CHAPTER 3

Government Regulation

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The manufacturing, processing, and use of chemicals, materials, tools, machinery, and equipment in industrial, construction, mining, and agricultural workplaces are often accompanied by environmental, health, and safety hazards and risks. Occupational and environmental factors cause or exacerbate major diseases of the respiratory, cardiovascular, reproductive, and nervous system and cause systemic poisoning and some cancers and birth defects. Occupational and environmental disease and injury place heavy economic and social burdens on workers, employers, citizens, and taxpayers.

Because voluntary efforts in the unregulated market have not succeeded historically in reducing the incidence of these diseases and injuries, government intervention into the activities of the private sector has been demanded by citizens, consumers, and workers. This intervention takes the form of the regulation of environmental health and safety hazards through standard setting, enforcement, and transfer of information. This chapter addresses the major regulatory systems (or regimes) designed to protect public and worker health from chemicals discharged from sources that pollute the air, water, ground, and workplace. The setting of standards and other legal requirements in these regulatory regimes has occurred over a more than 30-year 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. The concepts of risk assessment, cost–benefit analysis, and technology forcing have evolved—both through the development of case law and through changes in the political environment. Often, changes in one of the regulatory regimes has affected the other regulatory regimes as well.

Several themes run through the discussion of the different regulatory systems: distinctions between performance and design/specification standards*; differences in the extent to which economics or cost are taken into account in the setting and enforcement of standards; and distinctions between interventions that encourage technological innovation and those that encourage diffusion of existing technologies.

Actually, standards (what we will call direct controls*) can be classified in a number of ways. A performance standard is one that specifies a particular outcome—such as a specified emission level above which it is illegal to emit a specified air pollutant—but does not specify how that outcome is to be achieved. A design or specification standard, on the other hand, specifies a particular technology—such as a catalytic converter—that must be used. In either case, the 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. A human health-based standard, for example, might choose to protect only the average member of the population, or it might choose to protect 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. Moreover, some standards might be based on a combination of these factors. Many standards based on technological feasibility, for example, are also based on some concept of economic feasibility. Other requirements that could be considered "standards" include (a) information-based obligations, such as the disclosure of (and retention of, or provision of access to) exposure, toxicity, chemical content, and production data and (b) requirements to conduct testing or screening of chemical products.*

In the United States, toxic substances in the workplace have been regulated primarily through three federal laws: the Mine Safety and Health Act of 1969 (Box 3-1 and Figs. 3-1 and 3-2), the Occupational Safety and Health Act (OSHAct) of 1970, and the Toxic Substances Control Act (TSCA) of 1976. These federal laws have remained essentially unchanged since their passage, although serious attempts at reform have been made from time to time. Since 1990, sudden and accidental releases of chemicals (chemical accidents), which may affect both workers and community residents, are now also regulated under the Clean Air Act.

The OSHAct established the Occupational Safety and Health Administration (OSHA) in the Department of Labor to enforce compliance with

BOX 3-1

Essentials of the Mine Safety and Health Administration

James L. Weeks

The Mine Safety and Health Administration (MSHA) in the U.S. Department of Labor has responsibility for writing and enforcing regulations to protect the health and safety of the approximately 200,000 miners in the United States. These miners work in underground and surface mines that produce coal, metal ore, other nonmetal commodities (such as salt and trona), and in sand, stone, and gravel quarries. Mining is one of the most dangerous industries worldwide and in the United States. There are high rates of fatal and nonfatal traumatic injuries, occupational lung disease (coal workers' pneumoconiosis, silicosis, and lung cancer), and noise-induced hearing loss. Underground miners are also exposed to high concentrations of exhaust from diesel engines.

Historically, federal government intervention in mine safety and health was the responsibility of the U.S. Bureau of Mines in the Department of the Interior. The bureau was organized in 1910 for the purpose of investigating coal mine disasters, and over the next six decades, it acquired increasing authority and responsibility to enter and inspect mines and promote mine safety, but it had limited authority to compel compliance with safety regulations. When Congress passed the Federal Coal Mine Health and Safety Act of 1969, it significantly changed the relationship between the federal government and the mining industry. This act was passed after a widespread miners strike for compensation for black lung and a spectacular and disastrous explosion that caused 78 deaths in a mine in West Virginia. Among other things, the act created an agency to perform epidemiologic research (NIOSH), an agency to continue its engineering research and development to develop safe mining practices (Bureau of Mines, since then absorbed into NIOSH), and a federal program to compensate miners totally disabled by pneumoconiosis.

The 1969 act created the federal black lung program to compensate miners totally disabled by pneumoconiosis. This program has been controversial, in part, because of the many manifestations of disease caused by inhaling coal mine dust. One innovative aspect of the program is that it allowed for decisions about eligibility when etiology was ambiguous by establishing a series of presumptions based on the miner's clinical status and work history. Originally, claims were paid out of the general treasury, but, in 1981, claims were paid by the operator who last employed the miner or, if that operator could not be found, by a disability trust fund to which operators contribute based on their tons of coal produced. The 1969 act also created the Mining Enforcement and Safety Administration (MESA), which enforced the basic structure and function of regulation as described later.

The 1969 act was amended in 1977, with passage of the Mine Safety and Health Act. The 1977 Mine Act moved MESA to the Department of Labor, changed its name to MSHA, preserved the basic structure of the 1969 act, and extended authority beyond coal mining to all other mines and quarries. The 1977 act also required that miners receive 40 hours of training in safety and health when first hired and 8 hours annually thereafter.

MSHA is structurally similar to OSHA but differs in some important ways. Both agencies write and enforce regulations, and disputes are adjudicated by administrative law review commissions with opportunities to appeal decisions to federal district courts.

(continued)

BOX 3-1

***Essentials of the Mine Safety and Health Administration** (Continued)*

The standards-setting language in both acts is practically identical. Regulations covering toxic substances must be based on the best available evidence; must be designed to prevent material impairment of health for all miners, even if exposed for their entire working life; and standards must be feasible. Consequently, for the purpose of establishing regulations covering exposure to hazardous substances, the legal and scientific requirements of MSHA and OSHA are essentially the same.

But MSHA is significantly different from OSHA in its enforcement capabilities. Under MSHA, underground mines must be inspected four times and surface mines must be inspected twice each year. Most OSHA inspections are discretionary. Under MSHA, an inspector may, on his or her own authority, close all or part of a mine in case of imminent danger; the OSHA inspector does not have this authority and must get a court order. All mines are covered under MSHA, without exception; under OSHA, employers with 10 or fewer employees are exempt from general schedule inspection. Mine operators must submit a mine plan and have it approved before it can produce; only with confined spaces must employers under OSHA's jurisdiction obtain a permit and only then under limited conditions. Some numerical comparisons are informative. OSHA has jurisdiction over approximately 100 million workers, and MSHA has jurisdiction over less than 250,000, even though both agencies have approximately the same number of inspectors (including state plans). Thus, the number of inspectors per worker under MSHA is approximately 400 times that under OSHA.

Information about injuries and accidents in mining is more pertinent and more available. Mine-specific data on the number and rates of injuries, hours worked, and (coal) production is reported by mine operators to MSHA every quarter and some of it is available on the Internet. Surveillance data on exposure to dust, crystalline silica, other hazardous materials, and noise is also available from MSHA. Under OSHA, estimates of injury rates are available for SIC (Standard Industrial Classification) categories based on an annual survey of a sample of employers conducted by the Bureau of Labor Statistics. Employer-specific data are not available. Employers must post injury data annually, but they are not required to report it to OSHA. OSHA or workers' representatives may request it from each employer, but it is not available from a single source, as are MSHA's data. The accuracy and reliability of all surveillance data, however, is not guaranteed. Most injury and exposure data are provided by employers and passed on by either MSHA, OSHA, or the Bureau of Labor Statistics with little, if any, validation.

What has this regulatory intervention into the mining industry achieved? Before the passage of the 1969 Coal Mine Act, the fatality rate of U.S. miners was approximately 0.25 fatalities per 100 workers per year, four times that of miners in Western European coal-mining countries. For the first 10 years after the act, it declined each year to a level approximately the same as that in European mines. Since then, it has declined further, so that now, coal mines in the United States are among the safest in the world at an annual fatality rate of approximately 0.03 fatalities per 100 workers (see Fig. 3-2). Even so, the fatality rate in mining remains the highest of any major industrial group in the United States.

Trends in nonfatal injury rates are harder to measure because occurrence of these injuries varies significantly by occupation and among different age and experience cohorts. Trends in age- and experience-specific injury rates are not available. The crude rate of nonfatal injuries in coal mining has declined steadily, but this could be because very few new and inexperienced miners have been hired at the same time that the population of working miners is getting older and more experienced. This change in the age and experience distribution alone could account for the steady decline in the overall injury rate. Mine operators also must report certain accidents that do not cause injury but that signal the existence of hazards that could cause serious injury. These accidents include nonplanned roof falls, inundations with water, fires, and failure of ventilation.

(continued)

BOX 3-1

***Essentials of the Mine Safety and Health Administration** (Continued)*

This regulatory scheme has also significantly reduced miners' exposure to respirable dust and has reduced the prevalence of coal workers' pneumoconiosis (CWP). Respirable coal mine dust was measured at 6 to 8 mg/m^3 before the 1969 act but, for the same job, declined to less than 3 mg/m^3 within 6 months and to approximately 2 mg/m^3 in another year. For continuous mining operators, the level is now regularly below 1 mg/m^3. This progress was achieved in spite of mine operators claiming, in 1969, that it was impossible to reduce exposure to the statutory limit of 2 mg/m^3. Exposure remains high at some mines and with some mining methods, such as longwall mining. Consistent with this reduction in exposure, the experience-adjusted prevalence of CWP has also been reduced since passage of the 1969 and 1977 mine acts. Problems persist, however. Noise exposure remains high, exposure to crystalline silica is also elevated, where it is known, and underground miners are exposed to high levels of diesel exhaust.

MSHA's program of surveillance and control of exposure to respirable dust and its enforcement of dust regulations is part of a more comprehensive effort to prevent the occurrence and progression of CWP. Other aspects of this plan include a federal program to compensate underground coal miners totally disabled by CWP, a prospective study of a cohort of miners, engineering research and development on methods of monitoring and controlling exposure to dust, and a program to allow miners to transfer to less dusty jobs in a mine if they have a positive chest radiograph for CWP. All these facets of the prevention effort are and have been controversial, but nevertheless they contain the essential elements for preventing occupational disease: exposure monitoring, enforcement, disease surveillance, right to transfer, epidemiologic research, and engineering research and development.

