REGULATORY AGENCIES, CHEMICAL PROCESS INDUSTRY

1. Introduction

The chemical process industry is highly regulated in the environmental, health, and safety area. Everything is affected, from the siting of a new facility to the transportation of raw materials and finished products, from the working conditions for employees to operating requirements for processes, packaging of finished goods, and dealings with the community. In addition to the regulatory requirements of government agencies, the chemical industry is developing standards of its own to ensure proper protection of the environment, employees, and the community. These include Responsible Care (registered by the American Chemistry Council, Formerly the Chemical Manufacturers Association); International Standard Organization (ISO) 14000; Environmental Management Systems; the sustainable development program of International Chamber of Commerce (ICC); and others.

The American Chemistry Council (ACC), the chemical industry's main trade association, developed the Responsible Care initiative in 1988. This program, which began in Canada, is a commitment on the part of the chemical industry to continuously improve health, safety, and environmental performance and to respond to public concerns. More information can be found at ACCs home page at www.americanchemisty.com. The initiative is based on 10 guiding principles and, initially, was implemented by six codes of management practices, covering Community Awareness and Emergency Response (CAER). Distribution, Employee Health and Safety, Pollution Prevention, Process Safety, and Product Stewardship. In June, 2002, ACC added a seventh code on Plant Security. More than 35 countries around the world have adopted Responsible Care and are developing their own implementation programs. Additional information can also be obtained from the Synthetic Organic Chemical Manufacturers Associations (SOCMA) at www.socma.org, which is working with ACC on Responsible Care implementation, focusing more on smaller, custom and batch chemical manufacturers.

In an attempt to bring uniformity to environmental protection, the ISO followed up the ISO 9000 series of quality standards with the ISO 14000 environmental management standards. The ISO 14001, Environmental Management Systems, is a public statement of environmental policy, which includes a commitment both to comply with relevant environmental legislation and a commitment to continual improvement; a planning process that identifies environmental objectives at all relevant levels within the company; designated management representatives to implement the company's plans; and procedures to identify and correct nonconformance, including periodic environmental management system audits. It is expected that, similar to ISO 9000, ISO 14001 certification will also be needed by companies wishing to do business in the international market. A site with many ISO 14000 resource links is http://www.smallbiz-enviroweb.org/pollution/iso14000_links.html

2. Environmental Protection

The primary areas covered by EPA, and discussed below, are Water, Air, Solid and Hazardous Waste, Hazardous Chemicals, and the National Enviromental Policy Act. Under the Product Safety section, further along in this article, some other EPA laws (TSCA and FIFRA) are discussed. On-line sources for EPA laws, regulations, Federal Register citations, etc., can be found at: http://www.epa.gov/epahome/rules.html

2.1. Water. For a long time in the United States, the approach to water pollution control was through the establishment of water quality standards for receiving bodies of water, ie, rivers, streams, or lakes, with most limits established on a state-by-state basis. There was no effective, national, legal authority to limit the discharge of pollutants. In the late 1960s, the U.S. government revived an old law, the Rivers and Harbor Act of 1899 (the Refuse Act) (1). The law prohibited the discharge of anything into navigable waters unless a permit was obtained from the Corps of Engineers, thus providing a first step toward control of industrial discharges. This was followed by additional legislation, culminating in the passage of the Federal Water Pollution Control Act Amendments (FWPCA) of 1972 and the Clean Water Act (CWA) of 1977 (2). The objective of the FWPCA was to restore and maintain the chemical, physical, and biological integrity of the nation's waters.

Water Quality Standards. The first step in water quality standards is stream use classification. The individual states must decide what the uses of their water will be. The four categories, as defined by the EPA, are Class A, primary water contact recreation; Class B, propagation of desirable aquatic life; Class C, public water supplies prior to treatment; and Class D, agricultural and industrial uses. States may vary the definition of these classes to meet their own needs. The second step is to develop water-quality criteria, which is the specific concentration of a pollutant that is allowable for the designated use.

Effluent Guidelines and Standards. The CWA requires specific levels of control for dischargers. These are outlined in the Effluent Guidelines and Standards for various industrial categories. These standards limit the discharge of pollutants, usually in terms of a unit weight of pollutant per unit of either product or raw material, rather than a concentration in the discharge stream, in order to eliminate the use of dilution to meet limits.

The effluent standards are based upon the degree of reduction of a pollutant that can be achieved through the application of various levels of technology (Best Practical Technology—BPT; Best Available Technology—BAT; and Best Conventional Technology—BCT). Of special concern to the chemical industry are the following listed categories (3) (subpart N – http://www.epa.gov/docs/epacfr40/chapt-I.info/subch-N.htm):

Part 403: general pretreatment regulations for existing and new sources of pollution
Part 411: cement manufacturing point source category
Part 413: electroplating point source category
Part 414: organic chemicals, plastics, and synthetic fibers (OCPSF)

