GOVERNMENT REGULATION OF ENVIRONMENTAL AND OCCUPATIONAL HEALTH IN THE ENVIRONMENT IN THE UNITED STATES AND THE EUROPEAN UNION

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INTRODUCTION

The manufacturing, processing, and use of chemicals, materials, tools, machinery, and equipment in industrial, construction, mining, and agricultural workplaces often cause environmental, health, and safety hazards and risks. Occupational and environmental factors cause or exacerbate a wide variety of adverse health effects, placing heavy economic and social burdens on workers, employers, community residents, and taxpayers. In addition, consumer products, pharmaceuticals, and contaminated food present health risks to consumers.

Because voluntary efforts in the unregulated market have not succeeded in reducing the incidence of many of these health effects, the public has demanded government intervention into the activities of the private sector. This intervention takes many regulatory forms, including standard-setting, government-imposed liability, pollution-reduction markets, and mandatory disclosure of information. This chapter addresses the major regulatory systems (regimes) designed to protect public health and worker health from chemicals discharged from sources that pollute the air, water, ground, and workplace. (The regulation of hazards posed by consumer products, pharmaceuticals, and contaminated food is beyond the scope of this chapter. See Chapter 9 regarding Food Safety.)

The establishment of standards and other legal requirements in these regulatory regimes has occurred over more than 40 years, a period that has seen changes in the use of scientific and technical information in regulatory initiatives and in legal doctrine -- including the manner in which science, economics, and technological capability are viewed by the courts. Concepts of risk assessment, cost-benefit analysis, and technology forcing have evolved, through the development of case law and changes in the political environment. Often, changes in one regulatory regime have led to changes in other regulatory regimes.

Standards can be classified in several ways. A *performance standard* specifies a particular outcome, such as a specified emission level above which it is illegal to emit a specified air pollutant; however, it does not specify how that outcome is to be achieved. In contrast, a *design (specification) standard* specifies a particular technology, such as a catalytic converter, that must be used. Either type of standard can be based on (a) a desired level of protection for human health or environmental quality, (b) some level of presumed technological feasibility, (c) some level of presumed economic feasibility, or (d) some balancing of social costs and social benefits. Within each of these options, there is a wide spectrum of possible approaches. For example, a standard based on human health might protect only the average member of the population or, alternatively, the most sensitive individual. A technology-based standard might be based on what is deemed feasible for an entire industry, or on what is deemed feasible for each firm within the industry. Some standards might be based on a combination of these factors, such as both technological and economic feasibility.

Beyond standards are various information-based obligations that can also influence industrial behavior, such as (a) the required disclosure of -- and retention of, or provision of access to -- information on exposure, toxicity, chemical content, and production; and (b) required testing or screening of chemical products.

Under several new federal environmental laws, regulation in the United States in the 1970s and 1980s created the national model for *controlling* -- rather than preventing -- pollution in air, water, waste, and the workplace with an "end-of-pipe" focus. In the U.S., the 1946 Administrative Procedure Act gave affected parties the right to participate in administrative rule making and to challenge agency actions in the courts. More specific provisions in new environmental laws expanded these rights, and some gave nongovernmental organizations (NGOs) and citizens the right to go to court to enforce environmental standards against those who violate them. Eventually, European countries developed similar approaches to pollution control. Although initially citizens had fewer opportunities to challenge government and industry in court, this situation is changing as the European Union becomes the source of much environmental law for its member states.

As experience with end-of-pipe approaches accumulated, there was widespread recognition that *preventing* pollution -- rather than merely controlling it -- offered advantages for both the environment and industry. This recognition led, in the United States, to the Pollution Prevention Act of 1990, and in the Europe Union, to specific pollution prevention directives (such as the Integrated Pollution Prevention and Control Directive and the Seveso Directives) and several treaties among member states.

While the safety of food, drugs, and commercial products has been a continuing concern for some in the United States, there has been a renewed call for vigorous regulation of product safety both here and elswewhere after recent experiences with contaminated food, toothpaste, and toys, and with adverse reactions to widely-used medications. The European Union has also advocated for stronger regulation to ensure the safety of food, medications, and commercial products.

Differing approaches to the testing and screening of industrial chemicals are found in the Toxic Substances Control Act (TSCA), which was passed by the U.S. Congress in 1976, and the REACH Initiative, a regulation of the European Union that became effective in 2007. Table 30-1 lists selected regulatory initiatives that form the backbone of governmental regulation in the United States and the European Union.

In the United States, exposures to toxic substances in the industrial workplace have been regulated primarily through the Occupational Safety and Health Act (OSHAct) of 1970 and TSCA. These federal laws have remained essentially unchanged since being passed, although serious attempts at reform have been attempted. Since 1990, sudden and accidental releases of chemicals (chemical accidents), which may affect workers and community residents, have been regulated under both the Clean Air Act and the OSHAct.

The OSHAct established OSHA in the Department of Labor to enforce compliance with the act, NIOSH (within CDC) in the Department of Health and Human Services to perform research and

conduct health hazard evaluations, and the independent, quasi-judicial Occupational Safety and Health Review Commission to hear employer and worker appeals of OSHA citations. The evolution of regulatory law under the OSHAct has profoundly influenced other environmental legislation, including the regulation of air, water, and waste, but especially the evolution of TSCA. Within EPA, the Office of Pollution Prevention and Toxic Substances administers TSCA; the Office of Air, Water, and Solid Waste and the Office of Emergency Response regulate media-based pollution; and the Office of Chemical Preparedness and Emergency Response implements the chemical safety provisions of the Clean Air Act.

STANDARD SETTING AND OBLIGATIONS OF EMPLOYERS, MANUFACTURERS, AND USERS OF TOXIC SUBSTANCES

The Occupational Safety and Health Act of 1970

The OSHAct requires OSHA to (a) encourage employers and employees to reduce hazards in the workplace and to implement new or improved safety and health programs; (b) develop and enforce mandatory job safety and health standards; (c) establish separate, but dependent, responsibilities and rights for employers and employees for the achievement of improved safety and health conditions; (d) establish reporting and recordkeeping procedures to monitor job-related injuries and illnesses; and (e) encourage states to assume the fullest responsibility for establishing and administering their own occupational safety and health programs, which must be "at least as effective" as the federal program.

The coverage of the OSHAct initially extended to all employers and their employees, except selfemployed people; family-owned and -operated farms; state, county, and municipal workers; and workplaces already protected by other federal agencies or other federal statutes. In 1979, however, Congress exempted from routine OSHA safety inspections approximately 1.5 million businesses with 10 or fewer employees. (Exceptions to this are allowed if workers claim there are safety violations.) Because federal agencies (except the U.S. Postal Service) are not subject to OSHA regulations and enforcement provisions, each agency is required to establish and maintain its own effective and comprehensive job safety and health program. OSHA provisions do not apply to state and local governments in their role as employers. OSHA requires, however, that any state desiring to gain OSHA support or funding for its own occupational safety and health program must provide a program to cover its state and local government workers that is at least as effective as the OSHA program for private employees.

OSHA can begin standard-setting procedures either on its own or on petition from the Secretary of Health and Human Services, NIOSH, state and local governments, any nationally recognized standards-producing organization, employer or labor representatives, or any other interested person. The standard-setting process involves input from advisory committees and from NIOSH. When OSHA develops plans to propose, amend, or delete a standard, it publishes these intentions in the Federal Register. Subsequently, interested parties have opportunities to present arguments and pertinent evidence in writing or at public hearings.

Under certain conditions, OSHA is authorized to set emergency temporary standards, which take effect immediately, but are to be followed by the establishment of permanent standards within 6 months. To set an emergency temporary standard, OSHA must first determine that workers are in

grave danger from exposure to toxic substances or new hazards and are not adequately protected by existing standards. Both emergency temporary and permanent standards can be appealed to the federal courts, but filing an appeals petition does not delay the enforcement of the standard unless a court of appeals specifically orders it. Employers may apply to OSHA for a temporary variance from a standard or regulation if they lack the means to comply readily with it, or for a permanent variance if they can prove that their facilities or methods of operation provide employee protection that is at least as effective as that required by OSHA.

The OSHAct provides two general means of protection for workers: (a) a general statutory duty on all employers to provide a safe and healthful workplace; and (b) promulgation of specific standards to which specified categories of employers must adhere. The Act imposes on virtually every employer in the private sector a general duty to "furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm." A recognized hazard may be a substance whose likelihood of harm has been the subject of research, giving rise to reasonable suspicion even though an OSHA standard has not been promulgated to protect workers from that harm. Placed on OSHA is the burden of proving that a particular substance is a recognized hazard, that occupational exposure to it results in a likelihood of serious harm, and that a reduction in exposure is necessary to protect workers from that harm. Because standard-setting is a slow process, protection of workers through the employer's general duty could be especially important, but it is crucially dependent on the existence of reliable data on health effects and the willingness of a particular OSHA administration to use this statutory duty as a vehicle for protection.

The OSHAct specifically addresses the subject of toxic materials. It states, in Section 6(b)(5), that the Secretary of Labor (through OSHA), in promulgating standards dealing with toxic materials or harmful physical agents, "shall set the standard that most adequately assures, to the extent feasible, on the basis of the best available evidence that no employee will suffer material impairment of health or functional capacity, even if such employee has a regular exposure to the hazard dealt with by such standard for the period of his working life." These words indicate a specific intent to regulate exposure to those hazards, such as chemical carcinogens and reproductive toxicants, whose effects may not be felt for several years or decades.

