CHEMICAL MANUFACTURERS ASSOCIATION

October 19, 1987

CMA'S PRODUCT SAFETY GUIDELINES

The Chemical Manufacturers Association (CMA) is pleased to announce the availability of a September 1987 publication entitled "Product Safety Guidelines." A copy is attached.

The Product Safety Guidelines draw upon the experiences and expertise of CMA member company professionals responsible for product safety evaluation and management. The purpose of the Guidelines is to promote product safety through development and implementation of basic practices successfully adopted by some chemical manufacturers. Specifically, the Guidelines are intended to assist companies that are contemplating the need for a product safety program, or are in the process of establishing or improving product safety programs. The general information contained in these Guidelines may also assist member companies with educating and training non-technical employees, such as marketing staff, management trainees and others, who may not be directly involved in the product safety evaluation process.

If you have any questions about or comments on CMA's Product Safety Guidelines, please call Nancy G. Doerrer of my staff at 202/887-1282. Extra copies of the Guidelines may be obtained from Cheryl Howie at CMA by calling 202/887-1381.

Sincerely yours,

Geraldine V. Cox

Attachment

BOR 007377

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# PRODUCT SAFETY

## GUIDELINES

CMA

CHEMICAL MANUFACTURERS ASSOCIATION

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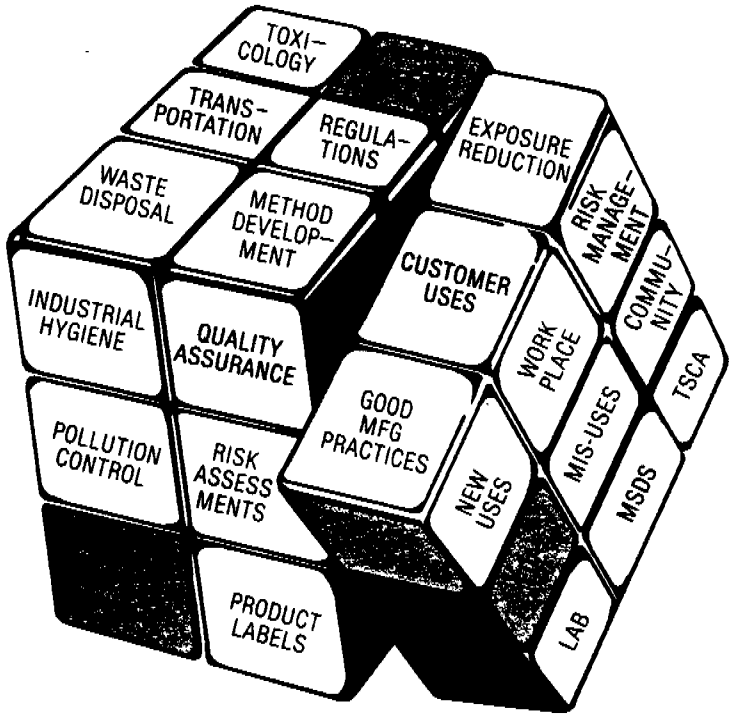


*Safe Products*
*Just Don't Happen—*
*They Are Designed That Way!*

*You Have To Get The Right Combination!*

BOR 007379

# PRODUCT SAFETY GUIDELINES

This publication was developed by the Product Safety Task Group of the Chemical Manufacturers Association, and was reviewed by CMA's Health and Safety Committee.

September, 1987

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# PURPOSE AND OBJECTIVES OF GUIDELINES

The Chemical Manufacturers Association (CMA) is a nonprofit trade association whose member companies represent more than 90 percent of the productive capacity of basic industrial chemicals within the United States and Canada. These Product Safety Guidelines draw upon the experiences and expertise of member company professionals responsible for product safety evaluation and management. Their purpose is to promote product safety through development and implementation of basic practices successfully adopted by some chemical manufacturers.

The CMA Board of Directors has issued the following statement as one of the Association's primary objectives:

> To provide leadership and guidance and to undertake programs to improve the chemical industry's service to the public by developing and promoting safe and clean practices in the manufacture, transportation, handling, and use of chemicals and chemical products.

