department or another department that has great influence within your company
- Insure that your plans include transportation alternatives, such as GM's "Detroit River Initiative"
- Know the status and locations of your shipments so you can locate them if intervention becomes possible (It may be appropriate to construct a "war room" concept may be appropriate for mid-size and larger companies.)

which is that the shipment of goods is no longer an off-line unintegrated activity—"let the shipping department handle it"—but a well-managed and sophisticated automated system that integrates the complete global supply chain system.

Under proposed U.S. legislation, motor carriers, rail lines and air carriers may have to provide advance electronic notice of their cargo, for example, eight-hour advance notice of air freight has been proposed. This may be especially difficult for the integrated carriers (or air express carriers) such as UPS and FEDEX to meet. Currently, this requirement cannot be met because freight continues to be loaded up to the final hour before takeoff. Instead, air-express carriers have proposed filing an electronic manifest in-flight, reaching Customs at least an hour before arrival, with some exceptions.

It is anticipated that other countries will also begin adopting components of U.S. legislation, unfortunately with local nuances, as they implement similar security measures further complicating the requirements to track, assess, and implement a global compliance system for the shipment of goods.

Perhaps, it is best to close this chapter with a quote from Great Britain's magnificent Prime Minister—Sir Winston Churchill:

One ought never to turn one's back on a threatened danger and try to run away from it. If you do that, you will double the danger. But if you meet it promptly and without flinching, you will reduce the danger by half.

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9

MATERIAL COMPLIANCE SYSTEMS

9.1 OVERVIEW OF MANAGEMENT SYSTEM

To effectively manage global material compliance (MC), an organization must have the following:

- well-defined processes (standard business processes)
- personnel that understand legislation and how they apply to supply chain issues
- technology that facilitates information flow between key stakeholders within and external to the organization

The ultimate goal being higher profit margins on finished goods through supply chain optimization.

In the early 1980s companies began implementing the precursor to material compliance systems (MCS) to ensure ongoing regulatory compliance. The focus of companies rapidly shifted from simply executing MC activities, to managing the quality of the processes and resulting output. Companies quickly came to see corporate control of compliance processes and output as critical to meeting regulatory requirements; however, it was still considered a labor intensive, "operational" activity with a U.S. focus.

The events of the early 1990s in Europe and the former Soviet Union resulted in a significant easing of U.S. and multilateral export controls on

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West-East trade. During the same time period, developments in other areas of the world, such as the Middle East, underscored the importance of non-proliferation controls on chemical, biological, and nuclear weapons and missile technology. In 1991, the United States introduced Enhanced Proliferation Control Initiative (EPCI) regulations. During this time period, the U.S. Commerce Department Bureau of Export Administration, currently called the Bureau of Industry and Security (BIS), first published Export Management System (EMS) guidelines to assist exporters developed programs to assess end-use or end-users of the exported product (BIS, 1997).

During the 1990s, significant new and modified legislation was introduced to better manage the creation, distribution, and use of MSDS and labels as well as to ensure proper training and documentation is in place for the transportation of dangerous (hazardous) goods. Legislation was also brought about to improve worker's conditions and ensure the safety of the public and the environment during the transportation of hazardous materials.

In response to the above events, most major corporations mastered (or believed they had) basic MC issues by the late 1990s. They then refocused their resources toward cost reduction and risk aversion—especially when they realized how much money it was costing to ensure ongoing compliance. As a result, MCS moved from being an "operational" issue to a "tactical" issue with a significant amount of MC activities being automated or semi-automated. The output of these systems, however, was not always consistent.

In the early 2000s, multinational companies have begun to reevaluate their MCS as they realize that their country-specific, independent, unilingual systems do not reinforce their integrated business process, but rather hinder it and are expensive to operate. In doing so, they also realized that the "ship button" present on a company's internal/external Web system was linked to a series of time-consuming, manual activities that frequently involved complex regulatory matters or the processing of significant amounts of data.

Companies now realize the importance of a robust MCS that is integrated with other management and information systems (e.g., quality, finance), can significantly reduce costs and can improve overall performance. It also allows an organization to put in place a system that is based upon "reasonable care" and therefore promotes compliance with the recently released U.S. Customs Informed Compliance Strategy as well as industrial associations guidelines and codes of practices.

This chapter presents the basic components of a robust MCS, as derived from General Management System (GMS) principles, and how they can be integrated with other management systems. Chapter 10 discusses the role of information systems in MCS.

9.1.1 General Management System Principles

Numerous papers have been published on GMS principles. The basic premise is that a GMS provides the overall structure by which an organization can

manage it activities in a cohesive manner. Examples of publication employed in the design of export, quality, environment, and occupational, health, and safety systems include the following:

- U.S. Bureau of Industry and Security (BIS), formerly the Bureau of Export Compliance, Export Management System (EMS) guidelines (BIS, 1997)
- International Organization for Standardization (ISO) Quality—9000 (ISO/DIS, 1994) and Environment—14001 standards (ISO/DIS, 1996)
- U.S. automotive industries prescriptive version of the ISO 9000 standard—QS 9000
- Occupational health and safety management system specification—OHSAS 18001 (created via the concerted effort from a number of leading standard bodies, certification bodies, and specialist consultants)

These standards typically do not specify absolute requirements, but rather a commitment, in a policy, to compliance with applicable legislation and regulations. They also typically present the "what" not the "how"; it is up to each company to use the methods that best suit their objectives, culture and business operation. In the case of the ISO standards, they also require a commitment to continual improvement with a focus on prevention while the BIS EMS guidelines promotes the maximization of sales while ensuring compliance with US Export laws and regulations. Table 9.1 presents the key components of the proposed MCS as expressed through pertinent sections of the above standards/guidelines.

The implementation of these standards/guidelines has a cost that is typically made up of several key elements, namely "control," "prevention," and "failure." Control costs are those incurred in monitoring any process, system, or effect to ensure that it stays within defined limits. Prevention costs are those incurred to assure quality or environmental performance. Both these costs can be in the form of salary paid to personnel, or investment in equipment and systems. In the case of the MCS, "failure" costs are where money is spent on the following:

- Providing excess inventory due to delays and uncertainties in custom clearance that has or may result in product/parts shortages
- Transportation and production costs when goods are returned or impounded as they are stopped from entering/leaving a country due to prohibition on material, incorrect containers, or documentation
- Additional marketing activities/customer contact as company's reputation for on-time delivery is shattered
- Litigation due to failure to abide by contracts
- Payment of monetary fines or providing resources to assist/accompany auditors from government agencies

The "loss opportunity costs" may include the following:

- Prohibitions on the import/export of goods by the company
- Missed opportunities in foreign markets due to inability/understand regulatory requirements
- Criminal indictments of officers and employees for fraud and other offences

An effective MCS should ensure that the correct relationship exists between prevention and failure, producing an increase in an organization's bottom line, and an enhanced reputation. The establishment of an MCS, by itself, may not relieve an organization of criminal and administrative liability under the law a violation occurred; however, it will serve in most jurisdictions as a mitigating factor in an investigation of the violation.

The following are the basic requirements for any successful management system.

Commitment A key step in the implementation of a MCS is to ensure that the company's chief executive officer (CEO) is committed. Commitment should be more than just statement that material compliance is important to the company. Commitment should take the form of providing appropriate resources, assigning a senior management representative and preaching supply chain optimization to other levels of management.

Management Role Senior management must create the correct culture for logistic management within their company. They must set up clear structures defining responsibility and authority, they must define performance levels and objectives for material compliance issues in terms of customer and market needs, legal requirements, operational performance, and, of course, finance. Managers must measure and "sell" the value created by MCS internally as well as externally through the company's supply chain. All senior managers must have a basic understanding of supply chain management issues and importance and be able to communicate this to other personnel within the company. It is important that management receive formal training to ensure a basic understanding of MCS. Only when management understands all the issues will they be able to support them, commit to them, and make them happen. Management must ensure that all personnel involved in a MCS receive appropriate training.

9.1.2 Key Components of a MCS

Leveraging the definition presented in the ISO 14001 standard for Environmental Management System and BIS Export Management System Guideline, a MCS can be defined as "*The part of the overall management system that*

includes organizational structure, planning processes, resources (with assigned responsibilities), customer/supplier screening, procedures and practices for developing, implementing, achieving, reviewing and maintaining logistic policy."

These components are applicable to all types and sizes of organizations with varying product mix that ship goods internationally. The particular resource commitment to the MCS and its complexity is a function of the amount of shipments (to/from the company); location of customers; product hazards, sensitivity, or restrictions; and the order processing system itself. A firm with several hundred employees that exports toys (without high-tech components) from the United States to Canada will probably not need detailed responsibility profiles or internal formal training programs, however, they must still ensure that they are thoroughly familiar with the pertinent legislation that affects their shipment or rely on third parties to assist.

Likewise, a small firm that exports bacterial agents and growth medium from the United States will require a more comprehensive system with emphasis on extensive screening of end-uses to ensure that the bacterial agents will not be used for a prohibited purpose.

The success of the system depends on commitment from all levels and functions, especially top management, as discussed previously. A systematic approach will enable organizations to establish and assess the effectiveness of their procedures, to set policy and objectives for MC, to achieve conformance with them, and demonstrate such conformance to others.

The following are key components of a MCS as derived from ISO 9001 and 14001 standards and the BIS Export Management System (EMS) Guidelines.

Logistic Policy The following definition, derived from ISO 14001, is proposed: "Statement by the organization of its intentions and principles in relation to its overall MC performance which provides a framework for action and for the setting of its logistic objectives and targets."

The policy statement identifies the direction for MC performance within a company and must be supported by procedures, instructions, programs, and controls that specifically relate to its achievement.

Planning In order to properly define an appropriate MCS, it is important to document the current workflow related to import, export, and transportation (IET) activities and identify areas of potential risk. This activity is similar approach to ISO 14001 Section 4.3.1—documentation of "significant aspects," ISO 9001 Section 4.2.3—potential use of failure mode effects analysis (FMEA) to identify and prevent any potential problems, or BIS EMS—the preparation of flow chart(s) that present the company's order processing system as part of the development of screening elements.

The company must also identify existing or proposed legislation related to the elements identified above. In a manner similar to ISO 14001 and BIS Export Management System requirements, a minimum commitment from a

company should be to comply with all pertinent legislation or other appropriate requirements.

During this stage the company must develop its objectives and targets in order to comply with its logistic policy. It is important to understand the terms used. In typical ISO terminology, an objective is an "*overall goal, arising from the policy, that an organization sets itself to achieve, and which is quantified where practicable.*" A target is a *"detailed performance requirement, quantified where practicable, applicable to the organization or parts thereof, that arises from the objectives and that needs to be set and met in order to achieve those objectives."* The term *quantified* is very important; if you quantify you can measure and if you measure you have objective evidence of performance.

Implementation and Operation The next stage is to prepare an MCS that is defined, for the purpose of this book using ISO 14001 extract, as *"that part of the overall management system which includes organizational structure, planning activities, responsibilities, practices, procedures and resources for developing, implementing, achieving, reviewing and maintaining the MC policy."*

The organization must define the management structure within the company and give clear responsibility and authority to all personnel who manage or control a MC impact. Typical responses by companies include the preparation of organization charts showing the relationships of various management levels and detailed job descriptions for key personnel. It is also common practice to identify within operation procedures some of the key authorities and responsibilities.

As with any management initiatives, training, awareness, and competence are required to ensure that all personnel within the company are aware of their roles within the management system. Training should be directed at understanding the MC risks and impacts related to each process or activity within the company. Competence means that it is not enough just to rely on training of personnel, some measure should exist to determine whether the person has the capability to perform the task to a suitable level. This may take the form of examination or practical demonstration.

Communication protocols need to be established and address both internal and external needs. Internally this communication could be with a shipping clerk responsible for preparation of hazardous goods shipment. Externally, communication might be with third-party transportation companies or port authorities to ensure that they are aware of a particular hazard that might have an environmental or worker impact if not treated in the correct manner.

As with any management system, documentation would need to be developed covering all MCS elements and document control systems put in place. Ideally, written procedures should be in place for all workflow activities that pose a potential risk, for example, screening of exports shipments leaving the United States as per Export Administration Regulations (EAR). In some cases the procedures may be very brief and reference a third-party software

that performs MCS-IS components or consulting/exporting firm while in other cases it can be very detailed and voluminous when activities are performed manually and involve multiple jurisdictions and hazardous goods. Note, in the case of the third-party software, a detailed users' manual as well as copies or, at a minimum, access to detailed specifications on regulatory requirements should be available if required.

The company should also identify any emergency situations related to environmental or worker impacts that could arise during storage or transportation of hazardous (dangerous) goods: spill, explosion, fire, etc. and draw up plans on what to do for each or link with "other" plans derived for environmental, health, and safety (EHS) impacts. In addition to preparing emergency plans the company should, where practical, test the effectiveness of such plans.

Checking and Corrective Action The company should have in place a monitoring program to measure all of the key workflow activities that are identified as posing a significant risk. The monitoring may take the form of inspections and compliance (i.e., with legislation) audits. If during the monitoring process the company finds noncompliance with its agreed specifications, corrective action should occur, including, where appropriate, notification to appropriate government agencies. This corrective action should be defined in procedures and should investigate and eliminate the root cause of the problem as per the approach described in the 9001 Quality Standard. The company should also monitor the effectiveness of any corrective actions taken.

As with numerous regulatory requirements, records will need to be produced to show conformance with legislation and performance being achieved. The records should cover all elements required by a MCS, with the "bare" minimum being those records required to comply with regulatory requirements. Without records it is impossible to establish whether the system is operating and effective in achieving the aims of the Policy.

A company must be able to audit the "performance" of the MCS—not just its conformance to legislation—thereby reenforcing the prevention of noncompliance events. This type of audit is referred to as a "system audit" and includes the review of the performance of each element of the management system against the company's procedures and instructions using personnel independent of the day-to-day activities. The ISO 14000 and 9000 series of Standards, the OSHA 18001 specification, and the recently released ISO 19011 standard discuss in detail this type of audit while the BIS Export Management System Guideline refers to "internal reviews" to confirm conformance against the firm's EMS by a person not involved in sales or the day-to-day operation of export control functions, including the EMS.

Management Review The final part of a successful MCS, as defined in the ISO 9001 and 14001 standards and the OHSAS 18001 specification, is the review of the performance of the system during a management review meeting. This will allow senior management to review the results of the system

and identify if any changes are required. Results may include internal audit results, custom audit findings, status of performance against objectives and targets, etc. If changes are needed the appropriate actions should be taken. The meeting should ensure continual improvement of the system.

9.1.3 Reasonable Care

The U.S. Customs recently developed an informed compliance strategy to maximize trade and promote the use of "reasonable care" by individuals/organizations who do business with Customs. Under this strategy, customs developed two complementary means for ensuring that importers, customs brokers, carriers, and other members of the international trade community comply with U.S. trade laws (U.S. Customs, 2002):

- Informed, voluntary compliance
- Enforce compliance

Informed, voluntary compliance, as envisioned by the Customs Modernization Act, is the preferable approach to trade compliance. When voluntary compliance is not achieved; however, enforced compliance actions will be taken by Customs against those members of the trade who have not exercised reasonable care.

To facilitate its informed compliance efforts, Customs is shifting its focus from a transaction-based operation to account-based processing. Accounts are defined as every person or firm with whom Customs does business, or in whom Customs has an interest related to trade compliance. This includes all relevant business entities such as importers, carriers, brokers, manufacturers, warehouse proprietors, and sureties. To effectively coordinate its informed compliance energies with selected accounts, the Customs Service has created the new position of "account manager." Customs national account managers will be assigned by Customs Headquarters to work with certain "high volume" accounts and with other Customs disciplines to identify areas of noncompliance within a company's operation, and to develop mutually beneficial strategies to establish and maintain high levels of trade (U.S. Customs, 2002).

The nature, scope, and impact of noncompliance will be evaluated in the context of the involved account's overall compliance history. Nonenforcement actions, such as increased outreach, education, and counseling of the account will be employed by Customs to address instances of noncompliance when an account has not demonstrated a failure to apply "reasonable care." Enforcement actions, such as seizure, investigation, and penalties will be reserved for those instances when an account has failed to live up to its obligation of using reasonable care or where necessary to prevent or penalize the introduction of restricted or prohibited goods into commerce. Both nonenforcement and

TABLE 9.1. Key Components of Various Management Systems

Requirement	ISO 9001	QS-9000	ISO 14001	OHSAS 18001	BIS EMS
Policy	4.1.1	4.1.1	4.2	4.2	Element 1
Management of risks/aspects	4.1.4 (role of FMEA)		4.3.1	4.3.1	Client Screen and Screening Elements
Organization	4.1.2.1	4.1.2.1	4.4.1	4.3.1	Element 2
Legal and other requirements		4.6-purchasing	4.3.2	4.3.2	All elements
Management review	4.1.3	4.1.3	4.6	4.6	
Management system—general	4.2.1	4.2.1	4.4.4	4.3.4	Screening elements
System procedures	4.2.2	4.2.2	4.4.6	4.4.4	Order processing System element
Planning	4.2.3	4.2.3	4.3	4.3	Screening
Objectives and targets			4.3.3	4.3.3	elements
Contract review and amendments	4.3.1–4.3.3	4.3.1–4.3.3	4.4.6		Screening elements
Document and data control	4.5.1–4.5.3	4.5.1–4.5.3	4.4.5	4.4.5	
Purchasing and verification of purchased product	4.6.1 and 4.6.4	4.6.1 and 4.6.4	4.4.6		
Customer supplied product	4.7	4.7	4.4.6		
Product identification and trace ability	4.8	4.8			
Process control	4.9	4.9	4.4.6	4.4.6	Order processing System element
Receiving and in-process inspection and testing	4.10.2–4.10.3	4.10.2	4.5.1	4.5.1	
Inspection and test records	4.10.5	4.10.5	4.5.3	4.5.3	Element 3
Inspection, measuring and test equipment —general	4.11.1	4.11.1	4.5.1	4.5.1	
Inspection and test status	4.12	4.12			Element 5
Control of non-conforming product	4.13.1	4.13.1	4.5.2	4.5.2	
Corrective and preventive action —general	4.14.1	4.14.1	4.5.2	4.5.2	Element 6

TABLE 9.1. ***Continued***

Requirement	ISO 9001	QS-9000	ISO 14001	OHSAS 18001	BIS EMS
Handling, storage, packaging, preservation and delivery—general	4.15.1	4.15.1	4.4.6	4.4.6	
Emergency Response			4.4.7	4.4.7	
Control of records	4.16	4.16	4.5.3	4.5.3	Element 3
Internal audits/ reviews*	4.17	4.17	4.5.4	4.5.4	Element 5
Training	4.18	4.18	4.4.2	4.4.2	Element 4
Servicing	4.19	4.19	4.4.6	4.4.6	

Notes: BIS EMS, Bureau of Export Administration Export Management System; ISO, International Organization for Standardization. Standards include 9000 series (quality management system) and 14000 series (environmental management system); QS, Automotive Quality System specification; OHSAS 18001, International occupational health and safety management system developed by 14 international standards organizations.

* ISO/DIS 19011 standard replaces ISO 10011 (Guidelines for auditing quality systems) and ISO 14010, 14011, and 14012 (Guidelines for environmental auditing: General principles, Audit procedures, and Qualification criteria for environmental auditors).

enforcement responses to noncompliance will be designed to remedy past violations and promote future compliance (U.S. Customs, 2002).

Rather than preparing a definition of reasonable care, Customs opted to compile a checklist intended to assist importers in meeting the responsibilities of reasonable care and in demonstrating their performance of reasonable care. A copy of the Custom reasonable care checklist has been provided in Appendix 3 of this book. The checklist presents a series of actions that importers can take to insure that they remain compliant with U.S. import laws and regulations.

Key MCS activities derived from the reasonable care actions include the following:

- obtain current rulings and legislation
- ensure same procedure following for handling of entries of identical merchandise at different entry ports
- hire staff experienced in and familiar with import legislation
- use experts for advice and assistance
- attend training sessions provided by customs and experts
- conduct periodic self-assessments
- establish an internal import compliance program that is documented

Activities that are all addressed during the development of a robust MCS are described in the following sections.

9.2 MATERIAL COMPLIANCE POLICY

In the following section, key extracts from ISO 14001 (Section 4.2), ISO 9001 (Section 4.1.1.), and BIS Export Management System (Element 1) are presented as a proposed approach to a MC policy. The proposed approach includes the following six requirements:

1) appropriateness
2) continual improvement
3) commitment to legal compliance
4) framework for MCS
5) deployment and use
6) availability

Appropriateness. The policy needs to be appropriate to the company's operations, processes, services, and products. In simple terms, the policy must reflect the items identified by the company as having significant impact on the supply chain.

Continual improvement. The documented policy must as a minimum focus on the need for continual improvement of the system, but may at the discretion of the company include supply chain performance. Note that this requirement is related to ISO standards and is not specified by the BIS EMS guidelines.

Commitment to legal compliance. The policy must include the management/organizations commitment to comply with all legislation applicable to material compliance. The organization may also stipulate conformance to industry standards and government guidelines that are not currently legally binding. The BIS EMS states that an important component of the commitment is "providing time, money and personnel to make the compliance program effective" and provides the following example of a commitment:

> **"Under no circumstances will sales be made contrary to U.S. export regulations. Special care should be taken to prevent transactions with entities involved in proliferation of weapons of mass destruction"**

Framework for MCS. The policy must provide the framework for the setting and reviewing of the company's objectives and targets for the MCS. This can be a difficult requirement to fully understand. It is intended that the policy provide the frame work and structure for the objectives and targets. By this it is meant that the policy should provide the focus on the company's key

aspects/impacts, but not discuss them in depth. The key risks the company would be those identified areas of potential risks (refer to Section 9.3.1 additional information on risk identification).

Deployment and use. The policy must be:

- Documented (in electronic or paper form)—this would normally be within a MCS manual but can be stand-alone. Typically the policy is dated and signed by a senior management representative, preferably the president, owner, or the chief executive officer, who is also responsible for the issuance of the policy.
- Implemented—this means that the company is able to demonstrate that the MCS is in place and achieving the requirements stated in the policy.
- Maintained—This means that the company must keep the policy up-to-date to reflect any changes in significant risks or management direction.
- Communicated—All personnel should be aware of the specific requirements of the MC policy: both as part of new employee orientation session and ongoing training programs. Personnel should also be aware of their responsibility and actions in helping to achieve the stated policy.

Availability. The policy should be available to appropriate supply chain stakeholders: suppliers, brokers, transportation companies, etc. It may also be appropriate to make the policy available to the public.

Each of the above, with potential exception of availability, needs to be addressed in the policy statement. In addition, the policy should be clearly written and fairly concise. The longer and more complicated the policy, the more probable that people will misunderstand it, or worse, just plain ignore it.

Note that the policy is the overall driving document upon which other key components of a MCS are prepared: objectives, targets, programs, and operations, which are discussed in the following sections.

A company should set its own frequency and triggers for conducting a review of the policy. By triggers we mean that the policy should be reviewed if any major changes happen within the company, these would include those reasons shown above.

9.3 PLANNING

9.3.1 Areas of Potential Risk

ISO 14001, Section 4.3.1, requires companies to identify aspects (i.e., key activities) related to the company's activities, determine those that are significant (i.e., pose potential risks) and manage those significant aspects. ISO 14004 (support document for ISO 14001) states, "*A significant aspect is an environmental aspect that has or can have a significant environmental impact.*" By

identifying significant aspects a company is able to provide focus, that is, to take action on the critical few aspects in an effective manner, rather than losing control by trying to tackle all issues. No similar requirement exists in ISO 9001.

Under OHSAS 18001, Section 4.3.1, companies must establish and maintain procedures for ongoing identification of hazards, the assessment of risks, and the implementation of necessary control measures. This requirement extends to both company employees as well as subcontractors and visitors who have access to the workplace. The assessment includes the classification of risks and identification of those that are to be eliminated or controlled

The BIS Export Management System guideline provides guidance on assessing "red flags" related to exporting activities (Appendix II—Know Your Customer Guidance) and assessing/redesigning an order processing system that minimizes risks (Order Processing System).

To ensure a robust MCS a similar approach is employed with the overall objective being the "careful management of the vital few, not the useful many." Consideration should be given to the time, cost, and reliability of the data used to identify key activities and their risks. Where a company already has sufficient information to identify its key activities, a detailed review may not be needed. If a detailed review is required, it should address the following areas as a minimum:

- Review of regulatory requirements pertinent to MCS
- Identification and assessment of risks posed by key MC activities
- Examination of all existing MCS practices and procedures
- Evaluation of the feedback from the investigation of previous noncompliance events and incidents

It is important to note that key activities may change in a company. If a new transportation mode is employed, order from a new customer is received, new chemicals shipped, or if import/export legislation changes the key activities may change. These changes should be reflected in the company's management system.

Having identified all the key activities related to their operation, an organization would then prioritize them into high, medium, or low risks. Key activities identified as having moderate to high risks would be used to form the framework within the policy, and subsequently be used for the setting of the objectives and targets and be covered by training programs, MCS documentation (manuals, procedures, work instructions and records), and reviews/audits. Risk level (as was significance with ISO 14001) is and will remain a very subjective subject and is sure to be the cause of much discussion.

An example of the interaction between key activities and risk is the following:

Key activity—Export of radioisotopes from the United States.

Risk—Significant risk as the goods are covered by EAR as they may be used for other purposes.

Objective—To ensure all shipments of radioisotopes are screened for both end use and end users.

Documentation—Requirement to create a customer profile (as per BIS EMS Guideline, Appendix A—Customer guidance) and procedures for conducting screening of transactions (as per BIS EMS Guideline—Screening Elements).

Summaries of both the BIS EMS Customer Guidance and Screening Elements are presented in Section 9.4.4 of this chapter.

9.3.2 Legal and Other Requirements

Both ISO 14001 (Section 4.3.2—Legal and Other Requirements) and BIS Export Management System Guidelines (Screening Elements) require companies to have a procedure(s) in place to identify and access all legislation related to ensuring compliance. The "Legal and Other Requirement" has no equivalent within ISO 9001. QS-9000, Section 4.6—Purchasing, contains additional requirements (not required by ISO 9001) relating to "All materials used in part manufacture shall satisfy current governmental and safety constraints on restricted, toxic and hazardous materials; as well as environmental, electrical and electromagnetic considerations applicable to the country of manufacture and sale."

ISO 14001 also requires companies to have a procedure(s) for identifying information on other requirements to which it subscribes. This is especially important when operating in jurisdictions in which there may not be ample legislation and hence guidance is required via company's own best management practices or industry association standards.

We are proposing that the concepts put forward in the ISO 14001 be adapted in a MCS. Based upon our experience in reviewing organizations, those that operate effectively employ procedures that:

- List the sources from which the legislation (all legislation, not just for U.S. facilities) is obtained on an ongoing manner (e.g., U.S. Export Administration Bulletin updates and Federal Register notices identifying parties' added/deleted from the Denied Persons List)
- Frequency of update
- Name of individual(s) responsible for review and assessment of potential impact on the organization
- Method of communicating said changes in legislation and corresponding impact to appropriate personnel within the organization

There are many ways for a company to satisfy the requirement related to legislation. These may involve (Lane and Phyper, 1998):

- Purchase legislation from government agencies and in-house assessment of relevance and impact
- Use library facilities and in-house assessment of relevance and impact
- Subscribe to newsletters that provide summary of regulatory changes and potential generic impacts
- License CD-ROMs/Intranet services containing legislation and conduct in-house assessment of relevance and impact
- License software that provides only pertinent parts of legislation and perform in-house assessment of impact
- License software that provide regulatory requirements as part of ongoing content and engine (algorithms) that are used to generate compliant documents
- Retain legal counsel or consulting services to provide information on requirements imposed by pertinent legislation

It is critical that an organization transfer regulatory requirements into their business workflow; just collecting CD-ROM of the latest regulatory requirements and doing nothing with them will not provide a defense of due diligence in the event of noncompliance with legislation (where allowed by statute) or mitigate potential penalties if convicted.

9.3.3 Objectives and Targets

In Section 4.3.3—Objectives and Targets of ISO 14001 organizations are required to document their environmental objectives and targets, and having documented them ensure they are kept up to date and valid.

A similar approach is proposed for a MCS whereby companies should, as a minimum, consider the following inputs (Lane and Phyper, 1998):

- Legal and other requirements
- Areas of potential risk (refer to Section 9.3.1)
- Technological options—What are the technological solutions available to manage risks?
- Financial limitations—Organization must give consideration to the price and effectiveness of available equipment, and make an appropriate decision
- Operational requirements—It is important to consider the operational needs of the company and ensure that the objectives and targets are practical

- Business requirements—Objectives and targets should be consistent with the business plans for an organization, they should take into account any future changes related to growth, new products, new markets, etc.
- Views of interested parties—Interested parties are any person or organization concerned with the performance of an organization

For the purpose of this book, an objective is the final destination for a particular MCS program, it is what you "wish to achieve." Targets are how you will measure your journey to your final objective(s). Alternatively, the objectives define the desired end result and hence interim targets should be set to enable monitoring of progress towards this final destination. These targets must be measurable and consistent with the stated objectives. Once developed, a company prepares a MCS program or programs to define exactly how the objectives and targets would be achieved (Lane and Phyper, 1998).