In the 1970s, OSHA set Section 6(b)(5) standards for asbestos, vinyl chloride, arsenic, dibromochloropropane (DBCP), coke oven emissions, acrylonitrile, lead, cotton dust, and a group of 14 carcinogens. In the 1980s, OSHA added standards for benzene, ethylene oxide, and formaldehyde, and tightened the standard for asbestos to reflect its status as a carcinogen. In the early 1990s, OSHA set standards for cadmium, bloodborne pathogens, glycol ethers, and confined spaces. The agency also lowered the permissible exposure limit (PEL) for formaldehyde from 1.00 to 0.75 ppm (averaged over an 8-hr period) and issued a process safety management (PSM) rule designed to reduce the incidence of chemical accidents. Standards were established for methylene chloride, in 1997, and hexavalent chromium, in 2006.

Under Section 6(b), the burden of proving the hazardous nature of a substance is placed on OSHA, as is the burden of establishing that the proposed controls are technologically and economically feasible for the regulated industries. The evolution of case law associated with the

handful of standards that OSHA promulgated through this section of the OSHAct has been important for the implementation of the OSHAct and environmental law generally. In reviewing OSHA's hazardous substance standards, the federal circuit courts of appeal squarely addressed the difficult issue of when scientific information is adequate to sustain the statutory requirement that the standards be supported by "substantial evidence" on the record as a whole. They also addressed (a) the extent to which economic factors were permitted or required to be considered in the setting of the standards, (b) the meaning of feasibility, (c) OSHA's technology-forcing authority, (d) whether a cost-benefit analysis was required or permitted, and (e) the extent of the jurisdiction of the OSHAct in addressing different degrees of risk.

The Toxic Substances Control Act of 1976

TSCA directs EPA to require data from industry on the production, use, and health and environmental effects of chemicals. TSCA also requires the manufacturer of new chemicals -and existing chemicals put to a significant new use -- to file a pre-manufacturing notification with EPA, detailing known information about the chemical. In addition, TSCA authorizes EPA to regulate production and use of those chemicals found to pose an unreasonable risk to human health or the environment. Such regulation may take a variety of forms, such as labeling requirements, tolerance levels, and outright bans on chemical use. EPA may also order a specific change in chemical process technology, or require repurchase or recall of banned chemicals. In addition, TSCA gives aggrieved parties, including consumers and workers, specific rights to sue to enforce the Act, with the possibility of awards of attorneys' fees. (This feature was not included in the OSHAct.)

EPA has issued a worker protection standard for asbestos (at the new OSHA limit of 0.2 fibers/cm³), which applies to state and local government asbestos-abatement workers not covered by OSHA. Although the potential for broader regulation of workplace chemicals exists under TSCA, EPA has not been aggressive in this area. Between 1977 and 1990, of the 22 TSCA regulatory actions taken on existing chemicals, 15 addressed polychlorinated biphenyls (PCBs), which EPA has a specific statutory directive to address under TSCA. Only three of the remaining seven regulations -- pertaining to asbestos, hexavalent chromium, and metalworking fluids -- have a strong occupational exposure component. Although EPA declared formaldehyde a probable carcinogen and IARC classified it as a definite (Group 1) carcinogen, EPA chose not to take regulatory action on it, opting instead to defer to OSHA workplace regulations.

Nonetheless, the OSHAct and TSCA together provide potentially comprehensive and effective information-generation and standard-setting authority to protect workers. In particular, the information-generation activities under TSCA can provide the necessary data to establish that a substance is a "recognized hazard" that, even in the absence of a specific OSHA standard, must be controlled by the employer to meet the OSHAct's general duty to provide a safe and healthful workplace.

The potentially powerful role of more comprehensive TSCA regulation was seriously challenged by the Fifth Circuit Court of Appeals in 1991, when it overturned an omnibus asbestos phase-out rule that was issued under TSCA in 1989. The court ruled that EPA could not ban a chemical under TSCA without having first determined that other regulatory alternatives that would have been less burdensome to industry would not have eliminated the unreasonable risk. This called for a more comprehensive, detailed, and resource-intensive analysis than the one EPA conducted prior to the promulgation of the asbestos rule. Rightly or wrongly, for more than a decade EPA has viewed this case (which was not appealed to the U.S. Supreme Court) as a significant impediment to future TSCA standards, and it has generally regarded regulation of chemicals under TSCA -- except for PCBs -- to be a nearly impossible task for the foreseeable future. Even so, TSCA continues to be important for its surviving authority to require the testing of chemicals and the reporting and retention of information. In 2009, the EPA administrator stated her support for engaging Congress in "writing a new chemical risk management law that will fix the weaknesses in TSCA."

THE CONTROL OF GRADUAL POLLUTION IN AIR, WATER, AND WASTE IN THE UNITED STATES

The Clean Air Act

Although significant changes were made to the statute in 1977 and 1990, the basic regulatory structure of the Clean Air Act (CAA) was established with the Clean Air Act Amendments of 1970. The CAA regulates both stationary and mobile sources of pollution, taking into account (a) the relative contributions of each to specific air pollution problems, and (b) the relative capacity of different kinds of sources within each category to reduce their emissions. The recognition that new sources using newer technology might be able to achieve greater emission reductions than old sources with older technology led to distinctions between new and existing sources in the Act's stationary and mobile-source provisions. Although driven by equity considerations regarding the relative financial and technical burdens of pollution reduction, this approach has unwittingly discouraged modernization or replacement of facilities and resulted in the operation of older facilities -- especially power plants -- beyond their expected useful life. For new sources within each industrial sector, the Act sought to achieve uniformity and to encourage technological innovation through the technology-forcing capability inherent in stringent standards. Court decisions recognizing EPA's technology- forcing authority under the CAA were greatly influenced by earlier decisions upholding OSHA's technology-forcing approach to worker protection.

Section 109(b)(1) of the CAA directed EPA to establish primary ambient air quality standards that would protect public health with an adequate margin of safety. As interpreted by the courts and supported by congressional history, these standards are to be established without consideration of economic or technological feasibility. In addition, Section 109(b)(2) mandates the establishment if secondary ambient air quality standards to protect the public welfare within a reasonable time. (See Chapter 6.)

Both the federal government and the states have key roles in protecting the ambient air under the CAA. Ambient air quality (concentration) standards are established by the federal government for a few "criteria" pollutants (identified below) designated by EPA. For each such pollutant, EPA establishes primary and secondary standards as discussed above. These ambient standards are to be attained through (a) emission limitations placed on individual existing polluters through permits issued by state government as a part of their state implementation plans (SIPs) (in Section 110); (b) nationwide emission limitations for new sources, established by EPA and known as new source performance standards (in Section 111); and (c) a combination of federal and state restrictions on mobile sources. An emission standard, in contrast to an ambient

concentration standard, is expressed as an emissions rate (mg emitted per 100 kg of product, per hour, day, week, quarter, year, BTU, passenger mile, or other unit of measurement).

The CAA does not establish ambient standards for substances designated as "hazardous air pollutants," but rather requires compliance with nationwide emission limitations set by EPA. Hazardous air pollutants are those recognized as extraordinarily toxic and eventually regarded as no-threshold or low-threshold pollutants. Initially, these were to be regulated (in Section 112) to protect public health with an ample margin of safety and, as with the primary ambient standards for criteria pollutants, emission standards for hazardous air pollutants were to be established without consideration of economic burden. These pollutants, Congress determined, were sufficiently dangerous to preclude any reliance on atmospheric dispersion and mixing as a means of reducing their ambient concentrations. The reliance on federal emission standards reflected congressional concern with (a) "hot spots" of localized intense pollution, and (b) the fact that release of these substances often is intermittent, or sudden and accidental, rather than continuous Ambient concentration standards were considered impractical and of little relevance for the sporadic and idiosyncratic sources of hazardous air pollutants, and uniform federal emission standard as a complement to the federal emission limitation on vinyl chloride.)

In the early stages of the implementation of the stationary-source provisions of the CAA, EPA focused on (a) the ambient air quality standards for criteria pollutants, and (b) emission standards for new sources of criteria pollutants and for all sources emitting any of seven regulated hazardous air pollutants (discussed below). Initially, prior advisory ambient standards were made mandatory for the following criteria pollutants: carbon monoxide, sulfur dioxide, oxides of nitrogen, large particulate matter, and photochemical oxidants. In 1979, the standard for photochemical oxidants was narrowed to cover only ground-level ozone, and was relaxed from 0.08 ppm to 0.12 ppm, averaged over 1 hour. The standard for coarse particulate matter (inhalable particulates up to 10 μ m in diameter, PM₁₀) was adopted in 1987. In 1997, the ozone standard was further revised to 0.08 ppm, and in the same rulemaking, the particulate standard was altered to place more stringent requirements on smaller ($<2.5 \mu m$) respirable particles $(PM_{2.5})$, with a 24-hour limit of 65 mg/m³. In 2006, the PM_{2.5} limit was further lowered to 35 mg/m³. A standard for a sixth criteria pollutant -- airborne lead -- was promulgated in 1978; in 2008, EPA lowered the permissible airborne lead concentration from 1.5 to 0.15 μ g/m³. (Current primary air quality standards set under Section 109 are found in Table 30-2). In addition, following a 2007 U.S. Supreme Court decision that EPA has the authority under the CAA to regulate carbon dioxide, it has indicated its intention to establish national limits on greenhouse emissions from automobiles and to regulate carbon dioxide emissions from power plants.