In sum, MSHA is an intensive intervention in a dangerous industry and, as such, is a laboratory on a number of issues important to worker health and safety generally. One important lesson from MSHA is that a concerted and multifaceted effort at controlling occupational hazards can succeed at reducing rates of traumatic fatalities and of pneumoconiosis. The important aspects of such an effort include sufficient resources, surveillance, exposure monitoring, worker training, epidemiologic research, and engineering research and development—all of which are supported, in one way or another, by regulatory authority.

the act, the National Institute for Occupational Safety and Health (NIOSH) in the Department of Health and Human Services (under the Centers for Disease Control and Prevention) to perform research and conduct health hazard evaluations, and the independent, quasijudicial Occupational Safety and Health Review Commission to hear employer contests of OSHA citations. The Office of Pollution Prevention and Toxic Substances in the Environmental Protection Agency (EPA) administers TSCA. The Office of Air, Water, and Solid Waste and the Office of Emergency Response in EPA regulate media-based pollution. The Office of Chemical Preparedness and Emergency Response in EPA is responsible for the chemical safety provisions of the Clean Air Act.

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.

STANDARD SETTING AND OBLIGATIONS OF THE EMPLOYER AND THE MANUFACTURER OR USER 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 mandatory job safety and health standards and enforce them effectively, (c) establish "separate but dependent responsibilities and rights" for employers

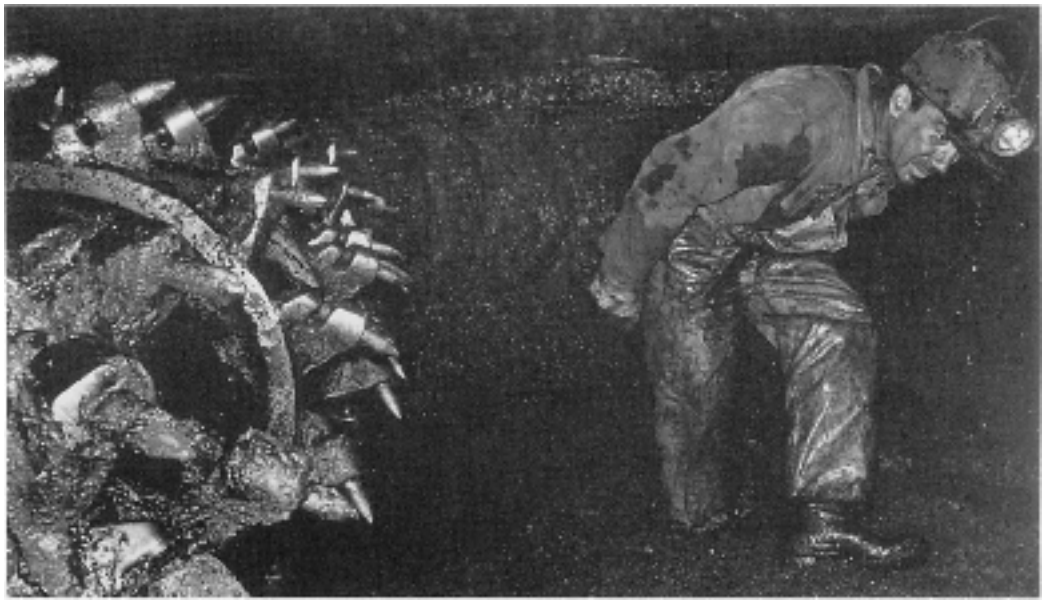

FIGURE 3-1 ● Mine hazards such as the increased dust exposure from continuous mining machines are regulated by the Mine Safety and Health Administration (MSHA). (Photograph by Earl Dotter.)

and employees for the achievement of better safety and health conditions, (d) establish reporting and record-keeping 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.

As a result of these responsibilities, OSHA inspects workplaces for violations of existing health and safety standards; establishes advisory committees; holds hearings; sets new or revised standards for control of specific substances, conditions, or use of equipment; enforces standards by assessing fines or by other legal means; and provides for consultative services for management and for employer and employee training and education. In all

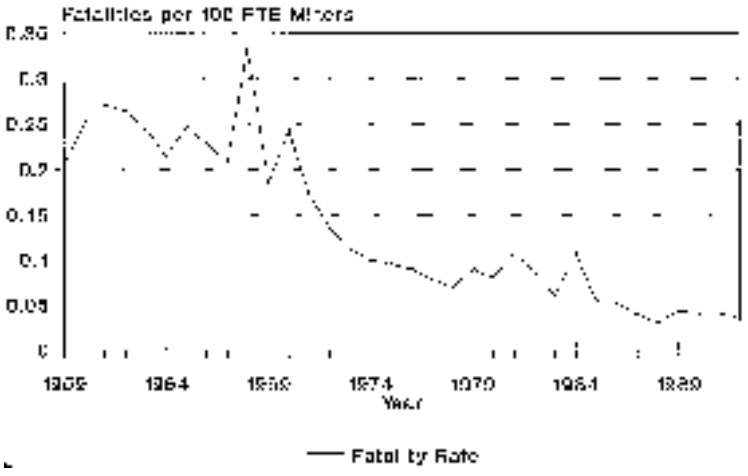

FIGURE 3-2 ● Underground bituminous coal mine fatality rates, 1959 to 1991. FTE, full-time equivalent miners. (From the Mine Safety and Health Administration.)

FIGURE 3-3 ● The Occupational Safety and Health Administration's (OSHA's) positive impact on general industry health and safety in the United States unfortunately does not extend to municipal workers, such as firefighters. (Photograph by Marvin Lewiton.)

of its procedures, from the development of standards through their implementation and enforcement, OSHA guarantees employers and employees the right to be fully informed, to participate actively, and to appeal its decisions (although employees are limited somewhat in the latter activity).

The coverage of the OSHAct initially extended to all employers and their employees, except self-employed people; family-owned and -operated farms; state, county, and municipal workers (Fig. 3-3); 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 petitions from other parties, including 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 which 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 through 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 make application 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.

OSHA requires employers of more than 10 employees to maintain records of occupational injuries and illnesses as they occur. All occupational injuries and diseases must be recorded if they result in death, one or more lost workdays, restriction of work or motion, loss of consciousness, transfer to another job, or medical treatment (other than first aid). Because this self-reported information relies on the employer determining that injuries and illness arose out of their "work-relatedness" at his or her facility, injuries, but especially illnesses, are acknowledged to be underreported.

Key OSHA Standards and Decisions

The OSHAct provides two general means of protection for workers: (a) a statutory general duty

to provide a safe and healthful workplace, and (b) adherence to specific standards by employers. 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. . . ." (emphasis added). A recognized hazard may be a substance for which the likelihood of harm has been the subject of research, giving rise to reasonable suspicion, or a substance for which an OSHA standard may or may not have been promulgated. The burden of proving that a particular substance is a recognized hazard and that industrial exposure to it results in a significant degree of exposure is placed on OSHA. Because standard setting is a slow process, protection of workers through the employer's general duty obligation could be especially important, but it is crucially dependent on the existence of reliable health effects data, as well as on the willingness of a particular OSHA administration to use this as a vehicle for protection.

The OSHAct addresses specifically the subject of toxic materials. It states, under Section 6(b)(5) of the act, 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" (emphases added). These words indicate that the issue of exposure to toxic chemicals or carcinogens that have long latency periods, as well as to reproductive hazards, is covered by the act in specific terms.

In 1971, under Section 6(a) of the act, allowing for their adoption without critical review, OSHA initially adopted as standards the so-called *permissible exposure limits* (PELs): the 450 threshold limit values (TLVs) recommended by the American Conference of Governmental Industrial Hygienists (ACGIH) as guidelines for protection against the toxic effects of these materials. In the 1970s, under Section 6(b), OSHA set formal standards for asbestos, vinyl chloride, arsenic, dibromochloropropane, coke oven emissions, acrylonitrile, lead, cotton dust, and a group of 14 carcinogens. In the 1980s, OSHA regulated benzene, ethylene oxide, and formaldehyde as carcinogens and regulated asbestos more rigidly as a carcinogen at 0.2 fibers/cm^3. In the early 1990s, OSHA regulated cadmium, bloodborne pathogens, glycol ethers, and confined spaces. OSHA also lowered the PEL for formaldehyde from 1 to 0.75 parts per million (ppm; averaged over an 8-hour period) and issued a *process safety management* (PSM) rule (see later discussion). More recent rule-making activity by OSHA is discussed later in this chapter.

The burden of proving the hazardous nature of a substance is placed on OSHA, as is the requirement that the proposed controls are technologically feasible. The necessarily slow and arduous task of setting standards, substance by substance, makes it impossible to deal realistically with 13,000 toxic substances or approximately 250 suspect carcinogens on NIOSH lists. Efforts were made to streamline the process by (a) proposing generic standards for carcinogens and (b) proposing a generic standard updating the TLVs (PELs). As discussed later, neither of these efforts was successful.

The inadequacy of the 450 TLVs adopted under Section 6(a) of the act is widely known. The TLVs originated as guidelines recommended by the ACGIH to protect the *average* worker from either recognized acute effects or easily recognized chronic effects. The standards were based on animal toxicity data or the limited epidemiologic evidence available at the time (1969) of the establishment of the TLVs. They do not address sensitive populations within the workforce or those with prior exposure or existing disease, nor do they address the issues of carcinogenicity, mutagenicity, and teratogenicity. These standards were adopted en masse in 1971 as a part of the consensus standards that OSHA adopted along with those dealing primarily with safety.

As an example of the inadequacy of protection offered by the TLVs, the 1971 TLV for vinyl chloride was set at 250 ppm, whereas the later protective standard (see later) recommended no greater exposure than 1 ppm (as an average over 8 hours)—a level still recognized as unsafe, but the limit that the technology could detect. Another example is the TLV for lead, which was established at 200 μg/m^3, whereas the later lead standard was established at 50 μg/m^3, also recognizing that that level was not safe for all populations, such as pregnant women or those with prior lead exposure. In 1997, OSHA promulgated a new PEL for methylene chloride of 25 ppm, replacing the prior TLV of 500 ppm. The ACGIH updates its TLV list every 2 years. Although

useful, an updated list would have little legal significance unless formally adopted by OSHA. OSHA did try, unsuccessfully, to adopt an updated and new list of PELs in its Air Contaminants Standard in 1989 (see later discussion). However, OSHA continues to maintain that it is intent on revising the list. The fact that the official OSHA TLVs are more than 30 years out of date compared with industry's own "voluntary" consensus standards is not welcomed, especially by the more modern firms in industry.