Part 415: inorganic chemicals manufacturing point source category
Part 417: soap and detergent manufacturing point source category
Part 418: fertilizer manufacturing point source category
Part 419: petroleum refining point source category
Part 422: phosphate manufacturing point source category
Part 428: rubber manufacturing point source category
Part 439: pharmaceutical manufacturing point source category
Part 446: paint formulating point source category
Part 447: ink formulating point source category
Part 454: gum and wood chemicals manufacturing point source category
Part 455: pesticide chemicals
Part 457: explosives manufacturing point source category
Part 458: carbon black manufacturing point source category

EPA has also developed pretreatment standards for industrial facilities that discharge directly to publicly owned treatment works (POTWs), known as "indirect discharges". The three types of pollutants of principal concern are pollutants that interfere with the operation of the POTW, pollutants that contaminate the sludges produced in the POTW, and pollutants that pass through the POTW or that are otherwise incompatible. One particular concern is volatile contaminants that can be stripped into the air during conventional wastewater treatment and become air pollution problems. These pretreatment standards are included in the effluent guidelines for the different industries.

National Pollutant Discharge Elimination System Permit Program To ensure adherence to the effluent standards, the EPA developed the National Pollutant Discharge Elimination System (NPDES) permit program. Any source discharging or planning to discharge to any U.S. water must obtain an NPDES permit. The NPDES permit application must list all pollutants to be discharged, including any priority pollutants, and it must indicate the proposed treatment methods and resultant effluent. The NPDES permit indicates the allowable discharge and requires self-monitoring. As a minimum, the effluent standards must be met, but more stringent limits may be required. Where no standards for a pollutant or industry exist, limits are decided on an individual basis.

In 1987, the Clean Water Act was amended to include storm water discharges under the NPDES permit program. EPA issued regulations in 1990 covering NPDES permit application requirements for storm water discharges associated with industrial activity. In addition to discharges generated within a facility, eg, from a process, storm water must be tested for contamination. Facilities must develop plans for minimizing storm water contact with chemicals on-site. For example, outdoor chemical storage areas should be paved and diked to contain any storm water that could be contaminated as a result of spills. Loading and unloading areas must also be protected.

Other Laws Many other laws have been passed to protect wetlands, coastal areas, and the oceans. The 1974 Safe Drinking Water Act (SDWA) (4) and 1996 SDWA Amendments sets maximum contaminant levels (MCLs) for a variety of chemicals that may cause any adverse effects on the health of persons and that can be present in drinking water. Although the greatest impact of this law is on providers of drinking water, there is an impact on the chemical industry. In order

to protect underground sources of drinking water, the act contains a program regulating underground injection control (UIC) wells, a method used by industry for disposing of certain types of wastes. The SDWA Amendments of 1996 emphasize risk-based standard setting, monitoring relief for the public water supply systems, small water supply system flexibility, and community-empowered source water protection.

The Oil Pollution Act (OPA) of 1990 (5) streamlined and strengthened EPAs ability to prevent and respond to catastrophic oil spills. A trust fund financed by a tax on oil is available to clean up spills when the responsible party is incapable or unwilling to do so. The OPA requires oil storage facilities and vessels to develop specific plans detailing how they will respond to large discharges. Regulations for aboveground storage facilities were developed by EPA, with the Coast Guard developing regulations for oil tankers.

2.2. Air. Studies have shown that 2500 years ago lead pollution caused by Greek and Roman silver smelters was a significant problem (6). Based on analysis of lake sediments and Greenland's ice, it was found that lead contamination from smelters in southern and central Europe was carried throughout the northern hemisphere. As long ago as the thirteenth century, air pollution has been linked to the burning of coal (6). The main concern was the smell from the sulfur in the coal and the effects of the soot. It was not until many years later that the effects of air pollution on people's health were discovered.

Various laws have been passed in the United States to control air pollution. The first law that had any real effect was the Clean Air Act (CAA) of 1970, which was followed by the Clean Air Act Amendments of 1977. Most recently, the Clean Air Act Amendments (CAAA) of 1990 (7) further changed and updated the requirements. The Clean Air Act (and its amendments) is the comprehensive Federal law that regulates air emissions from area, stationary, and mobile sources. EPAs air regulations can be found at http://www.epa.gov/docs/epacfr40/chapt-I.info/subch-C.htm.

National Ambient Air Quality Standards. Under the CAA, six criterion pollutants, ie, pollutants of special concern, have been established by the EPA: sulfur oxides (SO_x), particulates, carbon monoxide (CO), nitrogen oxides (NO_x), ozone (photochemical oxidants), and lead. National Ambient Air Quality Standards (NAAQS) were developed by EPA based on threshold levels of air pollution below which no adverse effects could be experienced on human health or the environment.

The NAAQS are expressed in the form of ground level concentrations (GLC), which are the concentrations of pollutant in the ambient air as measured at ground level, in units of either micrograms per cubic meter or ppm. In order to convert a source's emission in kilograms per hour to a GLC, dispersion modeling must be used.

State Implementation Plans. The CAA requires a state implementation plan (SIP) in each state. The SIP indicates how that state intends to meet the NAAQS. State implementation plans can include such ideas as emission limitations, economic incentives or disincentives, plant closings or relocations, and changes in either operating schedules or methods. Although many states previously required sources to obtain permits, the CAAA of 1990 established a mandatory permit program. An issue of importance to the chemical industry is the

complexity of amending a permit. Industry needs to have flexibility in revising permit conditions if plant operating conditions change.