In Section 112 of the CAA, Congress directed EPA to set emission standards for hazardous air pollutants at levels that protect public health with an ample margin of safety. It is likely that this directive reflected an early assumption that, although very dangerous, hazardous pollutants exhibited a finite threshold -- a non-zero level of exposure below which no harm would occur. As the 1970s progressed, however, there was a growing recognition among scientists that this assumption might be wrong and that for many hazardous pollutants there was no detectable level of exposure below which one could confidently predict that no harmful or irreversible effects (especially cancer or birth defects) would occur.

EPA was therefore faced with a major challenge. Arguably, given its mandate to protect public health with an ample margin of safety, EPA was required to ban the emission of several hazardous substances, which would essentially ban the use of these substances in many industries. Seeking to avoid this outcome, EPA adopted a policy of setting Section 112 emission standards at levels that could be achieved by technologically-feasible technology. (This was the approach then followed by OSHA in setting standards for exposure to workplace chemicals. For carcinogens, OSHA considered no levels to be safe, and it established control requirements for carcinogens at the limit of technological feasibility.)

Using this approach, EPA set finite (non-zero) standards for arsenic, asbestos, benzene, beryllium, coke oven emissions, mercury, vinyl chloride, and radionuclides. The standard-setting process was slow and had to be forced by litigation; it took 4 to 7 years to establish a final standard for each of these substances. Had EPA continued to set standards for more substances, and had it used the technological feasibility approach to spur the development of cleaner technology, environmental NGOs may well have been content to allow the implementation of Section 112 to proceed in this fashion. However, when the setting of new Section 112 standards stalled during the Reagan administration (1981-1988), the National Resources Defense Council, an environmental advocacy organization, decided to press the issue in court.

NRDC v. EPA, decided by the District of Columbia Circuit Court of Appeals in 1987, placed new limitations on EPA's approach to regulating hazardous air pollutants by ruling that EPA must determine an acceptable (usually non-zero) risk level for a hazardous air pollutant prior to setting a Section 112 standard for that pollutant. In reaction to this case and to revitalize the moribund standard-setting process, Congress amended Section 112 in 1990 to specify a two-tiered approach: the initial use of technology-based standards, with residual risks to be addressed later by health-based standards.

In the 1990 CAA amendments, Congress listed 189 substances as hazardous air pollutants, and directed EPA to add other substances to the list if they "present or may present...a threat of adverse human effects (including, but not limited to, substances which are known to be or may be reasonably anticipated to be, carcinogenic, mutagenic, teratogenic, neurotoxic, which cause reproductive dysfunction, or which are acutely or chronically toxic) or adverse environmental effects whether through ambient concentration, bioaccumulation, deposition or otherwise."

EPA was directed to set maximum achievable control technology (MACT) technology-based performance standards over a 10-year period for categories of major stationary sources -- defined as those emitting more than 10 tons per year of any single hazardous pollutant or more than 25 tons combined. MACT standards must require the maximum feasible degree of reduction (including a prohibition on emissions, where achievable), but must reflect the cost of achieving emissions reduction and any non-air and environmental impact and energy requirements. MACT standards for new sources must be at least as stringent as those met by the best-performing similar source, and MACT standards for existing sources must be at least as stringent as those met by the average of the best performing 12 percent of similar sources.

For categories of smaller (area) stationary sources, EPA is authorized to set standards that are less restrictive than the MACT standard, based either on generally achievable control technology (GACT) or the use of specified management practices. For pollutants with an identifiable health threshold, EPA is authorized to forgo the technology-based approach and to instead set health-based standards that ensure an ample margin of safety -- essentially the original mandate of Section 112. In addition, EPA was obligated to issue a report on risk, which it issued in 2004. If no new legislation recommended by that report is enacted within 8 years, EPA must issue such additional regulations as are necessary to protect public health with, in general, an ample margin of safety; specifically for carcinogens, these regulations must ensure that lifetime exposure risks are less than 1 in 1,000,000. EPA has made substantial progress on establishing MACT and GACT standards, but has just begun the task of developing risk-based or health-based approaches. The 1990 amendments to the CAA also placed an increased emphasis on toxic air pollutants emitted by mobile sources. In 2007, EPA issued the Mobile Source Air Toxics regulation, which was designed to lower benzene concentrations in gasoline and restrict automotive emissions of benzene and several other toxic substances.

Water Legislation

The two most important federal statutes regulating water pollution are the Clean Water Act (CWA) and the Safe Drinking Water Act (SDWA). The CWA regulates the discharge of pollutants into navigable surface waters and into smaller waterways and wetlands that are hydrologically connected to navigable waters. The SDWA regulates the level of contaminants in public drinking water supplies.

The Clean Water Act

The CWA had its origins in the Federal Water Pollution Control Act Amendments of 1972. The basic structure of the Act was then established, although it was refined and refocused by the Clean Water Act Amendments of 1977 and by the Water Quality Act Amendments of 1987. The CWA regulates the discharge of pollutants to surface waters from point sources, mainly industrial facilities and municipal sewage treatment plants (known under the Act as publicly owned treatment works, or POTWs). The CWA totally prohibits any discharge of a pollutant from a point source to surface waters unless it is done in conformance with the requirements of the Act. Since 1972, the Act has retained as an explicit national goal the elimination of all point-source discharges to surface waters by 1985. Although the no-discharge goal was not met -- and may never be fully attainable (by any date) -- it has helped focus implementation of the Act on gradual, but inexorable, pollution reduction as discharge limits are made more stringent over time.

The centerpiece of this pollution reduction scheme is the National Pollutant Discharge Elimination System (NPDES) permit. In theory, all point sources must have an NPDES permit before discharging pollutants to surface waters, but some (mostly smaller ones) still do not. The NPDES permit, which is issued after public notice and an opportunity for comment, is meant to incorporate all requirements of the Act, including applicable discharge limits. Point sources are subject both to limits based on technology and to limits based on water quality, and to the more stringent of the two when they overlap. The technology-based limits are established by EPA as national standards. To set these standards for industrial dischargers, EPA first divided industry into various categories, and then established effluent limits for each category, based on its assessment of what was technologically and economically feasible for point sources within that category. In addition, as required by the Act, EPA set different standards within each industrial category for (a) conventional pollutants (currently biochemical oxygen demand, fecal coliforms, oil and grease, pH, and total suspended solids); (b) toxic pollutants (now 129 designated chemical compounds); and (c) non-conventional pollutants, such as total phenols.

Recognizing that conventional pollutants usually are amenable to treatment by types of pollution control equipment that have long been used at conventional sewage treatment facilities, standards for conventional pollutants are set according to what can be obtained through the use of the best conventional pollution control technology (BCT), taking into account the reasonableness of the cost. In contrast, standards for toxic and non-conventional pollutants are set according to EPA's determination of the level of pollution reduction that can be achieved by applying the best available technology economically achievable (BAT). Originally, Congress had directed EPA to set health-based standards for toxic pollutants, on a pollutant-by-pollutant basis. However, this directive resulted in only a few standards, mostly for pesticide chemicals. The political difficulty of establishing national health-based standards for toxic chemicals led environmental NGOs, in a suit against EPA to compel regulation, to agree to a schedule for setting technology-based standards for a list of designated toxic pollutants. Congress formally endorsed this approach in 1977 by amending the Act to require EPA to set BAT standards for all of the toxic pollutants on that list.

Under the CWA, EPA is to consider both control and process technologies in setting BAT standards, which are to result in reasonable further progress toward the national goal of eliminating the discharge of all pollutants and are to require "the elimination of discharges of all pollutants [where] such elimination is technologically and economically achievable." An individual discharger may obtain a cost waiver from BAT standards for nonconventional pollutants if it cannot afford to comply, but no cost waiver is available from the standards for toxic pollutants. For new industrial sources within an industry category, EPA is to set standards based on best available demonstrated technology (BADT), which can be more stringent than BAT or BCT because of the greater technological flexibility inherent in the design and construction of a new facility. Although industry-wide costs are to be considered by EPA in establishing BADT standards, no waivers are available to individual applicants once the standards are set.

The CWA also imposes technology-based standards on POTWs, based on the limitations that can be met through the application of secondary sewage treatment technology. In essence, this requires an 85 percent reduction in biochemical oxygen demand and total suspended solids. Since 2000, the Act has also required POTWs to comply with EPA's combined sewer overflow (CSO) policy, which is designed to eventually terminate or substantially minimize the discharge of untreated or partially treated sewage during periods of high rain or snow melt.

In addition, the CWA imposes limitations on discharges by industrial sources into POTWs. Such discharges are known under the Act as indirect discharges (because the pollutants are not

discharged directly to surface waters but rather are discharged indirectly to surface waters through a public sewer system). Limitations on indirect discharges are known under the Act as pretreatment standards, because they have the effect of requiring the indirect discharger to treat its wastewater before discharging it to the POTW for further treatment. EPA has set national technology-based limitations, known as the categorical *pretreatment standards*, on indirect discharges of toxic pollutants by firms in certain industrial categories. The Act also requires the POTW to set such additional pretreatment limits and requirements as are necessary to ensure the integrity of the sewage treatment process and to prevent the indirectly discharged pollutants from passing through the sewer system and causing a violation of the POTWs discharge permit.