Under Section 6(b) of the OSHAct, new health standards dealing with toxic substances were to be established using the mechanism of an open hearing and subject to review by the U.S. Circuit Courts of Appeals. The evolution of case law associated with the handful of standards that OSHA promulgated through this section of the OSHAct is worth considering in detail. The courts addressed the difficult issue of what is adequate scientific information necessary to sustain the requirement that the standards be supported by "substantial evidence on the record as a whole." The cases also addressed the extent to which economic factors were permitted or required to be considered in the setting of the standards, the meaning of "feasibility," OSHA's technology-forcing authority, the question of whether a cost–benefit analysis was required or permitted, and, finally, the extent of the jurisdiction of OSHAct in addressing different degrees of risk.

The 14 Carcinogens Standard

In an early case challenging OSHA's authority to regulate 14 carcinogens, the District of Columbia Circuit Court of Appeals first addressed the issue of substantial evidence. For 8 of the 14 carcinogens, there were no human (epidemiologic) data. Industry challenged OSHA's ability to impose controls on employers in the absence of human data. Here the court expressed its view that some facts, such as the establishment of human carcinogenic risk from animal data, were on the "frontiers of scientific knowledge" and that the requirement for standards to be supported by substantial evidence in these kinds of social policy decisions could not be subjected to the rigors of other kinds of factual determinations. Thus, OSHA was permitted to require protective action against substances known to produce cancer in animals but with no evidence of producing cancer in humans. It was not until 1980 that the U.S. Supreme Court in the benzene case (see later) placed limits on the extent of OSHA's policy determination on carcinogenic risk.

The Asbestos Standard

In the challenge to OSHA's original asbestos standard, in which asbestos was regulated as a classic lung toxin and not as a carcinogen, the Industrial Union Department of the American Federation of Labor and Congress of Industrial Organizations (AFL-CIO) unsuccessfully challenged the laxity of the standard, claiming that OSHA improperly weighed economic considerations in its determination of feasibility. OSHA indeed was permitted to consider economic factors in establishing feasibility. The District of Columbia Circuit Court of Appeals went on to state, however, that a standard might be feasible even if some employers were forced out of business, as long as the entire asbestos-using industry was not disrupted. In 1986, OSHA revised the standard from 2.0 to 0.2 fibers/cm^3, thus finally acknowledging asbestos as a carcinogen.

The Vinyl Chloride Standard

In the industry challenge to OSHA's regulation of vinyl chloride at 1 ppm, the Second Circuit Court of Appeals reiterated OSHA's ability to make policy judgments with regard to matters "on the frontiers of scientific knowledge" when it declared that there could be no safe level for a carcinogen. In addition, the court said that because 1 ppm was the lowest feasible (here meaning, lowest detectable) level, OSHA was permitted to force employers to comply even though it had performed no formal risk assessment or knew how many tumors would be prevented by the adoption of this protective level. Another noteworthy aspect of the case was the recognition that OSHA could act as a *technology forcer* and require controls not yet fully developed at the time of the setting of the standard.

The Lead Standard

Protection from lead exposure had been provided through the TLV of 200 μg/m^3. This level was long recognized as inadequate for workers who accumulated lead in their body tissues and for women (and possibly men) who intended to have children. As a result, based on the limits of technological feasibility, OSHA promulgated a new standard that permitted no exposure greater than 50 μg/m^3 averaged over an 8-hour period. In addition, because this was still unsafe for many workers, OSHA also provided that workers be removed with pay and employment security if their blood lead levels (BLLs) exceeded 50 μg/dL or if there were grounds to remove them based on risks to their

reproductive system. The legality and necessity of this additional provision, known as *Medical Removal Protection* (MRP), was unsuccessfully challenged by the Lead Industries Association. OSHA specifically provided that workers in workplaces with air lead levels over an "action level" of 30 μg/m^3 have the benefit of a continuing medical surveillance program, including periodic sampling of BLLs and removal from exposure above the action level after finding a BLL in an individual worker above 50 μg/dL, with job return when the worker's BLL fell below 40 μg/dL.

Removal could also be triggered by other medical conditions deemed especially sensitive to risks associated with lead exposure, such as pregnancy. OSHA provided that workers' pay and seniority be maintained by the employer during any periods of medical removal (up to 18 months), even if such removal entailed sending the worker home. In actual practice, many employers have reduced the ambient air lead level well below 50 μg/m^3, which results in the removal of fewer workers. (In the 1980s, MRP was required in a limited way in the cotton dust and benzene standards. In 1998, medical removal requirements were added to the methylene chloride standard.)

The Benzene Standard

After the first serious successful industry challenge of an OSHA benzene standard in the Fifth Circuit Court of Appeals, the U.S. Supreme Court, in a controversial and divided majority opinion, chided OSHA for not attempting to evaluate the benefits of changing the PEL for benzene from 10 ppm (the former TLV) to 1 ppm. The Court argued that OSHA is obligated to regulate only "significant risks" and that without a risk assessment of some kind, OSHA could not know whether the proposed control addressed a significant risk. The Court was careful to state that it was not attempting to "statistically straitjacket" the agency, but that at a minimum the benefits of regulation needed to be addressed to meet the substantial evidence test. The Court did not give useful guidance concerning what constituted a significant risk. It stated that a risk of death of 1 in 1,000 was clearly significant, whereas a risk of 1 in 1 billion was clearly not so. This six-orders-of-magnitude range, of course, represents the area on which the political arguments have always been centered. The implications of the benzene decision for subsequent standards would come to reflect the political and philosophical leanings of future OSHA administrations. Unfortunately, worker protection has since gravitated to the largest permissible exposure, approximating 1 in 1,000 lifetime risk of cancer, to be contrasted with some public health protections under the Clean Air Act of 1 in 1,000,000.

There is little question that had OSHA submitted a risk assessment for benzene at the time, it could have argued that the risk it was attempting to address was actually significant. The precise requirement and nature of a risk assessment sufficient to meet the substantial evidence test remains unclear. In late 1985, OSHA again proposed to lower the PEL from 10 to 1 ppm, and, in 1987, the standard was set at that level. OSHA, however, after intervention by the Office of Management and Budget, declined to establish a short-term exposure limit.

The petroleum industry argued in the benzene case that not only must a risk assessment be performed, but a cost–benefit analysis must be done in which the risks of exposure are balanced against the benefits of the chemical. The question, however, was not decided in the benzene case but was addressed in a later case challenging OSHA's cotton dust standard. The Supreme Court not only acknowledged that cotton dust did represent a significant risk but also indicated that a cost–benefit balancing was neither required nor permitted by the OSHAct because Congress had already struck the balance heavily in favor of worker health and safety.

The Generic Carcinogen Standard

In 1980, OSHA promulgated a generic carcinogen standard by which questions of science policy, already settled as law in cases dealing with other standards, were codified in a set of principles. During the process of developing the generic carcinogen standard, OSHA and NIOSH developed lists of chemical substances that would probably be classified as suspect carcinogens. Each agency composed a list of approximately 250 substances. After revising the generic standard to reflect the need to determine if a particular carcinogenic risk was *significant*—as required by the U.S. Supreme Court in the benzene decision—OSHA declined to formally list any substance under the carcinogen standard. In setting or revising standards for formaldehyde, ethylene oxide, asbestos, and benzene, OSHA has proceeded to act as if the generic carcinogen standard did not exist, thus following the historically arduous and slow path to standard-setting.

Emergency Temporary Standards

In Section 6(c), the OSHAct authorizes OSHA to set, on publication in the *Federal Register* and without recourse to a formal hearing; *emergency temporary* (6-month) *standards* (ETSs) for toxic exposures constituting a "grave danger." Before OSHA lowered its permanent standard for asbestos from 2.0 to 0.2 fibers/cm^3, it attempted to protect workers by promulgating an ETS at 0.5 fibers/cm^3. In 1984, the Fifth Circuit Court of Appeals denied OSHA the ETS, arguing that the cost involved defeated the requirement that the ETS be "necessary" to protect workers. Attempts by OSHA to establish an ETS for hexavalent chromium likewise failed court review.

OSHA has issued nine emergency temporary standards under the OSHAct. Standards for vinyl chloride, dibromo-3-chloropropane (DBCP), and the first ETS on asbestos were not challenged in court and remained in effect until superseded by permanent standards. An ETS for acrylonitrile survived court challenge. ETSs on benzene, commercial diving, pesticides, 14 carcinogens, and asbestos were stayed or vacated by the courts.

Over the past decade, OSHA has avoided setting ETSs and instead has proceeded directly—but slowly—to establishing permanent standards for toxic substances under Section 6(b)(5). Thus, OSHA denied a 1993 request from Public Citizen for a temporary emergency hexavalent chromium standard but promised an advanced notice of rule making for 1995. After a successful court challenge, in October 2004, 9 years after OSHA's promised action, it finally issued a proposed revision of its 8-hour exposure limit, lowering the standard to 1 μg/m^3 from the previous 33-year-old standard of 52 μg/m^3, thus preventing 350 excess cancers annually. A 2001 petition requesting an ETS for beryllium was unsuccessful. However, OSHA is currently planning for a permanent standard.

Short-Term Exposure Limits

Short-term exposures to higher levels of carcinogens are in general considered more hazardous than longer exposures to lower levels. OSHA issued a new standard for exposure to ethylene oxide in 1984 but excluded a *short-term exposure limit* (STEL) that had originally been prepared, in deference to objections from the Office of Management and Budget. Ralph Nader's Health Research Group sued the Secretary of Labor in 1986 over OSHA's continuing failure to issue the STEL. In 1987, the District of Columbia Circuit Court of Appeals ordered OSHA to establish a STEL for ethylene oxide by March 1988. OSHA complied by setting a STEL of 5 ppm over a 15-minute period.

The Air Contaminants Standard

It is obvious that the slow, arduous process of promulgating individual health standards under Section 6(b)(5) of the OSHAct could never catch up with advances in scientific knowledge concerning the toxicity of chemicals. The ACGIH has updated its TLV list every 2 years, and although not as protective as workers and their unions would have liked, the recent updated lists did advance protection over the 1969 list that OSHA adopted into law in 1971. In 1989, OSHA decided to update the original list in a single rule-making effort through the 6(b) standard revision route. The agency issued more protective limits for 212 substances and established limits for 164 chemicals that were previously unregulated. Neither industry nor labor was satisfied with the standards. Industry, although giving general support, objected to the stringency of some of the PELs. Labor objected to their laxity, citing NIOSH recommendations not adopted, and generally objected to the rush-it-through process.