When defining objectives and targets it is important to ensure that they are expressed in terms that can be measured and take into account policy requirements as well as address all significant aspects.

Examples of MCS objectives and targets include:

1) Stakeholder
   - Objective: Ensure ongoing compliance with legislation
   - Target: 95% compliance on internal audit programs
   - Target: 95% preclearance of documents for importation of goods
   - Objective: Satisfied customers
   - Target: Less than 5% of shipments exceed quoted schedule
2) Costs
   - Objective: Cost-effective generation of (M)SDS
   - Target: 50% reduction in translation costs

9.3.4 Management Programs

Section 4.3.4—Management Programs of ISO 14001 requires organizations to develop and maintain environmental programs to define how the company's stated objectives and targets will be achieved. These programs must include such details as (Lane and Phyper, 1998):

- Clear definition of responsibility for all actions involved in achieving the objectives and targets. The definition of responsibility should be specific to each level of action required and not limited to a single individual such as the Management Representative.
- How the objectives and target are to be achieved.
- Time lines required for each activity.

In Section 4.5.1—Document Control General of ISO 9001, an organization must document, in procedures, how it will plan to ensure adequate control of all quality requirements. This is normally a subset of the systems requirements related to a specific product or service. A plan would normally identify all inspections, checks, tests, and reviews to be performed throughout the entire manufacturing and design process. Plans would normally include who, what, when, how, specification, and release. Section 4.4.2—Design and Development Planning requires an organization to define what, who, how, and when for all stages of the design process. The plan as a minimum would include checks on input and output, design reviews, checking, verification, and validation activities.

The same requirements as those stipulated in ISO 14001, Section 4.3.4, are proposed for a MCS. The program(s) should define in detail how objectives and targets will be achieved. In the event that the organization develops new product lines or markets the system in place must ensure that, where relevant, the MCS programs are updated.

9.4 IMPLEMENTATION AND OPERATIONS

9.4.1 Structure and Responsibility

In Section 4.4.1—Structure and Responsibility of ISO 14001, the roles, responsibility, and authorities to facilitate effective environmental management be clearly defined, documented and communicated. In addition to defining the roles, the organization must ensure that it has adequate resources to manage the environmental system.

In Section 4.1.2.1—Responsibility and Authority of ISO 19001, the requirements are similar to that defined above; namely, all personnel who manage, perform, or verify quality shall have their responsibilities and authorities documented. The organization would normally be defined in two ways within a quality manual. The first method is in the form of an organizational chart (sometimes known as an "organigram"). The organization chart should show clearly the relationship between all key personnel responsible for quality. The second requirement is to define the responsibility and authorities for key personnel, in relation to the MCS, in the company.

Element 2 of the BIS Export Management System guidelines requires the following:

- Ensure all compliance-related functions, duties, and responsibilities are clearly identified (including back-up personnel where appropriate), and documented (list and organization chart), said documentation kept up to-date and distributed throughout the organization.
- Personnel assigned export control functions should be given authority commensurate with their responsibilities with one individual being assigned role of Export Management System Administrator.

- Where practicable, assign export responsibility separately from the sales function to prevent conflict of objectives with sales staff providing required information on end-user, intended end-use, or end-destination of the export.

Leveraging the above requirements, an effective MCS should also require that sufficient resources be assigned. Resources include:

- adequate numbers of people
- adequately skilled personnel
- appropriate equipment
- adequate financial resources to achieve the objectives and targets set

The organizations management must appoint (in writing) a person or persons to the position of management representative, for example, if exporting, the Export Management System Administrator. The representative(s) can hold other responsibilities within the organization, but must have adequate resources in terms of time and training to perform the following:

- Ensure the MCS is established, implemented, and maintained
- Report on the performance of the MCS to the organization's top management for review and as a basis for improvement of the MCS

The very nature of a system is to build the controls and programs into the very fabric of management of a company.

As well as defining responsibility it is important to ensure that adequate communication occurs in the organization. Formal line of communication should be established with other departments that may become involved in MCS issues: for example, legal counsel, sales, shipping, purchasing/contracts, customer service, finance and accounting, traffic, and engineering (those personnel involved in classification of goods).

A key area for communication of responsibility relates to areas where significant risks have been identified, particularly those where significant legal liability or where emergency preparedness plans are defined. It would not be an acceptable situation for an emergency to happen and have everyone stop to read procedures to find out who should do what.

9.4.2 Training, Awareness, and Competence

Section 4.4.2—Training, Awareness, and Competence of ISO 14001 requires that organizations identify all the training needs for their staff whose work may create a significant impact on the environment. All training should be documented.

ISO 9001 requires a company to have effective operations and deliver good

quality to its customers, and the people working within the company should be qualified to do the task they are performing. Qualified means that the people should have either experience and/or training to an appropriate level to enable them to perform the task they are expected to do, and in doing the task correctly ensure good quality. It also requires that a review of training requirements be built into the system to ensure that training needs are identified and carried out effectively.

Element 4 of the BIS Export Management System guidelines requires the following:

- A qualified individual (poses practical work experience, attendance at seminars and knowledge of legislation) be designated (new position) as responsible for the establishment of a training program on export control issues.
- The training program should include format, agenda for sessions, and schedule for initial and ongoing training of each employee involved in export-related activities.
- Orientation training may include organization structure of export-related departments and functions, role of EMS Administrator, regulatory requirements, and company procedures (EMS manual).
- Refresher courses may include purpose/scope of export controls (license types/requirements), regulatory changes/modifications, destination and item restrictions, order processing/end-use screens for denied persons screens, diversion risk screen, nuclear, chemical and biological, and missile restrictions screens, procedures for exports, document checks and new customers and description of noncompliance and what to do if noncompliance is suspected.
- Records should be maintained of who took the training session, subject(s) covered, date(s), and instructor's name.

When considering training and competence it is important to consider full-time personnel, contractors, and any other personnel who may perform activities that have been identified as significant. These individuals may include personnel from sales, purchasing/contract, customer service, credit, order entry, shipping, traffic, and so on.

Where personnel perform tasks that pose potential risks (refer to Section 9.3.1), the organization must go beyond mere training. These personnel must be competent to perform the task. Competent means that the organization will have to identify what skill set is required for each task involving a significant aspect. Having designed the required skill set, the organization needs to define how competence will be judged. Competence can be demonstrated in many ways, through testing, through observation, or by setting a series of qualification (including experience) that staff must hold. It is up to each organization to define how it will judge competence.

9.4.3 Communications

Section 4.4.3—Communications of ISO 14001 requires companies to establish and maintain procedures for internal and external communication. No equivalent requirement exists within the quality system standard.

Element 6 of the BIS Export Management System requires companies to:

- Contact BIS office if assistance is required in determining the appropriateness of specific end-users or end-uses for the export of their goods, services, or technology.
- Contact BIS local Export Enforcement field offices if company personnel suspect that questionable, unauthorized, or illegal activity may have taken place, or that the customer is asking them to participate in such activities.

The following are examples of areas to be communicated. Internal communications should include all levels and functions within the organization (Lane and Phyper, 1998).

Internal Communications

- Policy—Organizations should ensure that staff, at all levels, understands the MCS policy and their role in helping to achieve it.
- Procedures—All personnel should be made aware of the requirements of any procedures related to the MCS that affect their work.
- Responsibility and authority—All personnel should be made aware of responsibilities within the MCS, particularly important for personnel involved with significant aspects.
- Significant risks—All staff should be as a minimum made aware of responsibility for significant risks that may affect their job.
- Emergency response plans—All personnel should be made aware of the existence of emergency response plans and their role in an emergency situation.
- Performance of system—Management will decide how much information is fed back to staff related to the performance of the MCS.
- Achievement of objectives and targets—It is good practice to feed back to all personnel the status of progress towards the organizations objectives and targets.

External Communication

- Policy—to key stakeholders
- Significant risks—to stakeholders who may play a role in managing these risks successfully
- Emergency preparedness and spills—this is important if significant risks can have an impact outside of the organization itself (need for evacua-

tion, reporting to government agencies, etc.). Typically, this involves a linkage to the companies EHS Management systems and the corresponding emergency plans

- Complaints—receiving, reviewing and responding to complaints from customers and suppliers
- Noncompliance event—as per local regulatory requirements, maybe required to immediately/forthwith report non-compliance events or potential events (appropriate to document what they may cover and discuss with legal counsel reporting process)
- Government requirements—preparation of correct documentation produced in appropriate format with accurate/compliant information that can then be submitted in timely manner

When defining its communication procedure, organizations should ensure they define who will be responsible for communicating with outside parties. The process to be used for external communication would need to clearly define receiving, reporting, taking actions, sanctioning, and responding.

9.4.4 MCS Documentation

ISO 14001, Section 4.4.4 EMS Documentation requires information on all "core" elements be described in some form of document. What is a core element? This means each company must identify how it meets all of the requirements specified within clauses 4.1 through 4.6. One way of doing this would be to prepare an EMS manual.

In Section 4.2.1—General of ISO 9001, a company must formally document its quality system. This means the company needs to prepare all of the things like the quality manual, quality procedures, work instructions, forms, and quality plans. The standard also requires all companies to identify within their quality manual the documentation structure of the system. This requirement has been introduced to ensure that in cases of conflict between the various levels of documentation, the user shall know which document they should follow.

In Section 4.2.2 of ISO 9001, procedures should be prepared covering how departments and functions operate. The first section of most of the ISO clauses defines the mandatory procedures such as contract review, purchasing, etc. Procedures only have to be prepared (other than where specifically called for) if the lack of them would or could result in a quality problem; for example, if person has had long and detailed training to perform a task, there is no need to write a procedures on what they should do.

Leveraging the aforementioned approach to MCS documentation results in the preparation of a MCS manual, procedures, and work instructions. The following is the proposed hierarchy of documentation (Phyper and Lane, 1998):

Level 1: "What" (e.g., manual)
Level 2: "How" (e.g., procedures and work instructions)
Level 3: "Evidence" (e.g., forms and records)

It is important to note that a document gives you information on what you should do to comply with the requirements of the system. A record tells you what actually did happen. The term *data* refers to electronically stored information/documentation and any related information (price lists, etc.) in paper or computerized format.

Manual. The manual should indicate how the organization intends to meet the requirements. The level of detail provided must be sufficient to describe the operation of the system. The manual may contain the required level of detail or may refer the user to more detailed procedures, instructions, process information, and plans. The following are key components of the MCS manual:

- MCS policy, objectives, and targets
- list of significant risks (or reference to where they can be found)
- description of management programs
- organizational structure for MCS
- responsibility and authority for MCS system (could include job specifications of the key personnel)
- definition of how the manual is actually controlled
- reference to where other documentation (e.g., procedures, work instructions, etc.) are stored and what they address
- document structure for your company (priority of documents in use)

It is very important to remember that the company's systems manual and other documents are user friendly (i.e., they should be easy for your personnel to use). This can be achieved by providing plentiful references, and menus, telling the user how to read it and how to find the information that they want.

It will be important to assess the overlap between the organization's MCS manual and other systems, for example, Environmental and Quality as per Section 9.1.3, Table 9.1, of this book. Typically integrated management system manuals cover Sections 4.1 to 4.20 of ISO 9001 and 4.1 to 4.6 of ISO 14001 (Note: ISO 14001 does not specifically require that the documented system be collated into one system manual).

Procedures. There is a set of written instructions in an agreed and controlled format that defines how specific operations, departments or functions are performed or operate. The procedures should be written to define how each function that can effect on the MCS could be controlled. The procedures should be short, simple, and concise as possible and user friendly. It is acceptable that you have as your procedures, flow charts as well as written proce-

dures. Typically a procedure should include the following (Phyper and Lane, 1998).

Title and unique number. Never rely on the name of a procedure, as sometimes it can get very confusing. You should always give a procedure a number to ensure effective document control. The procedure name and number should appear on all pages of the procedure.

Issues and revision status. The issue number covers the full release of the document, the revision will cover the revision of each page. The reason for doing this is quite simple; you don't want to have to reissue an entire document every time you make a change to one page. Having a revision allows you to change just one page.

Each page should carry a page number and the number of pages, so page 1 would be page 1 of 4, 2 of 4, 3 of 4, etc. It is also important that your procedure number and its issue and revision status appear on every page of the document.

Each procedure should have an approval authority. This can be done either by signing of each page or by signing a controlled page.

Date of approval. This is very important; you have to know the date at which a procedure becomes effective, when it is actually implemented. An example of this is when a change happens on the 1st January, instead of just the purchasing manager being able to sign purchase orders, the revision allows the assistant purchasing manager to sign purchase orders as well.

Format. Your procedures should be in an agreed standard format, so people working for different departments will understand how to use each procedure, and key elements required for a procedure are actually covered.

Introduction. This will tell you why the procedure is there, what it is supposed to do, i.e., define the method for producing and controlling purchase orders.

Scope. This will tell you what the procedure covers, e.g., assessment of subcontractors, their control, and maintenance.

Method. This will tell you how the task is to be performed. The method specifically will identify what needs to be done in any area, who should actually do it, how it should be done, and when it should be done, and what records should be maintained (quality records).

Work instructions. Work or Technical instructions are any documents that give instructions to people on how to do an individual task. Things like drawings, supplier instructions and operating instructions. Associated documentation would typically be forms like the audit checklist, invoice document, dispatch note, purchase order form, monitoring records, routing cards, corrective action and request.

9.4.5 Document Control

The following sections deals with Document Control, whereas requirements for storage of records is presented in Section 9.5.3.

ISO 14001, Section 4.4.5—Document Control requires that the organization establish procedures defining how it will control all documentation to ensure that the location be known; continued validity of each document by competent personnel; documents are written for groups using them; and elimination of obsolete material.

Section 4.5.1—General of ISO 9001 requires that all the documents that define the quality system and how it operates need to be controlled. This shall normally include your quality manual, quality procedures, work instructions, and forms. Data items that would need to be considered may include price lists, stock records, marketing materials, approved suppliers lists, and so on.

In the subsequent ISO 9001, Section 4.5.2—Document and Data Approval and Issue, the number of copies of your quality manual, procedures and instructions that have been issued must be known and who holds them. The ISO 9001 standard requires a master list or equivalent for all documents and as at minimum a distribution list for all of your controlled documents.

In Section 4.5.3—Document and Data Changes, an approved and documented system for making changes to documents is required. The authority, name of person(s) who can reissue a procedure and a document, and the signatures that must be on a document to make it formally reissued should be identified. In addition, a formal change procedure should be in place and address the following: how do you go about the change; who or which department is responsible; and what actions have to be taken to formally reissue a document.

Leveraging requirements from the above standards and guideline for a MCS results in the following requirements (Lane and Phyper, 1998):

- The location of all documents needing control should be known. This would cover such documents as manuals, procedures, instructions, specifications, import/expert permits, etc. The reason that the location of each document needs to be known is to allow for recall and replacement in the event of changes.
- The continued validity of each document needs to be checked by competent personnel. If the documents are found to be ineffective, out of date, or wanting in some way (usability) they should be revised and reissued in a controlled manner.
- Documents are written to provide information to personnel at differing levels and locations within a company. To be effective these documents must be available to the person whose job or process they cover. The best document in the world will achieve nothing if it is not provided to the location where it is needed.
- Having obsolete information available for use may lead to problems. If the user of these documents works to an old document, errors and problems previously corrected may be perpetuated. In some circumstances, retention of old information may be required (such as old procedures for

the purpose of auditing), where such documents are retained they should be marked clearly that they are obsolete. This will help to prevent their inadvertent use as a current document.

All documentation forming part of the MCS system must be (Lane and Phyper, 1998):

- Legible—This can cover such areas as typed versus hand-written, acceptable quality of photocopies, protection during use if used in harsh environment.
- Dated to indicate revision status and when document became effective—The date indicates when a document became effective. The revision status is important to ensure that users know and can check that they have the latest versions of documents in use.
- Easily identifiable—This normally entails the use of clear titles and unique numbering systems to avoid confusion in use.
- Maintained—Documents should be kept up to date to reflect any identified errors or improvements.
- Retained—Some documents within the system may require specific retention periods.
- Creation and modification responsibilities—Responsibility for creating and approval of each document must be defined; this is normally achieved by documenting this information on the cover sheet of the procedures.

The above requirements are the basics for any document control system. They allow for objective control over all documents within any system.

9.4.6 Operational Control

ISO 14001 Sub-Clause 6.4.6—Operational Control requires the organization to plan, including maintenance, all activities related to its significant environmental aspects to ensure that they are carried out in accordance with predetermined criteria. The organization must prepare documented procedures to cover areas identified as needing control. Criteria included within procedures may include temperature, time, sequence of operation, pressure, control limits, etc. The subclause specifies that procedures must be prepared where any opportunity exists of deviation from the environmental policy, objectives, or targets.

Clause 4.9—Process Control of ISO 9001 concerns itself with the control of the manufacturing processes from the receipt of an order: how is it planned, loaded to manufacturing, stored, and finally shipped to the customer. This includes things like capacity match planning and the preparation of required procedures and work instructions to make sure that all the various stages of the process are under suitable and effective control.

The BIS Export Management System provides the following screening elements and thus provides sample procedures for areas of key risks:

Element 1—Denied Persons Screen
Element 2—Product/Country License Determination Screen
Element 3—Diversion Risk Screen
Element 4—Nuclear Screen
Element 5—Missile Screen
Element 6—Chemical and Biological Weapons Screen
Element 7—Antiboycott Compliance Screen
Element 8—Informed Letter/Entity List Screen

The ISO 9001 is probably the best model for new operational controls in a MCS. These operational controls should be related to potential MCS risks. Not all operations that have potential risks require procedures. Each company needs to review its operations and decide which need procedural control. An operation that is under automatic control or has little impact may be deemed not to require procedural control. Operations that have a significant impact or the potential for a significant impact would need a procedure.

It is important to note that for identified significant risks the need for control and procedures extends beyond the company's own personnel to its subcontractors and suppliers. These procedures and controls should be made apparent to the subcontractors and suppliers; however, in some cases legal counsel should be consulted regarding liability issues related to influencing a subcontractor or supplier's actions.

9.4.7 Emergency Preparedness and Response

In subclause 4.4.7—Emergency Preparedness and Response, organizations are required to prepare and maintain procedures to identify and respond to any potential accident or emergency situations. The procedures would need to cover both the prevention of the situation and the subsequent methods for mitigating its impacts. As well as developing the procedures the company must also test the procedures periodically (where practicable). There is no equivalent requirement within the quality system standard.

The aforementioned requirements are proposed for a MCS. The type of procedures required would cover what to do in case of fire, flood, explosion, leak, etc. depending upon the completeness of procedures prepared for EHS. The procedures would need to be taught to all personnel who could be affected, this may include subcontractors, contractors, and might extend to residents close to the company's facilities (evacuation). The level of teaching required should ensure an automatic response from personnel without need to refer back to the procedures. The effectiveness of the procedures and training should be tested periodically (fire drills etc.).

Personnel involved with any risks that could be considered significant shall be competent to deal with any emergency situation. Competency would need to be demonstrated by some form of testing of that individuals understanding and ability.

9.5 CHECKING AND CORRECTIVE ACTION

9.5.1 Monitoring and Measurement

Subclause 4.5.1—Monitoring and Measurement of ISO 14001 requires the organization to establish and maintain documented procedures for monitoring and measurement of all operations and activities that are related to aspects identified as significant. The procedure(s) must include the recording of key information against which performance to the stated objectives and targets can be measured, and how the organization will use results of the monitoring and measurement to evaluate compliance with environmental legislation and regulations.

In Subclause 4.10.1—General of ISO 9001, the supplier shall maintain documented procedures for inspection and testing activities in order to verify that the specified requirements for the product are met. The required inspection and testing, and the records to be established, shall be detailed in the quality plan or documented procedures. Subclause 4.11—Inspection Measuring and Test Equipment requires the organization to prepare documented procedures to control, calibrate, and maintain all inspection, measuring, and test equipment that will be used by the organization to demonstrate conformance to specified requirements.

The requirements of 9001 and 14001 standards are basically the same. The intents of the two standards are different in focus—ISO 9001 focuses on product quality and ISO 14001 on control of the significant aspects. Inspections and monitoring activities will occur at different locations and measure differing aspects/features. We therefore recommend that the ISO 9001 standard be employed for the MCS.

Procedures will need to define how the following will be achieved pertinent to MC activities:

- how the company will identify appropriate equipment
- identify and calibrate all equipment at suitable intervals
- define how equipment will be calibrated
- identify calibration status on each piece of equipment
- maintain calibration records
- judge validity of previous inspections where error is found during calibration
- ensure suitable environmental conditions for use and calibration of equipment

- ensure equipment protected when not in use
- protect equipment against unauthorized adjustment.

In several cases, the activity described above may be covered by existing procedures that are part of another department's activities, for example, environmental, health, safety, security, etc.

9.5.2 Nonconformance and Corrective and Preventive Action

Section 4.5.2, Nonconformance and Corrective and Preventive Action, of ISO 14001 requires organizations to establish and maintain procedures for nonconformance, corrective, and preventive activities.

In Section 4.13—Control and Nonconforming Product of ISO 9001, as soon as you determine a product or a service as being nonconforming, you must immediately place identification on the nonconforming item to prevent its further use. Having identified the item and stopped anybody from using it, you now have to decide what you are going to do to put the situation right. In other words, can you rework the item, can you modify the item, or can you downgrade the item and use it as it is.

In Section 4.14.2—Corrective Actions, organizations must identify the "cause" of the problem. They then need to analyze and identify how to prevent the problem from occurring again in the future. Section 4.14.3—Preventive Actions stipulates that organizations must have preventative actions as well as corrective actions and places more emphasis on quality assurance activities (e.g., auditing, failure mode effect and criticality analysis, cause effect analysis etc.).

To ensure a well-run MCS, the use of nonconformance, corrective, and preventive actions as listed above is proposed. Thus, procedures should be prepared that clearly define (Lane and Phyper, 1998):

- responsibility and authority
- correction action process for any impacts caused
- method for investigating and instigating corrective action
- identifying the cause of the nonconformance
- action to prevent recurrence of nonconformance
- method for instigating preventive action
- ensuring that actions taken for corrective action are appropriate to the magnitude of the problem and impact encountered
- recording any changes in written procedures resulting from the corrective action

It is also important for the organization to update their procedures in response to any corrective action activities undertaken; this action is designed to prevent recurrence of a similar problem.

9.5.3 Records

Subclause 4.5.3—Records of ISO 14001 requires the organization to establish and maintain procedures identification, maintenance, and disposition of environmental records.

In Subclause 4.16—Quality Records of ISO 9001, a quality record is defined as any document that proves that the quality system is working. It is not just inspection or testing records as it also includes things like purchase requisitions, purchase orders, management review meetings minutes, etc.

Element 3 of the BIS Export Management System requires the following:

- All administrative and transaction records related to export control should be stored in an accurate and consistent manner;
- A procedure should be prepared that outlines the filing system, location of documents, document control and retention (5 years from the date of export, re-export, or any other termination of the transaction as defined in Section 762.6 of the EAR), and personnel responsible;
- The filing system should allow invoices, SEDs, delivery notes, and air waybills to be easily matched (refer to Section 9.4.6 of this book for additional information on operational procedures for work flow).

The BIS guidelines also provide a list of potential records (refer to Chapter 3.4.2 of this book) to be tightly controlled and recommends that the following also be stored: log used to ensure return of commodities previous exported under license exception for temporary exports and log used to ensure license exceptions are not exceeded.

Reviewing the above requirements and taking into account nature of MC, the following should be clearly defined for a MCS:

- responsibility and authority for records
- need for records to be legible
- need for the records to be identifiable and traceable to the activity
- how and where records will be stored and maintained
- retention times for all records taking into account regulatory requirements as a minimum

Examples of key records includes the following:

- training records
- audit results
- risks assessments
- information on applicable import, export, and transportation laws or other requirements
- complaint records

- transportation routes and medium (roadway, railway, etc.)
- product hazard information records
- inspection, maintenance, and calibration records
- pertinent contractor and supplier information
- incident reports
- information on emergency preparedness and response
- management reviews

It must be noted that the specific records to be retained at each organization may be unique, the above list is provided for reference only.

Note that the following definitions may be appropriate to distinguish records from documents:

- Document—Defines what the company should do, it is normally a manual, procedure, instruction, legal requirement, etc.
- Record—Defines what the company actually did, it is the record of an event having occurred.

9.5.4 MCS Audits

Subclause 4.5.4, Environmental Management System Audit, of ISO 14001 requires the organization to establish and maintain programs and procedures for periodic environmental systems audits.

ISO 8402:1994 defines an audit as "systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives." Section 4.17 dictates the use of audits of the system to ensure the continued effectiveness of and compliance with the documented quality system. Audits should be performed by qualified (has taken a suitable audit training course) personnel. Auditors must be independent of the function or procedure that they are auditing (see ISO 8402).

The following is a list of documents that should be obtained/reviewed prior to developing an MCS auditing system:

14001 Environmental Management Systems—Specification with Guidance and Use. Section 4.5.1 addresses the requirement to evaluate compliance against relevant environmental legislation and Section 4.5.4 and A.5.4 address the requirement to conduct EMS Audits.

19011 Guidelines for Quality and/or Environmental Management System Auditing

Note that ISO 19011 Standard, which was released at the end of 2002, replaces ISO 10011 and ISO 14010, 14011, and 14012.

Element 5 of the BIS Export Management System (EMS) Guideline requires organizations to:

- Recommend the designation of a qualified, independent person (not involved in sales or daily export functions) to conduct internal reviews.
- The reviewer should develop an adequate procedure and schedule for the reviews.
- The content of the review should include export management system documentation—to confirm documents verify the firm's compliance with legislation, documentation maintenance (e.g., export transaction records and records related to order processing checks)—compliance with legislation.
- The review should be conducted annually and include the preparation of a written report that is submitted to appropriate managers with written confirmation that follow-up and corrective actions occurred.

Appendix 2 of this book presents a copy of the BIS Export Management Systems Review Module that contains checklists to assess the organization EMS conformance. We have also included a copy of the U.S. Customs Service "Reasonable Care Checklist" in Appendix 2 to assist organizations review conformance to U.S. import legislation.

Note that U.S. BIS Export Management and Compliance Division (EMCD) offers several types of export management system reviews upon request from companies:

- Written evaluation only—review of procedures only
- On-site reviews—review of written procedures and onsite review of operational procedures.

Typically these reviews take two days for a new program and one day for an established program.

Leveraging the above requirements, the following must be defined and documented as part of a MCS audit program (not a review):

- Responsibility and authority—Who is responsible for audit scheduling, conduct of audits, reporting of results and close out actions for any problems identified?
- Audit scope—What specific areas, functions, procedures, clauses are to be audited?
- Frequency—What are the rules for deciding audit frequency? Are past audit and review findings and significance of risks involved in areas to be audited considered?

- Methodologies—How should an audit be conducted, who should be involved, what paperwork should be completed, what times are required for each audit? Critical that published methodology be used (refer to ISO 14010–14012 and 10011 as discussed above).
- Reporting results—How are audit results to be reflected to management for consideration during the management review?
- Auditor competence—What qualification and experience is each auditor expected to have?

The purpose of the MCS systems audits should be to:

- Establish whether the system in operation conforms to the organization's planned arrangements.
- Establish whether the system in operation conforms to the requirements specified within published framework, for example, this book or other externally published document describing MCS.
- To establish that the system has been properly maintained.
- To provide audit findings to management.

Any problems identified during the audit will require formal action; hence a noncompliance (or corrective action request) needs to be raised, identifying actions that must be taken to correct the problem by the company being audited.

9.6 MANAGEMENT REVIEW

Clause 4.6—Management Review of ISO 14001 requires that the senior management of an organization conduct a periodic management review of the environmental management system. It is important to ensure that all the company's personnel involved in defining the policy, objectives, and targets are involved in the review process.

In Subclause 4.1.3—Management Review of ISO 9001, executive management must formally review the effectiveness of the quality system. Is the system still effective? Does it still meet the needs of the required standard? There is little benefit in putting in a quality system and just running it, you have to make sure that quality system is working effectively for the company.

Utilizing the commonality of management reviews from ISO 9001/14001, it should be conducted to:

- review the MCS
- ensure its continuing suitability

- ensure its adequacy effectiveness
- facilitate continual improvement

The review meeting should include the following:

- possible need for changes to policy objectives and other elements of the MCS
- review of the results of the MCS audit
- review of changing circumstances
- extent to which objectives and targets have been met
- continuing suitability of the MCS in relation to changing conditions and information
- concerns amongst relevant interested parties

The frequency for conducting the management reviews shall be determined by the management of the organization concerned; the minimum is once a year.

A formal set of minutes should be produced from the review meeting. The review records should identify who attended the review, what was discussed, what actions were agreed, who was given those actions, and what the time scale for review and close out action was agreed. These minutes should be signed by the chairperson of the meeting and distributed to each person in attendance.

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10

MCS–INFORMATION SYSTEMS

10.1 INTRODUCTION

Material compliance systems (MCS) have historically been at a "tactical" level, were labor intensive, addressed only the primary business location (e.g., U.S. operations only), and were not updated in a timely manner as legislation changed. Over the last few years many organizations have developed or purchased MCS–Information Management Systems (MCS-IS) to reduce costs and ensure conformance.