For the first 15 to 20 years of the Act's implementation, the primary focus was the establishment and implementation of the technology-based limits, as discussed above. More recently, however, considerably more attention has been given to the Act's system of water quality-based limits, which is equally applicable to industrial sources and POTWs. Since 1972, the CWA has directed states to establish, and periodically revise, ambient (in-stream) water-quality standards for all of the lakes, rivers, streams, bays, and other waterways within their borders, and it has required EPA to set and revise these standards to the extent that a state declines to do so. In addition, the Act has required, since 1977, that NPDES permits include such additional discharge limits beyond the national technology-based limits as may be necessary to meet the ambient water quality standards of the waterway in question.

To help call attention to these water quality requirements, Congress in 1987 added what became known as the "toxic hot spot" provision of the CWA, which directed EPA and the states to (a) identify those bodies of water that were in violation of ambient water quality standards because of toxic pollution, (b) identify those point sources whose discharges of toxic pollutants were contributing to those violations, and (c) develop an individual control strategy for each such source -- which almost always meant a revision of the source's NPDES permit to add or tighten limits on toxic pollutants. Another provision of the Act that has prompted the addition or tightening of water quality-based discharge limits has been the requirement that the states (and, if they decline, the EPA) calculate a total maximum daily load (TMDL) for all waters that are in violation of ambient water quality standards. For any particular body of water, the TMDL for a particular pollutant is the total amount of that pollutant that may be discharged to the water body in a day without violating the relevant ambient water quality standard. When a TMDL is set, it often leads to a tightening of the NPDES permits of those point sources whose discharges are contributing to the particular violation of water quality standards. Although the TMDL requirement has been in the Act since 1972, the states and EPA have been slow to implement it. Over the past 15 years or so, however, as a result of several successful suits by environmental NGOs seeking to compel EPA to set TMDLs in the face of state inaction, the TMDL requirement has received greater attention. As a result, the inclusion of water quality-based limits in NPDES permits has become considerably more commonplace.

The Safe Drinking Water Act

Although some sources of drinking water are also regulated as surface waters under the CWA, the legislation specifically designed to protect the safety of the drinking water delivered to the public from public water systems is the Safe Drinking Water Act (SDWA). Passed in 1974 after a series of well-publicized stories about the number of potential carcinogens in the Mississippi

River water (used as drinking water by the City of New Orleans), the SDWA contains very little that is designed to address sources of drinking-water pollution. Instead, the SDWA directs EPA to set national health-based goals, known as *maximum contaminant level goals* (MCL goals) for various drinking-water contaminants and to set MCLs that are as close to the MCL goals as is technologically and economically feasible. All public water systems, defined as those with at least 15 service connections or that serve at least 25 people, are required to meet the MCLs.

Over the Act's first 8 years, EPA set only 23 federal drinking-water standards. Dissatisfied with the pace of implementation, Congress amended the Act in 1986 to spur EPA into action. It directed EPA to set standards (MCLs and MCL goals) for 83 specified contaminants within 3 years and to set standards for 25 additional contaminants every 3 years thereafter. Ten years later, with scores of MCLs and MCL goals then on the books, Congress scaled back. In a 1996 compromise endorsed by both environmental NGOs and water suppliers, Congress eliminated the requirement for 25 new standards every 3 years. At the same time, it added provisions that effectively ensured both that the standards that had been set would largely be allowed to remain in place and that new standards would be far slower in coming -- and likely would be relatively weaker because of the addition of a cost-benefit requirement.

Since then, the primary focus of the SDWA program has been bringing public water systems throughout the United States into compliance with the existing standards. Although the MCLs are set at a level deemed to be technologically and economically feasible, many water systems have had difficulty affording the cost of meeting, and monitoring for, the MCLs. To attempt to ameliorate the financial burden on municipal water systems, the SDWA has periodically made federal funds available for technology upgrades and infrastructure improvements. The task, however, remains a daunting one. In 2002, EPA estimated that approximately \$151 billion would be needed over the next 20 years to upgrade 55,000 community water systems in the United States.

Regulation of Hazardous Waste

Broadly speaking, the generation, handling, and disposal of hazardous wastes are regulated by the interaction of two federal statutes. The primary federal law regulating hazardous wastes is the Solid Waste Disposal Act. In 1970, Congress amended the Act with the Resource Conservation and Recovery Act (RCRA), and the law has come to be popularly known by that name. RCRA was given regulatory teeth with a set of 1976 amendments under which EPA, in 1980, promulgated regulations establishing a cradle-to-grave system for hazardous wastes that tracks the generation, transportation, and disposal of such wastes and establishes standards for their disposal. Initially, however, EPA's disposal standards were minimal to nonexistent and did little to discourage the landfilling of chemical wastes. This led Congress, in 1984, to pass sweeping amendments to RCRA that (a) established a clear federal policy against the landfilling of hazardous wastes unless they have first been treated to reduce their toxicity, and (b) gave EPA a specific timetable by which it had to either set treatment standards for various categories of waste or totally ban the landfilling of such waste. As a result, EPA has set treatment standards, commonly known as the land disposal restrictions (LDRs), for hundreds of types of hazardous wastes. These standards are based on EPA's assessment of the best demonstrated available technology for treating the waste in question. (See Chapter 10.)

Thus, RCRA directly regulates the handling and disposal of hazardous wastes. And, by establishing a set of requirements that must be followed once hazardous waste is generated, it also indirectly regulates the generation of hazardous wastes. RCRA regulations have increased the cost of disposing of most types of waste 100-fold over the past 25 years. In this way, RCRA has operated as a *de facto* tax on the generation of hazardous waste.

Another law that acts as an indirect check on hazardous waste generation -- and that provides additional incentive to ensure that waste is safely disposed -- is the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, also known as the federal Superfund law). Its two primary foci are (a) the remediation (clean-up) of hazardous waste contamination resulting from imprudent handling and disposal practices of the past, and (b) the recovery of remediation costs from those designated as responsible parties under the Act. CERCLA imposes liability for the costs of remediating a hazardous waste site, both on the owners and operators of the site and on those generators of hazardous waste who sent waste to the site. Because the owners and operators are often business entities that are no longer financially viable, CERCLA liability often falls most heavily on the generators. And CERCLA liability is strict liability, meaning that the exercise of reasonable care by the generator is not a defense. Further, unless the generator can establish a convincing factual basis for distinguishing its waste from all or part of the contamination being remediated, CERCLA liability is joint and several, meaning that each responsible party is potentially liable for the full cost of remediation. As a practical matter, this means that the cost of remediation will be borne by those among the responsible parties who are financially solvent, unless they can prove that the waste they sent to the site did not contribute to the contamination being remediated.

The prudent business entity, then, has a strong financial incentive to take such actions as will minimize the likelihood that it will face CERCLA liability in the future. As the only certain way to avoid such liability is to refrain from generating the waste in the first place, CERCLA does provide a rationale for pollution prevention. In addition, it provides business firms with an incentive to meet -- or perhaps to go beyond -- RCRA regulations in dealing with wastes that they generate.

Nevertheless, much hazardous waste is still generated in the United States. Some hazardous wastes are not adequately treated and not safely disposed, and some hazardous waste contamination is not being adequately addressed (or addressed at all). RCRA and CERCLA both contain what might reasonably be called loopholes and gaps in coverage. Hazardous waste contamination remains an ongoing issue. For example, EPA has not taken an aggressive approach toward "E wastes," the discarded electronic components that have become increasingly common in our computer-dominated society. In addition, the most common treatment methodology incorporated into EPA's RCRA treatment standards is incineration, which has brought with it release of airborne contaminants that has only recently been meaningfully addressed by regulation. There is no question, however, that the United States has made considerable progress since the late 1970s, when disposal of chemical wastes in unlined landfills -- at a cost of about \$15 per ton -- was common practice.

THE CHEMICAL SAFETY PROVISIONS OF THE U.S. CLEAN AIR ACT: OBLIGATIONS IMPOSED BY EPA AND OSHA TO PREVENT THE SUDDEN AND ACCIDENTAL RELEASE OF CHEMICALS

Although the first congressional response to the concern generated by the deadly industrial accident in Bhopal, India, in 1984, was the Emergency Planning and Community Right to Know Act of 1986, the chemical safety provisions of that law are focused almost solely on mitigation -- not on accident prevention. A much greater potential for a direct focus on accident prevention can be found in the 1990 amendments to the Clean Air Act, although that potential has yet to be realized by EPA and OSHA.

As amended in 1990, Section 112 of the Clean Air Act directs the EPA to (a) develop regulations regarding the prevention and detection of accidental chemical releases, and (b) publish a list of at least 100 chemical substances (with associated threshold quantities) to be covered by these regulations. The regulations must include requirements for the development of risk-management plans (RMPs) by facilities using any of the regulated substances in amounts above the relevant threshold. Each of these RMPs must include a hazard assessment, an accident prevention program, and an emergency release program. Similarly, Section 304 of the Clean Air Amendments of 1990 directed OSHA to promulgate a process safety management (PSM) standard under the OSHAct. Section 112(r) of the revised Clean Air Act also imposes a general duty on all owners and operators of stationary sources, regardless of the particular identity or quantity of the chemicals used on site. These parties have a duty to:

• Identify hazards that may result from accidental chemical releases, using appropriate hazard assessment techniques,

• Design and maintain a safe facility, taking the steps necessary to prevent such releases, and

• Minimize the consequences of accidental chemical releases that do occur.