The Eleventh Circuit Court of Appeals vacated the standard in 1992, ruling that OSHA failed to establish that a significant risk of material health impairment existed for each regulated substance (required by the benzene decision) and that the new exposure limit for each substance was feasible for the affected industry. OSHA decided not to appeal the decision to what it perceived as a conservative Supreme Court. Thus, the original and inadequate TLV list remains in effect, and 164 new substances remain unregulated. OSHA periodically expresses its intent on updating the list through new rule making, but no new action has been forthcoming.

In the meantime, OSHA could argue that those 164 substances are "recognized hazards" and enforceable through OSHA's general duty clause, but OSHA administrations have not been willing to emphasize this approach in the case of the TLVs, although OSHA has used the general duty obligation to force compliance with good ergonomic practices in nursing homes. In 20 years, OSHA has issued only about a dozen general duty citations for substances covered by the original TLV list. Recently, OSHA's reluctance to use the general duty obligation in the case of the outdated TLVs was in part due to the many congressional attempts to pass legislation prohibiting such use.

The Toxic Substances Control Act

TSCA enables 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, or of existing chemicals put to a significant new use, to file a premarket notification with EPA. EPA may regulate chemicals under TSCA—by requiring labeling, setting tolerances, or banning completely and requiring repurchase or recall—where the chemicals present "an unreasonable risk of injury to human health or the environment." EPA may also order a specific change in chemical process technology. In addition, TSCA gives aggrieved parties, including consumers and workers, specific rights to sue to enforce under the act, with the possibility of awards for attorneys' fees. (This feature was missing in the OSHAct.)

Under TSCA, EPA must regulate "unreasonable risks of injury to human health or the environment." EPA has issued a regulation for worker protection from asbestos at the new OSHA limit of 0.2 fibers/cm^3, which applies to state and local government asbestos abatement workers not covered by OSHA. Although the potential for regulating workplace chemicals is there, EPA has not been aggressive in this area. Between 1977 and 1990, of the 22 regulatory actions taken on existing chemicals, 15 addressed polychlorinated biphenyls (PCBs), which EPA has a specific statutory directive to address under TSCA. Only regulations pertaining to asbestos, hexavalent chromium, and metalworking fluids had a strong occupational exposure component. Although EPA declared formaldehyde a "probable carcinogen" and the International Agency for Research on Cancer classified it as a confirmed human carcinogen, EPA chose not to take regulatory action on this substance, opting instead to defer to OSHA workplace regulations.

Used together, the OSHAct and TSCA 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 have a substance qualify as a *recognized hazard* that, even in the absence of specific OSHA standards, must be controlled in some way by the employer to meet the general duty obligation under the OSHAct to provide a safe and healthful workplace.

The potentially powerful role of TSCA regulation was seriously challenged by the Fifth Circuit Court of Appeals in 1991, when it overturned the omnibus asbestos phase-out rule that EPA had issued in 1989. The court held that, under TSCA, EPA should not have issued a ban without having first considered alternatives that would have been less burdensome to industry. This would require the agency to perform a more comprehensive, detailed, and resource-intensive analysis. Rightly or wrongly, EPA has viewed this case (which was not appealed to the U.S. Supreme Court) as a significant impediment to future TSCA regulations, and the agency generally regards regulation of chemicals other than PCBs under TSCA to be a dead letter for now. With an unsympathetic Congress, there are no successful attempts to resurrect the regulatory authority of TSCA. However, TSCA continues to be important for its surviving authority to require the testing of chemicals and for its information reporting and retaining requirements (see the discussion later in this chapter on the *right to know*).

Control of Gradual Pollution in Air, Water, and Waste

The Clean Air Act

The modern Clean Air Act (CAA) came into being in 1970, and although significant changes were made in 1977 and 1990, the basic structure of the act has remained the same, with the addition of provisions for authority over acid rain, chlorofluorocarbons (CFCs), indoor air, and chemical safety. (The last of these is discussed later in this chapter.) The CAA regulates both stationary and mobile sources of pollution, taking into account the relative contributions of each to specific air pollution problems—and the relative capacity of different kinds of sources within each category to reduce their emissions. The recognition that sources using newer technology might be able to achieve greater emission reductions than older sources with older technology led to the act's distinction—both in the stationary and mobile source provisions—between new and existing sources. Although driven by equity considerations regarding the relative financial and technical burdens of pollution reduction, however, this approach unwittingly discouraged modernization or replacement of facilities and resulted in the operation of older (especially energy) facilities beyond their expected useful life. For new sources within each industrial sector, there was a recognition of the need for uniformity and also for encouraging technological innovation

through technology-forcing inherent in stringent standards.* (See Chapter 17.)

The 1970 CAA directed EPA to establish primary ambient air quality standards that would protect public health with "an adequate margin of safety." [see §109(b)(1)] As interpreted by the courts and supported by congressional history, these standards were to be established without consideration of economic or technological feasibility. In addition, secondary ambient air quality standards were to be established to protect "the public welfare"..."within a reasonable time" [see §109(b)(2)].

Both federal and state government were to be involved in protecting the ambient air. Ambient air quality (concentration) standards were to be established by the federal government, and these were 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) [§110]; (b) emission limitations for new sources, established not by the states but rather by EPA as *New Source Performance Standards* [§111]; and (c) by a combination of federal and state restrictions on mobile sources. In specifying compliance with federal emission standards, Congress expressed concern with possible *hot spots* of localized intense pollution and also with intermittent versus continuous versus sudden and accidental releases of harmful substances. Emission standards, in contrast with ambient concentration standards, are expressed as an emissions rate (mg emitted per 100 kg of product, per hour, per day, per week, per quarter, per year, per BTU, per passenger mile, or other unit of measurement).

The 1970 CAA also made a distinction between the federal control of criteria pollutants through ambient air standards and the control of *hazardous air pollutants* by means of federal emission limitations. Hazardous air pollutants were those recognized as extraordinarily toxic and eventually regarded as non- or low-threshold pollutants. Initially, these were to be regulated to protect public health with "an ample margin of safety" [§112] and, as with the standards for primary ambient air pollutants, standards 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. Because of their extraordinary toxicity, hot spots were to be avoided, and because ambient concentration air quality standards were considered impractical and of little relevance for sporadic and idiosyncratic sources, uniform federal emission standards were considered necessary. (Note, however, that California did establish an ambient standard complement to the federal emission limitation on vinyl chloride.)

In the early stages of the implementation of the stationary source provisions of the Clean Air Act (approximately 1970–1975), EPA focused on (a) the primary and secondary ambient air quality standards and (b) emission standards for both new sources of criteria pollutants and for all sources emitting seven regulated hazardous air pollutants (discussed below). Prior advisory standards for carbon monoxide (CO), sulfur dioxide (SO_2), oxides of nitrogen (NO_X), large particulate matter, and photochemical oxidants were made mandatory. In February 1979, the standard for photochemical oxidants was narrowed to cover only ground-level ozone, and the standard was relaxed from 0.08 ppm to 0.12 ppm averaged over a 1-hour period. The standard for particulate matter (PM_{10})—"inhalable" particulates up to 10 μm in diameter—was adopted in 1987. In July 1997, the ozone standard was further revised to 0.08 ppm. At the same time, the particulate standard was altered to place more stringent requirements on smaller (<2.5 μm) "respirable" particles ($PM_{2.5}$). A standard for a new criteria pollutant—airborne lead—was promulgated in October 1978. Current primary air quality standards set under Section 109 are found in Table 3-1.

In Section 112, Congress directed the administrator to set emission standards for hazardous air pollutants at a level that protects public health "with an ample margin of safety." It is likely that this phraseology reflected an early assumption that, though very dangerous, hazardous pollutants did exhibit a finite threshold (a nonzero level of exposure below which no harm would occur). As the 1970s progressed, however, there was a growing recognition that this assumption might be wrong, and that for many hazardous pollutants there was no level of exposure (at least at levels within the limits of detection) below which one could confidently predict that no harmful or irreversible effects (especially cancer or birth defects) would occur.

* *The court decisions recognizing EPA's technology-forcing authority were greatly influenced by OSHA's early technology-forcing approach to worker protection.*

TABLE 3-1

National Ambient Air Quality Standards

Carbon monoxide	Primary: 35 ppm averaged over 1 hour and 9.0 averaged over 8 hours; neither to be exceeded more than once per year. Secondary: none.
Particulate matter:	(Note that PM_{xy} below refers to particles equal to or less than xy μm in diameter.)
PM_{10}	Primary: 150 $\mu g/m^3$ averaged over 24 hours, with no more than one expected exceedance per calendar year; also, 50 $\mu g/m^3$ or less for the expected annual arithmetic mean concentration. Secondary: same as primary.
$PM_{2.5}$	Additional primary: 65 $\mu g/m^3$ averaged over 24 hours; 15 $\mu g/m^3$ annual maximum.
Ozone	Prior primary: 235 $\mu g/m^3$ (0.12 ppm) averaged over 1 hour, no more than one expected exceedance per calendar year (multiple violations in a day count as one violation). Prior secondary: same as primary. Revised (current) primary: 0.08 ppm averaged over 8 hours.
Nitrogen dioxide	Primary: 100 $\mu g/m^3$ (0.053 ppm) as an annual arithmetic mean concentration. Secondary: same as primary.
Sulfur oxides	Primary: 365 $\mu g/m^3$ (0.14 ppm) averaged over 24 hours, not to be exceeded more than. once per year; 80 $\mu g/m^3$ (0.03 ppm) annual arithmetic mean. Secondary: 1,300 $\mu g/m^3$ averaged over a 3-hour period, not to be exceeded morethan once per year.
Lead	Primary: 1.5 $\mu g/m^3$ arithmetic average over a calendar quarter. Secondary: same as primary.

This presented an implementation challenge for EPA. Arguably, given its mandate to protect public health "with an ample margin of safety," the agency was required to ban the emission of several hazardous substances. This would, as a practical matter, essentially ban the use of these substances in many industries. Seeking to avoid this result, EPA adopted a policy of setting Section 112 emission standards at the level that could be achieved by technologically feasible technology.* Using this approach, EPA set finite (nonzero) 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, the environmental groups may well have been content to allow the implementation of Section 112 to proceed in this fashion. When the setting of new Section 112 standards all but stalled during the Reagan administration, however, the NRDC was determined to press the issue in court.