These Guidelines are intended as a way of implementing that objective. Specifically, the Guidelines are intended to assist member companies that are contemplating the need for a product safety program, or are in the process of establishing or improving product safety programs.

The general information contained in these Guidelines may also assist member companies with educating and training non-technical employees, such as marketing staff, management trainees and others, who may not be directly involved in the product safety evaluation process.

These Guidelines are intended only to be illustrative of some types of existing product safety programs and concerns in the chemical industry. They do not constitute, and are not intended to propose, an industry standard on this subject.

# OUTLINE

These Product Safety Guidelines consist of an Introduction and four chapters. Chapter I describes the elements of the risk assessment process in which hazard and exposure assessments are integrated to characterize the risks associated with a given product. Chapter II is an overview of risk management practices which reduce the potential risks of a chemical product. In Chapter III, regulatory requirements and compliance are highlighted as important considerations in developing and maintaining a product safety program. The auditing process is identified in Chapter IV as a way of assessing the adequacy, effectiveness, and quality of a product safety program. Finally, three appendices identify some specific program elements, resources and references that may be useful during the evolution of a company's product safety program.

## INTRODUCTION

Throughout the U.S. chemical industry, companies have established product safety programs that promote safe research, development, manufacture, transportation, use and disposal of chemical products. Although the components of these programs may differ from company to company, each shares a common goal: to reduce and prevent risks to human health, safety and the environment.

Although the purpose of any product safety program is to minimize or eliminate the potential for harm from chemical products or processes, the scope and implementation of company programs may vary. These guidelines present general recommendations on the common elements and objectives of an effective product safety program. To be effective, it is important that a company set clear objectives for its program, gain management commitment, and communicate these objectives and commitment throughout the organization. A company should consider sharing its product safety program with customers, the community, and the concerned general public, particularly if there is wide distribution of the product(s). Communicating the program is important to effective risk management, which depends on the understanding and cooperation of company employees, product users and the general public.

A product safety program not only minimizes or eliminates risks; it also makes good business sense. An effective program can serve as a valuable marketing tool, since customers will want to use products whose safety has been assessed and communicated by a responsible supplier. Because product safety practices are essential for the protection of workers and the public, product safety is the responsibility of every company. Consequently, the philosophy and practices of an effective program should be integrated into all business practices.

## I. RISK ASSESSMENT

Risk assessment lays the foundation for a product safety program. It involves collection, critical review, and evaluation of diverse types of information. The purpose of risk assessment is to **identify** hazards and exposures associated with a product during all stages of its life cycle and, ultimately, to **characterize** the risks. Once the risks are known or estimated, employers, workers and consumers can take steps to eliminate or minimize the risks and avoid unsafe conditions and practices.

The risk assessment process for a chemical product involves four components:

- Collection of information
- Hazard assessment
- Exposure assessment
- Risk characterization

A risk assessment is inherently an "evergreen" process. This evergreen nature implies that a given risk assessment is a snapshot in time: new toxicological or epidemiological data, differing interpretations of data, new operating practices, process or formulation changes, revised transportation methods or schedules, or new uses may require a re-evaluation of risk assessment conclusions.

### A. Collection of Information

A file of available information on possible product hazards should be maintained and routinely updated. Sources of information for this file include published and unpublished scientific reports on health or environmental effects and exposures. Published sources can be accessed through commercial computer databases. The material safety data sheet (MSDS), and the reports and literature used to construct the MSDS, are a part of this file. In addition, information on conditions and practices involved in

the research, development, manufacture, transportation, use and disposal of a product are essential for the file. Available monitoring data, estimates of human exposure, and ecosystem measurements for each stage of the product's life cycle are also important additions to file information.

### B. Hazard Assessment

The hazard assessment leading to the establishment of safety guidelines should be carried out for two purposes:

1) to **identify** all reasonably foreseeable physical and/or health hazards;
2) to **estimate** a dose-response relationship or a no observable effect level (NOEL) for each health or environmental effect.

The following considerations are important elements, among others, to consider in developing a hazard assessment profile for a chemical product: human and mammalian toxicity; ecotoxicity; environmental fate; physical and chemical properties such as water solubility, vapor pressure or volatility, particle size, flammability, and reactivity.