Thus, firms are now under a general duty to anticipate, prevent, and mitigate accidental releases. In defining the nature of this duty, Section 112(r) specifies that it is a general duty in the same manner and to the same extent as that imposed by Section 5 of the OSHAct. Because Section 112(r) specifically ties its general duty obligation to the general duty clause of the OSHAct, case law interpreting the OSHAct provision should be directly relevant. In the 1987 *General Dynamics* case, the District of Columbia Circuit Court of Appeals held that OSHA standards and the general duty obligation are distinct and independent requirements and that compliance with a standard does not discharge an employer's duty to comply with the general duty obligation. Similarly, compliance with other Clean Air Act chemical safety requirements should not relieve a firm's duty to comply with the Act's general duty clause. In addition, the requirement that owners and operators design and maintain a safe facility would seem to extend the obligation into the area of primary prevention, rather than merely hazard control.

The Clean Air Act also requires each state to establish programs to provide small business with technical assistance in addressing chemical safety. These programs could provide information on alternative technologies, process changes, products, and methods of operation that help reduce emissions to air. However, these state mandates are unfunded and may not be uniformly implemented. Where they are established, linkage with state offices of technical assistance, especially those that provide guidance on pollution prevention, could be particularly beneficial.

Finally, the 1990 CAA amendments established the independent Chemical Safety and Hazard Investigation Board (CSHIB). The Board is to investigate the causes of "accidents," conduct research on prevention, and make recommendations for preventive approaches, much as the Air Transportation Safety Board does concerning airplane safety.

In response to its Clean Air Act mandate, OSHA promulgated a workplace PSM standard in 1992, designed to protect employees working in facilities that use highly hazardous chemicals and those working in facilities with more than 10,000 pounds of flammable liquids or gases present in one location. The list of highly hazardous chemicals in the standard includes acutely-toxic, highly-flammable, and reactive substances. The PSM standard requires each employer to:

• Compile safety information (including process flow information) on chemicals and processes used in the workplace,

• Complete a workplace process hazard analysis every 5 years,

• Conduct triennial compliance safety audits, develop and implement written operating procedures,

- Conduct extensive worker training,
- Develop and implement plans to maintain the integrity of process equipment,
- Perform pre-startup reviews for new (and significantly modified) facilities,
- Develop and implement written procedures to manage changes in production methods,
- Establish an emergency action plan, and
- Investigate accidents and near-misses at their facilities.

In 1996, EPA promulgated regulations setting forth requirements for the risk management plans (RMPs) specified in the Clean Air Act. The RMP rule is modeled after the OSHA PSM standard and is estimated to affect about 66,000 facilities. The rule requires a hazard assessment (involving an offsite consequence analysis, including worst-case risk scenarios and compilation of a 5-year accident history), a prevention program to address the hazards identified, and an emergency response program.

In 2002, seeking to achieve more comprehensive control of reactive hazards that could have catastrophic consequences, the Chemical Safety and Hazard Investigation Board urged OSHA to amend its 1992 PSM standard and EPA to amend its 1996 RMP regulation. The Board also asked OSHA to define and record information on reactive chemical incidents that it investigates or is required to investigate. These recommendations have largely been ignored. The Board also expressed concern that the material safety data sheets (MSDSs) issued by OSHA do not adequately identify the reactive potential of chemicals. And although EPA and OSHA signed a memorandum of understanding on the topic in 1996, U.S. General Accounting Office (GAO) report in 2001 called for better coordination on chemical safety among EPA, OSHA, the CSHIB, and other agencies.

In late 2009, legislation was being promoted to require OSHA to prepare or revise MSDSs for the list of chemicals in the PSM standard and to generally strengthen OSHA's approach to chemical safety. Many aspects of chemical safety are not covered by specific workplace standards. Most OSHA standards that apply to chemical safety have their origin in the consensus standards adopted in 1971 under Section 6(a) of the OSHAct, and are therefore very outdated.

However, the general duty obligation of the OSHAct imposes a continuing duty on employers to seek out technological improvements that would improve safety for workers.

POLLUTION PREVENTION AND INHERENTLY SAFER PRODUCTION IN THE UNITED STATES

End-of-pipe control focuses on (a) reducing or collecting the harmful emissions, effluents, or waste from industrial processes, and (b), in the case of workers' exposure, on ventilating the workplace or providing personal protective equipment -- usually without altering inputs, feedstocks, processes, or final products. Early preoccupation with minimizing air and water pollution often shifted the problem to the hazardous waste stream and/or increased workplace exposure, resulting in what is popularly known as a *media shift*. It also often changed the nature of the hazard by increasing the potential for chemical accidents (sudden and unexpected chemical releases, sometimes with accompanying fires and explosions), thus resulting in what is popularly known as a *problem shift*.

Pollution prevention -- what the Europeans call *cleaner production* or *cleaner technology* -- received its first political push in the United States in the mid-1980s with the pursuit of *waste minimization*, an economically-driven movement that grew out of a recognition that often the best way to avoid the rising costs of treatment and disposal of hazardous wastes is simply to generate less waste. Depending on the context and the time period, pollution prevention has also been known as *elimination of pollution at the source, source reduction*, and *toxics use reduction*.

Pollution prevention is not a refined version of pollution control. It involves fundamental changes in production technology: substitution of inputs, redesign and reengineering of processes, and/or reformulation of the final product. It may also require organizational and institutional changes. *Inherent safety*, also known as *primary accident prevention*, is the analogous concept for the prevention of sudden and accidental chemical releases. Inherent safety is a concept similar to -- and often a natural extension of -- pollution prevention. The common thread linking the two concepts is that they both attempt to prevent the possibility of harm, rather than reduce the probability of harm, by eliminating the problem at its source. The changes necessary for pollution prevention are often associated with improvements in eco-efficiency and energy efficiency. In the context of chemical production, they often involve the exploration of alternative synthetic pathways and green chemistry initiatives. The search for, and identification of, alternative production methods may also promote the development and use of inherently safer production technology, although the minimization of accident potential may require a somewhat different -- though not necessarily inconsistent -- set of changes.

The Pollution Prevention Act (PPA) of 1990 encourages both pollution prevention and inherent safety through the rubric of *source reduction* -- any practice which (a) reduces the amount of any hazardous substance, pollutant, or contaminant entering any waste stream or otherwise released into the environment (including fugitive emissions) prior to recycling, treatment, or disposal; and (b) reduces the hazards to public health and the environment associated with the release of such substances, pollutants, or contaminants. Explicitly included within the statutory definition are "equipment or technology modifications, process or procedure modifications, reformulation or redesign of products, substitution of raw materials, and improvements in housekeeping, maintenance, training, or inventory control." Explicitly excluded is any practice that "alters the

physical, chemical, or biological characteristics or the volume of a hazardous substance, pollutant, or contaminant through a process or activity which itself is not integral to and necessary for the production of a product or the providing of a service." Therefore, pollution prevention and primary accident prevention both come within the PPA's definition of source reduction. In contrast, recycling or reuse does not meet this definition unless it is done as part of a closed-loop production process -- as is often done in the metal-finishing industry when metals are recovered at the end of the process and immediately returned to the beginning of the process.

The PPA states, as the national policy, that pollution is to be addressed in a hierarchical fashion. First, "pollution should be prevented or reduced at the source whenever feasible." Second, "pollution that cannot be prevented should be recycled in an environmentally safe manner, whenever feasible." And, third, "disposal or other release into the environment should be employed only as a last resort." EPA established the Office of Pollution Prevention, as required by the PPA, but EPA's overall commitment to implementing the PPA has waned considerably since the early 1990s. Neither the Clinton nor Bush administrations wholeheartedly embraced the potential opportunities for fundamental change that the PPA represents, and EPA's source reduction strategy has largely been allowed to languish.

Nonetheless, many industrial firms have found it in their economic interest to adopt pollution prevention approaches, since they can eliminate the need for waste handling, disposal, and treatment and can save pollution control and abatement costs. However, these incentives may be absent concerning the prevention of chemical accidents, because these events are both rare and not statistically predictable; therefore, rational behavioral changes premised on cost avoidance is largely absent.

THE RIGHT TO KNOW AND INFORMATION-BASED STRATEGIES FOR ENCOURAGING ALTERNATIVE TECHNOLOGY IN THE UNITED STATES

The various media-based environmental laws (regulating waste as well as air and water pollution) incorporate several information-disclosure requirements. For example, under the Clean Air Act and Clean Water Act, pollution sources are required to monitor discharges of pollutants and report the results to EPA or the state. Similarly, those who generate, transfer, treat, store, or dispose of hazardous waste must maintain records of the types and amounts of wastes involved, and must supply these records to the appropriate agency. The existence of adequate and accurate information of this nature is essential to the optimal operation of both the command-and-control (or regulatory) approaches to risk reduction and to market-based approaches. Without such information, neither type of policy can succeed.