NRDC *v.* EPA, decided by the District of Columbia Circuit Court of Appeals, placed new limitations on EPA's approach to regulating hazardous air pollutants by requiring the EPA to determine an "acceptable" (nonzero) risk level prior to setting a hazardous air pollutant standard. In reaction to this case and to revitalize the moribund standard-setting process, Congress amended Section 112 in 1990 to use a two-tiered approach: the use of technology-based standards initially, with residual risks to be addressed (at a later date) by health-based standards. In the 1990 CAA amendments, Congress listed 189 other substances for

** This is the approach then followed by OSHA in setting standards for exposure to workplace chemicals. In the case of carcinogens, OSHA considered no levels to be safe and established control requirements at the limit of technological feasibility.*

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which *Maximum Achievable Control Technology* (MACT) technology-based standards were to be set over 10 years for major sources (defined as those emitting more than 10 tons per year of any single toxin or more than 25 tons combined). EPA was further mandated to issue a new rule, "where appropriate," adding pollutants "which 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." In addition, for nonmajor (that is, so-called area) sources, restrictions may be less—*Generally Achievable Control Technology* (GACT) or management practices. More stringent requirements are allowed for all new sources. Emission standards established under MACT must require "the maximum 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." For pollutants with a health threshold, EPA could alternatively consider regulating an ample margin of safety in establishing emission levels—essentially the original mandate of the 1970 CAA. Finally, EPA was obligated to issue a report on risk, which it did 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 an ample margin of safety—in general—and, specifically for carcinogens, protect against lifetime risks of one-in-a-million or more. EPA did make substantial progress on establishing MACT and GACT standards but has just begun working on risk- or health-based approaches.

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), and the SDWA regulates the level of contaminants in public drinking-water supplies. (See Chapter 19.)

The Clean Water Act

The modern Clean Water act has its origins in the Federal Water Pollution Control Act Amendments of 1972. The basic structure of the act was established at that time, although it was refined and refocused by the Clean Water Act Amendments of 1977 (from which it also took its name) and by the Water Quality Act Amendments of 1987. The regulatory focus of the CWA is the discharge of pollutants to surface waters from "point sources," principally industrial facilities and municipal sewage treatment plants (known under the act as *publicly owned treatment works*, or POTWs). The CWA flatly 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, and the statute has since 1972 retained as an explicit "national goal" the elimination of all point—source discharges to surface waters by 1985. Although the "no discharge" goal may never be attainable in practical terms, it has helped focus the act's implementation 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. In practice, however, many dischargers (mostly smaller ones) still do not. The NPDES permit, which is issued after public notice and an opportunity for comment, is to incorporate all of the various requirements of the act—including discharge limits—that are applicable to the point source in question. Point sources are subjected both to technology-based and water quality-based limits 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 industry categories and then established effluent limits for each category based on its assessment of what was technologically and economically feasible for the point sources within that category. Further, as required by the act, EPA set different standards within each industrial category for conventional pollutants (biochemical oxygen demand, fecal coliform, oil and grease, pH, and

total suspended solids), toxic pollutants (currently a list of 129 designated chemical compounds), and nonconventional pollutants (which simply are other pollutants, such as total phenols, which are listed neither under the conventional nor the toxic designation).

In recognition of the fact that conventional pollutants usually are amenable to treatment by the types of pollution control equipment that has long been in use at conventional sewage treatment facilities, the 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. The standards for toxic and nonconventional pollutants, on the other hand, are set according to EPA's determination of the level of pollution reduction that can be achieved through the application of 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, but this resulted in only a handful of standards (mostly for pesticide chemicals). The political difficulty of establishing national health-based standards for toxic chemicals led environmental groups, 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 technology 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. In addition, the act 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. In addition, the act requires the POTW to set such additional pretreatment limits and requirements as is necessary both 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 POTW's 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 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 the 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 has required EPA to set and revise these standards to the extent that a state declines to do so. Further, 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 identify

those waters that were in violation of ambient water quality standards because of toxic pollution, to identify those point sources whose discharges of toxic pollutants were contributing to those violations, and to develop an "individual control strategy" for that 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) to calculate a *total maximum daily load* (TMDL) for all waters that are in violation of ambient water quality standards. For any particular body or 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 inexorably 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 10 years or so, however, as a result of several successful suits by environmental groups seeking to compel EPA to set TMDLs in the face of state inaction, the TMDL requirement has come considerably more to the fore. Consequently, 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 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, it contains very little that is designed to address the 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 *maximum contaminant levels* (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 the agency 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 now on the books, Congress scaled back. In a 1996 compromise endorsed by environmental groups and water suppliers alike, 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—because of the addition of a cost–benefit requirement—relatively weaker).

Since then, the primary focus of the SDWA program has been bringing public water systems throughout the country 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 the nation's 55,000 community water systems.

The 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 officially known as the Solid Waste Disposal Act. In 1970, Congress amended that statute 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 (1) established a clear federal policy against the landfilling of hazardous wastes unless they have first been treated to reduce their toxicity and (2) gave EPA a specific timetable by which it had to either set treatment standards for various categories of waste or ban the landfilling of such waste altogether. Consequently, EPA has set treatment standards—which are 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.

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 by two orders of magnitude over the past 25 years. In this sense, RCRA operates as a *de facto* tax on the generation of hazardous waste. (See Chapter 20.)

Another statute that acts as an indirect check on hazardous waste generation (and that provides additional incentive to ensure that one's waste is safely disposed) is the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, also known as the federal Superfund law). The primary focus of this law is the remediation (cleanup) of hazardous waste contamination resulting from imprudent handling and disposal practices of the past and 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 that 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.

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 instance, CERCLA does provide a rationale for pollution prevention. Further, it provides firms with an incentive to meet—or perhaps to go beyond—RCRA regulations in dealing with such wastes as they do generate.

This is not to say, of course, that substantial amounts of hazardous waste are no longer generated in the United States, that all hazardous wastes are adequately treated and safely disposed, or that all instances of hazardous waste contamination are being adequately addressed (or addressed at all). RCRA and CERCLA both contain what might reasonably be called loopholes and gaps in coverage, and hazardous waste contamination remains an ongoing issue. Further, the most common treatment methodology incorporated into EPA's RCRA treatment standards is incineration, which has brought with it a release of airborne contaminants that has yet to be comprehensively addressed by regulation. There is no question, however, that the country has made considerable progress from the late 1970s, when disposal of chemical wastes in unlined landfills—at a cost of roughly $15 per ton—was the common practice.

The Chemical Safety Provisions of the Clean Air Act: Obligations Shared by EPA and OSHA

Although the first congressional response to the country's concern generated by the deadly industrial accident in Bhopal, India, 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 and 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.

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As amended in 1990, Section 112 of the Clean Air Act directs the EPA to develop regulations regarding the prevention and detection of accidental chemical releases and to publish a list of at least 100 chemical substances (with associated threshold quantities) to be covered by the 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. 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 such steps as are necessary to prevent releases, and
>
> . . . *minimize the consequences* of accidental releases which do occur." [emphases added]

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. Specifically, in the General Dynamics case, the District of Columbia Circuit Court of Appeals held that 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. Further, the requirement on owners and operators to design and maintain a safe facility would seem to extend their obligations into the area of primary prevention rather then 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 amendments established an independent Chemical Safety and Hazard Investigation Board (CSHIB). The board is to investigate the causes of accidents, perform research on prevention, and make recommendations for preventive approaches, much like the Air Transportation Safety Board does with regard to airplane safety.

As required by the 1990 Clean Air Amendments, in 1992 OSHA promulgated a standard requiring chemical PSM in the workplace that became effective later that year. The PSM standard is designed to protect employees working in facilities that use "highly hazardous chemicals" and employees 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 employers 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. Many aspects of chemical safety are not covered by specific workplace standards. Most that do apply to chemical safety have their origin in the consensus standards adopted under Section 6(a) of the OSHAct in 1971 and hence are greatly out of date. Arguably, the general duty obligation of the OSHAct imposes a duty to seek out technological improvements that would improve safety for workers.

In 1996, the EPA promulgated regulations setting forth requirements for the RMPs specified in the Clean Air Act. The RMP rule is modeled after the OSHA PSM standard and is estimated to affect some 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 2003, the Chemical Safety and Hazard Investigation Board urged OSHA to amend its 1996 regulations in order to achieve more comprehensive control of "reactive hazards" that could have catastrophic consequences and asked OSHA to define and record information on reactive chemical incidents that it investigates or is required to investigate. These recommendations have largely fallen on deaf ears. The board also expressed concern that the *material safety data sheets* (MSDSs) issued by OSHA do not adequately identify the reactive potential of chemicals. Legislation is being promoted to require OSHA to prepare or revise MSDSs for the list of chemicals in the PSM standard and generally strengthen OSHA's approach to chemical safety. Despite the fact that a memorandum of understanding between EPA and OSHA had been signed in 1996, in 2001 the U.S. General Accounting Office (GAO) issued a report indicating the need for better coordination between EPA, OSHA, the CSHIB, and other agencies.

ENFORCEMENT ACTIVITIES

Regulations and standard setting, of course, are only the beginning of the regulatory process. For a regulatory system to be effective, there must be a clear commitment to the enforcement of standards (see Chapter 37). Under OSHA, a worker can request a workplace inspection if the request is in writing and signed. Anonymity is preserved on request. When an inspector visits a workplace, a representative of the workers can accompany the inspector on the "walk-around."If specific requests for inspections are not made, OSHA makes random inspections of those workplaces with worse-than-average safety records. However, the inspection frequency is low. Furthermore, firms with significant exposures to chemicals may not be routinely inspected, simply because their record for injuries—which make up the overwhelming majority of the reported statistics—is good.

Inspections are usually conducted without advance notice, but an employer may insist that OSHA inspectors obtain a court order before entering the workplace. Federal OSHA continues to have approximately 1,000 inspectors, and state agencies have approximately another 2,000. OSHA and OSHA-approved state programs conducted approximately 97,000 annual inspections in the federal fiscal year 2002, focusing inspections on the most hazardous industries, construction and manufacturing. Clearly, not all 6 million workplaces covered by the OSHAct could be inspected on anything like a regular basis. With the relatively recent expansion of OSHA authority to cover U.S. post offices, the agency continues to be short of the resources needed to perform its statutory duties. In sharp contrast, the number of inspectors per worker is 10 times larger in British Columbia, Canada, and in many European countries.