The more proactive of these companies are leveraging the MCS-IS for "strategic" level assessments—who to compete against, in which markets, using what products, or how best to deploy company resources to maximize market opportunities. This new direction allows all personnel in the enterprise, from the shipping clerk to the CEO, to have visibility into compliance and hazardous materials issues impacting their decisions and thereby draw the right conclusions to maximize MCS performance, minimize costs, and ensure compliance to appropriate legislation at all levels of the organization.

10.1.1 Overall MCS-IS Components

The following are potential components of to an MCS-IS solution:

Applications—Software program that typically allows users to input and view data, may contain algorithms, allows the storage of assessed data,

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and generates forms/reports. Depending upon the application they may be deployed as stand alone on a personnel computer, accessible via network or intranet or Web service offering via the Internet.

Algorithms—Computer-coded equations that automate the process by which an organization generates regulatory classifications, regulatory documents or management reports. The algorithms may screen data to ensure compliance with allowable values (check if receiving person/company is on prohibited party list) or generate an output (may be text field, classification code, pictogram, or numeric value) for a form/report. Typically the equations can be subdivided into regulatory (i.e., interpret a regulatory requirement, e.g., DOT classification when flash point is <61 °C) or management based (i.e., generates interpretative sections of a MSDS or goes beyond government requirements, e.g., lower occupational reporting thresholds).

Engine—Typically refers to collection of algorithms that are interfaced to a MCS system or a business system, e.g., Enterprise Resource Planning (ERP) software, with limited, if any, view capability by a user. Information flows from business system to engine, is then assessed, and then sent back to the business system or another systems, without user intervention. Examples of a MCS engine may include screening of customer orders against prohibited or restricted party lists or national inventory lists.

Database—A database is a set of information organized for flexible searching and utilization. There is a wide array of databases that range from simple (e.g., tabular collection of information) to more complex models (e.g., relational model). Databases are the preferred method of storage for large multiuser applications, where coordination between many users is needed.

Content—Numeric values, lists of chemicals, or text that is used to generate reports or provide input to algorithms. Examples include the following: physical (e.g., pH, solubility value), chemical (e.g., reactivity in water), toxic (e.g., lethal dose to 50% of exposed population), and regulatory. The latter may include:

- classification [e.g., U.S. Department of Transportation (DOT) or European Agreement concerning the international carriage of dangerous goods by road (ADR)].
- lists of reportable chemicals and associated thresholds (US Tier II or SARA 313, Canadian National Pollution Release Information)
- prohibited party list, restricted party list, etc.
- national inventory list (absence on list may require registration of the material)

Depending upon the type of content, it may be generated by the company, obtained by a third party under contract that stipulates frequency (e.g., quarterly updates) and mode (e.g., CD-ROM, download

from Internet, etc.) or periodically obtained from an online public or commercial database. Over the last few years there has been a promulgation of government Web sites containing regulatory information (refer to Appendix 3—Material Management Web Sites and Appendix 4—Import/Export Web Sites).

It is important that the content be accurate, easily referenced, and updated in a timely manner, especially if related to legislation.

Data Import/Export—Most MCS-IS have the capability to import/export data to/from other business systems/government reporting systems either as file transfer or through an Application Programming Interface (API). Over the last decade there has been a propagation of government databases (e.g., U.S. Customs Prohibited Parties list) and reporting software/file structures (e.g., product registrations in Europe, U.S. EPA Form R diskette for electronic submission, U.S./British automated interfaces for exports). More and more government agencies want companies to receive government requirements online and report findings electronically, thereby reducing their own costs.

A well-thought-out system seamlessly integrates a company's business systems with a MCS-IS. The following are a few examples of typically business systems and the relevant data they main contain in terms of interfacing with a MCS-IS:

Formulation systems—store formulation information (pre- and postcommercialization) and potentially some physical, chemical, and toxicological data regarding current and future products and raw materials; information that may be critical for the generation of a (M)SDS and/or prohibitions on export.

Laboratory Information Systems (LIMS)—may contain physical, chemical, and toxicological data generated by a company that can be used in the generation of a (M)SDS and/or confirmation of the classification of the material according to appropriate legislation.

Enterprise Resource Planning (ERP) systems—An ERP solution helps manage company-wide business processes, using a common database and shared management reporting tools. Typically, ERP solutions support the operation of business processes by integrating business activities, including sales, marketing, manufacturing, accounting, and staffing. Touch points for interaction between ERP and MCS-IS may include:

- ERP to MCS-IS: transfer of sales order and information on material
- MCS-IS to ERP: transfer of regulatory classification and screening data (e.g., national inventory list, prohibited party list), as well as documentation (MSDS, labels, etc.)

Supply Chain Management (SCM)—SCM solutions allow an organization to efficiently integrate suppliers, manufacturers, warehouses, and stores, so that merchandise is produced and distributed at the right quantities,

to the right locations, and at the right time, in order to minimize system-wide costs while satisfying service-level requirements. Depending upon the MCS-IS solution, a variety of touch points may include queries on ability to manufacture or import a product in a particular country due to local legislation.

Track and Trace systems—These may be internal or external systems that assist an organization track the status of goods while they are being transported from one location to another. If third-party shipper(s) and brokers are being employed, the system would have to allow for integration of these systems in order to provide visibility in status of shipment. Typically, these systems also include landed cost capability.

10.1.2 Business Drivers

The following are examples of potential business drivers for an organization to implement a MCS-IS:

- Ensure ongoing compliance to constantly changing, global regulatory requirements as well as industrial association standards/codes of practice.
- Reduce the time period for the preparation of new documents and provide more accurate data thereby reducing the number of inquiries from government agencies and customers.
- Reduce the time period to ship goods and hence inventories (especially customs holding areas).
- Integrate MCS into regular business management operations, including ERP/SCM systems, as significant cost savings.
- Reduce expenditures associated with MCS activities (preparation of custom filings, translation costs for MSDS, etc.) and minimization/elimination of fines/penalties.
- Develop a single MCS-IS that complies with legislation in every country rather then regional information systems that must be rolled out separately and maintained—avoiding costly product launch delays and the need for ongoing data exchanges.
- Allow chemists to run "what-if" scenarios to find out what are the consequences of adding/eliminating a particular component in terms of where it is to be sold.
- Reduce the return or impoundment of goods due to prohibitions on the material, incorrect containers, or documentation.
- Reduce monetary fines or prohibitions on the import/export of goods by the company.
- Reduce the frequency and impact of an audit/inspection by government agencies.

US Export	Germany Import
Sanctions List (restricted parties and embargoes)	German National Inventory List
License Requirements for exports (need ECCN#)	Import restrictions
US compliant Material Safety Data Sheet required for both workers at product site and for transportation from U.S. to Germany.	Safety Data Sheet, in German, that addresses EU legislation (adapted by Germany) as well as unique German Requirements, e.g. WGK calculation
Proper packaging of material as per U.S. transportation legislation and IATA if by air	Proper packaging of material as per German legislation
Shipping Document (need HTS #), etc.	Shipping document (need HTS #)

Figure 10.1. Example of Required Checks.

Figure 10.1 presents an example of potential checks and documentation that may be required for the shipment of a hazardous (dangerous) good from the United States to Germany.

10.2 IDENTIFYING PREFERRED APPROACH

10.2.1 Documenting Business Requirements

It is important to clearly understand the business risks related to an MCS-IS and seek out ways to eliminate and/or minimize them:

- regulatory enforcement actions
- "runaway" costs associated with basic MC for global activities
- poor quality of documents provided to customers
- delays in product launches
- prohibitions on export of products or import of raw materials

Key activities that must be performed as part of a needs assessment include:

- Document current business processes that are related to MCS.
- Document existing MCS-IS, including the generation of a high-level data flow diagram containing all solutions (applications and databases) used to store, generate, or transfer data pertinent to an MCS.

- Document any deficiencies with the current MCS-IS and the impact on the business.
- Document future business processes—from research and development activities related to new formulations to shipment to customers—including potential "take back" of goods. As a minimum, requirements should include all internal management reports and government submissions.
- Translate future business process information into key business requirement related to a new/revised MCS-IS. If using external parties in the process, e.g., external label printing, ensure that their role is known and process to transfer information (and associated lead times) documented.
- Review and document potential optimization of the business process using a new/revised MCS-IS.
- Assess and document the capability of the existing IT infrastructure to address future business requirements as they relate to MCS-IS.

10.2.2 Documenting Current/Future Costs

The first step in conducting a financial assessment is to document current costs related to MCS-IS. Typically this requires the collection of the following information once the current and future business requirements are documented (refer to Section 10.2.1):

- Direct cost information
  - Cost for company personnel to track and obtain information on new/modified legislation
  - Translation costs for Graphical User Interface (GUI) of legacy applications and documentation
  - Cost for company personnel (or third party) to generate required government documentation and internal management reports
  - Cost for company (or third party) to perform screening of products against material compliance legislation
  - Cost of IT personnel (or third party) to support hardware component of MCS-IS
  - Cost of IT personnel (or third party) to support current applications/content and data repository related to MCS-IS
  - Maintenance cost, if commercial application
  - Subscription costs for content solutions (updates of regulatory information or physical, chemical and toxicological data)
  - Cost related to additional inventory to ensure sufficient supply due to delayed custom clearance
- Indirect cost information
  - Recent fines, penalties, prohibitions on importing/exporting
  - Damage to business reputation resulting from bad publicity
  - Cost of past delays in delivery of goods (e.g., storage costs)

It is important that all labor costs be "fully loaded," that is, include hourly wages and all indirect costs such as benefits, building and equipment occupancy, management, and so on, and that all hours be included. The statement that "the person is only spending an hour or two on MCS activities and therefore should not be included in the return on investment calculations" is inappropriate. It is important that all costs related to the supply chain (including MCS-IS) be assessed and minimized and that personnel focus on key business requirements, especially when more than one employee is working part time on MCS activities.

It is also important that a dollar value be provided for activities that are legally required, but not currently done. It is of no benefit to compare an existing process that is noncompliant with a new process that is in compliance without adjusting expenditures as follows:

1. Identify the cost if it is to be done manually (in-house staff or consultant).
2. Assign a value for the cost of typical noncompliance activities (e.g., fines, penalties, delay/stoppage of shipments, destruction of goods due to expiry), identify associated probabilities and calculate potential cost (cost of noncompliance times the probability of occurrence).
3. Calculate the present value of risk reduction for all risks mitigated by the software that can be verified after implementation.

Several organizations have used the approach—"we have not been caught"—when deciding that the current system is satisfactory as it is the low-cost option. However, a quick read of their corporate policy (most contain a statement regarding commitment to be in compliance with pertinent legislation) or calculation of a value using option 2, above, has them quickly reassessing their selection. Even though many organizations have not been fined, most have had their goods delayed as a result of incomplete documentation and thereby incurred real costs. In response to new EU legislation (Directive 99/45/EEC), the "European Classification and Labeling Inspections of Preparations, including Safety Data Sheets" (ECLIPS) has been developed. Regulatory inspections of companies and shipments began in January 2003 (refer to Section 4.2.2 of this book for additional information).

A sometimes-overlooked activity is the review of past experiences with similar projects/systems. This typically involves obtaining copies of post-implementation review for other projects and critically assessing the actual versus forecasted revenues to provide potential guidance on how to budget for any new MCS-IS project.

10.2.3 Maintain Status Quo, Build, or Buy?

Many departments traditionally rely on basic word processing or desktop publishing software packages or low-end database packages to produce and store regulatory data and documents. For a production environment with a small or

static set of products and a limited number of oversees customers this works well. The same holds true if you produce a moderate number of products that are sold domestically, or if your product formulations are fairly simple and classifications do not change. Authoring new documents or updating old ones are occasional tasks, and the potential impact on production, distribution, and compliance risk is relatively low.

Manufacturers that do not fit these profiles need more sophisticated solutions. For the manufacturer with hundreds or thousands of products, complex formulations and extensive international manufacturing and distribution, producing compliant documents on-demand in dozens of regulated markets and several different languages is a major challenge. In addition, professionals spend the majority of their time in mundane physical analysis, regulatory research, entering data, and checking of new and updated documents. With so much of their time consumed with these manual tasks that add little value, along with the pressure to get these documents out quickly, safety data sheets and labels suffer from inaccuracies that cause many downstream problems.

Companies with these needs are either developing sophisticated in-house systems or looking at specialized regulatory compliance management software packages tailored to their needs (e.g., developing a solution that automates the toxicology and regulatory analysis thus allowing highly trained experts to focus on judgment calls, proactive regulatory management, life-cycle analysis—any number of areas that contribute tactical or strategic value to the business).

Regulatory bodies frequently update regulations, providing information on what chemicals are regulated and to what extent. If companies fail to keep up with regulatory changes, their documents may be in noncompliance. This puts workers, consumers, and the company at risk. Fines, legal action, and civil suits could result. For example, if products are listed on California's Prop 65 list, the Material Safety Data Sheets must contain a very specific phrase about carcinogens. Companies that sell listed products within California can face a legal challenge from environmental experts who specifically look for this infraction.

The question now becomes, "Which is the better solution? Should I build it in-house or purchase a commercial system?"

In House System. Every company is specialized in its markets, structure, culture, and business processes. There's nothing like a homegrown system to make sure the functionality matches your needs. If in-house projects are commonplace in your organization, perhaps you can be fairly assured of good design, execution, and functionality with in-house development. Some commercial MCS-IS vendors can deliver ERP integration, but the vendor will have a bigger challenge tying to other corporate systems.

A downside of in-house MCS-IS systems is that building a robust solution can be extremely time-consuming and expensive. Building in intelligence and automation is also tougher than it looks—the output is frequently unsatisfactory because of missing content, incorrect analysis, or outdated compliance information. While typical software maintenance is expected, companies

seldom anticipate maintaining the compliance regulations in a home-grown, automated authoring capability. Keeping up with global legislation and translations may require a large, full-time staff, plus extensive outside expertise. The result is often an expensive, hard-to-maintain system that produces noncompliant documents.

Commercial Solutions. When assessing potential "off-the-shelf" software, careful consideration must be given to their ability to address key business requirements (initially and on an ongoing basis). An ideal commercial system allows for the same solution to be shared amongst various clients thereby also sharing the development and considerable maintenance costs.

Prior to selecting the preferred option—status quo, build or buy—it is important that performance metrics be identified to track progress of the organization toward creating an MCS-IS that increases the value of the organization. The following are examples of performance metrics:

- Designing solution set around opportunities utilizing existing systems where appropriate (refer to information collected in Section 10.2.1)
- Documenting current expenditures (as per Section 10.2.2) and opportunities to assist in tracking savings resulting from future solution
- Identifying opportunities via use of best management practices (BMP) to improve quality and reduce resources employing both internal and external systems where appropriate
- Quantifying opportunities within a business case [e.g., total annual and general activity costs, return on investment (ROI), internal rate of return (IRR), net present value (NPV)]

Refer to Table 10.1 for brief descriptions of ROI, IRR, and NPV.

In order to illustrate the potential influence of various cost items a fictitious assessment of MCS-IS options (status quo, build, or buy) has been prepared and is presented in Table 10.2. The assessment is based upon the following key business requirements:

- Generation and translation of regulatory documents (e.g., MSDS, labels, TSCA 12(b) notifications, etc.)
- Screening of all orders against legislation (e.g., prohibited party's list, national inventories, etc.)

As indicated in the table, it is important to collect and document "all" costs. Vendors or third-party developers will sometimes propose reduced license or development fees anticipating the recouping of monies during the implementation and ongoing support. Likewise, executives who have tight budget requirements will push for the cheapest option (typically the status quo), not taking into account the present value of risk reduction. Only when all factors are accounted for can a proper assessment of overall costs be performed.

TABLE 10.1. Definitions for Key Financial Indicators

Return on Investment (ROI)

$$\text{ROI} = \text{cumulative benefits/cumulative cost of new solution}$$

where cumulative benefits = status quo costs with current MCS-IS minus cost if system purchased (including license fees, implementation costs, maintenance cost, cost of content, and labour and operating cost of new system) over a designated payback period (e.g., 5 years). Cumulative cost of new solution = amount spent on new system: license fee, implementation costs, maintenance and content costs. *Note*: it does not include the operating cost of new system.

Internal Rate of Return (IRR)

The IRR is the discount rate that equates the present value of the expected future cash flows to the initial cost of the project or, as indicated below, the expected savings over the life of the project.

$$[CF^1/(1 + r)^1 + CF^2/(Hr)^2 + \ldots CF^n/(1 + r)^n] = 0$$

where CF = projected savings of investment, n = project's expected life, and r = IRR. As the value of CF and n are known, the equation must be solved for "r" value. For those individuals a little rusty on math, most spreadsheets contain the IRR functionality by typing in IRR (field containing the cost of the cumulative benefit at T = 0 years ":" field containing the cost of the cumulative benefit at T = 5 years "Plus" field for NPV at T = 0 years ":" and field for NPV at T = 5 years. Example: IRR (E19:E24 + F19:F24).

Net Present Value (NPV)

$$\text{NPV} = [CF^1/(1 + k)^1 + CF^2/(1 + k)^2 + \ldots CF^n/(1 + k)^n]$$

where CF = projected savings on investment, n = project's expected life, and k = appropriate discount rate or the project's cost of capital.

The value of k will depend upon the risk of the project, the level of interest rates in the economy, and several other factors. CF = current costs – projected costs. Current costs = maintenance fee for current third-party software (if pertinent), subscription costs related to current content provider, labour and operation costs. Projected cost = license fee, maintenance/subscription costs, labor and operation costs, implementation costs related to the new MCS-IS. As with IRR, most spreadsheets contain the NPV functionality.

Key Variables in the ROI, IRR, and NPV Determination

- Payback period—a key issue and should take into account the duration of implementation (at least the first performance release).
- Cost of capital—can significantly influence the ROI, IRR, and NPV calculations.

TABLE 10.2. Fictitious Assessment of MCS-IS Options

Cost Item	"Status Quo"		"Build In House"		"Buy"—Vendor #1		"Buy"—Vendor #2	
	Company	3rd Party	Company	3rd Party	Company	Vendor	Company	Vendor
1 Initial costs								
1.1 Development cost	NA	NA	$55,000	$575,000	NA	NA	NA	NA
1.2 License fee	NA	NA	NA	NA	NA	$400,000	NA	$300,000
1.3 Implementation	NA	NA	$150,000	$75,000	$50,000	$175,000	$110,000	$240,000
1.4 Hardware cost	NA	NA	$10,000	$50,000	$60,000	NA	$60,000	NA
Subtotal	**NA**	**NA**	**$215,000**	**$700,000**	**$110,000**	**$575,000**	**$170,000**	**$540,000**
2 Annual costs								
2.1 Software maintenance	$75,000	$25,000	$120,000	$25,000	NA	$77,000	NA	$68,000
2.2 Content maintenance*	$50,000	$100,000	$25,000	$100,000	$15,000	$77,000	$15,000	$100,000
2.3 Generation of regulatory documents	$375,000	$75,000	$150,000	$25,000	$150,000	NA	$150,000	NA
2.4 Screening of orders	$300,000	$50,000	$100,000	$25,000	$100,000	NA	$100,000	NA
2.5 Translation costs	$5,000	$90,000	$5,000	$90,000	$10,000	NA	$50,000	NA
2.6 Hardware & IT costs	$75,000		$50,000	NA	$50,000	NA	$50,000	NA
2.7 Present value of risk reduction**	$250,000	NA	$100,000	NA	$50,000	NA	$50,000	NA
Subtotal	**$1,130,000**	**$340,000**	**$550,000**	**$265,000**	**$375,000**	**$154,000**	**$415,000**	**$168,000**
Total cost (5 Year)	**$5,650,000**	**$1,700,000**	**$2,965,000**	**$2,025,000**	**$1,985,000**	**$1,345,000**	**$2,245,000**	**$1,380,000**
	$7,350,000		**$4,990,000**		**$3,330,000**		**$3,625,000**	

* Content maintenance includes all costs related to updating MCS-IS with regulatory, physical, chemical, and toxicological content.

** As indicated in Section 10.3.1, it may be appropriate to calculate the present value of risk reduction for all risks mitigated by the software that can be verified after implementation, e.g., lower probability of government inspections/audits, reduced clearance time at ports, reduced probability of shipments being stopped and turned back, etc.

If the selection process involves more then one commercial vendor the following potential criteria may be useful depending upon the company's business requirements:

- Global support—Does vendor have an infrastructure to support global implementation and ongoing support.
- Regulatory content—Does vendor's system address pertinent legislation in jurisdictions in which the company operates.
- Sector-specific requirements—several industrial associations have developed their own interpretation of key legislation. If a company is a member of these associations they will need to ensure that their new system addresses these requirements.
- Vendor's partners—Is vendor providing complete solution or partnering with other organizations. If the latter, what is the status of the integration, partners track record and financial stability.
- Ability to execute—Does vendor's team have a proven track record in implementing solution for organizations of similar size and business requirements.
- Financial stability—Is vendor going to be around in the next few years.

It is important that a document be put together summarizing the advantages/disadvantages associated with each potential MCS-IS option (status quo, build, or commercial vendor) and the reason for selecting the preferred option. This document should be accompanied by support documentation, either as an appendix or separate document that clearly provides the detailed information used to construct the summary tables.

10.3 IMPLEMENTATION OF SELECTED SOLUTION

10.3.1 Implementation Process

The following are brief overviews of the implementation process for a commercial and customized application (prepared almost exclusively for a company using in-house personnel or external consultants).

Commercial Application The following presents a "sample" implementation process for a commercial MCS-IS solution. The actual steps may vary depending upon the type of MCS-IS. The schedule will definitely vary according to the particular application being implemented, size of organization (global vs. single country), IT configuration (e.g., Internet or Citrix deployment versus LAN at several sites), etc. Detailed discussion of each component is presented in the following sections.

As indicated previously, performance releases (PR) are recommended for any large MCS-IS project. The term PR refers to a staged approach to imple-

menting a MCS-IS to ensure that client's business requirements are met in a systematic, value-added manner with well-defined scope and timelines. By modularizing the project, overall project risk should be minimized and ROI increased. The sooner an organization can leverage the key functionality of a MCS-IS the sooner they can recoup their investments. It is important to note that the duration of an implementation is a key input into the true calculation of ROI for a project.

The following is an overview of potential phases for an MCS-IS implementation:

Phase I—Planning and Definition Phase

Main Objectives:

- Establish the overall project plan (scope, sponsorship, staffing, etc.).
- Define the approaches to project management, change management, and skills transfer.
- Confirm the current workflow and define the future workflow leveraging the new MCS-IS.
- Prepare project plan for development and/or implementation of new MCS-IS.
- Begin the process of obtaining user buy-in/involvement.

Major Deliverables:

- Report that includes a detailed project plan (description of activities resources and Gantt chart). This report is sometimes referred to as a Preimplementation analysis (PIA) report.
- Sign off to proceed to project design phase.

Phase II—Design Phase

Main Objectives:

- Train key project team members.
- Identify solution "voids" and decide how they will be filled. Often a conference room pilot is used to allow users to assess the existing functionality of the commercial application.
- Define in detail the new business system, preparing specifications if functional changes are required.
- Define in detail all legacy data migrations and interfaces.
- Procure and install hardware.

Major Deliverables:

- Training to key project team members.
- Documented business process (if appropriate tested during a conference room pilot/prototype session).

- Specifications for all functional changes.
- Mapping document for all legacy data migrations and ongoing interfaces.

Phase III—Develop

Main Objectives:

- Complete functional enhancements.
- Complete templates for data migration.
- Complete interfaces.
- Carry out unit testing for aforementioned activities.
- Carry out integration testing and obtain user sign off. Note that some organizations establish a distinct project phase for integration testing.
- Documentation.
- Prepare training and knowledge transfer for all staff.

Major Deliverables:

- Approved MCS-IS.
- Training needs analysis and available training material / documentation.

Phase IV—Deploy

Main Objectives:

- Ensure MCS-IS is ready to go into production.
- Transfer legacy data.
- Initiate transfer of data through interfaces.
- Transfer of knowledge to users.

Major Deliverables:

- Trained and competent users.
- Operational solution that addresses business requirements.

Phase V—Evaluate and Support

Main Objectives:

- Capture knowledge acquired through the project and update the clients' knowledge base for future reference.
- Complete handover of MCS-IS to client.
- Plan for postimplementation activity.

Major Deliverables:

- Working MCS-IS.
- Project sign-off.

- Transfer of project to technical services personnel.
- Postimplementation review/audit.

Development Project Several published development frameworks could be employed to ensure the successful preparation of a custom MCS-IS. Typically, "success" is defined as the on-time delivery of the agreed-upon MCS-IS within defined budget.

In the following section, the Microsoft® Solutions Framework (MSF) Process Model is discussed as an example of a published development process. The MSF Process Model consists of four major milestones:

- vision/scope approved
- project plan approved
- scope complete/first use
- release

These four milestones are the synchronization points for critical planning, assessment, and coordination between the customers and the project team.

The following is a very brief overview of the four major milestones of the MSF Model. For additional information on MSF and Process Model refer to Microsoft Web site: *http://www.microsoft.com/business/services/mcsmsf.asp*.

The *envisioning phase* culminates in the vision/scope-approved milestone. Once a new product (or in the case of infrastructure deployment, a new service) gains interest and approval, a project team is assembled to define the product. A vision statement articulates the ultimate goals for the product or service and provides clear direction. The scope should define the limits for a particular version of the product or service, recognizing that additional development activities may be in future versions.

The *planning phase* culminates in the project plan approved milestone. The project plan contains the functional specification, the combined plans of each functional team (as defined in the MSF team model: development, testing, user education, logistics, program management, and product management), and a schedule. The functional specification provides the project team with enough detail to identify resource requirements and make commitments. At the project plan approved milestone, customers and team agree on what is to be delivered, and how it will be built. This is an important opportunity to reassess risk, establish priorities, and finalize estimates for schedule and resources.

The *developing phase* culminates in the scope complete/first-use milestone. An approved functional specification and associated project plan provide the baseline for focused development to begin. The development team sets a number of interim delivery milestones, each of which involves a full test/debug/fix cycle. At the scope complete/first-use milestone customers and team assess the product's functionality and verify that rollout and support

plans are in place. At this milestone, all new development is complete, and deferred functionality is documented for the next release.

The *stabilization phase* culminates in the release milestone. Testing activities are performed concurrently with code development. During the stabilizing phase these activities take center stage, as bug finding and fixing become the primary focus. At the release milestone the product is formally turned over to the operations and support groups. Typically, the project team either begins work on the next release or disperses to other development projects.

These four milestones are the critical planning, assessment, and coordination milestones between the customers and the project team. The deliverables at each of these milestones are placed under change control when the milestone is achieved. Change control is a formal procedure for gaining consensus on changes to stable documents or code thereby ensuring that the whole team bases their work on the same assumptions, guidelines, and goals.

10.3.2 Project Team

The assembly of a project team is sometimes a last-minute activity. The roles potential skill set of both internal and third-party teams are discussed below. The same individual may fill more than one role, but it is essential that consideration be given to who will fulfill each of these roles during and after implementation is performed.

Steering Committee—senior representatives from company and vendor/consulting firm (if pertinent). Meeting/conference calls on a monthly basis.

Project Manager(s)—Responsible for overall project success, timelines, budget, resources, etc. *Note*: if retaining a third-party to implement a custom solution or commercial application/content, it is critical that a project manager be assigned by the third party and the company and clarity be provided on their responsibility.

Purchasing Department Contact—Required if it involves third party to ensure all contract requirements are completed and manages the payment according to agreement upon method (monthly invoices or milestones).

Champion—Executive-level individual committed to the benefits and objectives of the MCS-IS implementation that will constantly remind and push all parties to achieve the vision and its benefits. Usually this person is also financially responsible for the project.

Super User(s)—At least one individual who will master the functionality of the new MCS-IS most important to their business. Super-users may be assigned geographically (e.g., North America, Europe, etc.) or functionally (e.g., EHS, shipping, distribution, etc.).

User(s)—Future users of the MCS-IS. These individuals may use part or all of the system.

Subject Matter Expert(s)—Communicates the regulatory and business needs during the design/functional fit and provides ongoing input/review of requirements. *Note*: if third party involved, will need experts from both company and third party to ensure success and correct interpretation of regulatory requirements and business needs.

Development Team (if development activity)—Need to define roles and responsibility for each component of the project and ensure some independence related to the quality assurance process. Also need to define team leader for these activities.

Implementation IT Consultants—If implementing custom or commercial application, IT consultants will be a critical part of team ensuring solution (once finalized) is installed, legacy data migrated, interfaces to other business systems constructed and tested, "tweaking" of some functionality performed, and go live test plans prepared.

Business System IT Experts—Personnel responsible for company's ERP, LIMS, or formulation systems that are to be integrated into MCS-IS.

Administrator—IT personnel who will maintain functions within the new MCS-IS, including user accounts and user security/access rights.

IT Network—IT personnel responsible for maintenance of the network being used by the MCS-IS.

IT Desktop—IT personnel responsible for ensuring workstation desktop access to the MCS-IS and maintenance of workstation hardware and software. If a thin-client deployment is used, considerable proficiency with the server(s) hosting the thin-client software is required, as all end-user "workstations" will be impacted by the performance.

IT Database—IT personnel responsible for the maintenance of the MCS-IS database and database servers.