Prevention of Significant Deterioration. EPA originally issued regulations for Prevention of Significant Deterioration (PSD) in December 1974 to protect clean air areas. Three air quality classes were designated: Class I to protect pristine areas, Class II to allow moderate development, and Class III to permit more intensive development. Most areas in the United States were initially designated as Class II. Many large national parks and wildlife areas have been classified as Class I.

As part of the PSD review, the applicant must show that BACT has been applied to all sources. Items to be evaluated include energy, environmental, economic, and other costs associated with each alternative technology as well as the associated benefits of reduced emissions. Another requirement is an ambient air quality analysis to show that the new emissions do not exceed either the NAAQS or PSD increments.

Nonattainment. EPA issued final rules for the Emission Offset Policy governing development in nonattainment areas. A new source must apply the lowest achievable emission rate (LAER) for the problem pollutant and must obtain a more than equivalent offsetting emission reduction from existing sources. Either the existing sources can be owned by the same company, or the reduction can be bought from other companies. In this way, new growth is allowed while air quality improvement is achieved.

Because nonattainment areas still exist, especially in urban areas, the 1990 CAAA contain new and more stringent requirements for such areas. The ambient air quality standards for ozone are of particular concern. Controls include tighter standards on emissions from motor vehicles, use of cleaner fuels, and additional controls on industrial facilities. One of the biggest impacts on the chemical industry is more stringent requirements for minimizing the emission of volatile organic compounds (VOCs). This can include process emissions as well as emissions from storage tanks.

Emission Standards. In order to have a nationwide basis for air pollution emission controls and to set a minimum emission limit, the EPA developed New Source Performance Standards (NSPS). The NSPS set specific pollutant emission limits or describe the best available control technology (BACT) that should be applied at that source. The EPA has issued NSPS, which apply to new construction as well as to large modifications, for many different sources. Sources in the chemical industry include the following:

Sulfuric acid production units (Subpart Cb)
Industrial–commercial–institutional steam-generating units (Subpart Db)
Nitric acid plants (Subpart G)
Sulfuric acid plants (Subpart H)
Petroleum refineries (Subpart J)
Volatile organic liquid storage vessels, including petroleum liquid storage vessels (Subparts K, Ka, and Kb)
Phosphate fertilizer industry

wet process phosphoric acid plants (Subpart T)

superphosphoric acid plants (Subpart U)
diammonium phosphate plants (Subpart V)
triple superphosphate plants (Subpart W)
granular triple superphosphate storage facilities (Subpart X)
Lime manufacturing plants (Subpart HH)
Ammonium sulfate manufacture plants (Subpart PP)
Asphalt processing and asphalt roofing manufacture (Subpart UU)
Equipment leaks of VOC in the synthetic organic chemicals manufacturing industry (Subpart VV)
Bulk gasoline terminals (Subpart XX)
Rubber Tire Manufacturing Industry (Subpart BBB)
Polymer manufacturing industry (Subpart DDD)
Equipment leaks of VOC in petroleum refineries (Subpart GGG)
Synthetic fiber production facilities (Subpart HHH)
Synthetic organic chemical manufacturing industry air oxidation unit processes (Subpart III)
Synthetic organic chemical manufacturing industry distillation operations (Subpart NNN)
Petroleum refinery wastewater system VOC emissions (Subpart QQQ)

The 1990 CAAA expands the control of hazardous air pollutants (HAP). Previously, only a small number of hazardous air pollutants were regulated, under the National Emission Standards for Hazardous Air Pollutants (NESHAP). This has been expanded to cover a list of 189 pollutants, many of which are associated with chemical operations. Facilities are required to install maximum achievable control technology (MACT). The MACT standards are issued by EPA for different industries and categories of sources. The applicability of these standards is based on a facility's potential to emit and whether or not it is a major source. Some categories of MACT standards in the chemical industry are Subpart F, for National Emission Standards for Organic Hazardous Air Pollutants from the Synthetic Organic Chemical Manufacturing Industry; Subpart G, for National Emission Standards for Organic Hazardous Air Pollutants from Synthetic Organic Chemical Manufacturing Industry Process Vents, Storage Vessels, Transfer Operations, and Wastewater; Subpart H, for National Emission Standards for Organic Hazardous Air Pollutants for Equipment Leaks; and Subpart I, for National Emission Standards for Organic Hazardous Air Pollutants for Certain Processes Subject to the Negotiated Regulation for Equipment Leaks.

Accidental Release Provisions The 1990 CAAA includes provisions similar to OSHAs process safety management standard for minimizing the accidental release of air toxics. Based on types and quantities of hazardous chemicals onsite, a facility is required to develop and implement risk management plans. The plans must be designed to prevent, detect, and respond to accidental hazardous chemical releases. In addition, facilities must provide this information to their local communities. The phrase that has been used to describe this information is worst-case scenarios. These requirements were revised under the Chemical Safety Information, Site Security and Fuels Regulatory Relief Act, enacted in 1999 (8).