OSHA can fine employers up to $7,000 for each violation of the act that is discovered during a workplace inspection and up to $70,000 or up to 6 months imprisonment if the violation is willful or repeated. The failure to abate hazards can result in a $7,000 fine per day. These penalties are very much less than those for violations of environmental statutes. Since Congress last adjusted OSHA's civil penalties, those fines are in effect 38 percent lower, when pegged to inflation. Management can appeal violations, amounts of fines, methods of correcting hazards, and deadlines for correcting hazards (abatement dates). Workers can appeal only deadlines. All appeals are processed through the Occupational Safety and Health Review Commission, established by the OSHAct.

The OSHAct requires OSHA to encourage states to develop and operate their own job safety and health programs. State programs, when "at least as effective" as the federal program, can take over enforcement activities. Once a state plan is approved, OSHA funds half of its operating costs. Approximately 20 state plans, which OSHA monitors, are in effect. State safety and health standards under such approved plans must keep pace with OSHA standards, and state plans must guarantee employer and employee rights, as does OSHA.

During the 1980s, OSHA inspection policy resulted in directives given to the field staff to deemphasize general duty violations. In addition, inspectors were actually evaluated by the managers of the establishments they inspected. Follow-up inspections after violations were often restricted to checks

by telephone. Thus, incentives for aggressive inspection activity were not great under the Reagan and Bush administrations. Although inspection activity increased under the Clinton administration, it has retreated under the second Bush administration. Although inspections were up in numbers, in the Clinton administration, the time spent on inspections was less.

Enforcement of laws administered by the EPA is initiated by the agency under its various legislative mandates. As with OSHA, agency activity has been greatly inadequate over the past 25 years, with increased responsibilities and the lack of a corresponding increase in human resources since 1980.

WORKER AND COMMUNITY RIGHT TO KNOW

The right of workers and citizens to be apprised of the substances to which they are exposed is popularly referred to as "the right to know." This simple term actually encompasses several rights and duties that are complex and complementary. Political and legislative initiatives focusing on the right to know arose during a time when direct regulation of toxic substances was being deemphasized by the federal agencies. Historically, regulatory initiatives under the 1970 OSHAct encompassing the worker right-to-know preceded by more than 15 years the more general community right-to-know efforts embodied in the 1986 Emergency Planning and Community Right to Know Act (EPCRA), but the worker right-to-know initiatives are relevant to, and greatly influenced, the evolution of the community right-to-know.

Although the initiatives for the worker right to know and the community right to know both initially focused on "scientific" information about chemicals—(a) product ingredients and the specific composition of pollution in air, water, and waste; (b) the inherent toxicity and safety hazard of the related chemicals, materials, and industrial processes; and (c) information related to exposure of various vulnerable groups to harmful substances and processes—disseminating or providing access to other categories of information, namely technological information, and legal information[1] may be even more important for empowering workers and citizens to facilitate a transformation of hazardous industry and practices. Technological information includes (a) monitoring technologies, (b) options that control or minimize pollution, waste, and chemical accidents, and (c) available substitute or alternative inputs, final products, and processes that prevent pollution, waste, and chemical accidents. Legal information refers to notification of the rights and obligations of producers, employers, consumers, workers, and the general public. Though important, legal information is not a fundamental type of information but rather the (mandated) diffusion of information about rights and duties stemming from the nature and exposure profiles of hazardous substances and processes.

Worker Right to Know

The transfer of information regarding workplace exposure to toxic substances has received considerable public attention. Workers need an accurate picture of the nature and extent of probable chemical exposures to decide whether to enter or remain in a particular workplace. Workers also need to have knowledge regarding past or current exposures to be alert to the onset of occupational disease. Regulatory agencies must have timely access to such information if they are to devise effective strategies to reduce disease and death from occupational exposures to toxic substances. Accordingly, laws designed to facilitate this flow of information have been promulgated at the federal, state, and local levels. Indeed, the right to know has become a political battleground in many states and communities and has been the subject of intensive organizing efforts by business, labor, and citizen-action groups.

In essence, the right to know embodies a democratization of the workplace. It is the mandatory sharing of information between management and labor. Through a variety of laws, manufacturers and employers are directed to disclose information regarding toxic substance exposure to workers, to unions in their capacity as worker representatives, and to governmental agencies charged with the protection of public health. The underlying rationale for these directives is the assumption that this transfer of information will prompt activity that will improve worker health.

Although the phrase *right to know* is a useful generic designation, it is an inadequate description of the legal rights and obligations that govern the transfer of workplace information on toxic substances. A person cannot have a meaningful right to information unless someone else has a corresponding duty to provide that information. Thus, a worker's right to know is secured by requiring a manufacturer or employer to disclose. The disclosure requirement can take a variety of forms, and

the practical scope of that requirement may depend on the nature of the form chosen. In particular, a duty to disclose only such information as has been requested may provide a narrower flow of information than a duty to disclose all information, regardless of whether it has been requested. The various rights and obligations in the area of toxics information transfer may be grouped into three categories. Although they share a number of similarities, each category is conceptually distinct:

1. The duty to generate or retain information refers to the obligation to compile a record of certain workplace events or activities or to maintain such a record for a specified period of time if it has been compiled. An employer may, for example, be required to monitor its workers regularly for evidence of toxic exposures (biological monitoring) and to keep written records of the results of such monitoring.
2. The right of access (and the corresponding duty to disclose on request) refers to the right of a worker, a union, or an agency to request and secure access to information held by a manufacturer or employer. Such a right of access would provide workers with a means of obtaining copies of biological monitoring records pertaining to their own exposure to toxic substances.
3. Finally, the duty to inform refers to an employer's or manufacturer's obligation to disclose, without request, information pertaining to toxic substance exposures in the workplace. An employer may, for example, have a duty, independent of any worker's exercise of a right to access, to inform workers whenever biological monitoring reveals that their exposure to a toxic substance has produced bodily concentrations of that substance above a specified level.

In general, the broadest coverage is found in rights and duties emanating from the OSHAct. By its terms, that act is applicable to all private employers and thus covers the bulk of workplace exposures to toxic substances. Most private industrial workplaces are also subject to the National Labor Relations Act (NLRA). Farm workers and workers subject to the Railway Labor Act, however, are exempt from NLRA coverage. TSCA provides a generally narrower scope. Although many of the act's provisions apply broadly to both chemical manufacture and use, its information transfer requirements extend only to chemical manufacturers, processors, and importers. On the state level, the relevant coverage of the various rights and duties depends on the specifics of the particular state and local law defining them. In general, common-law rights and duties evidence much less variation than those created by state statute or local ordinance.

Under OSHA's *Hazard Communication Standard,* employers have a duty to inform workers of the identity of substances with which they work through labeling the product container and disclosing to the purchaser (the employer) using MSDSs.

Employers are under no obligation to amend inadequate, insufficient, or incorrect information provided by the manufacturer. Employers must, however, transmit certain information to their employees: (a) information on the standard and its requirements, (b) operations in their work areas where hazardous chemicals are present, and (c) the location and availability of the company's hazard communication program. The standard also requires that workers must be trained in (a) methods to detect the presence or release of the hazardous chemicals; (b) the physical and health hazards of the chemicals; (c) protective measures, such as appropriate work practices, emergency procedures, and personal protective equipment; and (d) the details of the hazard communication program developed by the employer, including an explanation of the labeling system and the MSDSs and how employees can obtain and use hazard information.

Rights and duties governing toxic information transfer in the workplace can originate from a variety of sources. Some are grounded in state common-law, whereas others arise out of specific state statutes or local ordinances. Although the states have been increasingly active in this field, the primary source of regulation is federal law. Most federal regulation in this area emanates from three statutes: the OSHAct of 1970, the Toxic Substances Control Act of 1976, and the National Labor Relations Act (NLRA), the last of which is administered by the National Labor Relations Board (NLRB).

The scope of a particular right or duty depends on many factors. The first, and perhaps most important, is the nature of the information required to be transferred. As discussed above, the main categories of information can be divided into scientific, technological, and legal information. In the context of the workplace, scientific information can be divided into three subcategories:

1. Ingredients information provides the worker with the identity of the substances to which he or she is exposed. Depending on the circumstances, this information may constitute only the generic

PT: TIB/OTB PT2: TIB/OTB QC: IML/OTB PT: IML
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classifications of the various chemicals involved or may include the specific chemical identities of all chemical exposures and the specific contents of all chemical mixtures.
2. Exposure information encompasses all data regarding the amount, frequency, duration, and route of workplace exposures. This information may be of a general nature, such as the results of ambient air monitoring at a central workplace location, or may take individualized form, such as the results of personal environmental or biological monitoring of a specific worker.
3. Health effects information indicates known or potential health effects of workplace exposures. This information may be general data regarding the effects of chemical exposure, usually found in an MSDS or a published or unpublished workplace epidemiologic study, or it may be individualized data, such as worker medical records compiled as a result of medical surveillance.

The federal standard preempts state right-to-know laws in the worker notification area in a minority of jurisdictions; it would appear to be coexistent with state requirements in most jurisdictions, although its stated intent is to preempt all state efforts.

Under OSHA's Medical Access Rule, an employer may not limit or deny an employee access to his or her own medical or exposure records. The current OSHA regulation, promulgated in 1980, grants employees a general right of access to medical and exposure records kept by their employer. Furthermore, it requires the employer to preserve and maintain these records for 30 years. There appears to be some overlap in the definitions of medical and exposure records, because both may include the results of biological monitoring. Medical records, however, are in general defined as those pertaining to "the health status of an employee," whereas the exposure records are defined as those pertaining to "employee exposure to toxic substances or harmful physical agents."

The employer's duty to make these records available is a broad one. The regulations provide that on any employee request for access to a medical or exposure record, "the employer *shall* assure that access is provided in a reasonable time, place, and manner, but in no event later than 15 days after the request for access is made."

An employee's right of access to medical records is limited to records pertaining specifically to that employee. The regulations allow physicians some discretion as well in limiting employee access. The physician is permitted to "recommend" to the employee requesting access that the employee (a) review and discuss the records with the physician, (b) accept a summary rather than the records themselves, or (c) allow the records to be released instead to another physician. Furthermore, where information in a record pertains to a "specific diagnosis of a terminal illness or a psychiatric condition," the physician is authorized to direct that such information be provided only to the employee's designated representative. Although these provisions were apparently intended to respect the physician–patient relationship and do not limit the employee's ultimate right of access, they could be abused. In situations in which the physician feels loyalty to the employer rather than the employee, the physician could use these provisions to discourage the employee from seeking access to his or her records.