Trainer(s)—Training on the system will be required for a variety of stakeholders: e.g. super-users, users, IT staff, etc. Trainer(s) should have a working knowledge of the system and experience in training personnel on the particular topic. If "train the trainer" approach is employed, the company trainer must also develop these skill sets in order to be truly useful. In all cases, appropriate training material must also be provided.

Support/Helpdesk Liaison—Individual(s) acting as first-line support for the MCS-IS. These individuals may be internal to the organization, a third-party consulting firm, or commercial software vendor personnel. Capable of responding to the majority of frequently asked questions.

It is critical that all of the project's stakeholders be identified and their information needs be addressed: what information; means of conveying said information, and schedule for communication. It may also be appropriate to

define who will be involved in the preparation and review of the project plan and individual specifications. For example, IT and MCS professionals may be in agreement, but their customer may not approve of the workflow and hence may not be willing to provide monies for project. In some cases it may be appropriate to extend the stakeholders to include government agencies to ensure future compliance. Note that government agencies typically do not sign off on specifications for an application; however, the U.S. Food and Drug Administration (FDA) does participate in a review of workflow for pharmaceutical companies.

10.3.3 Project Management

The following is an overview of project management activities that may be key to the overall success of a MCS-IS project. For additional information on project management, refer to the Project Management Institute's "A Guide to the Project Management Body of Knowledge" (PMI, 2000).

- Allocating and directing staff resources for the project.
- Communications with stakeholders: company personnel in various departments (e.g., IT, foreign trade, EHS, logistics, etc.), third-party vendor (if applicable), customers, and government agencies.
- Maintaining and managing a log of action items and issues.
- Monitoring and reporting expenditures versus progress.
- Change control management if there are deviations from the contractual scope of work.
- Quality control (e.g., test plans).
- Handling financial aspects of the project such as approval of travel and expenses, subcontractor management, invoicing, and payment tracking.

In addition, the project manager will be responsible for preparing a project plan at the beginning of each phase, establishing a team with required skills, assigning tasks to individual team members, monitoring their progress, and ensuring that the project is completed on time and within budget. At the end of each phase, the project manager will also refine the original implementation plan and communicate any modifications in this plan to team members.

Communications. Routine progress meetings and reports create a structure and schedule for enabling proper project management.

Team meetings—Depending upon the size and the complexity of the project team, it may be appropriate for the team to meet every week via conference call. In addition to reviewing project status, this meeting is intended to address implementation decisions (derived from scope or issues that have arisen) that could impact outcome of the project. This meeting will also be used to communicate and discuss variations regarding the assumed scope of work at the beginning of the project. Other issues that may be handled during this meeting

include planning and logistics regarding site visits, access to company resources, required information/personnel to complete certain tasks, etc.

It is important to define:

- who will attend these meetings
- location of meetings
- who will prepare minutes
- who will track issues/resolution
- how this information will be communicated to the team
- what information will be communicated to other stakeholders

Steering committee meetings—A steering committee should be assembled with representatives from senior management of both the company and contractor. The frequency of meeting should be a function of overall project duration and significance of project to business and range from monthly to quarterly. The meeting should cover project schedule, project budget, status of success factors, major implementation decisions, and any significant risks that have or may arise that will effect the projects completion; refer to discussion of project risk in following section).

Other stakeholders—As mentioned above, communications with other stakeholders (e.g., business units, purchasing department, government agencies, etc.) must also be performed throughout the project. A list of stakeholders, contact name/information, required information, and frequency should be prepared at the beginning of the project.

Critical Success Factors. The critical success factors should be agreed upon and signed-off by all parties before initializing the implementation. Successful completion of each of these items will define the overall project's success. Examples of potential success factors:

- Generation of specific documents that comply with agreed upon legislation.
- Screening of specific regulatory lists against company's transactions.
- Installation and configuration of solution on company's system.
- Training of users on required functionality (basic users, super users, and IT requirements).
- Achievement of specific cost savings.

Project Management Tools. Prior to initiating the work, the team should agree upon what project management tools should be employed. These typically include:

- Commercial software for Gantt charts to track progress and milestones (can also be used for budget tracking and workload assessments of resources).

- Commercial spreadsheet software for outstanding issues and agreements, and budget consumed/remaining.
- Commercial time tracking tool, commercial database, or spreadsheet for project team members to record hours worked on various components of project.

The tracking of issues unfortunately is an all too often forgotten task designated to a stream of e-mails and conference calls. The following are considered basic components of an issue tracking table: issue number; type (defect, customization, enhancement), priority (high, moderate, and low); description, impact; recommendations/resolution; owner (i.e., person who will resolve), open date; resolution date; and status (open, closed, or future).

Note that it is critical that project management roles be identified at the initiation of the project: for example, who will update project schedule or budget and how often; who will assess impact of variance (see "Change Management" below); who will be involved in developing adaptive actions if there are project delays, and so on.

Change Management. It is critical that the project's statement of work not be modified or amended except via written change order signed by an authorized representative of both parties. If someone on the company's team requests or recommends changes during performance of the tasks associated with this statement of work, a written change request form setting forth the following should be submitted to the project manager for review and sign-off: (a) description of the proposed change(s), (b) impact on costs, (c) impact on project schedule, and (d) a revised statement of work.

Note that if the change is very significant or includes several key changes within a short time frame it may be appropriate to revisit the overall project schedule and plan.

Project Risks. It is important at the beginning of the project to document potential project risks, identify their potential impact, and, if considered significant, propose contingency plan. Examples of project risks include:

- Loss of key personnel from the team (e.g., transfer to another department, required to resolve a higher priority company issue/emergency).
- Project budget reductions due to changing financial status of company (e.g., cash flow issue results in elimination of third-party assistance).
- Changing company IT direction (e.g., switch in ERP/formulation software, requirement for common data warehouse).
- Internal "politics" over project budget, direction, personnel, etc.
- Vendor financial stability.

In many cases these risks are added to the project issues list spreadsheet as an additional tab or included with monthly summary report on status. Typically, risk categories that are addressed in this type of report include:

- description of risk
- impact of risk
- accountability to mitigate risk
- risk assurance status
- risk range derived by identifying the impact and probability qualitatively (low, medium, or high) and determining overall risk (impact × probability)
- status on manageability

Project Delays. It is critical that adaptive actions be planned and implemented when critical delays are identified and that an escalation process is put in place. The following steps should be taken when faced with potential issues/delays:

- Classify issue into high, moderate, or low priority (or as mentioned above, employ risk assessment approach).
- Assess potential project impact (budget/schedule) taking into account potential "work-around."
- Ensure proper resources assigned to tasks if high priority.
- Ensure all team members are aware of high-priority issues and, where appropriate, notify steering committee members.
- If significant risks, have a special meeting or conference call with senior representative of vendor firm (continue to have calls daily or weekly until issue is resolved).

Information Storage. As more and more companies rely on e-mail as the primary communication tool and projects involve a greater number of geographically dispersed personnel, there is a renewed need to ensure a central storage location for project information during the project and after, for example, Gantt charts, project budgets, specifications, outstanding issue list, etc. Therefore, the project manager or delegate needs to define:

- Location for all project information (e.g., may be located on local server—hence require copying of files if team member does not have access to system or part of e-mail tool—file folder under Lotus Notes).
- Who will maintain this information during project and after it is completed?
- What information is required to be stored at this location?
- How long to keep these files after the project?
- Requirements under the company's quality system (ISO 9000 is document storage and retention) and how the project must conform to these requirements.

10.3.4 Uncertainty of Implementation Costs

Depending upon the type of MCS-IS being implemented, uncertainty will exists in the overall costs of the implementation project. It is a customary practice in the software implementation services industry to account for this uncertainty with a contingency element added as a percentage of the total project cost. Cost uncertainties result from many factors and the degree of uncertainty is thought to be the highest at the start of a project when the least is known about the details of the project. Some examples of factors that contribute to uncertainties of costs include:

- The end users may not fully understand the detailed functionality of the application until several phases of the project have been completed. At that point the end users may want to take advantage of features that they did not fully understand initially or may want solutions for gaps that were uncovered during the deployment.
- Typically as the project proceeds, more and more customer stakeholders participate in the implementation decisions and frequently introduce some new requirements or at least have a different perspective or interpretation of certain requirements (initial requirements are usually obtained from a small sample population of stakeholders).
- The implementers might have a different interpretation or legitimate misunderstanding of a requirement(s) due to miscommunication.

The following are helpful tips on the preparation of a cost estimates:

- Contingency amounts should be applied to each activity and not to overall project, thus improving estimates and tracking of variances.
- Project management typically ranges from 10 to 25% of the overall budget and is dependent upon the level of complexity of the project.
- Significant time to perform appropriate quality assurance (QA) must be included and must not be cut at the first sign of cost overruns. Typically, QA ranges from 10 to 20% of the custom development work and an additional 5 to 10% for testing of the completed solution.
- Where appropriate payment be made based upon the successful completion of key project milestones—successful installation, completion of interfaces, etc.

10.3.5 Implementation Schedule

There are two key components to scheduling a successful implementation: Performance release (PR) and project milestones. PR refers to a staged approach to implementing a solution to ensure that business requirements are met in a systematic, value-added manner with well-defined scope and timeline. The PR

may be defined by geography (e.g., EU, followed by North America and then Pacific Rim) or functionality (e.g., generate SDS with distribution of SDS being conducted during PR2).

At the end of each component of a performance release, company and third party should sign off on the completion of the work, i.e. project milestones. Typically, the project team will not continue to a component until sign-off is received. This is especially the case with the design phase because the decisions made in this phase will determine how subsequent phases are executed and may be very costly and required significant time to alter.

The following major milestones are proposed. Dates for each milestone must be agreed to upon project initiation:

Commercial Application

- overall needs analysis and financial assessment
- preimplementation analysis report
- initial training for key users
- software installation and configuration;
- conference room pilot (if proposed solution requires detailed, hands-on assessment of future work flow and definition of customizations)
- delivery of specification for any customizations (e.g., reports/forms)
- completion of legacy database data conversion
- completion of custom modifications
- preparation of interfaces between systems
- training for all remaining users (data input, IT staff) and advanced training for super users
- testing of system/review of generated documents/transactions
- "go-live"

Development of Custom Solution (as per the Microsoft Development Model discussed in detail on Section 10.3.1):

- overall needs analysis/financial assessment
- envisioning
- planning
- stabilization

The following are helpful tips on the preparation of a project Gantt chart:

- Prior to starting the chart, talk to team members about their availability and commitment to the project; no matter what you think may be the appropriate time to conduct a task, they may not be available or consider the activity as a high priority.

- Ensure that review time periods (i.e., once a specification or mapping document has been prepared) are practical and allow for high-quality review but do not drag on.
- Allocate time to respond to reviewer's comments and perhaps another review cycle.
- Understand the role of all parties in getting changes done and the potential time line.
- Significant time must be assigned to testing once all customizations and interfaces are prepared, and then allow for modifications and retesting.

10.3.6 Do's and Don'ts

Numerous horror stories have occurred as project budgets have "ballooned" into the stratosphere, schedules have gone from months to years, and, in some cases, the entire project has been shelved. The following are do's and don'ts for a successful MCS-IS implementation:

Do's

1) Assign competent personnel to the project team, especially a project manager who has experience with Information Technology (IT) projects.
2) Focus on "must haves" not "nice to have" when developing, purchasing, or implementing an information system. The "must haves" should be based on business requirements (i.e., timely generation of forms) and regulatory requirements.
3) Employ performance releases (PR). A PR is designed to identify key components of functionality that can be delivered in a compressed time frame based on the immediate requirements of the project. PR should focus on business needs (not functionality) and expected completion dates and responsibility and be of short duration—well defined to give results quickly.
4) Ensure common understanding of deliverables, for example, have a very clear scope of overall deliverable, detail the success factors, sign-off on specifications if custom work or ensure users' manual provided if commercial solution, list legislation addressed by the system, etc. It is important to note that sales people "sell" products; they do not make them. Hence it is critical that common expectations be set on what the core product does and what it does not do. If modifications are required they must also be documented ensuring that the required functionality is obtained for a reasonable cost and within a workable time period.
5) Integrate if there is sufficient data. Automation can reduce cost and ensure high quality when processing large amounts of data. Signifi-

cant reductions, however, typically only come from the integration (e.g., interface with ERP) of systems, thereby eliminating duplicate manual data entry as well as associated errors on an ongoing basis vs. one-time legacy data loading.

6) Keep a running list of issues (e.g., defects, customization, enhancement), their priority (high, medium, low) and their status (open, future activity, closed).
7) Include sufficient contingencies and ensure the process clearly documents use of said contingencies (e.g., change order forms).
8) Identify project risk at the initiation of the project and, if considered significant, prepare appropriate contingency plan.

Don'ts

1) Assign project manager who has not managed large projects, has no information technology expertise, or has no "real authority."
2) Let junior personnel dictate required functionality based upon their current work process and not business requirements. Learn to say no to "nice to have" requests and delay them until PR2, PR3, or PR. . . . Scope creep kills projects!
3) "Jump" into coding without significant planning to ensure that new system will address business requirements in a cost-effective manner and not result in iterative loop of requests/code changes.
4) Allow team members to use the project to express their frustration, fears (especially in the case of potential layoffs if system is successful), or personal agenda. Do allow "constructive criticism" that includes clear examples of what is inappropriate or needs to be modified.
5) Make decisions autocratically or manage by committee. Aim for the middle ground, taking into account stakeholder input, however, a smaller group makes key decisions.
6) Try to do a global rollout of a large MCS-IS project as one project; break it into several short-duration performance releases.
7) Totally resist change or try to force the current workflow and procedures to be the only procedures that you can move forward with.

10.3.7 Training Program

As with any software implementation, training is required to educate users and system administrators about the application. It is critical that users be educated on the specific values of the system's functionality in order to leverage it to address key business concerns. A typical MCS-IS implementation includes several types of training for the various users. During a MCS-IS implementation, the following training sessions are recommended:

- training on Microsoft or similar development process (if custom development)
- initial application training
- basic application training
- advance application training
- IT training related to MCS-IS
- specialized workshop
- regulatory training
- technical support

Development Process Training. If the MCS-IS is being developed by an in-house team it is critical that the team follow a development process, thereby avoiding the dreaded "iterative loop development system." As indicated in Section 10.4.1 there are several models to follow, including the aforementioned MSF Process Model. If a third party will be preparing a customized solution, it is important that company personnel understand their development process and the key milestone employed.

Initial Training (Commercial Application). For a company in the early stage of an implementation, it is recommended that all key people involved in the project receive initial training on the system so that they can understand/participate in the implementation decisions. Additional users can be scheduled for training at a later stage.

Basic Training. Typically this is general training on the application provided to all customers. This may take the form of on-site training classes or be general classes put on by the vendors for customers. The latter typically reduces the cost when only a few personnel are being trained on the application; however, it typically does not allow discussion of company-specific business needs.

Advanced Training. Following a period of exploring the basic functionality of a commercial MCS-IS, more detailed training for some key users is recommended. This type of class is typically designed for super users (or heavy users) and also for key managers who will be the decision-makers in how their MCS-IS will be managed.

IT Training. In order to ensure ongoing smooth operation of the MCS-IS, IT personnel should receive appropriate training on the maintenance of the system and, if a commercial application, the process by which to load service packs and new versions. If interfaces to other business system have been constructed, IT personnel need to know in detail how to maintain them or who to call if there are problems, especially as some systems are considered mission critical.

Specialized Workshop. This can be a variation of the advanced training session where users explore advanced functionality of the system to address more complex business needs and, in particular, ways to leverage the solution to further reduce costs. It should not be a session on how to generate a list of

"nice to do's" that do not benefit the business process. The benefit of a workshop setting is that it allows an interactive dialogue between the trainer and the participants to explore issues pertinent to their business.

Regulatory Training. It is always critical to remember that a MCS-IS is a "tool" by which to assist with ongoing compliance in a cost-effective manner. Selected employees (personnel involved in activities as well as the company's auditors) need to understand their basic regulatory obligations (for all jurisdictions in which they operate) and, even if they do not become experts, be able to period check the MCS (including IS) component is functioning properly. The depth of the training will be a function of the employee's current knowledge and the particular activities and jurisdictions in which the business operates, transports, or sells goods.

Technical Support Training. Typically, if a commercial application is purchased, technical support (TS) is covered by the annual maintenance fee. In some large organizations, they have take over the first-line TS in exchange for a reduced maintenance fee and thereby need to have their personnel trained in TS issues associated with the product. If the solution is a customized MCS-IS, a TS system must be created by either agreement with the third party contracting company or in-house resources. In either case, training should be conducted on how they will respond to issues.

10.3.8 Installation and Configuration

In recent years the types of systems available and options by which to configure them has expanded significantly. The following is a list of potential information that may be required on the current system.

- operating system type and version (plus any service packs) for the application workstations and the database server
- database type and version
- network topology (diagram)
- network line speed (Ethernet, 10 or 100 Mbit, etc.) and description of the communications links between user sites and server site.
- hard disk space available, RAM, processor speed, and paging file size on the database server and workstation
- e-mail system in use
- security requirements related to data transfer and storage (especially if formulation information)

Once the above information has been compiled it must be compared against the requirements of the purchased commercial system or the specifications of the custom application. It is important to note that some corporate IT policies may prohibit or discourage the use of a particular part of a commercial application.

It is highly recommended to have different instances of the application and databases (sometimes this will require multiple servers) for acceptance (i.e., a test server) and production. All customizations, service packs, and upgrades should be loaded and tested extensively on the acceptance server before being installed on the production system. The acceptance system should mimic the production system—same operating environment, database (including version), etc.

10.3.9 Conference Room Pilot

A conference room pilot (CRP) or prototype workshop is typically an intensive 2–5 day activity that is typically recommended when the application's computations are quite complex and/or numerous key forms/reports are required that have interpretative components (i.e., not clearly prescribed by legislation). Key objectives for a CRP/prototype workshop include:

- Provide company personnel insight into algorithms employed.
- Confirm source(s) of data for application—legacy system, other business systems, and/or third-party systems.
- Review generated output to see if it addresses basic business/regulatory requirements.
- Determine what customizations may be required to standard algorithms and documents (forms/reports).
- Starting point for creation of list of key parameters for legacy data migration.
- Possibly evaluate other key business requirements such as user security and segregation of data types, data entry screens, etc.

In most cases a small representative set of company information would be entered into the solution via manual data load, transfer of partial information from legacy systems or electronic transfer from third-party systems.

With regards to the evaluation of documents (forms/reports), the following steps will be taken prior to the CRP:

- Selection of products to be used in assessment by company personnel.
- Input of product information into new MCS-IS.
- Enter additional legacy data, data from business systems, and/or data from third-party sources.
- Generate documents.
- Distribute documents for review.
- Distribute documentation on application that describes the logic behind the algorithms. For example, how the rules are applied based on different types of data inputs.

10.3.10 Custom Modifications (Commercial Application)

Modifications or supplements are almost always required to commercial applications. It is imperative to ensure that the following is performed:

- Ensure proper authority received for all customization requests, minimizing work not related to key business processes.
- Prepare specifications documents for all changes (unless trivial).
- Review and sign-off on all specifications by all relevant stakeholders.
- Modify program according to specifications.
- Test customizations to ensure they conform with specifications and function properly within the application/system.

The specification document should cover the following as a minimum: purpose, specified output, specified input, task overview, test plan, and approvals.

As mentioned in "Do's and Don'ts," Section 10.3.5, it is imperative that only the "must haves" be performed and that all "nice to haves" be either dropped from the project or included in a future performance release.

10.3.11 Legacy Data Migration

A key, and unfortunately sometimes overlooked, activity is the legacy data migration, that is, movement of data from the current MCS-IS to the new system. This activity may range from manual data entry (if the data format is inaccessible of poor quality, or if there are too few to warrant other means) to the development of a mapping tool for automatic transfer to the new system. Key activities include:

- Identification of key data that can be leveraged in the new system.
- Assessment of quality of key data.
- Preparation of mapping document and templates.
- Performing the actual data migration.

Identification of Key Data. It is important to review the future workflow (i.e., steps to be taken when the new MCS-IS is operational) and identify the following in the order specified:

- Information required to generate forms (e.g., MSDS) and reports (Tier II) or provide input to another systems to allow a transaction (e.g., customer order to proceed as material approved by the country being shipped to).
- Source of this information: generated by algorithms/calculations (referred to as "secondary data") or input into the system manually or from other business systems (referred to as "primary data").

- Primary data and where they are input to the system.
- Alternatives, if any, for primary data (e.g., published lists of national inventory lists).

Why go through this process? In most cases there is no reason to input secondary data (calculated values for transportation classification) into a system as it may cause problems, preventing use of algorithms in the future as the information may overwrite a field that would normally be calculated.

Data Quality. Once key data are identified, the next questions typically include, "Can the data be electronically extracted" and "Do we feel confident in the quality of the data." Some examples of inaccessible and accessible data include the following:

Inaccessible format—lines extracted from a Word document:

"Toluene—solubility of 515 mg/L at 20 °C and a VP at 20 °C of 0.037 atm."

"Benzene—several solubility values are available (1700–1830; 1780 mg/L at 18 °C is preferred) and a VP of 95.2 mm Hg (20 °C) should be used."

Accessible format—Table 10.3 presents fields from an access database:

TABLE 10.3. Accessible Format

Field Names	Chemical Name	Solubility	"S" Units	"S" Temp.	Vapor Pressure	VP Units	VP Temp.
Actual Record	Toluene	515	mg/L	20 °C	0.037	atm	20 °C
	Benzene	1780	mg/L	18 °C	95.2	mm Hg	20 °C

It is important to assign someone to review the quality of the selected data. Typically, company personnel who use this data have the best "feel" for its quality. If information is deemed to be questionable, two options exits for data cleaning: 1) employ another data source if available or 2) manually go through the data to identify deficiencies. The latter may be a time-consuming task, however, the old adage "garbage in, garbage out" can prove itself very true. This is one of the critical steps that will impact the go-live date.

Data Migration. The first step in a data migration is the preparation of a detailed mapping document and procedure; unless very few fields require transfer. The document should list the data to be transferred, description (e.g., copy of data dictionary, entity relationship diagram), frequency, etc. as well as field that it is to be transferred to and its limitations. Table 10.4 presents a sample of a typical mapping table for a customer master:

TABLE 10.4. Sample Mapping Table

Legacy System Field	Format	Translation	Maps to New MCS-IS Field	Comment
CMCNTY	Char (3)	ISO Country code	Country	
FORM	Char (1)	User can enter Y in this field to use Custom MSDS in new solution	UseLay	
PHON	Char (50)		Phone	Telephone # for MSDS Matters

10.3.12 Interfaces

The key to business processes today is the integration of data via interfaces with various ERPs, SCM, formulation systems, government reporting systems, etc. This allows the movement of information from one system to another in a cost-efficient, timely manner. Key activities include the assessment of the need for an interface, preparation of specifications, and the actual preparation of the interface(s).

- A listing and very brief description of each system including what types of data are provided, interface or conversion, and its technical environment.
- Mapping document (refer to Section 10.3.11, "Data Migration")
- Any known or anticipated issues with data integrity, data cleanup, or data conversion (e.g., critical data in free text only).

Application Programming Interfaces (API)—Allow applications to transfer data between each other. MCS-IS and ERP systems typically communicate in this manner.

Data Exchange—Typically refers to a portion of an application that provides an interface between two databases by converting the external database's data into a format that can be used by the application. Typically, the source database must be exported in a specified file format (e.g., ASCII file) to the application. The application may in turn export data to an ODBC-compliant database (e.g., Access).

Scripts—Scripts allow an application to be remotely controlled from any kind of computer capable of writing to a DOS-formatted drive. This makes real-time communication possible between the software you use for creating scripts and the MC application. For example, one can create a script for the application to print a document (MSDS or label) remotely. The communication protocol also allows many remote stations and hosts to communicate together.

XML (Extensible Mark-up Language)—Programming language that may replace HTML (hypertext mark-up language) as the language in which Web pages are written. XML commands allow the transfer of files from one Internet application/database to another.

Middleware/Adapter—These types of software programs allow users to pass information between systems with the middleware/adapter "translating" the information form one format (e.g., ASCII file) to another. This approach is very common when interfacing with ERP systems or a system that is receiving data from several sources.

10.3.13 Testing

Once a MCS-IS system is enhanced or a new system installed, a key step prior to going live is the testing phase. "Unit testing" on new features is done throughout the development cycle, as development units are made available. Once new development units are completed, "integration testing" is done to assure proper integration with the rest of the application. Following these are regression, performance, installation, and validation tests.

The following are types of tests performed during the implementation of a commercial application:

- Installation: The configuration plan should address tests to be conducted following installation.
- Data Migration from Legacy Systems: Mapping document may include validation tests or be part of a separate test plan.
- Interfaces: Mapping document may include the test plan or this may be present in a separate document. The test plan typically includes automated test scripts that allow a series of tests to be run and therefore quickly verify all the basic functionalitys of the application. Typically, this type of test can also be used to identify any major errors, memory leaks, or serious performance issues.
- Custom Algorithms: A test plan should be included as part of the specification document.
- Custom Forms: A test plan should be included as part of the specification document.

Integration testing verifies how all the features interact with each other. If the application is monolithic the integration test typically cover the system tests. It is especially important that all the features that directly access the database be verified and all output information checked for validity.

Test Documentation *Test specifications*—The test specification indicates what level of tests will be executed for the unit test or integration testing. For the latter it should include the versions of the operating systems, database

servers, and third-party applications that will be used to perform the tests. The test specifications should also include the system requirements that are suggested for the version of the application to be tested and the performance benchmark that will be used to measure the application's performance.

Test cases—The test cases include all steps necessary to test a specific function or behavior of the application. Each test case is updated and new test cases are generated to support the added features. These cases are then divided according to the unit test plans. Commercial software is available to assist in preparing test cases (e.g., Test Director).

Types of Testing The following are examples of tests that may be performed.

Unit Testing—Testing performed by developers on new units that are developed.

Integration Testing—Integration testing verifies how all the features interact with each other. If the application is monolithic, the integration test has to cover the system tests. It is especially important that all the features that directly access the database be verified and all output information check for validity. Test scenarios are written to test all internal relationships of the different components of the application.

Performance (Benchmark) Testing—Performance benchmarks should be established with the current release version and used as basis for the new development. The new version should match or exceed the current benchmark. Performance is measured for the most common operations, for example, data importation and generation of regulatory report/form.

Testing the Installation Program—The installation program is tested on a clean system with the operating system freshly installed. The installation is tested on all supported operating system and databases.

Beta Testing—A beta testing period typically accompanies all new service packs and upgrades of software. The duration of the testing may be a few weeks to several months, depending upon the size and complexity of the system. Typically, during this time period customers are invited to take part in the beta testing period. This is the last "test" of the application where it is used on different customer configuration. This is also the opportunity for customers to test, use, and comment on the application before it is officially released.

10.4 GO LIVE AND POST IMPLEMENTATION

10.4.1 Going Live

Key go-live activities include starting the system (and the associated flow of information through interfaces), backing-up the system, sign-off meeting/documentation, and post implementation review.

System Start-up. In order to reach this stage, both the acceptance and production environment have passed all key tests and all legacy data has been assessed, cleaned (if required), and transferred to the new system. Once these have been confirmed (and signed off) the next step is to initiate the transfer of data from various incoming business systems (ERP, formulation systems) and await the output (printer, electronic export of data to other systems).

Sign-off Meeting/Documentation. Once system start-up is complete, a sign-off meeting should be held and may include the following:

- Release of any funds being held back on the project.
- Clearly documenting any outstanding defects/functionality that were not required to go live, but are required as part of contract and obtain a schedule for their completion.
- Notify the purchasing department of the project completion.
- Discuss passage of the project to the maintenance team.

The latter may include company users and the vendor's technical support team (if commercial) or internal IT personnel (if developed in-house).

Post implementation Review. An often forgotten task is the postimplementation review. During this activity the "good and bad" associated with the project should be documented so that the company has a record for future reference. This information should then be reviewed prior to initiating any other MCS-IS projects at the company.

Post implementation Audit. In some cases, a client and/or vendor may want to conduct an audit of the implementation to determine if the predicted performance indicators (e.g., ROI) have been achieved.

10.4.2 Maintenance

Once a system is in place, the "real fun may begin"—the maintenance phase. It is critical that systems be in place for the following:

- technical support during the facilities' normal business hours
- backing up data on a regular basis
- resolution of catastrophic and critical defects
- upgrades of application
- update of regulatory content

Support. Support may take the form of telephone support, exchange of e-mails, on-line Internet support through a vendor Web site, or questions and answer lists/databases located on local server or a vendor's Web site. For telephone support it is important that be available during business hours in the locations using the system.

TABLE 10.5. Priority Codes

Priority	Description and Examples	Resolution
0	Urgent impact that causes interruption of critical business process. There are no workarounds for. priority 0 issues	Resources reallocated to address issue immediately. Company/vendor will work on continuously until issue is resolved. Feedback to be provided every 3 hours
1	Urgent impact that causes interruption of critical business process. There are workarounds, albeit cumbersome.	Workaround available but cumbersome. More permanent fix delivered as soon as possible during normal business hours. Feedback to be provided daily.
2	No impact on business processes.	Workaround available. Fix provided in future release.
3	No impact on business processes.	No workaround required. Fix provided in future release.