A hazard assessment includes a careful and systematic evaluation of available information on the product, and a consideration of experiences and available information on analogous products. The result of the hazard assessment is a reasonable estimation of a chemical substance's potential to cause harm.

### C. Exposure Assessment

For each stage of a product's life cycle, an exposure assessment should include an evaluation of human exposure and environmental impact. Potential sources of exposure throughout the life cycle of a product (research, development, manufacture, processing, transport, use and disposal) should be identified. The exposure assessment should identify the population groups exposed to a product, the environmental compartment to which it is released and/or migrates, and the levels, duration, frequency, and extent of exposure that approach or exceed hazard levels of reasonable concern. When a comparable degree of toxicity exists, substances with high exposure potential warrant more precise exposure assessments than substances of low exposure potential. Similarly, the results of the hazard assessment on a chemical product should dictate the extent and precision of the exposure assessment.

### D. Risk Characterization

The process of performing a risk assessment on a product involves an integration of the hazard and exposure assessments. The thought process involves a comparison of the dose-response relationship or NOEL for each health hazard with the exposure parameters for each applicable population subgroup or environmental compartment. The process is subject to professional and scientific judgment. By virtue of the inherent subjectivity of those judgments and the evergreen nature of technical information evolving on the chemical product, risk assessments are subject to periodic reevaluation and updating.

The purpose of the risk assessment process is to identify for the risk manager those hazard/exposure conditions which are unsafe or unacceptable and to give a qualitative or quantitative estimate of probable harm. The estimate of harm is judgmental — it may be a qualitative statement of high or low probability; it may include an expression of the margin of safety between a NOEL and ambient levels of exposure; or it may be a quantitative probabilistic estimate of risk.

## II. RISK MANAGEMENT

Once the probable risk(s) of a chemical product have been identified through the risk assessment process, management decisions can be made to help ensure product safety in the workplace, the community and the environment. It is the risk manager's responsibility to understand the risk assessment and its changing nature so that safe and cost-effective methods for the manufacture, processing, transportation, use and disposal of a product may be developed.

Risk management refers to the measures taken by a company to reduce the potential risk(s) of its product(s). Risk management can be as simple as product labeling or as complex as product reformulation. At one extreme, a company may choose to discontinue the manufacture or specific uses of a product. Alternatively, a company may implement a hazard communication program. Specific risk management steps are described below.

### A. Hazard Communication

Hazard communication is a primary risk management tool directed at those persons with exposure potential to a chemical product. This communication should provide sufficient information about hazards and appropriate protective measures to handle the product safely. All persons exposed to a product in the course of its life cycle should participate in the hazard communication program. For chemical products, hazard communication may be in the form of labeling, MSDSs, instructions for use, worker/user training and education, or a combination of these actions. The appropriate mode of communication will depend on the nature and severity of the hazards and the type and pattern of use. A company's hazard communication program should be closely coordinated with regulatory requirements, including, but not limited to, the provisions of the Hazard Communication Standard of the U.S. Occupational Safety and Health Administration (OSHA), Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA), and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). For many companies, the label, MSDS, and verbal instructions are important means of communicating potential chemical hazards and safe handling practices.

### B. Hazard Reduction

Where hazard communication alone would not adequately reduce potential product risk(s), a company should consider hazard reduction measures. These measures reduce risk(s) by partially or wholly eliminating the hazard(s). For example, a company may reduce the hazard of a formulated product by substituting chemical components that are less hazardous yet perform equally well. Reducing an impurity where the impurity is significantly more toxic than the major constituents is another way of reducing the hazard.

### C. Exposure Reduction

Exposure reduction measures should be considered for products with potential risks that cannot be sufficiently reduced by hazard communication and hazard reduction measures, or for those situations where exposure reduction is more cost effective. Exposure reduction measures are numerous and depend on the nature and source of the exposure. For example, engineering controls or the use of protective equipment may be appropriate exposure reduction measures when the exposure of concern is occupational. For consumer exposures, changes in use patterns may be appropriate.

Changing the physical form of the product, for example, transforming a powder to a liquid solution to eliminate dust, can also reduce exposure. Modifying shipping procedures or substituting a different type of container are effective ways to reduce exposure. Whatever specific measure is appropriate for a given product, the goal of exposure reduction is to minimize or eliminate risk(s).