Beyond the particular informational requirements attached to the various regulatory regimes, however, there is a class of more-broadly based information-disclosure requirements, popularly known as *right-to-know laws*. In essence, these laws give workers and community residents general statutory rights to (a) be apprised of the substances to which they are -- or may be -- exposed, and (b) to obtain information about the hazardous nature of these substances.

These laws have two risk-reduction goals: (a) to give information to potentially exposed persons that may enable them to take action to avoid or limit such exposure, and (b) to encourage those

who create such exposures -- the manufacturers and users of toxic chemicals -- to take actions to reduce or eliminate these exposures.

Many political and legislative initiatives focusing on the right to know emerged in the United States in the early 1980s, when the direct regulation of toxic substances was being deemphasized by federal agencies. Environment and worker advocates shifted their attention to information as an area of political action because the setting and enforcement of standards regulating toxic substances had slowed significantly.

Workplace information disclosure and reporting requirements began at the state and local level, and in 1983 were added at the federal level, when OSHA promulgated, under the OSHAct, the comprehensive Hazard Communication Standard. These workplace initiatives preceded the more-general community right-to-know requirements that were to come a few years later. Worker right-to-know initiatives greatly influenced the evolution of community right-to-know initiatives. Worker and community right-to-know laws largely focus on scientific information about chemicals: (a) the ingredients of chemical products and the specific composition of pollution in air, water, and waste; (b) the toxicity and safety hazards posed by the related chemicals, materials, and industrial processes; and (c) information related to exposure of various vulnerable groups to harmful substances and processes. The 1976 Toxic Substances Control Act (TSCA) had earlier given statutory authority to EPA to require firms to test the chemicals they produced or imported -- and gave citizens unprecedented access to toxicity and exposure information about industrial chemicals. However, barely had EPA staffed up a bureaucracy to implement TSCA when the Reagan antiregulatory revolution of the 1980s swept government. As a result, the EPA budget for TSCA fell by the wayside. TSCA's informational initiatives have yet to be fully developed.

In 1986, Congress amended the federal Superfund law with the Superfund Amendment and Reauthorization Act of 1986, known as SARA. Beyond strengthening certain provisions governing the clean-up of hazardous waste sites, Congress took, with SARA, a significant step toward reducing the likelihood of new hazardous substance contamination in the future. Title III of SARA created the Emergency Planning and Community Right to Know Act (EPCRA), a comprehensive federal community right-to-know program implemented by the states under guidelines promulgated by EPA. The central feature of EPCRA is broad public dissemination of information concerning the nature and identity of chemicals used at commercial facilities. EPCRA has four major provisions: emergency planning, emergency release notification, hazardous chemical storage reporting, and the Toxic Chemical Release Inventory (TRI) (Table 30-3).

The implementation of EPCRA began with the creation of state and local bodies to implement it. Section 301 required the governor of each state to appoint a state emergency response commission (SERC), to be staffed by "persons who have technical expertise in the emergency response field." In practice, these state commissions have tended to include representatives from the various environmental, public health, and safety agencies in the state. Each state commission, in turn, was required to divide the state into various local emergency planning districts and to appoint a local emergency planning committee (LEPC) for each of these districts. These state and local entities are responsible for receiving, coordinating, maintaining, and providing access to the various types of information required to be disclosed under the Act.

EPCRA established four principal requirements for reporting information about hazardous chemicals. Section 304 requires all facilities that manufacture, process, use, or store certain extremely hazardous substances in excess of certain quantities to provide emergency notification to the SERC and the LEPC of an unexpected release of one of these substances. Section 311 requires facilities covered by the OSHA Hazard Communication Standard to prepare and submit to the LEPC and the local fire department MSDSs for chemicals covered by the OSHA standard. Under Section 312, many of these same firms are required to prepare and submit to the LEPC an emergency and hazardous substance inventory form that describes the amount and location of certain hazardous chemicals on their premises. Section 313 requires firms in the manufacturing sector to report to EPA annually certain routine releases of hazardous substances. The Toxics Release Inventory (TRI) is the EPA database containing these hazardous release reports. In addition, Section 303 requires certain commercial facilities to cooperate with their respective LEPCs in preparing emergency response plans for dealing with major accidents involving hazardous chemicals. The applicability of these provisions to any particular facility depends on the amount of the designated chemicals that it uses or stores during any given year.

In 1990, Congress added two more chemical reporting requirements to federal law. The Pollution Prevention Act amended EPCRA to require firms subject to TRI reporting to annually report their source reduction (pollution-prevention) practices and waste management practices. In addition, the 1990 Clean Air Act Amendments directed EPA and OSHA to issue regulations governing prevention of chemical accidents. Under these regulations, each facility using certain chemicals above specified threshold quantities is required to (a) develop a risk management program to identify, evaluate, and manage chemical safety hazards; (b) submit a risk management plan (RMP) summarizing its program to EPA or the state; and (c) report accidental chemical releases above specified thresholds. In addition, chemical manufacturers and refineries must file start-up, shutdown, and malfunction (SSM) plans with EPA or state air regulators. Some RMP information is available at http://www.epa.gov/enviro. Worst-case chemical accident scenarios -- known as *offsite consequence analyses* (OCAs) -- are now available for reading, but not for copying, in locally designated reading rooms.

Taken as a whole, these requirements constitute a broad federal declaration that firms choosing to rely heavily on hazardous chemicals in their production processes may not treat information regarding their use of those chemicals as their private domain. Except for trade-secrecy protections (relating to specific chemical identity) that generally parallel those available under the OSHA Hazard Communication Standard, there are no statutory restrictions on the disclosure of EPCRA information to the general public.

Beyond such scientific information, however, disseminating (or providing access to) legal and technological information may be even more important for empowering workers and community residents to facilitate a transformation of hazardous industries and their practices. Legal information, in this context, refers to statements (or explanations) of the rights and obligations of producers, employers, consumers, workers, and the general public concerning potential or actual chemical exposures. Technological information includes information regarding (a) monitoring

technologies; (b) options for controlling or minimizing pollution, waste, or chemical accidents; and (c) available substitutes or alternative inputs, products, and processes that may prevent pollution, waste generation, and chemical accidents. Disseminating such technological information tends to have a far greater potential to induce technological change than does simply collecting and disseminating scientific information about chemical risks and exposures. (For an extensive discussion of worker and community right to know, see Ashford and Caldart [2008] in the Further Reading section at the end of this chapter.)

ENVIRONMENTAL LAW IN THE EUROPEAN UNION (EUROPEAN UNION)

Protection of the environment and the workplace are major challenges in Europe as well as in the United States. In the past, the European Community was strongly criticized for putting trade and economic development ahead of environmental and worker health and safety considerations. More recently, however, the European Union (EU), recognizing that sound development cannot be based on the depletion of natural resources, the deterioration of the environmental and labor protections in order to advance environmental and workplace goals. (The EU is also known as the European Community [EC], especially in its directives, regulations, and other legal documents.)

In the early years of the modern environmental era (1970 to 1980), the United States tended to lead the way, with enforceable emission and effluent standards for industry, mandatory environmental impact assessments for federal projects, and the incorporation of both the precautionary principle and the "polluter pays" principle into law. Since the Reagan antiregulatory revolution of the 1980s, support for the precautionary principle has declined in the United States while Europe has incorporated it into its legal framework. (See Ashford and Hall [2010].) Now, EU environmental law has gone beyond the United States in some respects, and contains initiatives not present in U.S. federal law, such as eco-labeling, restrictions on packaging, and mandatory recycling of vehicles and electronic products. The EU has also signed many multilateral environmental agreements that the United States has either not signed or not ratified, such as the Basel Convention on Hazardous Waste, the Convention on Biological Diversity, and the Biosafety Protocol.

The sources of EU law are the EU Treaties, general principles of law, international obligations, and secondary legislation, comprised of regulations, directives, and decisions. Regulations are directly binding in that they do not need to be implemented by the member states to be transformed into national law. In contrast, directives give member states a specified time to transpose them into national law. The EU also adopts non-binding conventions and resolutions. The European Community now negotiates international environmental agreements on behalf of all EU countries.

The Regulation of Air, Water, and Waste

There have been extensive changes in the EU's regulation of air, water, and waste over the past decade. The EU approach to air and water pollution generally parallels, and lags behind, that of the U.S. Clean Air Act, Clean Water Act, and Safe Drinking Water Act. Various directives address air pollution, such as the 2008 Directive on Air Quality and Management. A comprehensive Water Framework Directive replaced seven older directives and now anticipates

the development of water-quality concentration limits and polluter-discharge limitations. EU waste regulation goes beyond that of the United States in some areas, such as its Directive on Waste Electrical and Electronic Equipment (WEEE), which requires the producers of electrical and electronic products to finance the collection, treatment, recovery, and environmentally sound disposal of WEEE from households.

The Prevention of Chemical Accidents

One of the most important and well-known EU directives is the EU Directive on Major Accident Hazards of Certain Industrial Activities -- the Seveso Directive. First implemented in 1982, it requires member states to ensure that all manufacturers prove to a competent authority that (a) major hazards have been identified in their industrial activities; (b) appropriate safety measures, including emergency plans, have been adopted; and (c) information, training, and safety equipment have been provided to onsite employees. A revised version, the Seveso II Directive, came into effect in 1997. Seveso II introduced new concepts, such as *inherent safety*, and extended the scope of the directive to a broader range of installations. The emphasis on inherent safety (the safety analogue to pollution prevention) as the preferred approach places EU practice ahead of the U.S. practice, which continues to emphasize traditional, secondary accident prevention measures. Other updates in Seveso II included the introduction of new requirements for safety management systems, an emphasis on emergency planning and land-use planning, and stronger provisions on inspections performed by member states.