One of the key issues with support is ensuring that sufficient information is provided to the support person so that they can replicate the issue and then move to resolving it. Typically, if it cannot be replicated, it becomes much more difficult to resolve.

Many commercial software companies are requiring their key customers to allow remote access to reduce the time period required to replicate issues, especially where local configurations/interfaces may compound the true identify of the problem(s).

In order to ensure proper response and periodic root cause analysis of issues, it is important that all issues are tracked, regardless of whether the person assisting is internal or a third-party vendor.

Classification and Escalation Procedure. Typically, the first step by the support person will be to determine if the problem is caused by software, hardware, data, third-party software, is user related, etc. and assigning a priority code to the issue. The first activity is key for commercial software vendors, as they will typically direct customers to the company that manufacturers the third-party software if that is the source of the issue.

Table 10.5 gives examples of priority codes.

REFERENCE

Project Management Institute, 2000. "A Guide to the Project Management Body of Knowledge," (PMBOK Guide), ISBM—1-880410-23-0, Newton Square Pennsylvania.

APPENDIX 1

GLOSSARY

ABI U.S. Customs Automated Broker Interface. Approximately 99% of all U.S. import data is transmitted to U.S. Customs via ABI.

ACH U.S. Customs Automated Clearinghouse. Two ACH options are available: ACH Debit and ACH Credit.

ADR European agreement concerning the international carriage of dangerous goods by road (ADR).

AES The Automated Export System (AES). An electronic way to file the U.S. Shipper's Export Declaration (SED) and the ocean manifest information directly to U.S. Customs and Border Protection (CBP).

AWB Air waybill.

BIS The U.S. Bureau of Industry and Security (formerly the BXA).

BXA The U.S. Bureau of Export Administration (currently called BIS).

CBW Chemical and biological weapons.

Chemical and Biological Weapons Activities Any activity involved in design, development, production, or use of chemical or biological weapons (Section 744.4 of the EAR) in or by a country listed in Country Group D:3 (Supplement No. 1 to Part 740 of the EAR).

CCL U.S. Commerce Control List.

Consignee In general, the party receiving the goods during a shipment. In the case of U.S. export legislation, the foreign recipient of U.S. origin items who operates as a reseller and/or end user.

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Country Chart In terms of U.S. exports, a chart found in Supplement No. 1 to Part 738 of the EAR that contains certain licensing requirements based on destination and reason for control.

Country Groups For the control of exports from the United States, foreign countries are separated into five country groups designated by the symbols A, B, C, D, and E (see Supplement No. 1 to Part 740 of the EAR for a complete list of countries in each Country Group).

CTP Composite theoretical performance.

Denied Persons List (DPL) In general, a list of persons that is maintained by a country for which they do not allow the shipment of goods. In terms of the United States, a list (referenced in Supplement No. 2 to Part 764 of the EAR) of specific persons that have been denied export privileges, in whole or in part. The full text of each order denying export privileges is published in the Federal Register. Formerly known as the Table of Denial Orders (TDO).

DOC U.S. Department of Commerce.

DRP Diversion risk profile. Profile created to assess the probability that a party will divert goods in violation of export laws. It covers all aspects of export controls and is performed on a company's customer base and/or sales transactions.

EAB U.S. Export Administration Bulletin that provides updated information on export control changes and information. Part of a compliance department's library, if exporting from the United States, that complements the EAR.

EAR U.S. Export Administration Regulations.

ECCN Export Control Classification Number. Used to classify goods being exported from the United States. An ECCN is an alphanumeric classification used in the Commerce Control List (CCL) to identify items for export control purposes. An ECCN is different from a Schedule B number, which is used by the Bureau of Census to collect trade statistics. It is also different from the Harmonized Tariff System nomenclature, which is used to determine import duties.

EMS Export Management System. Describes the management system used to control the organizational activities related to the export of goods.

End-User In the United States, a consignee that uses U.S. items "as is" (e.g., as capital equipment), or incorporates them as integral parts, components, or materials in the production of primarily foreign origin commodities.

EPCI Enhanced Proliferation Control Initiative (EPCI) was announced in 1990 by the U.S. government to stem the spread of missile technology and nuclear, chemical, and biological weapons. Under EPCI, BXA can impose licensing requirements on exports and re-exports of goods and technology that normally do not require an export license when there is an unacceptable risk of use in or diversion to activities related to nuclear, chemical, or

biological weapons or missile proliferation, even if the end-user is not primarily weapons-related.

Exporter That person who, as the principal party in interest in the export transaction, has the power and responsibility for determining and controlling the sending of the items out of a country.

Items According to U.S. legislation, items refers to commodities, software, and technology.

Intermediate Product Product that is either created or used during the manufacturing process of a finished product.

Knowledge of a Circumstance The term may be a variant, such as "know," "reason to know," or "reason to believe" and includes not only positive knowledge that the circumstance exists or is substantially certain to occur, but also an awareness of a high probability of its existence or future occurrence. Such awareness is inferred from evidence of the conscious disregard of facts known to a person and is also inferred from a person's willful avoidance of facts.

License Legal document issued by a government authority for the purpose of conducting a regulated activity. In terms of U.S. Bureau of Export Administration (currently BIS), authorization for an export, re-export, or other regulated activity. The U.S. State Department licenses munitions, rockets, and spacecraft.

License Exception In terms of U.S. export legislation, an authorization described in Part 740 of the EAR that allows you to export or re-export, under stated conditions, items subject to the EAR that otherwise would require a license. Unless otherwise indicated, these license exceptions are not applicable to exports under the licensing jurisdiction of agencies other that the Department of Commerce.

MSDS Material Safety Data Sheet. Regulated document that must be generated by the manufacturers of a regulated material (or the distributor) to assist workers in understanding the hazards associated with a product or its ingredients. The MSDS term is typically used in North America whereas Safety Data Sheets (SDS) is used in Europe. The (M)SDS is created to enable professional users in particular to take the necessary measures as regards the protection of the environment and health and safety at the workplace.

MCS Material Compliance System. Components of management system responsible for the purchasing, research and development, testing, manufacturing, selling, documenting, and distribution of regulated materials.

Missile Technology Activities In terms of U.S. export legislation, any activity involved in the design, development, production, or use of missiles in or by a country listed in Country Group D:4 (see Supplement No. 1 to Part 740 of the EAR), whether or not that use involves a listed project (Section 744.3 of the EAR).

Mod Act U.S. Customs Modernization Act (December 1993), *Customs Modernization Act:*
Title VI of the North American Free Trade Agreement Implementation Act [P.L. 103–182, 107 Stat. 2057]. A major revision to the U.S. Import Law allowing improvements to Customs and Border Protection (CBP). Provides for full electronic processing, remote location filing, reconciliation, automated protest filing, electronic periodic payment, violation billing, electronic drawback, and electronic bonds.

NLR "No License Required." Applies to U.S. exports of items on the CCL not requiring a license according to the country chart or EAR99; provided no general prohibitions apply.

NAFTA North American Free Trade Agreement.

National Inventory Lists Several countries have put in place legislation to ensure that they have sufficient information on chemicals that are imported, manufactured, or exported from their borders. The legislation requires all new chemical substances to go through an approval process before being "listed" on a National Inventory List.

Nuclear Activities In terms of U.S. legislation, any nuclear activity as defined under Section 774.2 of the EAR.

OEE U.S. Office of Export Enforcement.

OEXS U.S. Office of Exporter Services.

Original Equipment Manufacturer (OEM) Firms that either make minor modifications or add value to purchased items before resale, or incorporate purchased items into a new end product. These firms are normally classified as resellers.

PLM Product Lifecycle Management. This is the new supply chain wording regarding the definition of all the steps required to produce a finish product. This includes receiving of chemical, research and development phase, regulatory checks, manufacturing, shipping, etc.

Reseller In terms of U.S. legislation, a consignee that receives U.S. items for the purpose of resale to other parties. This includes reselling items in the form received, making modifications or adding value (e.g., software or peripheral devices) before reselling or re-exporting items that are U.S. items, attaching a U.S. item in the same or essentially the same form as received to foreign equipment, etc.

SDS Safety Data Sheet. Refer to MSDS definition.

SDN Specially Designated Nationals. A list maintained by U.S. Treasury's Office of Foreign Assets Control (OFAC) of individual, firms and organizations who have violated U.S. embargoes. The Specially Designated Nationals and Blocked Persons List, commonly referred to as the SDN List, is a listing that contains the names and descriptions of individuals identified by the United States to pose a threat to the interests and security of the United States that include known narcotics traffickers, terrorists, and organizations financing these activities.

SDT Specially Designated Terrorists. A list of known terrorists maintained by OFAC.

SED Shipper's Export Declaration.

Special Comprehensive License In terms of U.S. legislation, a special license authorizing export of eligible items to approved consignees or end customers in specified countries, without dollar value or quantity limits (Part 752 of the EAR).

Systems Integrator A firm that purchases various components and accessories and integrates them into a unique system for resale. Virtually always classified as a reseller.

Trading Company/Firm A firm that procures items from a multitude of suppliers and exports them.

Tremcards One of the requirements of ADR is for the consignor to provide the driver of the truck with "instructions in writing." These must be provided in a language that the driver is able to read and understand, as well as in the languages of all the countries of origin, transit and destination. The content of these instructions has also been defined in the same section of ADR 2001, which hardly differs from Marginal 10 385 in ADR 1999. Tremcards stands for Transport Emergency Cards.

TSCA U.S. Toxic Substance Control Act. Gives EPA the ability to track the 75,000 industrial chemicals currently produced or imported into the U.S. EPA repeatedly screens these chemicals and can require reporting or testing of those that may pose an environmental or human-health hazard. EPA can also ban the manufacture and import of those chemicals that pose an unreasonable risk.

Workplace Safety Card Document that is generally created by the manufacturers of a regulated material (or the organization using the product) to assist workers understand the hazards associated with a product or its ingredients. It is a kind of short version of the (M)SDS to help the worker to learn quickly how to use and deal with the chemical.

APPENDIX 2

AUDIT/INSPECTION CHECKLISTS

The following sample audit/inspection checklists are provided to assist organizations assess their compliance level and status of material compliance system.

1) **Importing**—U.S. Department of the Treasury, U.S. Customs Service, "Reasonable Care—Checklist for Compliance," January 1998. Electronic copy available via *http://www.cbp.gov/ImageCache/cgov/content/laws/informed_5fcompliance_5fregs/icp021_2epdf/v1/icp021.pdf*
2) **Exporting**—U.S. Department of Commerce, Bureau of Export Administration (Currently Bureau of Industry and Security), Office of Exporter Services, "Export Management Systems Review Module," Draft, May 2000. Electronic copy available via *http://www.bxa.doc.gov/exportmanagementsystems/pdf/EMSModuleV2.pdf*

It is the intent of the authors to revise this handbook every two to three years. Therefore, if you come across a checklist that would assist an organization better manage their material compliance requirements please send it to one of the authors for potential inclusion.

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What Every Member of the Trade Community Should Know About:

REASONABLE CARE

(A Checklist for Compliance)

Basic Level of Informed Compliance
Publication for the U.S. Custom Service
U.S. DEPARTMENT OF TREASURY
U.S. Customs Service

January 1998

PREFACE

On December 8, 1993, Title VI of the North American Free Trade Agreement Implementation Act (Pub. L. 103–182, 107 Stat. 2057), which is also known as the Customs Modernization Act or "Mod Act," became effective. These provisions amended many sections of the Tariff Act of 1930 and related laws. Two new concepts which emerge from the Mod Act are "***informed compliance***" and "***shared responsibility***."

These concepts are premised on the idea that in order to maximize voluntary compliance with Customs laws and regulations, the trade community needs to be clearly and completely informed of its legal obligations. Accordingly, the Mod Act imposes a greater obligation on Customs to provide the public with improved information concerning the trade community's responsibilities and rights under the Customs and related laws. In addition, both the trade and Customs share responsibility in carrying out import requirements. For example, under section 484 of the Tariff Act, as amended, (19 U.S.C. §1484) the importer of record is responsible for using reasonable care to enter, classify and value imported merchandise, and provide any other information necessary to enable Customs to properly assess duties, collect accurate statistics and determine whether any other applicable legal requirement is met. The Customs Service is then responsible for fixing the final classification and value of the merchandise.

The failure of an importer of record to exercise reasonable care may lead to delay in the release of merchandise or the imposition of penalties. This office has been given a major role in meeting Customs informed compliance responsibilities. In order to provide information to the public, Customs intends to issue a series of informed compliance publications, and possibly CD-ROMs and videos, on topics such as value, classification, entry procedures, determination of country of origin, marking requirements, intellectual property rights, record keeping, drawback, penalties and liquidated damages.

The Penalties Branch, International Trade Compliance Division, Office of Regulations and Rulings has prepared this publication on ***Reasonable Care***, as part of a series of informed compliance publications advising the trade community of changes in Customs procedures as a result of the Mod Act. It is hoped that this material, together with seminars and increased access to Customs rulings, will help the trade community in improving voluntary compliance with the Customs laws.

The information provided in this publication is for general information purposes only. Recognizing that many complicated factors may be involved in customs issues, an importer may wish to obtain a ruling under Customs Regulations, 19 C.F.R. Part 177, or obtain advice from an expert (such as a licensed Customs Broker, attorney or consultant) who specializes in Customs matters. Reliance solely on the general information in this pamphlet may not be considered reasonable care.

Comments and suggestions are welcomed, and should be addressed to

the Assistant Commissioner at the Office of Regulations and Rulings, U.S. Customs Service, 1300 Pennsylvania Avenue, N.W., Washington, D.C. 20229. Stuart P. Seidel, Assistant Commissioner.

REASONABLE CARE CHECKLIST FOR IMPORTERS

General Questions for All Transactions:

1) If you have not retained an expert to assist you in complying with Customs requirements, do you have access to the Customs Regulations (Title 19 of the Code of Federal Regulations), the Harmonized Tariff Schedule of the United States, and the GPO publication "Customs Bulletin and Decisions?" Do you have access to the Customs Internet Website, Customs Electronic Bulletin Board or other research service to permit you to establish reliable procedures and facilitate compliance with Customs laws and regulations?
2) Has a responsible and knowledgeable individual within your organization reviewed the Customs documentation prepared by you or your expert to ensure that it is full, complete and accurate? If that documentation was prepared outside your own organization, do you have a reliable system in place to insure that you receive copies of the information as submitted to Customs; that it is reviewed for accuracy; and that Customs is timely apprised of any needed corrections?
3) If you use an expert to assist you in complying with Customs requirements, have you discussed your importations in advance with that person and have you provided that person with full, complete and accurate information about the import transactions?
4) Are identical transactions or merchandise handled differently at different ports or Customs offices within the same port? If so, have you brought this to the attention of the appropriate Customs officials?

Questions Arranged by Topic

Merchandise Description & Tariff Classification

Basic Question: Do you know or have you established a reliable procedure or program to ensure that you know what you ordered, where it was made and what it is made of?

1. Have you provided or established reliable procedures to ensure you provide a complete and accurate description of your merchandise to Customs in accordance with 19 U.S.C. 1481? (Also, see 19 CFR 141.87 and 19 CFR 141.89 for special merchandise description requirements.)

2. Have you provided or established reliable procedures to ensure you provide a correct tariff classification of your merchandise to Customs in accordance with 19 U.S.C. 1484?
3. Have you obtained a Customs "ruling" regarding the description of the merchandise or its tariff classification (See 19 CFR Part 177), and if so, have you established reliable procedures to ensure that you have followed the ruling and brought it to Customs attention?
4. Where merchandise description or tariff classification information is not immediately available, have you established a reliable procedure for providing that information, and is the procedure being followed?
5. Have you participated in a Custom*s* pre-classification of your merchandise relating to proper merchandise description and classification?
6. Have you consulted the tariff schedules, Customs informed compliance publications, court cases and/or Customs rulings to assist you in describing and classifying the merchandise?
7. Have you consulted with a Customs "expert" (e.g., lawyer, Customs broker, accountant, or Customs consultant) to assist in the description and/or classification of the merchandise?
8. If you are claiming a conditionally free or special tariff classification/provision for your merchandise (e.g., GSP, HTS Item 9802, NAFTA, etc.), How have you verified that the merchandise qualifies for such status? Have you obtained or developed reliable procedures to obtain any required or necessary documentation to support the claim? If making a NAFTA preference claim, do you already have a NAFTA certificate of origin in your possession?
9. Is the nature of your merchandise such that a laboratory analysis or other specialized procedure is suggested to assist in proper description and classification?
10. Have you developed a reliable program or procedure to maintain and produce any required Customs entry documentation and supporting information?

Valuation

Basic Questions: Do you know or have you established reliable procedures to know the "price actually paid or payable" for your merchandise? Do you know the terms of sale; whether there will be rebates, tie-ins, indirect costs, additional payments; whether "assists" were provided, commissions or royalties paid? Are amounts actual or estimated? Are you and the supplier "related parties?"

1. Have you provided or established reliable procedures to provide Customs with a proper declared value for your merchandise in accordance with 19 U.S.C. 1484 and 19 U.S.C. 1401a?

2. Have you obtained a Customs "ruling" regarding the valuation of the merchandise (See 19 CFR Part 177), and if so, have you established reliable procedures to ensure that you have followed the ruling and brought it to Customs attention?
3. Have you consulted the Customs valuation laws and regulations, Customs Valuation Encyclopedia, Customs informed compliance publications, court cases and Customs rulings to assist you in valuing merchandise?
4. Have you consulted with a Customs "expert" (e.g., lawyer, accountant, Customs broker, Customs consultant) to assist in the valuation of the merchandise?
5. If you purchased the merchandise from a "related" seller, have you established procedures to ensure that you have reported that fact upon entry and taken measures or established reliable procedures to ensure that value reported to Customs meets one of the "related party" tests?
6. Have you taken measures or established reliable procedures to ensure that all of the legally required costs or payments associated with the imported merchandise have been reported to Customs (e.g., assists, all commissions, indirect payments or rebates, royalties, etc.)?
7. If you are declaring a value based on a transaction in which you were/are not the buyer, have you substantiated that the transaction is a bona fide sale at arm's length and that the merchandise was clearly destined to the United States at the time of sale?
8. If you are claiming a conditionally free or special tariff classification/provision for your merchandise (e.g., GSP, HTS Item 9802, NAFTA, etc.), have you established a reliable system or program to ensure that you reported the required value information and obtained any required or necessary documentation to support the claim?
9. Have you established a reliable program or procedure to produce any required entry documentation and supporting information?

Country of Origin/Marking/Quota

Basic Question: Have you taken reliable measures to ascertain the correct country of origin for the imported merchandise?

1. Have you established reliable procedures to ensure that you report the correct country of origin on Customs entry documents?
2. Have you established reliable procedures to verify or ensure that the merchandise is properly marked upon entry with the correct country of origin (if required) in accordance with 19 U.S.C. 1304 and any other applicable special marking requirement (watches, gold, textile labeling, etc)?
3. Have you obtained a Customs "ruling" regarding the proper marking and country of origin of the merchandise (See 19 CFR Part 177), and

if so, have you established reliable procedures to ensure that you followed the ruling and brought it to Customs attention?

4. Have you consulted with a Customs "expert" (e.g., lawyer, accountant, Customs broker, Customs consultant) regarding the correct country of origin/proper marking of your merchandise?
5. Have you taken reliable and adequate measures to communicate Customs country of origin marking requirements to your foreign supplier prior to importation of your merchandise?
6. If you are claiming a change in the origin of the merchandise or claiming that the goods are of U.S. origin, have you taken required measures to substantiate your claim (e.g., Do you have U.S. milling certificates or manufacturer's affidavits attesting to the production in the U.S.)?
7. If you are importing textiles or apparel, have you developed reliable procedures to ensure that you have ascertained the correct country of origin in accordance with 19 U.S.C. 3592 (Section 334, Pub. Law 103–465) and assured yourself that no illegal transshipment or false or fraudulent practices were involved?
8. Do you know how your goods are made from raw materials to finished goods, by whom and where?
9. Have you checked with Customs and developed a reliable procedure or system to ensure that the quota category is correct?
10. Have you checked or developed reliable procedures to check the Status Report on Current Import Quotas (Restraint Levels) issued by Customs to determine if your goods are subject to a quota category which has "part" categories?
11. Have you taken reliable measures to ensure that you have obtained the correct visas for your goods if they are subject to visa categories?
12. In the case of textile articles, have you prepared or developed a reliable program to prepare the proper country declaration for each entry, i.e., a single country declaration (if wholly obtained/produced) or a multi-country declaration (if raw materials from one country were produced into goods in a second)?
13. Have you established a reliable maintenance program or procedure to ensure you can produce any required entry documentation and supporting information, including any required certificates of origin?

Intellectual Property Rights

Basic Question: Have you determined or established a reliable procedure to permit you to determine whether your merchandise or its packaging bear or use any trademarks or copyrighted matter or are patented and, if so, that you have a legal right to import those items into, and/or use those items in, the U.S.?

1. If you are importing goods or packaging bearing a trademark registered in the U.S., have you checked or established a reliable procedure to ensure that it is genuine and not restricted from importation under the "gray-market" or parallel import requirements of U.S. law (see 19 CFR 133.21), or that you have permission from the trademark holder to import such merchandise?
2. If you are importing goods or packaging which consist of, or contain registered copyrighted material, have you checked or established a reliable procedure to ensure that it is authorized and genuine? If you are importing sound recordings of live performances, were the recordings authorized?
3. Have you checked or developed a reliable procedure to see if your merchandise is subject to an International Trade Commission or court ordered exclusion order?
4. Have you established a reliable procedure to ensure that you maintain and can produce any required entry documentation and supporting information?

Miscellaneous Questions

1. Have you taken measures or developed reliable procedures to ensure that your merchandise complies with other agency requirements (e.g., FDA, EPA/DOT, CPSC, FTC, Agriculture, etc.) prior to or upon entry, including the procurement of any necessary licenses or permits?
2. Have you taken measures or developed reliable procedures to check to see if your goods are subject to a Commerce Department dumping or countervailing duty investigation or determination, and if so, have you complied or developed reliable procedures to ensure compliance with Customs reporting requirements upon entry (e.g., 19 CFR 141.61)?
3. Is your merchandise subject to quota/visa requirements, and if so, have you provided or developed a reliable procedure to provide a correct visa for the goods upon entry?
4. Have you taken reliable measures to ensure and verify that you are filing the correct type of Customs entry (e.g., TIB, T&E, consumption entry, mail entry, etc.), as well as ensure that you have the right to make entry under the Customs Regulations?

U.S. DEPARTMENT OF COMMERCE
BUREAU OF EXPORT ADMINISTRATION
OFFICE OF EXPORTER SERVICES

EXPORT MANAGEMENT SYSTEMS REVIEW MODULE

DRAFT DOCUMENT

A tool created for exporters to use to verify ongoing performance of EMS responsibilities. This is an example to build upon and does not include all Export Administration Regulations restrictions and prohibitions.

May 2000

Administrative Element Written Review **Element 1: Management Policy** Date_____ **Statement** Clear commitment to export control from upper management to all employees involved with export related activities.	Y	N	Operational Review Date_____ Comments
1. Are there written procedures to ensure consistent, ongoing maintenance of this Element?	__	__	
A. Is a responsible person designated to update the statement when management changes or at least annually?	__	__	
B. Is the policy included in employee training in:	__	__	
1) Orientation programs?	__	__	
2) Refresher training?	__	__	
3) Electronic training modules?	__	__	
4) Employee procedures manuals?	__	__	
C. Is the statement distributed to all export-related personnel?	__	__	
D. Is the statement communicated on an ongoing basis by:	__	__	
1) Company publications?	__	__	
2) Company awareness posters?	__	__	
3) Daily operating procedures?	__	__	
4) Other means, i.e., bulletin boards, in meetings, etc.?	__	__	
2. Is there a statement from management that communicates clear commitment to export control?	__	__	
A. Is it from current senior management? Signed? Dated?	__	__	
B. Does it explain why corporate commitment is important?	__	__	
C. Does it indicate that no sales will be made contrary to the US EAR?	__	__	
D. Does it convey the dual-use risk of the items to be exported?	__	__	
E. Does it address weapons of mass destruction activities concerns?	__	__	
1) Nuclear proliferation?	__	__	
2) Missile technology proliferation?	__	__	
3) Chemical and biological proliferation?	__	__	
F. Does it contain a description of penalties applied in instances of compliance failure?	__	__	
1) Imposed by Department of Commerce?	__	__	
2) Imposed by your company?	__	__	
G. Does it include the name, position, e-mail address & telephone number of the person to contact with questions concerning the legitimacy of a transaction or possible violations?	__	__	
3. Are adequate resources dedicated to the maintenance of the EMS program?	__	__	
4. Did export-related personnel have a copy of the statement?	__	__	
5. Is the statement part of the new employee orientation training and refresher training?	__	__	

Administrative Element Written Review **Element 2: Responsible Officials** Date_____ Identification of personnel for all export control related functions, duties, responsibilities, positions, and employees in the firm.	Y __	N __	Operational Review Date_____ Comments _____
1. Are there written procedures to identify all export control related personnel in the company?	__	__	
2. Is there a list that identifies individuals, their positions, addresses, telephone numbers, e-mail addresses, and their respective export control related activities?	__	__	
A. Does it include all domestic sites?	__	__	
B. Does it include all international sites?	__	__	
3. Has an EMS Administrator been designated for oversight of the program?	__	__	
4. Is there a system of back up personnel identified?	__	__	
5. Are export-related tasks clearly defined in written procedures?	__	__	
6. Does each export control person understand the importance of his/her function related to export compliance and where he/she fits in the overall flow?	__	__	
7. Are there any conflicts of interest in responsible offices (or individuals) and tasks?	__	__	

Administrative Element Written Review **Element 3: Record keeping** Date_____ A program for record keeping required by the EAR as well as other administrative records.	Y	N	Operational Review Date_____ Comments
1. Are there written procedures to ensure compliance with Export Administration Regulations requirements?	__	__	
A. Is an individual designated as responsible?	__	__	
B. Is the retention period defined?	__	__	
C. Is the physical location for storage defined?	__	__	
2. Is there a list of records to maintain within the procedure?	__	__	
A. Does the list include the following **Administrative Records**:	__	__	
1) Commodity Classification records?	__	__	
2) Commodity Jurisdiction Letters?	__	__	
3) Advisory Opinion Letters?	__	__	
4) BXA 748P, Multipurpose Application Form?	__	__	
5) BXA 748P-A, Item Appendix?	__	__	
6) BXA 748P-B, End-User Appendix?	__	__	
7) BXA 711, Statement by Ultimate Consignee and Purchaser?	__	__	
8) Accompanying attachments, riders, or conditions?	__	__	
9) International Import Certificates?	__	__	
10) End-User Certificates?	__	__	
11) License Exception TSR Written Assurances?	__	__	
12) AES electronic filing authorization?	__	__	
13) NDAA Reports?	__	__	
14) High Performance Computer Records?	__	__	
15) Transmittal & acknowledgment of license conditions?	__	__	
16) Log administering control over use of Export/Re-export license?	__	__	
17) Is a log maintained to ensure return or commodities previously exported under the License Exception TMP?	__	__	
18) Is a log maintained to ensure License Exception LVS limits are not exceeded?	__	__	
19) Humanitarian Donations GFT Records?	__	__	
B. Are there instructions for the accurate completion and filing for the following **Transaction Records**:	__	__	
1) Commercial Invoices (with Destination Control Statement)?	__	__	
2) Shippers Export Declarations?	__	__	
a) Description of item(s)?	__	__	
b) Export Control Classification #?	__	__	
c) License Number(s)	__	__	
d) License Exception Symbol(s)?	__	__	
e) Schedule B Number(s)?	__	__	
3) Air Waybills and/or Bills of Lading?	__	__	
C. Is there conformity of the above documents?	__	__	
D. Does the list include EMS Manual and changes as well as EMS operating procedures?	__	__	
E. Does the list include a current copy of EAR with Export Administration Bulletin (EAB) Updates?	__	__	
F. Does the list include a copy of the current Denied Persons List and Entity List and all *Federal Register* notices identifying parties added to, or deleted from the list? (Other USG Agency lists?)	__	__	

Administrative Element **Element 4. Training** An ongoing program of training and education to all employees, domestically and internationally, regarding the EAR requirements and EMS procedures.	Written Review Date_____	Y	N	Operational Review Date_____ Comments
1. Are there written procedures that describe an ongoing program of export control/compliance training and education?		__	__	
A. Is a qualified individual designated to conduct training?		__	__	
B. Is there a schedule to conduct training (including date, time, place?)		__	__	
C. What training materials are used (module, videos, manuals)?		__	__	
D. Are training materials current and accurate?		__	__	
E. Are attendance logs used for documentation, which include, agenda, date, trainer, trainees, and subjects?		__	__	
F. Is frequency of training defined?		__	__	
G. Is a list of employees/positions defined who should receive export control/compliance training?		__	__	
2. Do training methods include:		__	__	
A. Orientation of new employee(s)?		__	__	
B. Formal (structured setting, agendas, modules used)?		__	__	
C. Informal (less structured basis, verbal, daily, on-the-job exchanges)?		__	__	
D. Circulation of written memoranda and e-mails to a small number of personnel., (usually group specific instruction)?		__	__	
E. Refresher courses and update sessions scheduled?		__	__	
F. Back up personnel training?		__	__	
3. Does content of training materials include:		__	__	
A. Organizational structure of export-related departments and functions?		__	__	
B. The role of the EMS Administrator and Key Contacts?		__	__	
C. U.S. export/reexport regulatory requirements?		__	__	
D. EMS company operating procedures?		__	__	
E. The purpose and scope of export controls?		__	__	
F. Licenses & Conditions/License Exceptions & parameters?		__	__	
G. Regulatory changes and new requirements?		__	__	
H. Destination and item restrictions?		__	__	
I. Order processing screens (i.e., Denied Persons List (“DPL”), Diversion-Risk etc.)?		__	__	
J. Procedure concerning exports/reexports with documented checks?		__	__	
K. New customer review procedures?		__	__	
L. Identification and description of non-compliance?		__	__	