2.3. Solid and Hazardous Waste. Regulation of pollution resulting from solid waste disposal was formulated at a much slower pace than regulation of air or water pollution. It was not until the Resource Conservation and Recovery Act (RCRA) of 1976 (9) was passed that substantial controls were authorized. RCRA gives EPA control of hazardous waste from "cradle-to-grave". In 1984, HSWA, the Federal Hazardous and Solid Waste Amendments were enacted. Other related laws are the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), commonly known as Superfund, in 1980, and the Superfund Amendments and Reauthorization Act (SARA) in 1986. These additional laws are discussed below. EPA has information about RCRA on-line at: http://www.epa.gov/rcraonline/.

The main objectives of RCRA are to protect public health and the environment and to conserve natural resources. The act requires EPA to develop and administer the following programs: solid waste disposal practices providing acceptable protection levels for public health and the environment; transportation, storage, treatment, and disposal of hazardous wastes practices that eliminate or minimize hazards to human health and the environment; the use of resource conservation and recovery whenever technically and economically feasible; and federal, state, and local programs to achieve these objectives.

The section of the RCRA of most concern to the chemical industry is Subtitle C, the hazardous waste management regulations. The purpose of this section is to regulate hazardous wastes from their generation to their disposal. Facilities that generate, treat, store, or dispose of hazardous wastes are covered by these regulations.

The RCRA definition of solid waste covers a wide range of materials, including solid, liquid, semisolid, or contained gaseous material resulting from industrial, commercial, mining, and agricultural operations. A hazardous waste is a substance that must either be listed by the EPA or have a hazardous characteristic. Several types of solid wastes are specifically excluded from hazardous waste regulation because of their great volume or for other reasons. These include household wastes and some agricultural, mining, and fossil fuel combustion and exploration wastes.

A solid waste is considered hazardous if it is either a listed waste or a characteristic waste. Listed wastes include a list of specific processes that generate a waste and a list of discarded commercial chemical products. There are four hazardous waste characteristics: ignitability, corrosivity, reactivity, and toxicity. The last refers to the leachability of a waste and the resultant toxicity in the groundwater using the analytical method referred to as toxicity characteristic leaching procedure (TCLP). A list of substances included under TCLP is shown in Table 1 (Section 261.24, http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr261_00.)

It is the generator's responsibility to determine if a substance is hazardous. Generator requirements include recordkeeping, labeling, using proper containers, providing information to transporters, following the manifest system, and periodic reporting to the EPA. The manifest system is a set of papers that is passed from the generator to the transporters of the waste, to those responsible for final disposal, and back to the generator to signify that the waste has been disposed of properly.

Regulations for owners and operators of hazardous waste treatment and storage and disposal facilities (TSDFs) cover both interim and general status. Any facility operating prior to November 30, 1980, is considered existing and is granted interim status if notification has been sent to EPA. The requirements cover operating methods and location, design, and construction of TSDFs. These include tanks; surface impoundments; waste piles; land treatment; landfills; incinerators; thermal treatment; chemical, biological, and physical treatment; and underground injection.

Groundwater and air quality monitoring are required for all facilities that have the potential to generate emissions. There are also requirements for contingency plans in the case of accidents, closure and post-closure plans, and financial requirements to ensure that closure plans can be followed. Permit applications must include an estimate of the composition, quantity, concentration, and frequency or rate of disposal, treatment, transport, or storage.

Regulations covering nonhazardous solid waste are mainly at the state and local level. Some states are starting to run out of space for landfills. As a result, regulations are starting to increase for nonhazardous solid waste. Most of these are designed to encourage better management of solid waste, including source reduction, recycling, and reuse. One type of solid waste that is regulated separately is medical waste. Although this typically comes from hospitals and doctors' offices, some laboratory wastes from chemical plants, such as syringes used to inject samples into analytical equipment, may need to be handled specially.

RCRA also regulates underground storage tanks (USTs). The USTs must be registered with a facility's designated state agency. Regulations include requirements for leak detection or inventory control system and tank testing; recordkeeping and reporting; corrective action; financial responsibility for corrective action and/or third-party liability; and closure once the tanks are taken out of use.

Under HSWA, waste minimization and a national land disposal ban program were promulgated. Included under HSWA are these requirements: proper hazardous waste management; waste minimization; reduction in land disposal practices; prohibition of open dumping; encouragement of state authriozed RCRA programs; encouragement of research and development; and encouragement of recovery, recycling, and treatment alternatives.

In 1980, the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), known as the Superfund legislation (10) was authorized. This act provides a means for the federal government to collect money from industry for use in cleaning existing and abandoned hazardous waste disposal sites and spills. Two kinds of response actions are allowed: short-term removals where prompt response is needed to control releases or threatened releases, particularly those that are life threatening and long-term remedial response actions to permanently reduce the dangers associated with releases of hazardous substances posing a serious threat. For operating facilities, there are regulations requiring reporting of spills and releases, based on reportable quantities (RQs), to the National Response Center (NRC). In addition, requirements for cleanup of facilities contaminated by past releases, as well as abandoned contaminated facilities, are included.