## III. REGULATORY REQUIREMENTS AND COMPLIANCE

Chemical regulations exist that affect product safety considerations. Although there are degrees of overlap in company policies, programs, and procedures in regulatory compliance and product safety, the following point cannot be overstated: complying with regulatory requirements does not protect against product liability actions, although it may reduce liability exposure. Conversely, failure to comply with regulations can, and almost certainly will, be the basis for litigation.

Regulatory requirements need to be considered in developing a product safety program. Indeed, product safety programs are most cost effective when the dual goals of meeting regulatory requirements and developing voluntary systems for safe product management are achieved. Listed below are some regulatory concerns relevant to product safety.

Under the premanufacture notification (PMN) provisions of the Toxic Substances Control Act (TSCA), the U.S. Environmental Protection Agency (EPA) has identified chemicals on the basis of structure/activity similarities for which the EPA perceives potential health or environmental risk. EPA has taken restrictive actions under Section 5(e) of TSCA. These actions include certain risk management requirements designed to ensure safe use (e.g., warning label(s) or MSDS statements, worker or user protection measures, or toxicity testing for targeted areas of concern). EPA has also issued or proposed several testing requirements for specific compounds on a mandatory or negotiated basis under Section 5 of TSCA. While there may not be uniform agreement that these regulatory requirements are necessary based on predicted hazards, the fact that the requirements exist for chemicals and certain chemical classes suggests that product safety programs should be designed with full understanding and anticipation of regulatory concerns.

In an attempt to establish a consensus on risk assessment, EPA issued the following five Risk Assessment Guidelines in September, 1986:

Guidelines for Carcinogen Risk Assessment
Guidelines for Mutagenicity Risk Assessment
Guidelines for the Health Risk Assessment of Chemical Mixtures
Guidelines for the Health Assessment of Suspect Developmental Toxicants
Guidelines for Exposure Assessment

It is apparent that the guidelines represent the thinking of a substantial portion of the regulatory community. Hence, it is important that these guidelines play a role in the process of arriving at a sound risk assessment for a chemical product.

The OSHA Hazard Communication Standard requires hazard warnings on MSDSs and labels for all "appropriate" hazards. MSDSs on hazardous products and hazard communication training for employees must be provided. These requirements, more specifically stated in the text of the Standard, are an integral part of a product safety program. The elements of a hazard assessment, exposure assessment, risk assessment and risk management are inherent in compliance with the OSHA Hazard Communication Standard.

Specific guidance exists for effective hazard communication of chemical products through labeling, as addressed in the proposed ANSI Z129.1-1987: American National Standard for Hazardous Industrial Chemicals — Precautionary Labeling. CMA acted as the Secretariat to the American National Standards Institute in the development of this document, cognizant of OSHA Hazard Communication Standard requirements. ANSI Z129.1-1987 can, consequently, be useful in regulatory compliance and in meeting established industry standards for labeling purposes.

Communication with the public is a component of a product safety program. Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA) states numerous requirements under the "Emergency Planning and Community Right-to-Know" provisions that directly address community outreach. The Act includes these and other requirements: emergency planning and notification, community right-to-know provisions, reporting of chemical quantities and releases, and the development and submission of toxic chemical release forms. In addition to reviewing SARA for specific requirements, a product safety manager may decide to participate in active CMA programs or other industry plans that address important product safety concerns, for example,

CMA's Community Awareness and Emergency Response (CAER) program, and CMA's Air Quality Program. These industry initiatives, established prior to the enactment of SARA, fulfill some of the Title III regulatory requirements, but additionally help satisfy the goal of a product safety program: to reduce and prevent risks to human health, safety and the environment.

## IV. AUDITING

Auditing a product safety program involves an evaluation of the program's efficacy and a comparison of the program's goals with actual performance.

The complexity and interrelationship of the product safety function with local, state and federal regulations and with health, safety and environmental disciplines reinforces the need for auditing. The purpose of auditing is to assess the effectiveness and adequacy of a product safety program and to help maintain awareness of product safety considerations. In addition, auditing enhances awareness within an organization that product safety is the responsibility of all employees.