Administrative Element **Element 5: Internal Reviews** An internal audit system or compliance review program.	Written Review Date_____	Y	N	Operational Review Date_____ Comments
1. Are written procedures established to verify ongoing compliance?		__	__	
2. Is there a qualified individual (or auditing group) designated to conduct internal reviews?		__	__	
3. Is there a schedule for reviews?		__	__	
4. Is there a description of the review process?		__	__	
5. Is a review module or self-assessment tool used?		__	__	
If yes, does the review tool evaluate:		__	__	
A. Corporate management commitment in all aspects of the review-not just the Written Policy Statement Element?		__	__	
B. Formalized, written EMS procedures compared to operational procedures?		__	__	
C. A set of questions for each Element in the EMS written program to verify compliance?		__	__	
D. Accuracy & conformity of export transaction documents?		__	__	
E. Maintenance of documents, as required in the written EMS program.		__	__	
F. Correct authorization used?		__	__	
G. Are export control screens documented?		__	__	
H. Whether there is a current, accurate product/license determination matrix consistent with the current EAR & *Federal Register* notices?		__	__	
I. Whether there is a flow chart of the order processing system that clearly communicates export control screens?		__	__	
J. Whether there is a procedure to stop/hold transactions if problems?		__	__	
K. Whether all key export-related personnel are interviewed?		__	__	
L. Whether there is clear, open communication between all export-related divisions?		__	__	
M. How is the performance of export control checks verified on a daily basis?		__	__	
N. Does it include sampling of the completed screens performed during the order processing?		__	__	
O. Whether export control procedures and EMS manuals are consistent with EAR changes that have been published?		__	__	
P. Whether the company's training module and procedures are current with EAR and *Federal Register* notices?		__	__	
6. Is there a written report of each internal review?		__	__	
A. Are there written results of the review?		__	__	
B. Is the appropriate manager notified if action is needed?		__	__	
C. Are internal reviews performed annually, every six months, quarterly, etc.?		__	__	
D. Are spot checks/informal self-assessments performed?		__	__	
E. Are they documented?		__	__	
7. Is there evidence of a conflict of interest between the reviewer and the division being reviewed?		__	__	
8. Is a history maintained of reviews to monitor repeated deficiencies?				
9. Is there a "best practice" that should be shared with other divisions in the company to improve effectiveness and efficiency of export controls and promote consistency of procedures?		__	__	
10. Are other Departments aware of their export control-related responsibilities, i.e., legal dept., human resources, information management, etc.)		__	__	

Administrative Element **Element 6: Notification** A system for notifying designated officials of possible non-compliance with the EAR	Written Review Date_____	Y	N	Operational Review Date_____ Comments
1. Does the company have an on-going procedure for monitoring compliance of consignees, end-users and other responsible parties involved in export transactions?		—	—	
2. Are there internal procedures in place to notify management within the company if a responsible party is determined to be in non-compliance?		—	—	
3. Are there internal procedures in place to notify the appropriate U.S. Government officials when non-compliance is determined? (i.e., Export Administration's Office of Exporter Services ("OEXS"), Export Enforcement, etc.)		—	—	
4. Do all employees receive export control awareness training (think about potential deemed exports and hand-carry scenarios)?		—	—	
5. Has corporate policy been implemented which stresses to all employees an affirmative duty to notify export control officials in the event of possible non-compliance?		—	—	
Order Processing System				
1. Are there written procedures to ensure that checks and safeguards are in place within the order processing flow and responsibility for all checks are assigned? A. Is the Order Processing System described by: (1) flow charts? (2) narrative? B. Does the flow chart visually display: (1) checks performed prior to data input or acceptance of order? 1. receipt of order? 2. DPL screen? 3. entity list? 4. antiboycott screen? 5. nuclear screen? 6. missile technology screen? 7. chemical & biological weapons screen? 8. product/country licensing determination (classification) 9. diversion risk screen? 10. Shipper's Export Declaration (SED), Shippers's Letter of Instruction (SLI)? —Air Waybills (AWB) and/or Bills of Lading? —shipment?				
Note—Refer to following Element for additional questions.				

Order Processing Element Written Review Date_____	Y	N	Operational Review Date_____ Comments
An Order Processing System affixing responsibility for all required export control checks/reviews.	__	__	_____
1. Are there written procedures to ensure that checks and safeguards are in place within the order processing flow and responsibility for all checks are assigned?	__	__	
2. Is the Order Processing System displayed visually in an order flow chart?	__	__	
3. Is there a narrative that describes the process?	__	__	
4. Are the following screens included in the order process?	__	__	
A. Are pre-order entry screen checks performed (i.e., know your customer red flags)?	__	__	
B. Is the DPL screen described?	__	__	
C. Is the Entity List screen described?	__	__	
D. Are the Antiboycott red flags considered?	__	__	
E. Is the nuclear screen performed?	__	__	
F. Is the missile technology screen performed?	__	__	
G. Is the chemical & biological weapons screen performed?	__	__	
H. Is the product/country licensing determination screen performed?	__	__	
I. Is the diversion risk screen performed?	__	__	
J. Does the Order Processing System procedure include a description of administrative control over the following documents: Shipper's Export Declaration (SED), Shippers' Letter of Instruction (SLI)? Airway bills (AWB) and/or Bills of Lading?	__	__	
5. Does the procedure explain the order process from receipt of order to actual shipment?	__	__	
6. Does the procedure include who is responsible for each screen throughout the flow?	__	__	
7. Does the procedure describe when and what screening is performed (frequency of screening)?	__	__	
8. Are hold and cancel functions implemented?	__	__	
9. Does the procedure clearly indicate who has the authority to make classification decisions?	__	__	
10. Are supervisory or Export Control Administrator ("ECA") sign-off procedures implemented at high risk points?	__	__	

Screening Element **Element 1: Denied Persons Screen (DPL)** A methodology for review of orders/shipments/transactions against the DPL.	Writen Review Date_____	Y	N	Operational Review Date_____ Comments _____
1. Is there a written procedure to ensure screening of orders/shipments to customers covering servicing, training, and sales of items against the DPL?		__	__	
2. Are persons/positions identified who are responsible for DPL screening (consider domestic and international designees)?		__	__	
3. Is there a procedure to stop orders if a customer and/or other parties are found on the DPL?		__	__	
4. Is there a procedure to report all names of customers and/or other parties found on the DPL?		__	__	
5. Do the procedures include a process of what is used to perform the screening and if distribution of hard copies is required, who is responsible for their update and distribution?		__	__	
6. Is the DPL checked against a customer base?		__	__	
A. Are both the customer name and principal checked?		__	__	
B. Is there a method for keeping the customer base current?		__	__	
C. Is there a method for screening new customers?		__	__	
7. Is the DPL checked on a transaction base?		__	__	
A. Is the name of ordering party's firm and principal checked?		__	__	
B. Is the end-user identity available? If so, is a DPL check done on the end-user?		__	__	
C. Is the check performed at the time an order is accepted and/or received?		__	__	
D. Is the check performed at the time of shipment?		__	__	
E. Is the check performed against backlog orders when a new or updated DPL is published?		__	__	
8. Does documentation of screen (whether hard copy or electronic signature) include:		__	__	
A. Name of individual performing the check?		__	__	
B. Date of screen performed?		__	__	
C. Date of current denied persons information used to perform the check?		__	__	
D. Is the date of the DPL used to check the transaction documented? Is it current?		__	__	
9. Are other trade-related sanctions, embargoes and debarments imposed by agencies other than the Department of Commerce checked?		__	__	
A. Department of Treasury (Office of Foreign Assets Control):		__	__	
1) Specially Designated Terrorists?		__	__	744.13
2) Specially Designated Nationals and Foreign Terrorist Organizations?		__	__	744.14
B. Department of State:		__	__	
1) Trade-related sanctions (Bureau of Politico-Military Affairs)?		__	__	
2) Suspensions & debarments (Center for Defense Trade, Office of Defense Trade Controls)?		__	__	
10. Are domestic transactions screened against the DPL?		__	__	

Screening Element Written Review **Element 2. Product/Country License Determination Screen** Date_____ A system for assuring compliance with export licensing decisions, product/country restrictions, License Exception Parameters, and License Conditions.	Y	N	Operational Review Date_____ Comments
1. Are there written procedures for assuring compliance with product and country export restrictions?	__	__	
2. Do procedures include reexport guidelines?	__	__	
3. Is there a written procedure that describes how items (including commodities, software, and technology) are *classified* under ECCNs on the CCL?	__	__	
A. Does a technical expert within the company classify the items?	__	__	
B. Does the manufacturer of the item classify the item?	__	__	
C. Is there a written procedure that describes when a classification will be submitted to BXA and who will be responsible?	__	__	
D. Is there a written procedure that describes commodity jurisdiction determinations?	__	__	
4. Is an individual designated to ensure that Product/Country License determination guidance is current and updated?	__	__	
5. Is a Matrix or Decision Table used?			
A. Are instructions provided easily understood and applied?	__	__	
B. Do instructions provided specify who, when, where and how to check each shipment against the matrix?	__	__	
C. Does the matrix/table display ECCNs and product descriptions?	__	__	
D. Appropriate shipping authorizations, License Required, License Exception (specify which) EAR 99, NLR?	__	__	
E. Does the matrix communicate License Exception parameters/restrictions?	__	__	
F. Are license conditions and restrictions included within the matrix/table?	__	__	
G. Does the matrix/table cross-reference items to be exported with license exceptions normally available (based on item description and end destination?	__	__	

Screening Element Written Review **Element 2. Product/Country License Determination Screen** (contd.)	Y	N	Operational Review Date_____ Comments
H. Does the matrix/table clearly define what license exceptions may be available for each item (also clearly state which license exceptions may not be used due to General Prohibitions)?	__	__	
I. Are country restrictions displayed?	__	__	
J. Is country information up-to-date?	__	__	
K. Are item restrictions displayed? (i.e., technical parameter limitations, end-user limitations.)	__	__	750.7(d)
L. Are reporting prompts built into the matrix/table?	__	__	742.15 and 740.7
M. Are Wassenaar reports required? When?	__	__	
N. Is National Defense Authorization Act Notification (NDAA) required?	__	__	
O. Are NDAA Post shipment verifications required?	__	__	
P. Is the matrix automated?	__	__	
Q. Is the matrix manually implemented?	__	__	
R. Is there a distribution procedure to ensure all appropriate users receive the tool and instructions for use?	__	__	
S. Is there a list to indicate the name of the person responsible for using the tool?	__	__	
6. Is there a "hold" function to prevent shipments, if needed, during processing?	__	__	
7. Is there a procedure to distribute and verify receipt of license conditions?	__	__	
A. Is there someone designated to distribute and follow-up with acknowledgment verification?	__	__	
B. Is there a response deadline defined when conditions are distributed?	__	__	

Screening Element **Element 3: Diversion Risk Screen** To review orders against a Diversion Risk Profile (DRP).	Written Review Date_____	Y	N	Operational Review Date_____ Comments _____
1. Are there procedures to screen orders for diversion risk red flag indicators?		—	—	
2. Is a checklist used based upon the red flag indicators?		—	—	Part 732, Supplement 3
3. Does the written screening procedure identify the responsible individual who performs the screen check?		—	—	
4. Is the DRP considered at all phases of the order processing system?		—	—	
5. Is DRP performed on a transaction basis?		—	—	
6. Is DRP performed on a customer base?		—	—	
7. Is a checklist documented and maintained on file for each and *every order*?		—	—	
8. Is a checklist documented and maintained on file in the *customer profile*?		—	—	
9. Is the customer base checked at least annually against the red flag indicators or when a customer's activities change?		—	—	
10. General Prohibition 6—Prohibits export/reexport of items to embargoed destinations without proper license authority. Are embargoed destination prohibitions communicated on the product/country matrix and part of the red flag indicators?		—	—	
11. General Prohibition 10—prohibits an exporter from proceeding with transactions with knowledge that a violation has occurred or is about to occur. Is there anything that is suspect regarding the legitimacy of the transactions?		—	—	
12. Are Missile Technology, Chemical and Biological Weapons, and Nuclear Screens performed? (See Screening Elements 4, 5, & 6 in the EMS Guidelines.)		—	—	

Screening Element Written Review **Element 4: Nuclear Screen** Date_____ A system for assuring compliance with the prohibited nuclear end uses/users in Part 744.2 and 744.6 of the EAR and 744, Supplement 4.	Y	N	Operational Review Date_____ Comments
1. Prior to exporting, is there a written procedure for reviewing exports and reexports of all items subject to the EAR to determine whether they might be destined to be used directly or indirectly in any one or more of the prohibited of nuclear activities?	__	__	744.2
2. Is a person/position identified who is responsible for ensuring screening of customers and their activities against the prohibited end-uses/users?	__	__	
3. Does the procedure describe when the nuclear screen should be performed?	__	__	744, Supplement 4
4. Does the procedure include a check against the Entity List?	__	__	
5. If yes, is there a procedure to maintain documented Entity List screen decisions on file to verify consistent, operational review?	__	__	
6. Is your nuclear screen completed on a:	__	__	
A. transaction basis?	__	__	
B. against a customer base?	__	__	
C. before new customers are approved?	__	__	
7. Does the check include documentation of the signature/initial of the person performing the check, and the date performed to verify consistent, operational performance of the check?	__	__	
8. Is the customer base checked and the check documented at least annually in the Customer Profiles? (See EMS Guidelines, Screening Element 3, Diversion Risk Screen).	__	__	
9. Is it clear who is responsible for the annual check?	__	__	
10. Is there a list of all employees responsible for performing nuclear screening?	__	__	
11. Is there a procedure to verify that all responsible employees are performing the screening?	__	__	
12. Are nuclear checklists (or other tool) distributed to appropriate export control personnel for easy, efficient performance of the review?	__	__	
13. Have export/sales personnel been instructed on how to recognize prohibited nuclear end-use activities?	__	__	
14. Does the procedure include a review of U.S. person activities against prohibited activities?	__	__	744.6
15. Does the procedure include what to do if it is known that an item is destined to a prohibited end-use/user?	__	__	

Screening Element Written Review **Element 5: Missile Technology (MT) Screen** Date_____ A system for assuring compliance with the prohibited missile end-uses/users in part 744.3 and 744.6 and 744, Supplement 4.	Y	N	Operational Review Date_____ Comments
1. Prior to exporting, is there a written procedure for reviewing exports and reexports of all items subject to the EAR to determine whether the items:	__	__	744.3
A. are destined to or for a project listed in the footnote to Country Group D:4?	__	__	740, Supplement No. 1
B. or can be used in the design, development, production or use of missiles in or by a country listed in Country Group D:4, whether or not that use involves a listed project?	__	__	
C. If D:4 countries are listed with the EMS procedures, are they current?	__	__	
2. Is a person/position identified who is responsible for ensuring screening of customers and their activities against the prohibited end-uses/users?	__	__	
3. Does the procedure describe when the missile technology screen should be performed?	__	__	744, Supplement 4
4. Does the procedure include a check against the Entity List?	__	__	
5. If yes, is there a procedure to maintain documented Entity List screen decisions on file to verify consistent, operational review?	__	__	
6. Is your missile screen completed on a:	__	__	
A. transaction basis?	__	__	
B. against a customer base?	__	__	
C. before new customers are approved?	__	__	
7. Does the check include documentation of the signature/initial of the person performing the check, and the date performed to verify consistent, operational performance of the check?	__	__	
8. Is the customer base checked and the check documented at least annually in the Customer Profiles?	__	__	
9. Is it clear who is responsible for the annual check?	__	__	
10. Is there a list of all employees responsible for performing missile screening?	__	__	
11. Is there a procedure to verify that all responsible employees are performing the screening?	__	__	
12. Are missile checklists (or other tool) distributed to appropriate export control personnel for easy, efficient performance of the review?	__	__	744.6
13. Have export/sales personnel been instructed on how to recognize prohibited missile end-use activities?	__	__	
14. Does the procedure include a review of U.S. person activities against prohibited activities?	__	__	
15. Does the procedure include what to do if it is known that an item is destined to a prohibited end-use/user?	__	__	744.6

Screening Element Written Review **Element 6: Chemical & Biological** Date_____ **Weapons (CBW) Screen**	Y	N	Operational Review Date_____ Comments
A system for assuring compliance with the prohibited chemical & biological weapons end-uses/users in Part 744.4 and 744.6 and 744, Supplement 4.	—	—	_____
1. Prior to exporting, is there a written procedure for reviewing exports and reexports of all items subject to the EAR for license requirements if the item can be used in the design, development, production, stockpiling, or use of chemical or biological weapons in or by a country listed in Country Group D:3? NOTE: If D:3 countries are listed within the EMS procedures, are they current?	—	—	744.4 Part 740, Supplement No. 1
2. Is a person/position identified who is responsible for ensuring screening of customers and their activities against the prohibited end-uses/users?	—	—	
3. Does the procedure describe when the chemical & biological weapons screen should be performed?	—	—	
4. Does the procedure include a check against the Entity List?	—	—	Part 744, Supplement 4
5. If yes, is there a procedure to maintain documented Entity List screen decisions on file to verify consistent, operational review?	—	—	
6. Is your chemical & biological weapons screen completed on a:	—	—	
A. Transaction basis?	—	—	
B. against a customer base?	—	—	
C. before new customers are approved?	—	—	
7. Does the check include documentation of the signature/initial of the person performing the check, and the date performed to verify consistent, operational performance of the check?	—	—	
8. Is the customer base checked and the check documented at least annually in the Customer Profiles?	—	—	
9. Is it clear who is responsible for the annual check?	—	—	
10. Is there a list of all employees responsible for performing chemical & biological weapons screening?	—	—	
11. Is there a procedure to verify that all responsible employees are performing the screening?	—	—	
12. Are chemical & biological weapons checklists (or other tools) distributed to appropriate export control personnel for easy, efficient performance of the review?	—	—	
13. Have export/sales personnel been instructed on how to recognize prohibited chemical & biological weapons end-use activities?	—	—	
14. Does the procedure include a review of U.S. person activities against prohibited activities?	—	—	
15. Does the procedure include what to do if it is known that an item is destined to a prohibited end-use/user?	—	—	744.6

Screening Element Written Review **Element 7: Antiboycott** Date_____ **Compliance Screen** A Method to Review Orders Against Antiboycott Compliance Red Flags.	Y	N	Operational Review Date_____ Comments
	—	—	_____
1. Is there a written procedure to screen transactions and orders/shipping documents against antiboycott red flags?	—	—	Part 760
2. Are persons/positions identified who are responsible for performing this screen?	—	—	
3. Is the antiboycott screening performed by using a profile checklist?	—	—	
4. Does the checklist include the following:	—	—	
A. the firm's name?	—	—	
B. name/initials of individual performing the screen check?	—	—	
C. date screen check is performed?	—	—	
5. Is there a procedure to "hold" orders if there is a red flag during the processing of orders?	—	—	
6. Is a person designated to resolve red flags or report them to the Office of Antiboycott Compliance?	—	—	
7. Have all units that might possibly come into contact with the red flags been trained to identify the red flags?	—	—	
8. Are antiboycott red flags included in training materials in Element 4?	—	—	

Screening Element Written Review **Element 8: Informed** Date_____ **Letter/Entity List Screen** A Procedure to Review Customers and Other Parties Against the Entity List.	Y	N	Operational Review Date_____ Comments
1. Is there a written procedure to screen transactions against the Entity List to determine whether a license is required for exports or reexports of specified items to specified end-users, because BXA has determined that there is an unacceptable risk of use in, or diversion to prohibited proliferation activities?	__	__	Part 744, Supplement 4
2. Is the screening documented, including the following?	__	__	
A. the firm's name?	__	__	
B. name/initials of individual performing the check?	__	__	
C. date check is performed?	__	__	
D. is screen check combined and performed with another check (i.e., Denied Persons List check)?	__	__	
3. Is the *Federal Register* monitored daily for the addition of new entities to the Entity List?	__	__	
4. If matches occur, is there a "hold" function implemented within the order processing system that stops the order until a decision is made as to whether a license is required?	__	__	

Overall Evaluation

1) Was management commitment demonstrated throughout the system?
2) Are their adequate resources to do the tasks?
3) Was ongoing export control communication demonstrated?
4) Are the written procedures current?
5) Are the written procedures consistent with operational procedures? If not, which needs to be amended, written or operational?
6) Were designated responsible persons (names current?) well trained in export control tasks?
7) Were there gaps in performance of export management procedures or was a smooth "SYSTEM" in place?
8) Was adequate documentation in place to verify performance of all export control tasks?

APPENDIX 3

MATERIAL MANAGEMENT WEB SITES

The following is a summary of Internet web sites that may be used to obtain current information on material compliance legislation. If any of the enclosed information is incorrect, has changed or been updated, or new sources have been identified, please notify the authors so that they can include these changes in future revisions of the handbook.

An up-to-date listing of all government Web sites pertinent to material compliance activities is provided on the Atrion International Internet Site. This site can be found at *http://www.atrionintl.com/*. Select the Atrion Exchange area and then register for the "ChemAware" tool, which can be accessed free of charge.

3.1 INTERNATIONAL

Chemical safety information from intergovernmental organizations—IPCS INCHEM: http://www.inchem.org/

European Environment Information and Observation Network—EIONET: http://eionet.eea.eu.int/

Global Information Network on Chemicals—GINC:
http://www.nihs.go.jp/GINC/

International Air Transport Association—IATA:
http://www.iata.org/index.asp
Press releases—http://www.iata.org/PR

Global Materials Compliance Handbook, Edited by John Phyper, Philippe Ducas & Peter J. Baish
ISBN 0-471-46739-1 Copyright © 2004 by John Wiley & Sons, Inc.

International Labour Organization—ILO: http://www.ilo.org

International Chemical Safety Cards—ICSC: http://www.ilo.org/public/english/protection/safework/cis/products/icsc/dtasht/index.htm

International Occupational Safety and Health Information Centre (CIS): http://www.ilo.org/public/english/protection/safework/cis/products/safetytm/toc.htm

Labeling symbols: http://www.ilo.org/public/english/protection/safework/cis/products/icsc/dtasht/symbols/index.htm

Legislative texts on OSH—index of countries, provinces, organizations: http://www.ilo.org/public/english/protection/safework/cis/legosh/index.htm

R phrases: http://www.ilo.org/public/english/protection/safework/cis/products/icsc/dtasht/riskphrs/index.htm

S phrases: http://www.ilo.org/public/english/protection/safework/cis/products/icsc/dtasht/sftyphrs/index.htm

International Maritime Organization—IMO:

http://www.imo.org/HOME.html

Latest news: http://www.imo.org/Newsroom/mainframe.asp?topic_id=583

UNECE Transport Division: http://www.unece.org/trans/Welcome.html

European Agreement Concerning the International Carriage of Dangerous Goods by Inland Waterways—ADN

Annexed regulations: http://www.unece.org/trans/danger/adnreg.html

European Agreement concerning the International Carriage of Dangerous Goods by Road—ADR

ADR 2001 (English): http://www.unece.org/trans/danger/publi/adr/adr2001/English/ContentsE.html

ADR 2001 (French): http://www.unece.org/trans/danger/publi/adr/adr2001/French/TDMF.html

ADR 2001 (Russian) http://www.unece.org/trans/danger/publi/adr/adr2001/Russian/ContentsR.html

United Nations—ONU: http://www.un.org/english/index.html, www.unece.org/trans/danger/danger.htm

3.2 NORTH AMERICA

Canada

Canadian Centre for Occupational Health and Safety—CCOHS: http://www.ccohs.ca/

Comission de la santé et de la sécurité du travail—CSST: http://www.csst.qc.ca/

Environment Canada: http://www.ec.gc.ca/

Accelerated Reduction __ Elimination of Toxics—ARET: http://www.ec.gc.ca/aret/

Domestic Substances List—DSL: http://www.ec.gc.ca/CEPARegistry/subs_list/Domestic.cfm

National Pollutant Release Inventory—NPRI: http://www.ec.gc.ca/pdb/npri/

Non-Domestic Substances List—NDSL: http://www.ec.gc.ca/CEP Registry/subs_list/NonDomestic.cfm

Health Canada: http://www.hc-sc.gc.ca/

Workplace Hazardous Materials Information Systems—WHMIS: http://www.hc-sc.gc.ca/ehp/ehd/psb/whmis.htm

Ontario Designated Substances—ODS: http://www.gov.on.ca/lab/ohs/ohse.htm

Transport Canada: http://www.tc.gc.ca/

Canadian Transport Emergency Centre of the Department of Transport—Canutec: http://www.tc.gc.ca/canutec/

ERG 2000 online: http://www.tc.gc.ca/canutec/erg_gmu/erg2000_menu.htm

Transport Dangerous Goods—TDG: http://www.tc.gc.ca/tdg/

Newsletter: http://www.tc.gc.ca/tdg/newsletter.htm

Regulations: http://www.tc.gc.ca/tdg/regulations.htm

Schedule III—Special Provisions—English: http://www.tc.gc.ca/actsregs/TDG/english/sch-iii.html

Schedule III—Special Provisions—French: http://www.tc.gc.ca/actsregs/tdg/french/ann-iii.html

Mexico

http://www.stps.gob.mx/312/312_1114.htm

http://www.cddhcu.gob.mx

Occupational Exposure Limits

http://www.stps.gob.mx/312/normas/nom010/nom-010.htm

United States

Hazmat Safety

ERG 2000 (English): http://hazmat.dot.gov/gydebook.htm

ERG 2000 (Spanish): http://hazmat.dot.gov/erg2000/sp_erg2000/sp_gydebook.htm

Hazmat safety: http://hazmat.dot.gov/

National Fire Protection Association—NFPA: http://www.nfpa.org/Home/index.asp

National Institute for Occupational Safety and Health—NIOSH: http://www.cdc.gov/niosh/homepage.html

International Programme on Chemical Safety: http://www.cdc.gov/niosh/ipcs/icstart.html

Pocket Guide to Chemical Hazards—NPG: http://www.cdc.gov/niosh/npg/npg.html

Occupational Safety & Health Administration—OSHA: http://www.osha.gov

U.S. Department of Transportation—DOT: http://www.dot.gov/

States Transportation Web sites: http://www.dot.state.tx.us/othrtran/othrtran.htm

U.S. Environmental Protection Agency—EPA: http://www.epa.gov/

Terms of the environment: http://www.epa.gov/OCEPAterms/

3.3 EUROPE

Austria

Abfallwirtschaft: http://www.vlr.gv.at/abfallwirtschaft/

Federal Environment Agency: http://www.ubavie.gv.at/

Belgium

Federal Department of the Environment: http://environment.fgov.be/

Ministere de la Justice: http://194.7.188.126/justice/index1.htm

Bulgaria

Ministry of Environment and Water: http://www.moew.government.bg/

Ministry of Transport and Communications: http://www.mtc.government.bg/

Czech Republic

ChemServis: http://www.chemservis.cz/

Ministerstvo vnitra (Ministry of the Interior of the Czech Republic): http://www.mvcr.cz/

Regulation by year: http://www.mvcr.cz/sbirka/

Ministry of Industry and Trade: http://www.mpo.cz/reader/?MIval=cw_usr_view_Folder&ID=0&LANG=CZ

Ministry of the Environment: http://www.env.cz/

Ministry of Transport and Communications: http://www.mdcr.cz/
Department of Crisis Management: http://cep.mdcr.cz/default_en.htm

Denmark

Arbejdstilsynet: http://www.arbejdstilsynet.dk/

Danish Emergency Management Agency: http://www.brs.dk/
ADR 2001: http://www.brs.dk/fagomraade/tilsyn/forbyg/farligtgods/adr_2001.htm

Danish Environmental Protection Agency—DEPA: http://www.mst.dk/

Retsinformation: http://www.retsinfo.dk/

Estonia

Estonian Legal Translation Center: http://www.legaltext.ee/indexen.htm
Environmental Laws: http://www.legaltext.ee/en/andmebaas/document.asp?tyyp=X&ptyyp=A&query=03
SDS—Chemicals Act (consolidated text Oct 2000): http://www.legaltext.ee/en/andmebaas/ava.asp?m=026

Ministry of Social Affairs: http://www.sm.ee/gopro30/Web/gpweb.nsf/htmlPages/index.html

Ministry of the Environment: http://www.envir.ee/

Europe

Centro de Documentación Europea—Universidad de Alicante: http://www.cde.ua.es/
Official Journal Search: http://www.cde.ua.es/cde/doce.htm