CERCLA was amended in 1986 by the Superfund Amendments and Reauthorization Act (SARA) (11). Several important changes were made including: stressed the importance of permanent remedies and innovative treatment technologies in cleaning up hazardous waste sites; required Superfund actions to consider the standards and requirements found in other State and Federal environmental laws and regulations; provided new enforcement authorities and settlement tools; increased State involvement in every phase of the Superfund program; increased focus on human health problems posed by hazardous waste sites; encouraged greater citizen participation in making decisions on how sites should be cleaned up; and increased the size of the trust fund to $8.5 billion.

In 1990, the Pollution Prevention Act (PPA) (12) was authorized. The purpose is to look at source reduction rather than waste treatment and disposal. PPA focuses industry, government, and public attention on reducing the amount of pollution through cost-effective changes in production, operation, and raw materials use. Other areas of pollution prevention looked at includes other practices that increase efficiency in the use of energy, water, or other natural resources. Such practices include recycling, source reduction, and sustainable agriculture.

2.4. Hazardous Chemicals. The Emergency Planning and Community Right-to-Know Act (EPCRA) (13), promulgated as part of the Superfund Reauthorization Act and originally known as SARA, Title III, requires facility emergency plans, spill and release reporting, annual inventory reporting, and annual toxic chemical emissions and pollution prevention reporting. It is known as the national legislation on community safety. The regulations under SARA and EPCRA can be found at http://www.epa.gov/docs/epacfr40/chapt-I.info/subch-J.htm.

The annual toxic emissions reports are called Toxic Release Inventory (TRI) reports, also known as Section 313 or Form R reports. These reports must include information on any on- or off-site releases, disposal, treatment, or recycling of the listed toxic chemicals. Reporting requirements depend on the amount of the chemicals used or manufactured as well as the type of use. Sections 311 and 312 cover right-to-know requirements.

The facility emergency plans and the annual inventory reporting must be shared with the community, through the local emergency planning committee (LEPC) and the state emergency response commission (SERC). The facility must also provide material safety data sheets (MSDSs) to the LEPC and other emergency responders. Because the SERCs and LEPCs include fire fighters, health officials, government representatives, the media, community groups, industrial facilities, and emergency managers, all necessary elements of the planning process should be represented.

Both CERCLA and EPCRA have requirements for reporting releases to the air, ground, or water. Lists of reportable chemicals or family of chemicals and their reportable quantity (RQ) have been issued (14). A reportable quantity is the amount, in pounds or kilograms, below which a release does not have to be reported. CERCLA requires only the reporting of releases from the CERCLA list; however, EPCRA requires reporting releases of both EPCRA- and CERCLA-listed substances. Reportable releases under CERCLA must be reported to the

National Response Center, at (800) 424–8802. Reporting under EPCRA requires notifying the facility's LEPC (or relevant local emergency response personnel if there is no LEPC) and the SERC of any state likely to be affected. If a facility is near the border of another state, that state may have to be notified as well. Notification is required to be immediate, which is usually defined as within 30 min of the release. State or local authorities may have additional or different reporting requirements. Failure to report release in a timely manner can result in severe penalties from the regulatory authorities.

2.5. Multimedia Permitting. EPA has started looking at chemical plants with a multimedia view, ie, not just an air problem or a water problem, but how all aspects of a plant's operations, emissions, releases, etc, fit together. The driving force behind this is pollution prevention, not just treating wastes that are produced, but eliminating the production of the wastes in the first place. Of concern to the chemical industry is the possibility of toxic use reduction (TUR) regulations. These require reduction in use, or even elimination, of chemicals that are deemed toxic. The chemical industry believes that with sufficient knowledge and proper controls, chemicals can be handled safely. Their focus is on reuse and recycling of chemicals in order to minimize emissions and releases.

2.6. National Environmental Policy Act. The principal goal of the National Environmental Policy Act (NEPA) (15) is to establish a national policy that ensures continued growth and technological advancement while maintaining the quality of the environment. It is considered the basic national charter for protection of the environment. It establishes policy, sets goals, and provides means for carrying out the policy.

Any Federal agency sponsoring action that significantly affects the environment, eg, granting a construction permit or introducing new legislation, must issue a detailed report describing the environmental impact of the proposed action and alternatives. This report is called an environmental impact statement (EIS). An EIS is written and issued by the federal agency involved with a particular project. The agency, however, relies on the owners of the proposed facility to provide the information contained in the EIS. The section on alternatives is considered the most important part of the EIS. The proposed project and its alternatives are usually described in detail. The environmental impacts of the proposal and the alternatives are presented. Based on all of this information, the federal agency determines if the proposed project is environmentally acceptable.

3. Product Safety

3.1. Toxic Substances Control Act. EPA regulates the manufacture, use, and exposure to hazardous or toxic chemicals under a number of laws. For the chemical industry, the law of prime concern is the Toxic Substance Control Act (TSCA) (16), which was passed by the U.S. Congress in 1976. The two main goals of TSCA are acquisition of sufficient information to identify and evaluate potential hazards from chemical substances, and regulation of the production, use, distribution, and disposal of these substances. TSCA regulations can be found at http://www.epa.gov/docs/epacfr40/chapt-I.info/subch-R.htm.