The scope and depth of a product safety audit program will vary depending upon many factors, including an organization's product lines, markets, and channels of distribution. Consequently, there is no single formula that can describe the "right" audit for a company. In fact, an audit should be tailored to the needs and commitment of a given organization and should be flexible enough to accommodate a rapidly changing legal, regulatory, social, and technical environment. Some common elements of a product safety audit program are listed in Appendix B.

## APPENDIX A: Elements of a Product Safety Program

Company activities that may be included in a product safety program and that may be subject to auditing include:

- research and development
- manufacturing
- labeling
- MSDSs
- technical literature
- sales practices
- marketing practices
- distribution channels
- end-use
- packaging
- shipping modes
- importing requirements
- exporting requirements
- toxicological/ecological testing programs
- risk assessment/risk management documentation
- purchasing
- employee awareness
- quality specifications/assurance
- training programs
- tollers'/contractors' practices
- hazard communication
- new employee orientation
- generation and maintenance of records
- disposal practices
- transportation programs
- regulatory compliance with:
  - -- Toxic Substances Control Act (TSCA)
  - -- Food, Drug and Cosmetic Act (FDCA)
  - -- Occupational Safety and Health Act (OSHA)
  - -- OSHA Hazard Communication Standard
  - -- Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)
  - -- Comprehensive Environmental Response, Compensation, and

Liability Act of 1980 (CERCLA or Superfund)

-- Title III, Superfund Amendments and Reauthorization Act of 1986 (SARA)
-- International requirements (including requirements of foreign governments or international and intergovernmental organizations, for example, the EEC Sixth Amendment, the Organization for Economic Cooperation and Development's (OECD's) Decision on Mutual Acceptance of Data, etc.)
-- Resource Conservation and Recovery Act (RCRA)
-- Right-to-Know legislation (worker and community; state and federal)
-- Hazardous Materials Transportation Act
-- Federal Hazardous Substances Act (FHSA)

## APPENDIX B: Elements of an Audit Program

Although there are differences between companies in auditing practices, several possible elements are identified below (see also Appendix A):

A. Ground rules or standards for auditing are established from a sound working knowledge of the organization, its products, processes, geographical areas, markets, etc. These standards should be fully understood and supported by management with respect to stated purposes, objectives, and obligations.

B. The audit program should be documented and should contain realistic expectations. An established written audit protocol covers the following common elements:

- initiating the audit process (i.e., data gathering)
- executing the audit
- closure of the site audit and appropriate dissemination of a summary report
- documentation of findings/recommendations
- development of corrective action plan(s), if needed
- follow-up to ensure timely implementation of corrective action plans

C. Selection of the audit team is important. Individuals with the following qualifications should be included:

- skilled in applicable discipline(s)
- understanding of the facility, process, etc.
- trained properly to conduct an audit from a technical, professional, and personal viewpoint, i.e., the audit should be constructive, as opposed to adversarial
- capable of independent judgment

D. The auditor and auditee must know the established ground rules or standards by which judgments on a product safety program are to be made. Included would be some or all of the following resources:

- company policies
- written standard operating procedures (SOPs), practices or guidelines
- legal requirements
- professional judgment

E. The audit should provide assurances that a sound and thorough assessment has been made. This can be accomplished through the following procedures:

- documentation of the scope of the audit and the audit team's findings
- development and communication of the facility's response and corrective action plan
- communication of the audit process and findings to management
- periodic follow-up until all issues are addressed and resolved

## APPENDIX C: Resources and References


1. American Industrial Hygiene Association. A Guide to Product Health and Safety and the Right-to-Know, 1986.

   Can be ordered from:

   American Industrial Hygiene Association
   475 Wolf Ledges Parkway
   Akron, Ohio 44311-1087
   216/762-7294

2. American National Standard for Hazardous Industrial Chemicals — Precautionary Labeling (ANSI Z129.1-1987). (To be published in late 1987 by the American National Standards Institute following review and acceptance by the ANSI Board of Standards Review.)

   Can be ordered from:

   American National Standards Institute
   1430 Broadway
   New York, New York 10018
   212/354-3300

3. Business and Industry Advisory Committee to the OECD. BIAC Guides for Manufacturers and Traders Exporting Chemicals, 1985.