European Agency for Safety and Health at Work: http://europe.osha.eu.int/

European Chemicals Bureau—ECB: http://ecb.jrc.it/
EINECS Information System: http://ecb.jrc.it/Einecs-List/einecssearch.htm
Newsletters: http://ecb.jrc.it/NewsLetter/
Online European Eisk Assessment Tracking System—EURATS: http://ecb.jrc.it/Risk-Assessment/orats.htm

European Council of Paint, Printing Ink and Artist Colours Industry—CEPE: http://www.cepe.org/

European Environment Information and Observation Network—EIONET: http://www.eionet.eu.int/

European Union in the US: http://www.eurunion.org/
Dangerous Substances: http://www.eurunion.org/legislat/chemical.htm

Office for Publications—EUR-OP: http://eur-op.eu.int/general/en/index.htm

The European Chemical Industry—CEFIC: http://www.cefic.be/

The European Union On-Line: http://europa.eu.int/

CELEX: http://europa.eu.int/celex/

Chemicals: http://europa.eu.int/comm/enterprise/chemicals/

ECICS Consultation: http://europa.eu.int/comm/taxation_customs/dds/cgi-bin/eciquer?Periodic=0&Lang=EN verResponse

Energie and Transport: http://europa.eu.int/comm/dgs/energy_transport/index.html

EUR-LEX: http://europa.eu.int/eur-lex/en/index.html

Mailboxes (to send questions): http://europa.eu.int/geninfo/mailbox/dg_en.htm

Official Journal Search: http://europa.eu.int/eur-lex/en/search/search_oj.html

Official Journal: http://europa.eu.int/eur-lex/en/oj/availability.html

Safety Data Sheet (Directive 2001 58 EC of 27 July 2001): http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=32001L0058&model=guichett

The Future of Europe—Debate: http://europa.eu.int/futurum/

The Regional Environmental Centre for Central and Eastern Europe: http://www.rec.org/

Finland

Environmental Administration: http://www.vyh.fi/

Ministry of Environment: http://www.vyh.fi/eng/moe/moe.html

Finlex: http://www.finlex.net/

Finnish Institute of Occupational Health—Työterveyslaitos: http://www.occuphealth.fi/

Finnish Institute of Occupational Health Databases of the Information Service Centre—Tietopalvelukeskus

Kemikaalit-Database (Chemicals): http://www1.occuphealth.fi/kemikaali/kemikaali.html

International Chemical Safety Cards—ICSC: http://www.occuphealth.fi/tt/kemkort/ipcsnfin/finnish.htm

Ministry of Social Affairs and Health: http://www.vn.fi/stm/english/index.htm

France

Institut National de Recherche et de Securité—INRS: http://www.inrs.fr/index_fla.html

Fiche de Données de Sécurité (F.D.S):
http://encpb.scola.ac-paris.fr/france/inrs_3rb/communication/fds.html
La Fiche de Données de Sécurité—ND 2089-173-98:
http://www.inrs.fr/dossiers/nd2089.pdf
Les Fiches Toxicologiques: http://www.inrs.fr/dossiers/fichtox/somft.htm
Risques Chimiques: http://www.inrs.fr/indexnosdoss.html

International Chemical Safety Cards—ICSC: http://www.cdc.gov/niosh/ipcs/french.html

Legifrance—Journal Officiel:
http://www.legifrance.gouv.fr/html/frame_jo.html

Germany

Bundesangzeiger Verlag: http://www.bundesanzeiger.de/

Bundesministerium für Verkehr, Bau- und Wohnungswesen—BMVBW: http://www.bmvbw.de/
ADR 2001: http://www.bmvbw.de/Archiv-.404.8357/.htm

Catalogue of Substances Hazardous to Water—WGK:
http://www.umweltbundesamt.de/wgs/wgs-index.htm

Federal Environment Ministry—BMU: http://www.bmu.de/fset1024.php

Federal Institute for Occupational Safety and Health—FIOSH: http://www.baua.de/english/prax/index.htm
Technische Regeln für Gefahrstoffe (TRGS):
http://www.baua.de/prax/ags/trgs.htm

Institut fur Chemie—University of Berlin: http://www.chemie.fu-berlin.de
R Phrases: http://www.chemie.fu-berlin.de/chemistry/safety/r-saetze.html
S Phrases: http://www.chemie.fu-berlin.de/chemistry/safety/s-saetze.html

International Chemical Safety Cards—ICSC:
http://www.cdc.gov/niosh/ipcs/german.html

Greece

Hellenic Parliament: http://www.parliament.gr/

Hungary

Hungary's EU Integration: http://www.kum.hu/euint/index.html
Danger Labels: http://www.fjokk.hu/magyaricsc/symbols/index.htm
R Phrases: http://www.fjokk.hu/magyaricsc/riskphrs/index.htm
S Phrases: http://www.fjokk.hu/magyaricsc/sftyphrs/index.htm

International Chemical Safety Cards—ICSC:
http://www.fjokk.hu/magyaricsc/valtoz.htm
Hazard Symbols and Labels:
http://www.fjokk.hu/magyaricsc/symbols/index.htm

Risk Phrases: http://www.fjokk.hu/magyaricsc/riskphrs/index.htm
Safety Phrases: http://www.fjokk.hu/magyaricsc/sftyphrs/index.htm

Ministry of the Environment: http://www.ktm.hu/

Veszélyes Anyag Jogszabályok Gyûjteménye:
http://www.ktm.hu/jogsz/va/vaciml.htm
R & S Phrase—Labels: http://www.ktm.hu/jogsz/va/0110201.htm
Waste Sentences: http://www.ktm.hu/jogsz/va/0500401.htm

Ireland

Health and Safety Authority: http://www.hsa.ie/

Italy

Gazzetta Ufficiale: http://www.gazzettaufficiale.it/index.jsp
Minister of Justice: http://www.giustizia.it/

Latvia

Ministry of Environmental Protection and Regional Development:
http://www.varam.gov.lv/welcome.htm
Klasifikavimas ir Ženklinimas (Informacija):
http://www.am.lt/VI/rubric.php3?rubric_id=527

Lithuania

Ministry of the Environment: http://www.am.lt/VI/
Klasifikavimas ir Ženklinimas (Informacija):
http://www.am.lt/VI/rubric.php3?rubric_id=527

Netherlands

EMIS (Energie en Milieu InformatieSysteem): http://www.emis.vito.be/
Environmental Laws (in Dutch): http://www.emis.vito.be/asp/
frame.asp?titel=wet/wet-titel.htm&navigatie=/wet/navigatie/wet-navigatie.htm&inhoud=/wet/teksten/

National Institute of Public Health and the Environment:
http://www.rivm.nl/

Centre for Substances and Risk Assessment: http://www.rivm.nl/csr/

Social and Economic Council—SER:
http://www.ser.nl/default.asp?desc=en_index
OEL: http://www.ser.nl/overdeser/default.asp?desc=overdeser_mac_waarden_index#stofnaam

Norway

Arbeidstilsynet: http://www.arbeidstilsynet.no/

Direktoratet for Brann-og Elsikkerhet: http://www.dbe.no/Internett.asp

ADR 2001: http://dynaweb.dbe.no/dynaweb/dbelover/adr_2001/@Generic__BookView;cs=default;ts=default;lang=no

LovData: http://www.lovdata.no/

Norwegian Pollution Control Authority—SFT: http://www.sft.no/

R & S Phrases, Labeling Symbols: http://www.sft.no/nyheter/horing/kjemikalier/kjemikaliemerking_vedlegg1-3.doc

Produktregisteret: http://www.produktregisternet.no

Product Registration Form (English): http://www.produktregisteret.no/guidelines/declform.doc

Product Registration Form (Norwegian): http://www.produktregisteret.no/veiledningen/Deklarasjonsskjema%202002.doc

Product Type Codes (English): http://www.produktregisteret.no/guidelines/APPENDIX%207.htm

Product Type Codes (Norwegian Bokmål): http://www.produktregisteret.no/veiledningen/VEDLEGG%207.htm

State of the Environment: http://www.environment.no/

Chemicals: http://www.miljostatus.no/Tema/Kjemikalier/kjemikalier.stm

Faresymbolene: http://www.miljostatus.no/Tema/Kjemikalier/fare/fare.stm

Stofflisten—en Oversikt over Farlige Stoffer: http://www.miljostatus.no/Tema/Kjemikalier/stoffliste/stoffliste.asp

Poland

Infrastructure: http://www.mi.gov.pl/source.php?plik=transpor

Ministry of Environment: http://www.mos.gov.pl/index_glowny.shtml

Waste Sentences: http://www.mos.gov.pl/mos/akty-p/odpady.html

Ministry of Transport: http://www.mi.gov.pl/index.php

ADR 2001: http://www.mi.gov.pl/source.php?plik=adr_omow

Transport (ADR 2001 txt): http://www.mi.gov.pl/source.php?plik=transpor

Serwis: http://www.abc.com.pl/serwis/publik.htm

Form Titles: http://www.abc.com.pl/serwis/du/1999/0241.htm

R & S phrases, labeling symbols): http://www.abc.com.pl/serwis/du/2002/0250.htm

Portugal

Direcção-Geral Das Condições do Trabalho: http://www.dgct.mts.gov.pt/

Pro Trabalho: http://www.madinfo.pt/protrabalho/conteudo.html

SDS: http://www.madinfo.pt/protrabalho/legis/subst_perigosas_rotulagem/p_n1152_97.htm

Sistema de Informação Documental Sobre Direito do Ambiente—SIDDAMB: http://www.diramb.gov.pt/mainframes.htm

Romania

ADR 2001: http://www.isetar.ro/indexe.html

Russia

Fire Laws: http://www.0-1.ru/law/default.asp

Gost Environmental Management Systems: http://www.stroybirja.ru:8101/gost/ssbt/

Nexter.ru: http://docs.nexter.ru/

Material Safety Data Sheet. Basic Principles (12.1.052-97 (1 1999)): http://docs.nexter.ru/files/ghost/gosty/ssbt/gost_r_12.1.052_97__s_izm._1_1999_.zip

Occupational Safety Standards System: http://docs.nexter.ru/index.php?mode=1&part_id=60

Preparation and Implementation of Basic Legislation on Occupational Safety: http://turva.me.tut.fi/tacis/

R & S Phrases (doc): http://turva.me.tut.fi/tacis/russian/doc/CHEM.DOC

R & S Phrases (text): http://turva.me.tut.fi/tacis/russian/text/CHEM.TXT

The Legislation in Russia: http://law.optima.ru/

Slovakia

Centre for Chemical Substances and Preparations: http://www.cchlp.sk/

Ministry of Economy of the Slovak Republic: http://www.economy.gov.sk

Vynos 2 2002: http://www.economy.gov.sk/priem/vynos22002/index.htm

Ministry of Transport, Post and Telecommunication of the Slovak Republic: http://www.telecom.gov.sk

Safework: http://www.safework.gov.sk/

SDS Danger Label: http://www.safework.gov.sk/chemia.htm

Slovakia Legislation: http://www.mia.sk/

Slovenia Republic

R & S Phrases: http://www.bens-buinac.com/storitve/kemikalije_r_in_s_stavki.html

SDS Template: http://www.17slon.com/kbg/glosarji/varnlist.doc

Law: http://zakonodaja.gov.si/

Ministry of Health: http://www.gov.si/mz/

Chemicals: http://www.gov.si/mz/aktualno_kemikalije2.html

Ministry of Transport of the Republic of Slovenia: http://www.sigov.si/mpz/

Official Gazette of the Republic of Slovenia: http://www.uradni-list.si

R&S—Danger Label—SDS: http://objave.uradni-list.si/bazeul/URED/1999/073/B/523583904.htm

Urad za Kemikalije Republike Slovenije: http://www.gov.si/mz/organivsestavi3.html

Zakoni: http://www.gov.si/mz/zakoni.html

Spain

Boletín Oficial del Estado: http://www.boe.es/

International Chemical Safety Cards—ICSC: http://www.mtas.es/insht/ipcsnspn/spanish.htm

Ministerio de Fomento: http://www.mfom.es/

Ministerio de Sanitad y Consumo: http://www.msc.es/

Hazard Symbols and Labels: http://www.msc.es/salud/ambiental/legis_preparados/pictogramas.htm

Risk Phrases: http://www.msc.es/salud/ambiental/legis_preparados/frasesr.htm

Safety Phrases: http://www.msc.es/salud/ambiental/legis_preparados/frasess.htm

Ministerio de Trabajo y Asuntos Sociales: http://www.mtas.es/

VLEX: http://v2.vlex.com/es/asp/default.asp

Sweden

Fire & Rescue Operations Involving Dangerous Goods and Chemicals: http://www.srv.se/funktioner/frameset/default.asp?om_id=60

ADR-S 2001: http://www.srv.se/funktioner/publish/mallar/2.asp?si_id=1721

National Chemicals Inspectorate—KEMI: http://www.kemi.se/

News: http://www.kemi.se/default_eng.cfm?page=aktuellt/pressmedd/default_eng.htm

Produktregistret—Produktanmalan (Product Registration Form): http://www.kemi.se/prodreg/pdf/produktanmalan.pdf

Produktregistret (Product Registration): http://www.kemi.se/default.cfm?page=prodreg/default.htm

Risk Phrases: http://www.kemi.se/klass_mark/risk_ny.htm

Safety Phrases: http://www.kemi.se/klass_mark/skydd_ny.htm

Swedish Work Environment Authority: http://www.av.se/

Switzerland

Information System for Dangerous and Ecologically Relevant Substances—IGS-SIC: http://igs.naz.ch/

SFOPH Toxic Substances List: http://igs.naz.ch/examples/servlet/de.kisters.igs.igs40.servlets.igs40Servlet?DATEISERVLET=1&SOCKET=2099&DATEI=haupt.htm&SPRACHE=en&DATENBESTAND=Giftliste&USER_ID=0UID0

Swiss Agency for the Environment, Forests and Landscape: http://www.umwelt-schweiz.ch/buwal/eng/index.html

Waste Management: http://www.buwal.ch/abfall/e/index.htm

Swiss Federal Office of Public Health—SFOPH: http://www.bag.admin.ch/

Chemical Products (French): http://www.bag.admin.ch/chemikal/f/index.htm

Chemical Products (German): http://www.bag.admin.ch/chemikal/d/index.htm

Turkey

Ministry of the Environment: http://www.cevre.gov.tr/

Safety Data Sheet: http://www.cevre.gov.tr/cevrehukuku/tebligler/guvenlikform.htm

Turkish Chemical Manufacturers Association—TCMA: http://www.tksd.org.tr/

MSDS Regulations: http://www.tksd.org.tr/msds.doc

R & S Phrases: http://www.tksd.org.tr/Risk%20ve%20Gvenlik%20Cmlecikleri.doc

Turkish Ministry of Transportation: www.ubak.gov.tr

Ukraine

Ministry of Transport of Ukraine: http://www.mintrans.kiev.ua/

United Kingdom

Health & Safety Executive—HSE: http://www.hse.gov.uk/

List of Symbols Indications of Danger, Risk and Safety Phrases: http://www.hse.gov.uk/hthdir/noframes/chip/chip8.htm

Her Majesty's Stationery Office: http://www.hmso.gov.uk/
Legislation: http://www.hmso.gov.uk/legis.htm
United Kingdom Legislation: http://www.legislation.hmso.gov.uk/
National Chemical Emergency Centre—NCEC: http://www.the-ncec.com/

3.4 PACIFIC RIM

Australia

Australia's Environnet: http://www.environet.ea.gov.au/
Department of Transport and Regional Services: http://www.dotrs.gov.au/
Australian Dangerous Goods—ADG: http://www.dotrs.gov.au/land/RoadTransport/Danger/dgoodsum.htm
Land Transport: http://www.dotrs.gov.au/land/index.htm
Environment Australia: http://www.ea.gov.au/
National Occupational Health & Safety Commission—NOHSC: http://www.nohsc.gov.au/

China

Chemical Information: http://www.cheminfo.gov.cn/
China Safety: http://www.chinasafety.gov.cn/
CSDS—GB16483-2000: http://www.chinasafety.gov.cn/chemsafety/csbz-1.htm
International Chemical Safety Cards—ICSC: http://211.101.154.202/
Chemical Products: http://211.101.154.202/icsc_index1.asp
R & S Phrases: http://211.101.154.202/icsc_wxxfh.htm
Symbols of the United Nations Committee for the Transport of Dangerous Goods: http://211.101.154.202/icsc_biaozhi.htm

Japan

International Chemical Safety Cards—ICSC: http://www.nihs.go.jp/ICSC/
ICSC—Form Titles: http://www.nihs.go.jp/ICSC/web-sp.html
Ministry of the Environment: http://www.env.go.jp/index.html

Korea

International Chemical Safety Cards—ICSC: http://nier.go.kr/
Ministry of the Environment: http://www.me.go.kr:50000/user/index.html

Malaysia

Department of Chemistry Malaysia: http://www.kimia.gov.my/
Bulletin OSH: http://www.kimia.gov.my/osha/indexbm.html

Department of Standards Malaysia—DSM: http://www.dsm.gov.my/

New Zealand

Hazardous Substances & New Organisms—HSNO: http://www.hsno.govt.nz/

Ministry of the Environment: http://www.mfe.govt.nz/

Occupational Safety and Health Service of the Department of Labour—OSH: http://www.osh.dol.govt.nz/

Thailand

International Chemical Safety Cards—ICSC: http://visitor:visitor@www.ilobkk.or.th/asiaosh/icsc/icscinx.asp

APPENDIX 4

IMPORT/EXPORT WEB SITES

The following is a summary of Internet Web sites that may be used to obtain current information on import/export legislation. If any of the enclosed information is incorrect, has changed or been updated, or new sources have been identified, please notify the authors so that they can included these changes in future revisions of the Handbook.

4.1 INTERNATIONAL

BNA (Bureau of National Affairs): A very good source of international import/export information.
www.bna.com/

CUSTOMS Info™ By KPMG LLP. Formerly by Fuglei & Associates: A very good harmonized tariff classification tool and import/export information source at reasonable cost.
http://www.customsinfo.com/

Federation of International Trade Association's (FITA) Web site provides links to many Web sites containing information on importing and exporting goods internationally.
http://fita.org/webindex/

FedEx's international Web site provides links for finding the necessary documents for international shipments, estimating duties and taxes, as well

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as an International Resource Center, which provides numerous international tools and reference materials.
http://www.fedex.com/us/international/

International Trade Administration (ITA) is part of the U.S. Department of Commerce and has four organizational units: *Commercial Service, Trade Development, Market Access and Compliance, and Import Administration*. They provide many links to other country's customs Web sites.
http://www.ita.doc.gov/, *http://www.trade.gov/td/tic/*

LeBoeuf, Lamb, Greene & MacRae, LLP is large law firm with an international trade and customs compliance practice.
www.llgm.com/

Market Access Database, a Service Provided by DG Trade, European Commission
http://mkaccdb.eu.int/mkdb/stb/mkstb.pl?action=countries

Sandler and Travis Trade Advisory Service. Provides alerts concerning changes in customs programs and international trade research.
http://www.strtrade.com

Stockholm International Peace Research Institute (SIPRI). List of countries that have signed international agreements to enforce export controls on sensitive materials.
http://projects.sipri.se/expcon/natexpcon/country_matrix.html

World Customs Organization. Harmonized System (HS)
http://www.wcoomd.org/ie/En/Topics_Issues/topics_issues.html

World Tariff, 2001. "Frequently Asked Questions: Why is my product's HS classification different in the EU-15 than in the US?"
http://www.worldtariff.com/faq.htm

4.2 NORTH AMERICA

Canada

Administrative Monetary Penalty System (AMPS): *www.ccra.gc.ca/customs/general/menu-e.html*

Canadian Automated Export Declaration (CAED): *www.statcan.ca/english/exports/*

Canada Customs and Revenue Agency (CCRA): *www.ccra.gc.ca*

Canada's Business and Consumer Site: *strategis.ic.gc.ca*

Department of Foreign Affairs and International Trade: *www.dfait.gc.ca*

Export Source (Team Canada Inc.'s export information site): *www.exportsource.gc.ca*

Industry Canada: *www.ic.gc.ca*

Statistics Canada: *www.statcan.ca*

Statistics Canada, 2002. Harmonized System, Statistics Canada Web site: *http://www.statcan.ca/trade/htdocs/hsinfo.html?*

Strategis, 2002. Trade Data Online. Industry Canada Web site: *http://strategis.ic.gc.ca/sc_mrkti/tdst/engdoc/tr_homep.html)*

Mexico

Country Commercial Guide (in English): *http://www.usatrade.gov/Website/CCG.nsf/CCGurl/CCG-MEXICO2002-CH-6:-0054F221*

Customs (in Spanish): *http://www.aduanas.sat.gob.mx/principal.htm*

United States

Office of Foreign Asset Control: *http://www.treas.gov/offices/enforcement/ofac*

United States Customs Service: *www.customs.ustreas.gov*

U.S. Customs Services. 2002. Memorandum for Trade Community Members—Informed Compliance Strategy: *http://www.customs.gov/imp-exp1/comply/ma-incmp.htm*

U.S. Customs Service Customs—Trade Partnership Against Terrorism (C-TPAT): *http://www.customs.gov/xp/cgov/toolbox/import/commercial_enforcement/ctpat/*

U.S. Customs Service Importer Self Assessment Program: *http://www.customs.gov/xp/cgov/toolbox/import/regulatory_audit_program/importer_self_assessment/*

U.S. Export Regulations: *www.access.gpo.gov/bis/ear/pdf/730.pdf*

Updates Denied Parties List via BXA home page link: *http://www.bxa.doc.gov.*

Web sites for U.S. classifying goods (imports and exports):

Export (Schedule B, administered by U.S. Census): *http://www.census.gov/foreign-trade/schedules/b/*

Import (HTS, administered by USITC): *http://www.usitc.gov/taffairs.htm*

Export Control Classification Number (ECCN): *www.bxa.doc.gov/factsheets/Do_I_NeedAnECCN.html*

4.3 EUROPE

The European Commission Taxation and Customs Union Directorate General's Web site provides an overview of specific aspects of the customs code, including rules on origin, valuation, transit and the tariff. *http://europa.eu.int/comm/taxation_customs/customs/customs.htm*

Links to trade information about member and candidates countries are provided at:

http://europa.eu.int/comm/taxation_customs/customs/customslinks.htm
http://www.trade.gov/td/tic/
http://www.eurunion.org/states/home.htm

Customs Web sites of member countries (English Web sites provided if available):

Austria: *http://www.bmf.gv.at/ministerium/ministerium/englisch/*
Belgium: *http://www.minfin.fgov.be/*
Denmark: *http://www.toldskat.dk/*
Finland: *http://www.tulli.fi/english/index.html*
France: *http://www.finances.gouv.fr/DGDDI/*
Germany: *http://www.zoll-d.de/english_version/index.html*
Greece: *http://www.e-oikonomia.gr/*
Ireland: *http://www.revenue.ie/services/customs.htm*
Italy: *http://www.agenziadogane.it/index.htm*
Luxembourg: *http://www.etat.lu/DO/*
The Netherlands: *http://www.belastingdienst.nl/9229237/v/index.htm*
Portugal: *http://www.dgaiec.min-financas.pt/sitedgaiecinternet/index.html*
Spain: *http://www.aeat.es/inicio.htm*
Sweden: *http://www.tullverket.se/en/*
United Kingdom: *http://www.hmce.gov.uk/*, *http://www.uktradeinfo.com/*

4.4 PACIFIC RIM

Australia: *http://www.customs.gov.au/*
China: *http://www.b2bchina.com.hk/* (English translations of various laws so not a clear, concise description of the requirements . . .)
http://web.ita.doc.gov/ticwebsite/apweb.nsf/369805ed9847f616852568e8004ea41d/e75d303aa6517740852568e8004ecd43!OpenDocument
Japan: *http://www.customs.go.jp/index_e.htm*, *http://www.jetro.go.jp/cgi-bin/se/export_to_japan/index.cgi*
Korea: *http://www.customs.go.kr/eng/*
Taiwan: *http://wwweng.dgoc.gov.tw/english.asp*, *http://www.apectariff.org/tw/content2.htm*

APPENDIX 5

OCCUPATIONAL EXPOSURE LIMITS LEGISLATION

5.1 OVERVIEW OF OEL

Occupational exposure limits (OELs) are concentrations, not to exceed, of hazardous compounds in workplace air values set by competent national authorities or other relevant national institutions. OELs for hazardous substances represent an important tool for risk assessment and management and valuable information for occupational safety and health activities concerning hazardous substances (EASHW, 2002).

Although OELs are connected to national laws or European laws, the character of the OELs varies between jurisdictions in terms of obligation, indication, and recommendation. Some jurisdictions prepare more than one list, one with an obligatory (binding) character, and one with a more indicative or orientating character. In all cases, it is strongly recommended that you consult the relevant national legislation (EASHW, 2002).

National scientific institutes and scientific committees prepare OEL-value levels. These may be based on cases of human exposure and effects on epidemiological studies of exposure-response relationships. Others are based on the results of animal studies. For some substances, international proposals or official values from other countries are included in the list. All concerned groups such as authorities, industry, employers' and employees' associations, consumers, and the scientific community can provide proposals for new OELs. It is usual for the final decision regarding limit values to be made by govern-

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mental authorities, often based on advice from committees consisting of members from all concerned groups (EASHW, 2002).

The levels of the OEL values for some substances differ between jurisdictions. The reasons for this include divergence in assessment methods and differing assessments on the actual risks of the chemicals themselves.

The most common limit values are air limit values defining the maximum concentration of a hazardous substance in the workplace air. The maximum admissible or accepted concentration varies from substance to substance according to its toxicity.

All air limit values define at least two basic influence factors, concentration and time. The concentration is usually given in milliliters per cubic meter (mL/m^3), also known as parts per million (ppm) or milligrams per cubic meter (mg/m^3), and the average exposure time in minutes or hours. The average exposure time for most OEL lists is eight hours per day.

Some substances have a single absolute limit while for others peak concentrations are determined. In these cases, one substance has two limit values. In addition to the "normal" 8-hours OEL there is a highest acceptable short term or peak concentration limit (sometimes also referred to as a short-term exposure limit (STEL)). These short-term OELs are intended to protect workers during brief exposure to dangerous substances (this can be 30 minutes or less) (EASHW, 2002).

Genotoxic substances are substances that damage genetic material. They, along with carcinogenic substances with genotoxic or unknown modes of action, are treated differently. Because no harmless minimum concentration can be determined for genotoxic substances, the technically possible minimum air concentration becomes the main criterion for the limit value definition or a pragmatic limit for additional risk (per working year) of cancer is used. In the European Union, the Scientific Committee on Occupational Exposure Limits (SCOEL) follows the same strategy and prepares either a health based or a pragmatic OEL value for hazardous compounds. The EU Commission proposes a pragmatic OEL when genotoxic, carcinogenic, or sensitizing substances are concerned (EASHW, 2002).

In the following sections information on various regions OEL values are presented. Appendix 3 presents Internet addresses for government web sites where additional information on OELs can be obtained.

5.2 NORTH AMERICAN OEL

United States

The occupational safety systems in the United States vary from state to state. In the following section information is provided on the major providers of OELs in the United States—American Conference of Government Industrial Hygienists (ACGIH), Occupational Safety and Health Administration

(OSHA), and National Institute for Occupational Safety and Health (NIOSH).

ACGIH Since 1946, the ACGIH has published maximum allowable concentrations (MAC). There were later renamed to "threshold limit values" (TLVs). The ACGIH is a professional organization of occupational hygienists from universities and governmental institutions. Occupational hygienists from private industry can join as associate members.

Today, nine ACGIH committees focus their energies on a range of topics such as agriculture safety and health, air sampling instruments, bio-aerosols, biological exposure indices, construction, industrial ventilation, infectious agents, chemical substance TLVs, and physical agent TLVs. The different committees propose once yearly new threshold limits or best working practice guides. The list of TLVs includes more than 700 chemical substances and physical agents, as well as dozens of biological exposure indices (BEI) for selected chemicals. Substances are nominated by the TLV Committee based on new occupational exposure data or requests of governmental organizations, workers, industry, etc. The committee decides which substances selected for consideration are to be studied and votes at least once a year on action items.

The committee has developed selection criteria for substances, taking into account scientific evidence or workplace experience. Every TLV or BEI is developed and based on the available, relevant, scientific data for that agent.

Threshold limit values are defined as an exposure limit "*to which it is believed nearly all workers can be exposed day after day for a working lifetime without ill effect*" (ACGIH, 2003).

The ACGIH defines different TLV-Types as there are:

1. Threshold Limit Value-Time-Weighted Average (TLV-TWA): the time-weighted average concentration for a conventional 8-hour workday and a 40-hour workweek, to which it is believed that nearly all workers may be repeatedly exposed, day after day, without adverse effect.
2. Threshold Limit Value-Short-Term Exposure Limit (TLV-STEL): the concentration to which it is believed that workers can be exposed continuously for a short period of time without suffering from 1) irritation, 2) chronic or irreversible tissue damage, or 3) narcosis. STEL is defined as a 15-minute TWA exposure, which should not be exceeded at any time during a workday.
3. Threshold Limit Value-Ceiling (TLV-C): the concentration that should not be exceeded during any part of the working exposure.
4. Excursion Limits: There is a general excursion limit recommendation, which applies to those TLV-TWAs that do not have STELs: Excursions in worker exposure levels may exceed three times the TLV-TWA for no more than a total of 30 minutes during a workday, and under no cir-

cumstances should they exceed five times the TLV-TWA, provided that the TLV-TWA is not exceeded.