The Integrated Pollution Prevention and Control Directive (IPPC)

The purpose of the European Union's Integrated Pollution Prevention and Control Directive (IPPC), adopted in 1996 and amended four times since, is to provide a high level of environmental protection by *preventing* pollution wherever practicable, and by otherwise reducing (controlling) emissions to air, water, and land from a range of industrial and agricultural sectors and activities. Its implementation is known as the Sevilla Process, named after the EU institution located in Seville, Spain, that establishes the permit conditions.

The IPPC represents a shift in focus in EU environmental law from separate emphases on air pollution, water pollution, and waste -- usually employing "end-of-pipe" or secondary prevention approaches -- to an integrated emphasis on preventing pollution (and sudden and/or accidental releases) at the source. In this way, it parallels the U.S. approach articulated in the 1990 Pollution Prevention Act.

Unlike many of the very general EU Directives, the IPPC places specific restrictions on member states to ensure that individual firms (in the energy industries, the production and processing of metals, the mineral industry, the chemical industry, waste management, livestock farming, and others defined in Annex I of the directiv)comply with operating permits. The basic obligations defined in the permits require each regulated installation to:

• Use the best available pollution-prevention measures and techniques -- those that produce the least waste, use the least hazardous substances, and maximize the recovery and recycling of substances generated;

- Prevent all large-scale pollution;
- Prevent, recycle, or dispose of waste in the least polluting way possible;
- Use energy efficiently;

- Ensure accident prevention and damage limitation; and
- Return sites to their original state when the activity is over.

In addition, each permit must contain several specific provisions, including:

- Emission limit values for polluting substances (with the exception of greenhouse gases if an emissions-trading scheme applies);
- Any required soil, water, and air protection measures;
- Waste management measures;

• Measures to be taken in exceptional circumstances, such as when leaks, malfunctions, or temporary or permanent stoppages occur;

- Minimization of long-distance or transboundary pollution; and
- Monitoring of releases.

Approximately 60,000 installations across the European Union were required to operate with IPPC permits by late 2007. (Because it was acknowledged that the implementation of these new and considerably tougher BAT rules on all existing installations in the European Union could be expensive, the directive granted the covered installations an 11-year transition period counting from the day the directive became effective.) The permits were to be coordinated in addressing together all waste and pollution streams and were to be based on the concept of best available techniques (BAT) for minimizing pollution from various point sources in order to achieve a high level of protection of the environment as a whole. In the European context, BAT can include performance requirements that anticipate innovation, and not simply the levels of control achievable by existing technologies (as is generally implied by the related term best available technology in the U.S.) In many cases, BAT means radical environmental improvements within industries. Sometimes it may be costly for companies to adapt their plants to BAT. Identification of required performance levels achievable by BAT is undertaken by the EU Center in Seville and published in its Best Available Techniques Reference Documents (BREFS). In accordance with the United Nations Aarhus Convention (discussed below), and with appropriate safeguards for commercial and industrial secrecy, this information must be made available to interested parties.

Access to Information and Participatory Rights

The EU has several directives implementing the United Nations Aarhus Convention on Access to Information and Public Participation on Decision Making and Access to Justice in Environmental Matters. The Aarhus Convention enunciates three basic rights:

1. Access to environmental information: The right of everyone to receive environmental information that is held by public authorities. This not only includes information on the state of the environment, but also on environmental policies and measures taken, and on human health and safety indicators related to the state of the environment. Citizens are entitled to obtain this information within 1 month of the request and without having to say why they require it. In addition, public authorities are obliged, under the Convention, to actively disseminate environmental information in their possession.

2. <u>Public participation in environmental decision-making</u>

The right to participate from an early stage in environmental decision-making. Arrangements are to be made by public authorities to enable citizens and environmental organisations to comment on proposals for projects affecting, or plans and programs relating to, the environment. These

comments are to be taken into due account in decision-making, and information on the final decisions and the underlying rationale are to be provided to the public.

3. <u>Access to justice</u>: The right to challenge, in a court of law, public decisions that have been made without respecting the two aforementioned rights, or in violation of environmental law in general.

In the EU, the initial effort to implement the Aarhus Convention came with the issuance of three EU directives, each of which corresponds to one these three rights. First, EU Directive 2003/04/EC calls for the creation of lists and registers of environmentally-relevant information, preferably using electronic databases. EC Regulation 166/2006, which also implements the Aarhus Convention, established the European Pollutant Release and Transfer Register (PRTR), which harmonizes rules under which the member states are to regularly report information on pollutants to the European Union Commission. Not only does the Convention create a right of access (if requested), but it also creates a duty to inform.

The Convention's second right anticipates public participation in decision-making in a timely manner. The Convention "invites the parties to promote public participation in the preparation of environmental policies as well as standards and legislation that may have a significant effect on the environment." The EU took a first step toward the implementation of this participatory ideal with the promulgation of Directive 2003/35/EC

The third right, access to justice -- through access to the courts and to judicial, or at least governmental, review of decision-making, met with considerable initial resistance, because in many European countries with parliamentary governments, regulations and laws are not usually challenged through review in the courts. Eventually, however, the EU adopted this right in Directive 2005/370/EC.

There is an important caveat to this set of directives in the EU, however, as particular member states may choose to limit the extent to which these participatory rights are extended to their citizens. Accordingly, executive branch rule-making may continue to operate behind closed doors, especially in parliamentary systems. Whether the participatory goals of the Aarhus Convention will be realized remains to be seen, and may ultimately depend on citizen and NGO pressure.

Worker Health and Safety

While occupational health and safety standards set by OSHA in the United States are mandatory, the EU employs both mandatory obligations and standards, such as established for carcinogens and mutagens in Parliamentary & Council Directive 2004/37/EC, and "indicative" standards, such the indicative Occupational Exposure Limits (OELs) established in Council Directive 2000/29/EC and Commission Directive 2006/15/EC. The individual member states implement the indicative OELs through their national laws, and have the discretion to, but need not, make them mandatory. The member states may also establish more stringent levels of protection, or may choose to protect workers from hazards not covered by EU initiatives. The EU establishes a hierarchy of measures to be used by employers to reduce the risk from hazardous substances in the workplace. In order of preference, these are:

• Elimination of the need to use the substance (prevention of exposure);

- Substitution with a less-hazardous substance;
- Technical and organizational measures to reduce employee contact with, or the air concentration of, the substance; and

• Aas a last resort, the use of personal protective equipment by employees. While this is similar to the U.S. preference for engineering controls instead of personal protective equipment, the focus on primary prevention and cleaner and inherently safer technology for worker protection has not been a hallmark of U.S. regulation. In the United States, the emphasis on pollution prevention has been primarily in the environmental -- as opposed to occupational -- context.

The REACH Initiative

In an effort to obtain more extensive information on the nature of chemicals used within the EU, and to lay the foundation for regulation of these chemicals, the European Commission issued a regulation in 2006 establishing the REACH (**R**egistration, **E**valuation, and **A**uthorization of **Ch**emicals) system. (See also Chapter 26.) REACH is the European corollary to TSCA, which was passed almost 30 years earlier in the United States. REACH came into force in 2007 and created the European Chemicals Agency (ECHA), which became fully operational 1 year later to administer European chemicals policy. (More information is available at http://echa.europa.eu.)

The main elements of REACH are implementation of uniform procedures (to be in place by 2012) for the registration and evaluation of new and existing chemicals, transfer of responsibility for producing and assessing chemicals data to industry, expansion of the responsibilities of downstream users, and regulation of chemicals through an authorization process. Chemicals of "very high concern" can be placed on the market only by explicit authorization. It is expected that animal testing will be kept to a minimum and that alternative testing methods, such as short-term bioassays and structure-activity relationships, will be used instead.

There are an estimated 30,000 chemicals used on a significant scale in the EU, and the requirements for their registration (to be completed over a period of 11 years) depend on the amount produced annually. Generally, the system is three-tiered. All chemicals produced in amounts from 1 to 10 tons per year may be initially registered upon the submission of only minimal toxicological information. A safety assessment report is necessary for substances produced in quantities over 10 tons per year (estimated to be about 15,000 substances). This report must identify the relevant chemical properties and exposure profiles, and must also identify risk-reduction measures to ensure the safe use of the chemical by the producer through downstream users. In addition, a safety data sheet identifying necessary risk reduction measures must be supplied to, and if necessary modified by, all actors in the supply chain. All substances produced in quantities greater than 100 tons per year (estimated to be about 10,000 substances), and all substances produced in smaller quantities that are suspected of being hazardous (estimated to be about 5,000 substances), will be initially evaluated by the relevant authorities in the member states after registration. ECHA approves evaluations, prioritizes candidates for authorization. and determines whether restrictions or authorization (of use or introduction into commerce) is warranted.

In contrast to the well-defined data requirements for risk assessment, the responsibility for risk management is defined only cursorily and superficially in REACH. Manufacturers and importers

must identify and apply the "appropriate" measures to "adequately control" the risks identified in the chemical safety assessment, and must, where suitable, recommend them in the required safety data sheets.

