GLOBAL MATERIALS COMPLIANCE HANDBOOK



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JOHN PHYPER

Atrion International Inc.

PHILIPPE DUCAS

Atrion International Inc.

PETER J. BAISH

Independent Contractor to Sandler & Travis Trade Advisory Services





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To my wife, Christine, for her patience, and daughters, Megan and Madison, for constantly reminding me of the important things in life.

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To my wife, Catherine, for her understanding and loving. Also to Stéphanie, Pascale, and Pierre-Olivier, who are the most beautiful gifts of my life. P.D.

To my wife, Mary Alice, and children, Meg, Sarah, Liz, and P.T., I love you! P.J.B.

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.

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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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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-

OVERVIEW 3

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.