One important aspect of TSCA is the premarket or import notification program. Before a manufacturer produces or imports a new chemical substance, EPA must be given 90 days' notice, the premanufacture notification (PMN). The notice includes all testing done by the manufacturer to determine the health effects of the chemical. Information on a facility's pollution prevention plans with regard to the manufacturing operation must also be included. EPA then has 45 days from the end of the review period to determine if the production or distribution of the chemical should be restricted or prohibited because the chemical presents an unreasonable risk. The manufacturer has an additional 30 days to object to EPAs decision. EPA has established an inventory of chemicals manufactured or processed in the United States (17). Any substance not on the list by August 30, 1980 is considered a new chemical and must be described in the premarket notification. Exemptions are given for substances registered as pesticides or regulated by the FDA.

As part of TSCA, EPA can require the testing of any chemical if there is the possibility of an unreasonable risk to health or environment or if there is significant human or environmental exposure. If the substance poses an unreasonable risk, EPA can prohibit the manufacture, processing, or distribution of the substance; limit the amount of the substance that can be manufactured, processed, or distributed; prohibit a particular use for the substance; limit the concentration of the substance during manufacture, processing, or distribution; regulate disposal methods for the substance; and require manufacturers to maintain records of the process and to conduct tests to assure compliance with EPA rules.

Another section of TSCA requires the manufacturer to notify EPA if there is any indication of substantial risk from any chemical. Failure to do so by the manufacturer within a specified time period may result in civil penalties or possibly criminal prosecution.

TSCA also addresses the problem of polychlorinated biphenyls (PCBs) and chlorinated fluorocarbons (CFCs). EPA has developed regulations on the cleanup, handling, and disposal of PCBs. The manufacture and use of CFCs has been banned for all but essential uses, in accordance with the Montreal Agreement, an international treaty on worldwide use of CFCs.

3.2. Federal Insecticide, Fungicide, and Rodenticide Act. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (18) covers the use and manufacture of pesticides, rodenticides, etc, and includes such things as biocides and preservatives. Prior to manufacture, these regulated products must be registered with EPA. Registration assures that pesticides will be properly labeled and will not cause unreasonable harm to the environment. There are very specific labeling and container requirements for these products. Users (farmers, utility companies, and others) must register when purchasing pesticides. Later amendments to the law require users to take exams for certifications as applicators of pesticides. More details on these regulatory requirements are given in the articles FUNGICIDES, PESTICIDES, INSECT CONTROL TECHNOLOGY, and INDUSTRIAL ANTIMICROBIAL AGENTS. Regulations under FIFRA can be found at http://www.epa.gov/docs/epacfr40/chapt-I.info/subch-E.htm.

3.3. Food, Drug, and Cosmetic Protection. There are several laws (with corresponding regualtions) that protect food, drugs, and cosmetics. The

first is the Federal Food, Drug, and Cosmetic Act (FFDCA) (19). The other one of interest to the chemical industry is Food Quality Protection Act (FQPA) (20).

3.4. Transportation. The U.S. Department of Transportation (www.dot.gov/) regulates the transport, packaging, and handling of hazardous substances, including chemicals. In addition, there are international laws and regulations. Substances are characterized based on their type of hazard and assigned identification numbers. The type of packaging that can be used for different types of hazards is regulated. For example, there are only certain types of containers that can be used for flammables or corrosives. When hazardous materials are transported, the vehicle, eg, truck, tank truck, and tank car, must be placarded to show the hazard. The bill of lading must describe the material, including the hazards. The material safety data sheet (MSDS) must be available. In addition, there are many training requirements for those employees handling, packaging, or transporting hazardous chemicals. Only certified transporters may transport hazardous chemicals.

4. Employee Safety

4.1. Occupational Safety and Health Act. OSHA has broad responsibilities for protecting the workplace. The Occupational Safety and Health Act is administered by the Occupational Safety and Health Administration under the U.S. Department of Labor (21). The act covers all health and safety aspects of a worker's environment. OSHA laws, regulations, *Federal Register* citations, etc., can be found on-line at: http://www.osha.gov/fso/ca.html.

Subpart Z of the Act, Toxic and Hazardous Substances, lists allowable employee exposure to many different chemical substances (22). These are given as ambient air concentrations over a certain time period, usually an 8-h time-weighted average. Sometimes a ceiling concentration is given as well. Certain substances, eg, vinyl chloride, benzene, and formaldehyde, are discussed in terms of necessary controls and limits. The monitoring of employee exposure is called industrial hygiene (qv).

In the Hazard Communication Standard, OSHA requires that all employees are trained in the hazards of the materials they are working with. This standard also requires that MSDSs be available for all hazardous chemicals at the worksite, accompany all shipments, and be sent to all customers. An MSDS summarizes all of the important health, safety, and environmental information about a substance. A version of this standard also applies to laboratories, including research and development facilities, and requires the development of a laboratory hygiene plan.

Included in the OSHA regulations are standards for safe work practices such as lock-out/tag-out and confined space entry, personal protective equipment, storage of hazardous materials, welding process, forklift operation, and requirements for fire protection. Basically, all activities within a chemical facility are covered by OSHA standards.