Some TLVs include also skin and carcinogenity notations and biological exposure indices.

The ACGIH-TLVs do not have legal standing in the United States as they are only recommendations. In the United States, OSHA defines the regulatory limits. However, ACGIH-TLVs and the associated criteria documents typically act as the basis for setting TLVs in the United States and in many other countries. ACGIH exposure limits are in many cases more protective than OSHA's.

OSHA OSHA publishes permissible exposure Limits (PELs). PELs are regulatory limits on the amount or concentration of a substance in the air and they are enforceable. The initial set of limits from 1971 was based on the ACGIH TLVs. An attempt to extend the number of TLVs to other widely used chemicals was proposed by OSHA in 1989. OSHA additionally proposed in 1992 to apply most of these new and revised limits to construction, maritime, and agriculture. OSHA currently has around 500 PELs for various forms of approximately 300 chemical substances, many of which are widely used in industrial settings. Existing PELs are contained in a document called "29 CFR 1910.1000," the air contaminants standard.

If OSHA determines that a specific standard is needed, an advisory committee may be called upon to develop specific recommendations. There are two standing committees and ad hoc committees that may be appointed to examine special areas of concern to OSHA. All advisory committees, standing or ad hoc, must have members representing management, labor, and state agencies, as well as one or more designees of the Secretary of HHS. The two standing advisory committees are:

- National Advisory Committee on Occupational Safety and Health (NACOSH), which advises, consults with, and makes recommendations to the Secretary of HHS and to the Secretary of Labor on matters regarding administration of the Act.
- Advisory Committee on Construction Safety and Health, which advises the Secretary of Labor on formulation of construction safety and health standards and other regulations.

OSHA uses in a similar way as the ACGIH the following types of OELs: TWAs, action levels, ceiling limits, STELs, excursion limits, and in some cases BEIs.

NIOSH The NIOSH has the statutory responsibility for recommending exposure levels that are protective to workers. NIOSH has identified recommended exposure levels (RELs) for around 700 hazardous substances. These

limits have no legal force. NIOSH recommends their limits via criteria documents to OSHA and other OEL setting institutions.

Types of RELs are TWA, STEL, ceiling, and biological exposure indices. The recommendations and the criteria are published in several different document types, for example, current intelligence bulletins (CIB), alerts, special hazard reviews, occupational hazard assessments, and technical Guidelines.

Other U.S. OEL Publishers—Other exposure limits exist in the United States, published by organizations including:

- The American Industrial Hygiene Association (AIHA)
- The Mine Safety and Health Administration (MSHA)
- The American National Standards Institute (ANSI)
- The U.S. Navy.

Canada

Canadian autonomous regions have different occupational safety and health systems, which are applied according to the provincial regulations. The provinces are also presented at the Canada—EU Co-operation site on Workplace Safety and Health.

Québec The Regulation of the Quality of the Workplace deals with OELs. Appendix A of the regulation contains a list of contaminants. The Joint Committee of the Board of the Directors of the Commission for Occupational Health and Safety revises the OEL list. The Joint Technical Committee (JTC) consists of employer and labor representatives and experts advisers. In the list of OELs, all substances listed by the ACGIH are included. Types of OELs are TWA, STEL, and ceiling. There are carcinogenity notations but no BEIs. The OELs and their criteria are published in the Official Gazette. The OELs have legal force and they are often reviewed.

Ontario The OELs are reviewed through the OEL Task Force, including labor, management, and ministry representatives. Criteria documents from other countries are used during revisions. Revised or new OELs are published in the Ontario Gazette. Some regulations for specific substances can be found on the Internet in the electronic "Gazette" under Occupational Health and Safety Act. A complete list of OELs is available only as paper version. The OELs have legal force.

Alberta The OELs are contained in the Chemical Hazards Regulation (Alberta Regulation 393/88). The Technical Committee of Occupational Exposure Limits, established by Alberta's Occupational Health and Safety, recommends and revises OELs. The committee consists of experts from the

industry, academia, labor and government. The OELs and criteria documents are published in the Occupational Health and Safety magazine and legally binding.

Mexico

The Secretariat of Labor and Social Welfare (STPS) is responsible for setting standards regarding permissible exposure limits (PEL). The list is based on the ACGIH threshold limit values.

The scientific basis is the use of ACGIH criteria documents. The Secretariat of Commerce and Industrial Development (SECOFI) publishes the standards in the Official Journal of the Federation. The standards have legal force. The Mexican Federal Official Journal (Diario Oficial de la Federación) is available via website of the Secretaría de Economía.

5.3 EUROPE

The European Union has developed a program for the protection of workers against risks from dangerous substances. The objectives of this program are to prevent or limit the exposure of workers to dangerous substances at workplaces and to protect the workers that are likely to be exposed to these substances. Setting occupational exposure limits is an essential part of this strategy, which is endorsed under the following directives (EASHW, 2002):

- Council Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work
- Council Directive 80/1107/EEC on the protection of workers from the risks related to exposure to chemical, physical, and biological agents at work
- Council Directive 88/642/EEC amending the Council Directive 80/1107/EEC on the protection of workers from the risks related to exposure to chemical, physical, and biological agents at work
- Council Directive 98/24/EC on the protection of the health and safety of the workers from the risks relating to chemical agents (the "Chemical Agents Directive")

In 1990, at the request of the Council, the European Commission set up an informal group of scientists, known as the Scientific Expert Group (SEG), to give advice on setting limit values, after reviewing the different approaches in the member states. To encourage the occupational exposure limits (OELs), the European Commission decided to formalize the SEG and with its Decision 95/320/EC of 12 July 1995 has set up a formal base for the work on the scientific evaluation of the risk at the workplace related to chemical substances. The

major task of the Scientific Committee Group on Occupational Exposure Limits (SCOEL) is to give advice on the setting of OELs based on scientific data and, where appropriate, propose values (EASHW, 2002).

The commission has approved a guidance note (as an internal working document) on procedures to set limit values, which is to be updated in the light of experience, after an extensive consultation of the tripartite Advisory Committee for Safety, Hygiene, and Health Protection at Work (ACSHH). This guidance note sets out the arrangements for the scientific review and evaluation for establishing OELs in the European Union. It includes the procedure to be followed and how, and at what stage, the interested parties (government, industry, workers, the scientific community, and other relevant organizations) can make their contribution to this procedure (EASHW, 2002).

The European Agency for Safety and Health at Work has compiled the following information on OELs for European countries, not just EU member states.

Austria

The Austrian OEL list is based on international and national sources such as the ACGIH (see under United States for more details) and the German MAK-Commission. The Ministry of the Economy and Labour (Bundesministerium für Wirtschaft und Arbeit, or BMWA) fixes these limit values. The Austrian list is published in the Austrian Governmental Journal as an ordinance entitled "Grenfzwerte für Arbeitsstoffe und über krebserzeugende Arbeitsstoffe" (Grenfzwerteverordnung 2001—GVK 2001). The list is published also on the Internet on the homepage of the "Association of Austrian Safety Engineers." Die Sektion IX—Zentral-Arbeitsinspektorat (Central Labour Inspectorate) controls their implementation (Bundesgesetzblatt, 2001).

Belgium

In Belgium, exposure limits are known as threshold limit values (TLVs). Following the Royal Decree of 11.4.95 (BS 14.6.95), some of the TLVs have been changed to adapt to European Union guidelines, but the source of many limits in Belgium remain the ACGIH TLV list. The Royal Decree of 3.5.99 (BS 7.12.99) added a column "C" for carcinogenic to relevant substances.

Denmark

In the Danish OSH system, the Limit Values for Substances and Materials (LVSM) (Grænseværdier for stoffer og materialer) are administrative instructions that are enforced under the Working Environment Act. The Ministry of Labor sets up the regulation on these limit values and the Labor Inspectorate (Arbejdstilsynet) supervises their execution. The Labor Inspectorate publishes the OEL list. In the sphere of the act, employers are obliged to keep the expo-

sure as low as reasonably possible and the limit values should never be exceeded.

The Labor Inspectorate decides on the OELs after consulting with the social partners (representatives of employee and employers) on the technical and economical feasibility of the proposed limit value level. The scientific background is studied by the OEL setting committee acting under the Council on Working Environment (Arbejdsmiljørådet). The committee refers to the OEL criteria documentation provided by the EU (SCOEL), United States (ACGIH, OSHA, NIOSH), Germany (MAK), the Netherlands (DECOS), Nordic Expert Group (NEG), and to the experience of the Inspectorate within the Danish workplaces. Usually, the committee gives a proposal for a limit value and a preferred safety factor (1, 2, 5, 10, 20 . . .) for the substance.

In Denmark, most of the OEL values are set for the average air concentration. For lead, there is also set a biological exposure limit (Biologisk eksponeringsværdi) for concentration in blood. An OEL is an average concentration in eight hours working period. The substances, which can be taken into body via skin, are annotated by "H" ("Huden"). The allergic potential is not marked, but it is tentatively taken into account when setting the limit value level. For acutely toxic substances, like strong irritants, there is annotation L ("Loftværdi") on the limit value tables. The limit value for this substance must not be exceeded even for a short (less than 15 minutes) time. Especially for acutely neurotoxic substance, the limit value should not be exceeded even for 5 minutes.

For specific hazardous substances, the Limit Values for Substances and Materials list the substances, which are considered human carcinogens by the International Agency for Research on Cancer (IARC) or EU Commission. These substances are regulated by a specific order set by the Ministry of Labor. These substances are also annotated by "K" (kræftfremdkaldende, carcinogenic) on the OEL value tables. In addition, organic solvents are given a specific list of limit values, as they have to be particularly considered at workplaces.

Germany

In Germany, the limit values for hazardous substances are documented in Technical Rules for Dangerous Substances (TRGS). The air limit values for concentrations of substances (MAK- and TRK-Values) are published in the TRGS 900 ("Limit Values in the Air at the Workplace) and biological tolerance values for occupational exposures for substances in blood, urine, etc. (BAT values) are covered in the TRGS 903. The Technical Rules for Hazardous Substances (TRGS) describe the substances with respect to the current status of knowledge about the health hazards, typical industrial use and safety and hygiene requirements are based on the Hazardous Substances Ordinance (GefStoffV), which is derived from the Chemicals Act (ChemG). All exposure limit values are consistent national values based on common national legisla-

tion. The Federal Ministry publishes new or revised limit values half-yearly for Labor and Social Affairs.

The Committee on Hazardous Substances (Ausschuss für Gefahrstoffe—AGS) establishes the technical rules. This committee consists of members from all concerned groups. The authorities are represented by delegates of the labor inspections from the German "Lander" (Federal States) and from the institution for statutory accident insurance and prevention (BG, HVBG) and national institutions like the Hazardous Substances Division of the Federal Institute for Occupational Safety and Health (BAuA), the Federal Environmental Agency (UBA), the Federal Institute for Health Consumer Protection and Veterinary Medicine (BgVV) or the Federal Institute for Material Research and Testing (BAM). The employers, the producers and sellers of chemicals, the trade unions, and the consumers are also represented.

Limit values are developed and proposed by national scientific sources (in Germany mainly the DFG Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area, in short: MAK-Commission), the Committee on Hazardous Substances (technical-based MAK- or TRK-Values) or by scientific departments of the chemical industry. For some substances, international scientific proposals or official values from other countries are included in the list.

There are two kinds of air OELs, the TRKs, which are Technical Occupational Exposure Values, and MAKs, which are Maximum Concentration of a Chemical Substance in the Workplace. In addition to these, there are special rules for individual substances or substance groups e.g. for hydrocarbon mixtures, diesel engine emissions or different types of fibres and dust (asbestos). The Biological Tolerance Values at the Workplace for the concentration of some substances in human body are defined in the BAT-Values.

The MAK-values are average values (daily eight-hour exposure) and apply to healthy adults, not to, for example, young people or pregnant women. Substance specific acceptable peak concentrations—including the highest possible duration of such peaks—are defined. If the substance can be taken up through the skin, this is marked.

The Technical Occupational Exposure Limit (TRK) is the concentration of a chemical substance in the air within a working area, which may be reached in accordance with the best available technology (state of the art). This type of limit value is usually applied to substances which are carcinogenic or mutagenic category 1 (substances that have been shown to produce cancer in humans), or category 2 (substances to be considered carcinogenic in humans (as indicated by animal experiments). In some cases, the Committee on Hazardous Substances proposes technical-based MAK-values based on the TRK-concept (TRGS 102). This type of limit value usually applies to substances that are carcinogenic or mutagenic category 3 (substances suspected of having a carcinogenic potential) and to important industrial substances for which no harmless minimum concentration can be determined (e.g., cobalt, metal working fluids).

France

In France, the Occupational (Air) Exposure Limits (OELs) are called "Valeurs limites d'exposition professionnelle aux agents chimiques en France" (VL). This VL is defined as the concentration of an agent in the air (in the working area) that a person can inhale for a defined duration without a risk of changes to his or her health. Furthermore, the VL should be seen as a minimum requirement. The VLs are fixed by the Ministry of Employment and Solidarity (Ministère de l'Emploi et de la Solidarité). Some values are also recommended by the National Illness Insurance Fund (CNAM). There are currently two types of OELs; statutory and compulsory OELs for certain extremely hazardous substances and recommended OELs for most of the substances.

The OELs are established and revised by the Scientific Committee for Surveillance of the Workplace (Comité Scientifique pour la Surveillance des Atmosphères de Travail), working under the High Council for the Prevention of Occupational Hazards Environment. The committee is made up of experts, scientists, and industrialists involved with chemicals. The OELs are based on the review on the international scientific literature and studies undertaken by the regional authorities in France. Then the technical and economical feasibility of the proposed health based OEL is studied mostly by the industry participating in the limit setting and reviewing. After endorsement the OELs are published in the French Official Journal, Official Bulletin and in the publications of the National Institute of Safety Research (Institut National de Recherche et de Sécurité, INRS). The INRS publishes parts of the VL on the Internet.

Two types of OEL values exist in France. Short-term exposure limit values (valeurs limites d'exposition à court terme) are ceiling values for measured over one duration of maximum 15 minutes and average exposure limit values (valeurs limites de moyenne d'exposition) are measured or estimated over the duration of 8 hours.

Finland

The Finnish OEL system can be divided into legally enforcing binding limit values (sitovat raja-arvot) and more orientating concentrations known to be harmful (haitalliseksi tunnetut pitoisuudet, HTP-arvot). Both of these are connected to the Labor Protection Act, which oblige the employer to provide the employee healthy and safe working conditions. The OEL list is published by the Finnish Institute of Occupational Health in English and Finnish.

The Ministry of Social Affairs and Health decides on Occupational Exposure Limits according to the proposal of the Advisory Committee for Occupational Health and Safety on Chemicals. The Council of State nominates the Advisory Committee for Occupational Health and Safety on Chemicals that operates under the Ministry of Social Affairs and Health. The Committee together with the Ministry's Occupational Safety and Health Department prepares the list of harmful concentrations. The Committee selects a Subcom-

mittee of Exposure Limits, which does the actual preparation work. The subcommittee members (four) are from the Ministry, chemical industry, employers' organizations, and the trade union. The subcommittee has three secretaries, who prepare drafts for short documentation with a specific emphasis on the dose-effect relationships. The exposure limit is recommended after identifying the critical effect and reviewing the related literature.

All air limit values define two basic influence factors, the concentration—in mg/m^3 or ppm—and the average exposure time in minutes or hours. The exposure times are averaged for 15 minutes and eight hours. Besides, some substances have momentary limit values, which should never be exceeded. The possible skin penetration is remarked by "Skin" (Iho). This annotation does not take into account the possibly corrosion or irritation potential of the substance. The potency to cause allergy may be considered when setting the OEL, but it is not annotated on the OEL list. Limit values of the contents of substances in biological samples ("Biologisten altistusindikaattorien raja-arvot"), such as blood, urine, or alveolar air have been set for several substances to amend the air limit values and help to measure the real exposition at workplaces.

Greece

A comprehensive law on "health and safety for workers" and several ensuing presidential decrees have achieved harmonization to European Union legislation. Among a large number of topics, which are addressed in this legislation (e.g., occupational factors, working conditions), it includes provisions on enforceable occupational exposure limits for nearly 600 chemicals (Journal of Occupational Health, 2001).

Most of the OELs reported are equivalent to threshold limit values (TLV) for time-weighted average (TWA) published by the American Conference of Industrial Hygienists (ACGIH).

Italy

The Italian exposure limits are identical with the TLVs established by the ACGIH in the United States. The list exists as paper version. An updated list of the Italian laws concerning dangerous substances is available in the Internet at the URL of the National Institute of Occupational Safety and Prevention (ISPESL). The laws on the risks arising from exposure to chemical, physical, and biological agents are also explained on the comprehensive ISPESL Web site (refer to Appendix 3).

Ireland

In Ireland, the Occupational (Air) Exposure Limits (OELs) are defined as the maximum permissible concentration of a chemical agent in the air at the workplace to which workers may be exposed in relation to an 8-hour or a 15-minute

reference period. These limits are set out in Schedule 1 to 1999 Code of Practice for the Safety, Health and Welfare at Work (Chemicals Agents) Regulations, 1994 (S.I. No. 445 of 1994). The 1999 Code of Practice can be obtained as a priced publication from the HSA.

The establishment of OELs in Ireland is based on the Safety, Health and Welfare at Work (Chemical Agents) Regulations, 1994 (S.I. No. 445 Of 1994).

Luxembourg

The exposure limits in Luxembourg are adopted from various international health and safety agencies, such as International Commission on Non-Ionising Radiation Protection (ICNIRP) and the Commission Internationale d'Eclairage (CIE; France). The exposure limits in Luxembourg are based on the regulation of 19 July 1991. OELs used in Luxembourg are the same as used in Germany, unless specific OELs are provided.

The legislation can be found on the Internet on the Web site of the Inspectorate for Labor and Mines (Inspection du Travail et des Mines). The Inspectorate works under the Ministry of Labor and Employment. (Ministère du Travail et de l'Emploi).

The Netherlands

In the Netherlands, there are two types of OELs: legally binding and administrative OELs. They both have a different basis and a different status. The Occupational Exposure Limits (OELs) are called MAC-values (Maximaal Aanvaarde Concentraties). The MAC is defined as the maximum allowed concentration of a gas, vapor, mist, or dusty agent in the air of the working area. In the Netherlands, the OEL values are set for 8-hours, time-weighted, maximum-allowed concentration (TWA), for 15-minutes average concentration (15-minutes TWA). Additionally, there is also MAC-C, which is a ceiling value, which should not be exceeded at any time. MAC-values can be found on the Internet. They are also available on the Nationale MAC-lijst 2001 by the Ministry of Social Affairs and Employment in the Hague.

The legally binding OELs are set according to the health-based recommended occupational exposure level provided by the Dutch Expert Committee on Occupational Standards (DECOS) of the Health Council. The legal status is based on the Dutch Occupational Law and the Labor Inspectorate controls the implementation. A yearly working programme is made by the Ministry of Social Affairs and Employment for substances to be entered in the "three-steps" program for evaluating the need of limit values.

The DECOS prepares an evaluation report based on literature study. The draft report is made public (also on the Webster of the DECOS) and interested parties are invited to comment the draft report. After incorporation of comment, the final version is published by the Health Council and presented to the State Secretary of the Ministry of Social Affairs and Employment. The

health-based value is then evaluated by the Subcommission MAC-values of the National Economic Development Council for social and economical aspects and the technical feasibility. Finally, the State Secretary of the Ministry of Social Affairs and Employment derives the legally binding OEL based on both reports. The value is then published in the State Courant. A press release is used to make the new OEL known to the public.

Administrative OELs are not legally binding. They are regulated in a policy rule based on the working condition regulations. The Labor Inspectorate considers these values as levels that should in any case not be exceeded to protect workers. Mostly these are TLVs from ACGIH (USA).

Portugal

In Portugal, the occupational exposure limits for dangerous substances are published in the Portuguese Standard 1796 of 1988. The publisher is the Portuguese Institute of Quality. The Standard 1796 is currently being reviewed. The VLEs (OELs) reported in this standard as well as in the new standard are equivalent to the limit values published by ACGIH. In the future, Portuguese standards should contain time-weighted average for 8 hours (TLV-TWA), ceiling values (TLV-C), and the short-term exposure limits (STEL).

Exposure limits have been legislated in the decree-law 274/89 for lead and their ionic composites (transposing Council Directive 82/605/EEC) and in the decree-law 273/89 for monomerous vinyl chloride (transposing Council Directive 78/610/EEC). Currently, the transposition of the Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) and the Directives 91/392/EEC of 29 May 1991 and 2000/39/EC of 8 June 2000 about exposure limit values of some chemical substances, is being concluded.

Spain

The legal framework for limit values for hazardous substances (in Spanish: VLA = Valores Límite Ambientales) is under reconstruction. Besides the European directive-based legislation (based for example on EC Directive 98/24/CE), two Spanish regulations exist. Since 1961, a national ordinance about health impairing and dangerous activities at work places is in force (Reglamento de Actividades Molestas, Insalubres, Nocivas y Peligrosas). This ordinance did not include single OELs. When OELs were needed in practice the ACGIH's limit values were used. Since 1998, the "National Institute for Occupational Safety and Health" (Instituto Nacional de Seguridad e Higiene en el Trabajo) publishes a guide including a list of OELs (more than 500) and instructions for the use and application of these values.

These new OELs published by the INSHT are developed by a working group of the National Commission of Safety and Health at Work (Comisión

Nacional de Segurida y Salud en el Trabajo). Their work is based on the Spanish law about the prevention of risk at the work places from November 1995 and the Royal Decree 39/1997. All limit values for hazardous substances are recommendations. They become legally binding when they are used by the Labor Inspectorate or other authorities in orders or instructions for companies. The current OELs are published on the Internet and on paper (Límites de exposición profesional para agentes químicos en España 2000). Both versions are available in Spanish. These limit values are renewed yearly by the INSHT.

The limit values for air-concentrations of carcinogenic and mutagenic substances are published in different special regulations. The list of OELs includes remarks about the mutagenic, carcinogenic, and genotoxic potential of a substance. Substances with possible skin penetration are marked with "v.d." (vía dermica).

The INSHT defines three different types of TLVs. VLA-ED (Valores Límite Ambientales Exposición Diaria), the limit for the daily average concentration. For a 30-minute period, an employee's exposure can be three times the VLA-ED. The exposure should never exceed the level of five times the VLA-ED.

VLA-EC (Valores Límite Ambientales Exposición de Corta Duración) is the limit for short-term exposure concentration. The VLA-EC that should not be exceeded during any part of the working exposure. It may be used as an OEL for at most 15 minutes per day. VLB (Valores Límite Biológicos) is a limit value for the content of the substance in biological media (i.e., blood, urine). VLBs have been defined for dozens of substances.

Sweden

The "hygienic limit values and measures for air pollutants" (Hygieniska gränsvärden och åtgärder mot luftföronreningar, Arbetarskyddsstyrelsens författningssamling; AFS 2000:3) is an instruction given by the Swedish Work Environment Authority (Arbetsmiljöverket) with the empowerment of the Work Environment Ordinance (Arbetsmiljöförordningen; SFS 1977:1166). These regulations are grounded on the Work Environment Act (Arbetsmiljölagen; SFS 1977: 1160). The limit values are a starting point of the chemical risk management. According to the national regulations, the employer is obliged to keep the exposure level as far below the limit value as possible.

The scientific background documentation is prepared by the Criteria Group of the National Institute of Working Life (Kriterigruppen för hygieniska gränsvärde, Arbetslivsinstitutet). The group drafts a consensus report after reviewing the scientific literature on toxicological grounds. These reports are published in the "Arbete och Hälsa" series. The National Board of Occupational Safety and Health (Arbetarskydsstyrelsen) proposes an OEL according to the consensus report for the Labor Market Parties. After the communication, the directorate of the National Board gives a new ordinance

on Occupational Exposure Limit (OEL) Values. The Work Environment Inspection (Arbetsmiljöinspektionen) controls the execution of the OEL ordinance.

Most of the OELs are maximal values of air concentrations in workplace air. The concentration limits are averaged over certain time periods, which are generally 8 hours ("maximal limit value," nivågränsvärde) and 15 minutes ("short-term limit," kortidsvärde). The ceiling values (takgränsvärde) are momentary limit values and the reference time is as short as 5 minutes. In the OEL lists, "K" (Cancerframkallande, Grupp C) denotes carcinogenic substances, "S" (Sensibiliserande, Grupp D) denotes sensitisers, and "R" (Reproduktionsstörande, Grupp E) denotes substances that are toxic to reproduction. In addition, the "hygienic limit values and measures for air pollutants" concludes lists of substances, which are banned (Grupp A) or subject to license (Grupp B). Isocyanates, which are included on the OEL list, are regulated also by specific instructions on "hard plastics" (Härdplaster; AFS 1996:4). H" ("Huden") denotes the substances with capacity of skin penetration on the OEL lists. The allergic potential is considered when setting the limit value.

Biological monitoring can provide information on the exposure for many substances. For lead and cadmium, the National Board of Occupational Safety and Health (Arbetarskydsstyrelsen) has set biological exposure limit values. Regulations concerning these are defined in "Medical control on cadmium work" (Medicinsk kontroll vid kadmiumarbete; AFS 2000:7) and "Lead" (Bly—Ändrigen av AFS 1992:17; AFS 2000:13)

United Kingdom

Occupational exposure limits in the U.K. function under the Control of Substances Hazardous to Health Regulations (COSHH) and its mirror legislation in Northern Ireland. The COSHH regulations require the employer to ensure that the employee's exposure to substances hazardous to health is either prevented or, if not practically possible, adequately controlled. The OELs in the U.K. can be divided into maximum exposure limits (MELs) and occupational exposure standards. Exposure should be reduced as far below an MEL as possible, while reduction to the substance specific level OES is considered adequate. The list of exposure limits is known as EH40 and is available from HSE Direct.

All legally enforceable OELs in the U.K. are air limit values. The maximum admissible or accepted concentration varies from substance to substance according to its toxicity. There are some OELs for multisubstance exposure prescribing process emissions like welding fumes. Biological monitoring results may be used as indicators of exposure, although they have not got legal status. The Biological Monitoring Guidance Values (BMGV) are provided also in the HSE series EH40.

The exposure times are averaged for eight hours (time-weighted average, TWA) and 15 minutes (short-term exposure limit, STEL). For some sub-

stances, a brief exposure is considered so critical that they are set only a STEL, which should not be exceeded even for a shorter time. The potency to penetrate through skin is annotated in the OEL list by remark "Skin." Carcinogenicity, reproduction toxicity, and irritation and sensitization potential are considered when preparing a proposal for an OEL according to the present scientific knowledge. The OELs do not cover some hazardous substances that have their own specific legislation, most notably asbestos and lead.

Health and Safety Commission's Advisory Committee on Toxic Substances (ACTS) recommends new OELs or revision on a current OEL value. The Working Group on the Assessment of Toxic Chemicals (WATCH) is a technical subcommittee of ACTS, which considers the evidence on the occupational exposure and health effects of substances, including whether a MEL or OES would be appropriate by the agreed indicative criteria, and if an OES, its value. After the ACTS (constituting of representatives of employers, workers, government and environmental and consumer experts) has approved a MEL or OES it is endorsed by the Health and Safety Commission (HSC).

Norway

In Norway, OELs are issued by the Central Labor Inspection (Arbejdstilsynet). The inspection has established a working group with representatives from the employers, employees, and direction of the inspection. Criteria documents from the Nordic Countries, Germany and United States and Norwegian workplace experience are used as scientific bases. There are values for TWA, STEL, and Ceiling. There are also, for example, skin and carcinogenicity notations. The standards are recommendations and they are not legally binding until they are used by the labor inspection in orders or instructions for companies. The list is reviewed yearly.

5.4 PACIFIC RIM

Australia

The Australian National Occupational Health and Safety Commission (NOHSC) sets the OELs. The commission consists of employee and employer organizations, trade unions, and industry and government representatives. The Exposure Standards Expert Working Group (ESEWG) recommends OELs for individual substances.

A great number of the adopted exposure standards have been obtained from the ACGHI list of threshold limit values. The National Commission has considered these values and those found to be acceptable were adopted. The Exposure Standards Working Group has reviewed a smaller number of substances in detail and appropriate values have been assigned.

The OELs are instruments of an advisory character, except where a law,

other than the National Occupational Health and Safety Commission Act, or an instrument made under such a law, makes them mandatory. The application of any National Commission document in any particular State or Territory of Australia is the prerogative of that State or Territory.

More information on the Australian OSH regulations is available on the Web site of the Australian and European Union Cooperation on Workplace Safety and Health.

Japan

The Japanese Association of Industrial Health, a private academic organization, recommends permissible exposure limits (PELs). These OELs have no legal force. The majority of Japanese PEL list values are the same as ACGIH threshold limit values. The types of PELs are TWA, STEL, ceilings, and BEI (see under United States for an explanation of these terms). The OELs and their criteria documents are once a year published in the Japanese Journal of Industrial health.

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