If this risk management element of REACH is to be meaningful, there must be a clear definition of "adequate control" and sanctions for noncompliance. Currently, the point of reference for "adequate control" appears to be the probable no-effect concentration (PNEC) for the environment and the derived no-effect level (DNEL) for human health. (The DNEL is equivalent to the no observed adverse effect level [NOAEL] in U.S. parlance.) However, the sanctions for exceeding these levels are not clear. In addition, the sanctions for failing to identify risks during the registration process are very limited, and often are insufficient to overcome the producer's incentive to withhold such information.

Chemicals with certain hazardous properties -- known as *substances of very high concern* -- must be separately authorized. These include: (a) substances that can cause cancer or mutations or are toxic to reproduction (the so called CMR-substances); (b) those that are persistent, bioaccumulative, and toxic (PBT), or very persistent and very bio-accumulative (vPvB); and (c) substances, such as endocrine disrupters, that are identified on a case-by-case basis as causing probable serious effects to humans or the environment of an equivalent concern. For any of these substances, the burden of proof shifts from the authorities to the producers, regardless of the amount of the substance produced. An analysis of alternative substances or technologies -- and a substitution plan -- must be provided by the firm seeking suthorization. In general, an authorization of the chemical for certain uses will be issued if the producer is able to prove either that the risks of these uses can be "adequately controlled" or that their socioeconomic benefits exceed their risks. These relatively broadly-worded requirements leave wide discretion to the implementing authorities. In the event that the risk cannot be adequately controlled, an analysis of alternative substances or technologies -- and a substitution plan -- must be provided by the firm seeking authorization to the implementing authorities. In the event that the risk cannot be adequately controlled, an analysis of alternative substances or technologies -- and a substitution plan -- must be provided by the firm seeking authorization.

A FINAL COMMENT

The Barack Obama administration is reversing many of the anti-regulatory initiatives of the George W. Bush administration, and the federal government appears to be recommitting itself to elevating the status of health, safety, and environmental law in the United States. This will doubtless have complementary effects in the European Union and on international environmental accords as well. It may also lead to more coherent and harmonized policies among the industrialized nations.

Acknowledgement

This chapter borrows heavily, with permission, from Nicholas A. Ashford and Charles C. Caldart (2008) "Environmental Protection Laws" in <u>International Encyclopedia of Public Health, First</u> <u>Edition</u>, vol. 2, pp. 390-401, Elsevier; Nicholas A. Ashford and Charles C. Caldart (2008). <u>Environmental Law, Policy, and Economics: Reclaiming the Environmental Agenda</u>, MIT Press; and Nicholas A. Ashford and Ralph P. Hall (2010). <u>Technology, Globalization, and Sustainable</u> <u>Development</u>, Yale University Press, forthcoming.

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An analysis of the differences between pre-regulatory estimates of cost and actual post-regulatory costs of OSHA regulation, focusing on the importance of taking technological change into account.

TABLE 30-1: Selected US AND EU Environmental Initiatives

The United States	The European Union		
The Occupational Safety & Health Act (OSHAct) 1970	Occupational Health Directives		
The Toxic Substances Control Act 1976	The REACH Directive 2003		
The Clean Air Act (CAA) 1970, 1977, 1990	The Air Directives 1996, 2008		
Water Legislation The Clean Water Act (CWA) 1972, 1977, 1987 The Safe Drinking Water Act 1974, 1986, 1996	The Water Directive 2000		
Hazardous Waste The Resource Conservation and Recovery Act (part of the Solid Waste Disposal Act) 1970, 1976, 1984	The Waste Directive 1975 WEEE 1991		
Cleanup of Contaminated Land and Water The Oil Spill Provisions of the CWA 1972 The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) (the "Superfund") 1980, 1986	The Liability Directive 2004		
Pollution Prevention and Inherent Safety The Pollution Prevention Act 1990 Safety additions to the CAA and the OSHAct 1990 (workers) and CERCLA 1986 (the community)	The Integrated Pollution Prevention and Control Directive 1996; The Seveso Directives1982, 1996		
The Safety of Food, Drugs, and Other Consumer Products The Consumer Product Safety Act 1972, 2008 The Federal Hazardous Substances Act 1960, 2008 The Food, Drug, and Cosmetic Act 1938, 1958, 1996	Product, Drug, and Food Safety Directives		
Worker and Community Right-to-Know OSHAct Hazard Communication Standard 1983 Environmental Planning and Community Right to Know Act (EPCRA) 1986	Incorporation of the Aarhus Convention into EU law (2006)		

	Sonar Amptone Am Quanty Standards					
Particulate	(note that PM _{xy} below refers to particles equal or less than xy microns					
Matter:	in diameter)					
PM_{10}	<u>Primary</u> (1970) – 150 μ g/m ³ averaged over 24 hrs, with no more than					
	one expected exceedance per calendar year; also, 50 µg/m'or less for					
	the expected annual arithmetic mean concentration.					
	<u>Secondary</u> – same as primary.					
D) (D^{-1} D^{-1} (1007) (5 ($\frac{3}{2}$) 1 ($\frac{3}{2}$) 1					
$PM_{2.5}$	<u>Prior Primary</u> (1997) - 65 μ g/m [°] averaged over 24 hrs; 15 μ g/m [°] annual					
	$\begin{array}{c} \text{maximum} \\ \text{D} 1 \text{ D} (2000) 25 (3) \\ \text{maximum} 1 \text{ D} 241 \\ \text{maximum} 1 \text{ D} 1 \text{ D}$					
-	<u>Revised Primary (2006) - 35 µg/m³ averaged over 24 hrs</u>					
Ozone	<u>Prior Primary</u> (1979) – 235 μ g/m ³ (0.12 ppm) averaged over 1 hr, no					
	more than one expected exceedance per calendar year (multiple					
	violations in a day count as one violation). Revoked June 2005.					
	Codified August 2005.					
	<u>Prior Secondary</u> – same as primary.					
N 74 .	<u>Revised Primary (1997) – 0.08 ppm averaged over 8 hr.</u>					
Nitrogen	<u>Primary</u> (19/0) – 100 μ g/m ³ (0.053ppm) as an annual arithmetic mean					
Dioxide	concentration					
	<u>Secondary</u> – same as primary.					
Sulfur Oxides	<u>Primary</u> (1970) – 365 μ g/m ³ (0.14 ppm) averaged over 24 hrs, not to be					
	exceeded more than once per year; 80 μ g/m ³ (0.03ppm) annual					
	arithmetic mean.					
	<u>Secondary</u> – 1300 μ g/m ³ averaged over a 3-hr period, not to be					
	exceeded more than once per year.					
Lead	<u>Primary</u> (1977): 1.5 μ g/m ³ arithmetic average over a calendar quarter.					
	Secondary: same as primary.					
	<u>Revised Primary</u> and Secondary (2008): 0.15 μ g/m ⁻ arithmetic average					
	over a calendar quarter.					

Table 50-5. El CNA Chemicais, Reportable Actions, and Reporting Thresholds						
	Section 302	Section 304	Sections 311/312	Section 313 (TRI)		
	Emergency Planning	Unexpected	Chemicals in	Routine		
		Releases	storage	Emissions		
Chemicals	356 extremely	>1,000	500,000 products	650 toxic		
Covered	hazardous substances	substances	with MSDSs*	chemicals and		
			(required under	categories**		
			OSHA regulations)			
Reportable	Threshold Planning	Reportable	TPQ or 500 pounds	25,000 pounds		
Actions	Quantity 1-10,000	quantity, 1-5,000	for Section 302	per year		
and	pounds present on site	pounds, released	chemicals; 10,000	manufactured or		
Thresholds	at any one time	at any time	pounds present on	processed; 10,000		
	requires notification of	within a 24-hour	site at any one time	pounds a year		
	the SERC and LEPC	period;	for other	used; certain		
	w/i 60 days upon on-	reportable to the	chemicals, Copy if	persistent		
	site production or	SERC and NEPC	requested to	bioaccumulative		
	receipt of shipment.		SERC/LEPC;	toxics have lower		
			annual inventory	thresholds; annual		
			Tier I/Tier II report	report to EPA and		
			to	the state by July		
			SERC/LEPC/local	1.		
			fire department by			
			March 1.			

Table 30-3: EPCRA Chemicals, Reportable Actions, and Reporting Thresholds

* MSDSs on hazardous chemicals are maintained by a number of universities and can be accessed through http://www.hazard.com

** The TRI reporting requirement applies to all federal facilities that have 10 or more full-time employees, and those that manufacture (including importing), process, or otherwise use a listed toxic chemical above threshold quantities, and that are in one of the following sectors: Manufacturing (Standard Industrial Classification (SIC) codes 20 through 39), Metal mining (SIC code 10, except for SIC codes 1011,1081, and 1094), Coal mining (SIC code 12, except for 1241 and extraction activities), Electrical utilities that combust coal and/or oil (SIC codes 4911, 4931, and 4939), Resource Conservation and Recovery Act (RCRA), Subtitle C hazardous waste treatment and disposal facilities (SIC code 4953), Chemicals and allied products wholesale distributors (SIC code 5169), Petroleum bulk plants and terminals (SIC code 5171), and Solvent recovery services (SIC code 7389). (Source: The Community Planning and Right-to-Know Act, EPA 550-F-00-004, March 2000.)