Similar constraints do not apply to employee access to exposure records. Not only is the employee ensured access to records of his or her own exposure to toxic substances, but the employee is also ensured access to the exposure records of other employees "with past or present job duties or working conditions related to or similar to those of the employee." In addition, the employee has access to all general exposure information pertaining to the employee's workplace or working conditions and to any workplace or working condition to which he or she is to be transferred. All information in exposure records that cannot be correlated with a particular employee's exposure is accessible.

One criticism of the OSHA regulation is that it does not require the employer to compile medical or exposure information but merely requires employee access to such information if it is compiled. The scope of the regulation, however, should not be underestimated. The term *record* is meant to be "all-encompassing," and the access requirement appears to extend to all information gathered on employee health or exposure, no matter how it is measured or recorded. Thus, if an employer embarks on any program of human monitoring, no matter how conducted, he or she must provide the subjects access to the results. This access requirement may serve as a disincentive for employers to monitor employee exposure or health if it is not clearly in the employer's interest to do so.

The regulations permit the employer to deny access to "trade secret data which discloses manufacturing processes or . . . the percentage of a chemical

substance in a mixture," provided that the employer (a) notifies the party requesting access of the denial; (b) if relevant, provides alternative information sufficient to permit identification of when and where exposure occurred; and (c) provides access to all "chemical or physical agent identities including chemical names, levels of exposure, and employee health status data contained in the requested records."

The key feature of this provision is that it ensures employee access to the precise identities of chemicals and physical agents. This access is especially critical for chemical exposures. Within each "generic" class of chemicals, there are a variety of specific chemical compounds, each of which may have its own particular effect on human health. The health effects can vary widely within a particular family of chemicals. Accordingly, the medical and scientific literature on chemical properties and toxicity is indexed by specific chemical name, not by generic chemical class. To discern any meaningful correlation between a chemical exposure and a known or potential health effect, an employee must know the precise chemical identity of that exposure. Furthermore, in the case of biological monitoring, the identity of the toxic substance or its metabolite is itself the information monitored.

Particularly in light of the public health emphasis inherent in the OSHAct, disclosure of such information does not constitute an unreasonable infringement on the trade secret interests of the employer. In general, chemical health and safety data are the least valuable to an employer of all the proprietary information relevant to a particular manufacturing process.

TSCA imposes substantial requirements on chemical manufacturers and processors to develop health effects data. TSCA requires testing, premarket manufacturing notification, and reporting and retention of information. TSCA imposes no specific medical surveillance or biological monitoring requirements. However, to the extent that human monitoring is used to meet more general requirements of assessing occupational health or exposure to toxic substances, the data resulting from such monitoring are subject to an employer's recording and retention obligations.

EPA has promulgated regulations requiring general reporting on several hundred chemicals, including information related to occupational exposure. The EPA administrator may require the reporting and maintenance of those data "insofar as known" or "insofar as reasonably ascertainable." Thus, if monitoring is undertaken, it must be reported. EPA appears to be authorized to require monitoring as a way of securing information that is "reasonably ascertainable."

In addition to the general reports required for specific chemicals listed in the regulations, EPA has promulgated rules for the submission of health and safety studies required for several hundred substances. A health and safety study includes "[a]ny data that bear on the effects of chemical substance on health." Examples are "[m]onitoring data, when they have been aggregated and analyzed to measure the exposure of humans . . . to a chemical substance or mixture." Only data that are "known" or "reasonably ascertainable" need be reported.

Records of "significant adverse reactions to [employee] health" must be retained for 30 years under Section 8(c). A rule implementing this section defines significant adverse reactions as those "that may indicate a substantial impairment of normal activities, or long-lasting or irreversible damage to health or the environment." Under the rule, human monitoring data, especially if derived from a succession of tests, would seem especially reportable. Genetic monitoring of employees, if some basis links the results with increased risk of cancer, also seems to fall within the rule.

Section 8(e) imposes a statutory duty to report "immediately . . . information which supports the conclusion that [a] substance or mixture presents a substantial risk of injury to health." In a policy statement issued in 1978, the EPA interpreted "immediately" in this context to require receipt by the agency within 15 working days after the reporter obtains the information. Substantial risk is defined exclusive of economic considerations. Evidence can be provided by either designed, controlled studies or undesigned, uncontrolled studies, including "medical and health surveys" or evidence of effects in workers. From 1978 to 2003, EPA received more than 25,000 8(e) submissions. During the years 2001 and 2002, 19 to 21 percent of these reports addressed reproductive/developmental toxicity; 7.5 to 14 percent, ecotoxicity; 9 to 11 percent, cancer; and 5 to 11 percent, mutagenicity.[2]

In the EPA's rule for Section 8(c), Section 8(e) is distinguished from Section 8(c) in that "[a] report of substantial risk of injury, unlike an allegation of a significant adverse reaction, is accompanied by information which reasonably supports the seriousness of the effect or the probability of

its occurrence." Human monitoring results indicating a substantial risk of injury would thus seem reportable to EPA. Either medical surveillance or biological monitoring data would seem to qualify. Section 14(b) of TSCA gives EPA authority to disclose from health and safety studies the data pertaining to chemical identities, except for the proportion of chemicals in a mixture. In addition, EPA may disclose information, otherwise classified as a trade secret, "if the Administration determines it necessary to protect . . . against an unreasonable risk of injury to health." Monitoring data thus seem subject to full disclosure.

In addition to the access provided by OSHA regulations, individual employees may have a limited right of access to medical and exposure records under federal labor law. Logically, the right to refuse hazardous work (see later discussion), inherent in Section 7 of the NLRA and Section 502 of the Labor Management Relations Act, carries with it the right of access to the information necessary to determine whether or not a particular condition is hazardous. In the case of toxic substance exposure, this right of access may mean access to all information relevant to the health effects of the exposure and may include access to both medical and exposure records. These federal labor law provisions are clearly not adequate substitutes for OSHA access regulations, however, because there is no systematic mechanism for enforcing this right.

Collective employee access, however, is available to unionized employees through the collective bargaining process. In four cases, the NLRB has held that unions have a right of access to exposure and medical records so that they may bargain effectively with the employer regarding conditions of employment. Citing the general proposition that employers are required to bargain on health and safety conditions when requested to do so, the NLRB adopted a broad policy favoring union access: "Few matters can be of greater legitimate concern to individuals in the workplace, and thus to the bargaining agent representing them, than exposure to conditions potentially threatening their health, well-being, or their very lives."

The NLRB, however, did not grant an unlimited right of access. The union's right of access is constrained by the individual employee's right of personal privacy. Furthermore, the NLRB acknowledged an employer's interest in protecting trade secrets. Although ordering the employer in each of the four cases to disclose the chemical identities of substances to which the employer did not assert a trade secret defense, the NLRB indicated that employers are entitled to take reasonable steps to safeguard "legitimate" trade secret information. The NLRB did not delineate a specific mechanism for achieving the balance between union access and trade secret disclosure. Instead, it ordered the parties to attempt to resolve the issue through collective bargaining. Given the complexity of this issue and the potential for abuse in the name of "trade secret protection," the NLRB may find it necessary to provide further specificity before a workable industry-wide mechanism can be achieved.

The legal avenues for worker and agency access to information relevant to workplace exposures to toxic substances have been expanded substantially. Despite certain inadequacies in the current laws and despite current attempts by OSHA to narrow the scope of some of these even further, access to toxics data remains broader than it has ever been. By itself, however, this fact is of little significance. The mere existence of information transfer laws means little unless those laws are used aggressively to further the objective of the right to know: the protection of workers' health.The various rights and duties governing toxics information transfer in the workplace present workers, unions, and agencies with an important opportunity. The extent to which they seize this opportunity is a measure of their resolve to bring about meaningful improvement in the health of the American worker.

The category of technological information is not addressed in the context of worker right to know, although it has been argued that shifting the focus of debate between workers and management from the risks in the workplace to a discussion of [technological] solutions may be a much more fruitful avenue for collective bargaining.[3] In contrast, information about technology and approaches for reducing toxic substance exposure and the chances of sudden and accidental releases of chemicals (discussed below) is reflected in community right-to-know initiatives.

Community Right to Know

In 1986, Congress amended the federal hazardous waste cleanup law (commonly referred to as the Superfund statute) with the Superfund Amendment and Reauthorization Act of 1986 (known as SARA). Beyond cleanup, Congress took in SARA what may prove to be a significant step toward reducing the likelihood of new hazardous substance

contamination in the future. Title III of SARA, called the Emergency Planning and Community Right to Know Act (EPCRA), now codified at 42 U.S.C. §§11001, *et seq*., is a comprehensive federal community right-to-know program, implemented by the states under guidelines promulgated by EPA. The central feature of this federal program is broad public dissemination of information pertaining to the nature and identity of chemicals used at commercial facilities.

Although EPCRA is not a workplace right-to-know law *per se*, it does provide an alternative means through which many employees can learn about toxic substance use, not only in their own workplaces but in other workplaces in which they may wish to work.

EPCRA has four major provisions:

- Emergency planning (§§301–303)
- Emergency release notification (§304)
- Hazardous chemical storage reporting requirements (§§311–312)
- The Toxic Chemical Release Inventory (TRI) (§313)

The various requirements are summarized in Table 3-2 and are discussed below.

The implementation of EPCRA began with the creation of state and local bodies to implement this community right-to-know program. Section 301 of the act required the governor of each state to appoint a *state emergency response commission* (SERC), to be staffed by "persons who have technical expertise

TABLE 3-2

EPCRA Chemicals, Reportable Actions, and Reporting Thresholds

	Section 302	Section 304	Sections 311/312	Section 313 (TRI)
Chemicals covered	356 extremely hazardous substances	>1,000 substances	500,000 products with MSDSs[a] (required under OSHA regulations)	650 toxic chemicals and categories[b]
Reportable actions and thresholds	Threshold planning quantity 1–10,000 lb present on site at any one time requires notification of the SERC and LEPC within 60 days upon on-site production or receipt of shipment.	Reportable quantity, 1–5,000 lb, released in a 24-hour period; reportable to the SERC and LEPC.	TPQ or 500 lb for Section 302 chemicals; 10,000 lb present on site at any one time for other chemicals. Copy if requested to SERC/LEPC; annual inventory Tier I/Tier II report to SERC/LEPC/ local fire department by March 1.	25,000 lb per year manufactured or processed; 10,000 lb a year used; certain persistent bioaccumulative toxics have lower thresholds; annual report to EPA and the state by July 1.