In response to a number of major incidents at chemical facilities, OSHA has issued process safety management standards. For a selected list of hazardous substances, a facility is required to have a process safety management program

in place. This includes training to ensure employees know how to deal with hazards, analyses of processes using these hazardous substances, and management of change to ensure that any changes to equipment, processes, types of chemicals used, etc, are analyzed. Unlike EPAs accidental release provisions that focus on protection of the community, the focus of this standard is on protecting employees on-site.

After debating the issue for over 20 years, on April 5, 2002, OSHA finally announced its Comprehensive Plan on Ergonomics to address musculoskelatal disorders (MSDs) in the workplace. OSHA is using a four-pronged approach to reduce injuries and illnesses from MSDs in the workplace. These include: guidelines, enforcement, outreach and assistance, and research. OSHA will develop industry or task-specific guidelines for a number of industries based on current incident rates and available information about effective and feasible solutions. This work will take into account guidelines and best practices already developed including OSHAs own Meatpacking Guidelines.

The National Institute of Occupational Safety and Health (NIOSH), under the Department of Health and Human Services, works with OSHA. It is NIOSHs responsibility to determine safe exposure limits for chemical substances and to recommend to OSHA that these limits be adopted as standards.

5. Acronyms

Acronyms in common use in the regulatory arena include the following [a listing of environmental terms and acronyms from EPA can be found on-line at http://www.epa.gov/OCEPAterms/]:

Air quality control region (AQCR)
Advanced wastewater treatment (AWT)
Best available control technology (BACT)
Best available technology (BAT)
Best conventional pollutant control technology (BCT)
Biochemical oxygen demand (BOD)
Best practicable control technology (BPCT)
Clean Air Act (CAA)
Clean Air Act Amendments (CAAA)
Community Awareness and Emergency Response, under Responsible Care (CAER)
Comprehensive Assessment Information Rule, under TSCA (CAIR)
Confidential business information (CBI)
Comprehensive Environmental Response, Compensation, and Liability Act, also known as the Superfund Law (CERCLA)
Chlorinated fluorocarbon (CFC)
Code of Federal Regulations (CFR)
Chemical oxygen demand (COD)
Consumer Product Safety Commission (CPSC)
Clean Water Act (CWA)
Department of Transportation (DOT)

Environmental impact statement (EIS)
Environmental Protection Agency (EPA)
Environmental Planning and Community Right-to-Know Act (EPCRA)
Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
Freedom of Information Act (FOIA)
Federal Water Pollution Control Act (FWPCA)
Good engineering practice (GEP)
Ground-level concentration (GLC)
Good laboratory practice (GLP)
Government Printing Office (GPO)
Hazardous air pollutant (HAP)
Lowest achievable emission rate (LAER)
Local Emergency Planning Committee (LEPC)
Leaking underground storage tanks (LUST)
Maximum achievable control technology (MACT)
Material Safety Data Sheet (MSDS)
National Ambient Air Quality Standard (NAAQS)
National Environmental Policy Act (NEPA)
National Emission Standards for Hazardous Air Pollutants (NESHAP)
National Institute for Occupational Safety and Health (NIOSH)
Nitrogen oxides (NOx)
National Pollutant Discharge Elimination System (NPDES)
Notice of Proposed Rulemaking (NPRM)
National Response Center or Nuclear Regulatory Commission (NRC)
New Source Performance Standard (NSPS)
Occupational Safety and Health Act (and Administration) (OSHA)
Polychlorinated biphenyl (PCB)
Permissible exposure limit (PEL)
Premanufacture notification, under TSCA (PMN)
Publicly owned treatment work (municipal wastewater treatment facility) (POTW)
Potentially responsible party, under Superfund (PRP)
Prevention of Significant Deterioration (PSD)
Resource Conservation and Recovery Act (RCRA)
Reportable quantity (RQ)
Superfund Amendments and Reauthorization Act (SARA)
Safe Drinking Water Act (SDWA)
State Emergency Response Commission (SERC)
Standard Industrial Classification Code (SIC)
State implementation plan (SIP)
Sulfur oxides (SOx)
Significant new use rule, under TSCA (SNUR)
Synthetic organic chemical industry (SOCMI)
Spill prevention control and countermeasure plan (SPCC Plan)
Toxicity characteristic leaching procedure (TCLP)
Threshold planning quantity (TPQ)
Toxic Release Inventory (TRI)
Toxic Substances Control Act (TSCA)

Treatment, storage, and disposal facility (TSDF)
Total suspended particulates (air) (TSP)
Total suspended solids (wastewater) (TSS)
Time-weighted average (TWA)
Underground-injection controls (UIC)
Underground storage tank (UST)
Volatile organic compounds (VOC)