   Can be ordered from:

   United States Council for International Business
   1212 Avenue of the Americas
   New York, NY 10036

   or

   Business and Industry Advisory Committee to the OECD
   13/15 Chaussee de la Muette
   75016 Paris
   FRANCE
   Telephone: 45 24 48 38

4. Chemical Manufacturers Association. Commitments. Washington, D.C., 1984.

5. Chemical Manufacturers Association. Guideline for New Chemical Risk Evaluation for Premanufacture Notification under the Toxic Substances Control Act. Washington, D.C., 1986.

6. Chemical Manufacturers Association. Proceedings of the Product Safety Conference. Washington, D.C., September 23-24, 1986.

7. Chemical Manufacturers Association. Risk Analysis in the Chemical Industry. Government Institutes, Inc. Rockville, Maryland, 1986.

8. Chemical Manufactur rs Association. Risk Management of Existing Chemicals. Government Institutes, Inc. Rockville, Maryland, 1985

All CMA publications can be ordered from:

Chemical Manufacturers Association
2501 M Street, NW
Washington, DC 20037
202/887-1100

9. Department of Health and Human Services (DHHS) Committee to Coordinate Environmental and Related Programs (CCERP). Risk Assessment and Risk Management of Toxic Substances. Atlanta, GA, April, 1985.

   Can be ordered from:

   Centers for Disease Control
   1600 Clifton Road, N.E.
   Atlanta, GA 30333

10. Environmental Protection Agency. Risk Assessment and Management: Framework for Decision Making. Washington, D.C., 1984.

    Can be ordered from:

    U.S. Environmental Protection Agency
    Office of Public Affairs
    MS A-107
    401 M Street, S.W.
    Washington, D.C. 20460
    202/382-4384

11. Executive Enterprises Publications Co., Inc. Product Risk Reduction in the Chemical Industry. Executive Enterprises, Inc. New York, 1985.

    Can be ordered from:

    Executive Enterprises, Inc.
    33 West 60th Street
    New York, New York, 10023

12. National Research Council, National Academy of Sciences. Risk Assessment in the Federal Government: Managing the Process. National Academy Press. Washington, D.C., 1983.

    Can be ordered from:

    National Academy Press
    2101 Constitution Avenue, N.W.
    Washington, D.C. 20418

13. The Swedish Plastics and Chemicals Suppliers' Association (PKL). How To Administrate Products Control. Stockholm, April, 1986.

    Can be ordered from:

    The Swedish Plastics and Chemicals Suppliers' Association
    Box 5512, S-114 85
    STOCKHOLM, Sweden

## GLOSSARY OF TERMS

**Hazard:** a chemical substance's potential to cause harm.

**Hazard Assessment:** an evaluation process in which a substance's potential to cause harm is further defined in terms of its physical and chemical properties, available animal and human toxicity data, established dose-response relationship(s), potency, environmental disposition, and other factors.

**Ecosystem:** a defined geographical habitat consisting of biological communities that interact with one another.

**Ecotoxicity:** a chemical substance's potential to cause an adverse effect in an environmental (non-human) population.

**Environmental Fate:** the transport, stability, persistence, degradation and other interactions of a chemical in the environment.

**Exposure:** a situation or instance of contact between a chemical substance and a person, plant, animal, or the environment.

**Exposure Assessment:** the process of measuring or estimating exposure to a chemical substance, including consideration of potential sources of exposure, route(s) of exposure, levels of exposure, frequency and duration of exposure, and likely environmental, animal or human population groups likely to be exposed.

**Product:** broadly defined to include a chemical product itself or variant of a product, for example, a raw material, intermediate, solvent, catalyst, monomer, polymer, etc.

**Risk:** the probability that harm will occur from exposure to a chemical substance.

**Risk Assessment:** the qualitative or quantitative probability that a chemical substance will cause harm, as determined through the process of integrating hazard and exposure assessments.

**Risk Management:** the steps taken to reduce the potential risk(s) of a chemical product. Risk management decisions are made on the basis of risk assessment determinations, social and economic benefits, and likely costs of controls and/or alternatives.