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8. *Chemical Safety Information, Site Security & Fuels Regulatory Relief Act*, 42 USC 7412(r) (1999).
9. *Resource Conservation and Recovery Act* of 1976, 42 USC §§321 et seq.
10. *Comprehensive Environmental Response, Compensation, and Liability Act*, 42 USC §§9601et seq.
11. *Superfund Amendment and Reauthorization Act*, 42 USC 9601 et seq, (1986).
12. *Pollution Prevention Act*, 42 USC 13101 and 13102 et seq. (1990).
13. *Emergency Planning and Community Right-to-Know Act*, 42 USC §§11001 et seq.
14. *Comprehensive Environmental Response, Compensation, and Liability Act* (CERCLA) Reportable Releases: 40 CFR 302, "EPA Designation, Reportable Quantities, and Notification Requirements for Hazardous Substances under CERCLA," Table 302.4, "Lists of Hazardous Substances and Reportable Quantities;" EPCRA Section 304 Reportable Releases: 40 CFR 355, "The List of Extremely Hazardous Substances and their Threshold Planning Quantities," Appendix A, Alphabetical Order, and Appendix B, CAS Number Order.
15. *National Environmental Policy Act*, 42 USC §§4321–4347.
16. *Toxic Substances Control Act*, 15 USC §§2601 et seq. (1976).
17. *Toxic Substances Control Act*, Chemical Substances Inventory; further information can be obtained from Industry Assistance Office, Pesticides and Toxic Substances, Environmental Protection Agency, Washington, D.C.
18. *Federal Insecticide, Fungicide and Rodenticide Act*, 7 USC 135 et seq. (1972).
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20. *Food Quality Protection Act*, Public Law 104-170 (1996).
21. *Occupational Safety and Health Act*, 29 USC §§651–678.
22. *Occupational Safety and Health Act*, 29 CFR 1910.1000.

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Subscriptions to *Federal Register* can be obtained through the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C., 20402, (202) 512–1800. *Federal Register* and the *Codes of Federal Regulations* are available at those public libraries designated as U.S. Federal repositories; The US Government Printing Office can be accessed on-line at: http://www.access.gpo.gov/. Their on-line bookstore is at http://bookstore.gpo.gov. On-line find the Federal Register at http://www.gpo.gov/su_docs/aces/aces140.html

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TRADE ASSOCIATIONS AND OTHER SOURCES OF INFORMATION

American Chemistry Council (formerly the Chemical Manufacturers Association), 1300 Wilson Blvd., Arlington, Va., 22209, (703) 741–5000, which offers information about Responsible Care (a registered trademark of ACC) and regulatory impact on the chemical industry, www.americanchemistry.com

Synthetic Organic Chemical Manufacturers Association, 1850 M St. NW, Suite 700, Washington, D.C. 20036, (202) 721–4100, which offers information about regulatory impact on the chemical industry, particularly small and batch operations, www.socma.org

NANCY R. PASSOW
Write For You!/NRP Associates, Inc.

Table 1. **Maximum Concentration of Contaminants for Toxicity Characteristic**

EPA hazardous waste number	Contaminant	CAS Registry Number	Regulatory level, mg/L
D004	arsenic	[7440-38-2]	5.0
D005	barium	[7440-39-3]	100.0
D018	benzene	[71-43-2]	0.5
D006	cadmium	[7440-43-9]	1.0
D019	carbon tetrachloride	[56-23-5]	0.5
D020	chlordane	[57-74-9]	0.03
D021	chlorobenzene	[108-90-7]	100.0
D022	chloroform	[67-66-3]	6.0
D007	chromium	[7440-47-3]	5.0
D023	*o*-cresol	[95-48-7]	4200.0
D024	*m*-cresol	[108-39-4]	4200.0
D025	*p*-cresol	[106-44-5]	4200.0
D026	cresol	[1319-77-3]	4200.0
D016	2,4-dichlorophenoxy	[94-75-7]	10.0
D027	1,4-dichlorobenzene	[106-46-7]	7.5
D028	1,2-dichloroethane	[107-06-2]	0.5
D029	1,1-dichloroethylene	[75-35-4]	0.7
D030	2,4-dinitrotoluene	[121-14-2]	30.13
D012	endrin	[72-20-8]	0.02
D031	heptachlor (and its epoxide)	[76-44-8]	0.008
D032	hexachlorobenzene	[118-74-1]	30.13
D033	hexachlorobutadiene	[87-68-3]	0.5
D034	hexachloroethane	[67-72-1]	3.0
D008	lead	[7439-92-1]	5.0
D013	lindane	[58-89-9]	0.4
D009	mercury	[7439-97-6]	0.2
D014	methoxychlor	[72-43-5]	10.0
D035	methyl ethyl ketone	[78-93-3]	200.0
D036	nitrobenzene	[98-95-3]	2.0
D037	pentachlorophenol	[87-86-5]	100.0
D038	pyridine	[110-86-1]	35.0
D010	selenium	[7782-49-2]	1.0
D011	silver	[7440-22-4]	5.0
D039	tetrachloroethylene	[127-18-4]	0.7
D015	toxaphene	[8001-35-2]	0.5
D040	trichloroethylene	[79-01-6]	0.5
D041	2,4,5-trichlorophenol	[95-95-4]	400.0
D042	2,4,6-trichlorophenol	[88-06-2]	2.0
D017	2,4,5-trichlorophenoxy (silvex)	[93-72-1]	1.0
D043	vinyl chloride	[75-01-4]	0.2