MSDS, material safety data sheet; OSHA, Occupational Safety and Health Administration; EPA, Environmental Protection Agency; EPCRA, Emergency Planning and Community Right to Know Act; SERC, State Emergency Response Commission; LEPC, Local Emergency Planning Committee; TRI, Toxics Release Inventory; TPQ, Threshold Planning Quantity.

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

[b] 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.

in the emergency response field." In practice, these state commissions have tended to include representatives from the various environmental and 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. Finally, Section 313 requires firms in the manufacturing sector to provide to EPA an annual reporting of certain routine releases of hazardous substances. These reports comprise what is known as the *Toxics Release Inventory* (TRI). 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.

Taken as a whole, these requirements constitute a broad federal declaration that firms that choose to rely heavily on hazardous chemicals in their production processes may not treat information regarding their use of those chemicals as their private domain. Indeed, except for trade secrecy protections 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. Indeed, Section 324 of the act mandates that most of the information subject to EPCRA reporting requirements "be made available to the general public" upon request and requires that each local emergency planning committee publicize this fact in a local newspaper. However, since the September 11 terrorist attacks, EPA is undertaking a review of the proper balance to strike between the public's right to know and the possible increased risk to disseminating information collected under the informational provisions of various legislation.

EPCRA requires certain industries to report the releases and transfers of certain chemical substances to air, water, land, or transferred off-site. The data have to be entered on a standardized form and are collected by EPA in the TRI, which is publicly available.[*] The number of chemicals that are covered is about 650—double the number required in 1987.

The TRI imposes its requirements on firms having more than 10 employees and that manufacture or process[†] More than 25,000 pounds per year, or use 10,000 pounds per year of the designated chemicals. For some six *persistent, bioaccumulative, and toxic chemicals* (PBTs), EPA lowered the reporting thresholds in 1999 to 100 lb, for 11 highly persistent and highly bioaccumulative chemicals to 10 lb, and for dioxin and dioxin-like compounds to 0.1 g. All 6,100 facilities of the manufacturing sector and several other industries including metal and coal mining, electric utilities, and commercial hazardous waste treatment, among others, are required to report. Approximately 6 to 7 percent of all chemical releases are subject to TRI reporting. In addition to the reporting requirements for chemicals releases, EPCRA now includes requirements to report pollution-prevention activities.[‡] The potential power of TRI depends on the extent to which the data represents actual releases and the quality of the data, as well as the capacity of the public to understand and interpret the data. Considering the representativeness of the data, TRI focuses only

[*] *The data can be found on EPA's Webpage <http://www.epa.gov/tri/>.*

[†] *The term* manufacture *means to produce, prepare, import, or compound a toxic chemical. The term* process *means the preparation of a toxic chemical, after its manufacture, for distribution in commerce. See 42 U.S.C. 11023 (b)(1)(C). See also 42 U.S.C. 11023 (a)(b)(1) and (g)(2).*

[‡] *The Pollution Prevention Act (PPA) of 1990 advocates a general shift in approach from pollution control to pollution prevention. The PPA amends EPCRA and adds further requirements to report the firms' pollution-prevention activities to EPA. These include source-reduction and waste-management practices.*

on the releases of chemicals and does not include releases that occur during the whole life cycle of a product. A reported reduction of reported chemical releases does not necessarily mean a total reduction of all releases, because there could be shifts in releases from covered to not-covered chemicals. The firms are not required to produce risk information about the covered substances but only have to report their releases, so the public may have an inadequate picture of what changes in reported releases mean in terms of reduction (or increases) in overall risk. In addition, within the covered substances, no distinction is highlighted between the different severity (health or environmental consequences) of different releases. Aside from the recent exception of reporting the specific categories of the persistent, bioaccumulative, and toxic chemicals, unless interested observers factor in differential hazardousness of different releases, they cannot make a meaningful assessment of changes in overall risk. In addition, many of the releases directly to air and water have simply been transferred to the waste stream, and it is extremely difficult to evaluate the resulting consequences for overall risk.

Although there are limitations of using the TRI data as a good environmental indicator, the publication of the data appeared to have had an enormous positive impact on the reduction of reported releases. During the 1988–2001 period, on- and offsite releases of the core chemicals were reduced by 55 percent while the production of chemicals increased. Forty percent of the decreases were already reached by 1995. However, although emissions to air and water decreased, there were corresponding large increases in hazardous waste. As a result, the success of the TRI reporting is far from clear.

The September 11 terrorist attacks have brought in a new dimension to the right to know. The Clean Air Act requires that chemical manufacturers and refineries file *start-up, shut-down, and malfunction* (SSM) plans with EPA or state air regulators. Industry has argued that public access to this information increases the vulnerability of those facilities to terrorist attacks and has requested of EPA that industry not be required to routinely submit those plans. EPA countered with a proposal that the information could be screened before dissemination. EPA has since dismantled its risk management website containing general information about emergency plans and chemicals used at 15,000 sites nationwide, allowing selective access to sensitive information contained in the Offsite Consequence Analysis—about "worst case" chemical accidents—in special reading rooms.

THE RIGHT TO REFUSE HAZARDOUS WORK

The NLRA and the OSHAct provide many employees a limited right to refuse to perform hazardous work. When properly exercised, this right protects an employee from retaliatory discharge or other discriminatory action for refusing hazardous work and incorporates a remedy providing both reinstatement and back pay. The nature of this right under the NLRA depends on the relevant collective bargaining agreement, if there is one. Nonunion employees and union employees whose collective bargaining agreements specifically exclude health and safety from a no-strike clause have the *collective* right to stage a safety walkout under Section 7 of the NLRA. If they choose to walk out based on a good-faith belief that working conditions are unsafe, they will be protected from any employer retaliation. Union employees who are subject to a comprehensive collective bargaining agreement may avail themselves of the provisions of Section 502 of the NLRA. Under this section, an employee who is faced with "abnormally dangerous conditions" has an *individual* right to leave the job site. The right may be exercised, however, only where the existence of abnormally dangerous conditions can be objectively verified. Both exposure and medical information are crucial here (see Chapter 4).

Under a 1973 OSHA regulation, the right to refuse hazardous work extends to all employees, *individually*, of private employers, regardless of the existence or nature of a collective bargaining agreement. Section 11(c) of the OSHAct protects an employee from discharge or other retaliatory action arising out of his or her "exercise" of "any right" afforded by the act. The Secretary of Labor has promulgated regulations under this section defining a right to refuse hazardous work in certain circumstances: where an employee reasonably believes there is a "real danger of death or serious injury," there is insufficient time to eliminate that danger through normal administrative channels, and the employer has failed to comply with an employee request to correct the situation.

Under the federal Mine Safety and Health Act, miners also have rights to transfer from unhealthy work areas if there is exposure to toxic substances

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or harmful physical agents or if there is medical evidence of pneumoconiosis.

ANALYSIS OF OSHA'S PERFORMANCE AND COMMENTARY ON NEW INITIATIVES

In the 1980s, OSHA turned to negotiated rulemaking allowed by the revisions to the Administrative Procedure Act. However, negotiation for the benzene standard failed, and, in 1983, OSHA issued a standard essentially the same as had been remanded by the U.S. Supreme Court, but with the required scientific/risk-assessment justification. OSHA then promulgated formally negotiated standards for formaldehyde in 1992 and methylenedianiline in 1992 and used an informal negotiation process for the butadiene standard issued in 1996, but they were neither as protective as the law would have allowed nor as technology-forcing.[4]

Although OSHA standard-setting efforts continued in the latter part of the 1990s, its early commitment to worker protection has been further seriously compromised by both procedural requirements imposed by new legislation and by the chilling effect that this legislation has had on agency willingness to set stringent standards. This legislation—the Regulatory Flexibility Act, the Paperwork Reduction Act, the Unfunded Mandates Reform Act, the Small Business Regulatory Enforcement Fairness Act, and the National Technology Transfer and Advancement Act—has placed time-consuming burdens on the agency, contributing to a serious slowdown and resource intensiveness in the development of standards, compounding the effects of executive (presidential) orders requiring the Office of Management and Budget to review OSHA's assessment of costs and benefits for major rules, defined as those having more than $100 million in costs per year.

Equally disturbing is the inadequacy of protection offered by some of the new health standards. The standard for the carcinogen methylene chloride was finally promulgated in 1997—after 13 years of delay. The United Autoworkers Union (UAW) first petitioned OSHA in 1987 for a reduction of the permissible 8-hour exposure allowed by the prior PEL of 500 to 10 ppm. OSHA promulgated a standard of 25 ppm, without medical removal protection. That level was argued to present a lifetime cancer risk of 1 in 1,000 for the average exposed worker (and ensured that 95 percent of the workers were exposed to no lifetime risk higher than 3.6 in 1,000), a risk considerably greater than that allowed in prior standards for individual carcinogens, such as vinyl chloride and benzene (but in line with the lax formaldehyde standard), and in sharp contrast to the level of 1 in 1 million required by the Clean Air Act of 1990 for environmental ambient air exposures to carcinogens. Originally challenging the standard in court as being too lax, the UAW negotiated a legal settlement with the opposing industry for a revision of the standard, retaining the 25 ppm level but adding medical surveillance and removal requirements. Legislation introduced in Congress to veto the standard was unsuccessful.

As discussed earlier, OSHA has to make findings of fact with regard to both the significance of the risk and the feasibility of a proposed standard. Unfortunately, OSHA has pulled back from its historically protective determinations of these factors by (a) being content to regulate near the 1 per 1,000 lifetime risk, which was the *lower* bound of significance suggested by the U.S. Supreme Court in its benzene decision; and (b) finding gratuitously that a proposed standard is feasible, rather than protecting workers to the extent feasible—that is, to the limits of feasibility, using its technology-forcing authority. A study undertaken by the now-defunct Congressional Office of Technology Assessment (OTA) examined the postpromulgation costs of past OSHA standards (including vinyl chloride, ethylene oxide, lead, cotton dust, and formaldehyde) and, in general, found them to be a fraction of the prepromulgation estimates. The OTA concluded:

> OSHA's current economic and technological feasibility analyses devote little attention to the potential of advanced or emerging technologies to yield technically and economically superior methods for achieving reductions in workplace hazards. . . . Opportunities are missed to harness leading-edge or innovative production technologies (including input substitution, process redesign, or product reformulation) to society's collective advantage, and to achieve greater worker protection with technologically and economically superior means.
>
> [I]ntelligently directed effort can yield hazard control options—attributes that would, no doubt, enhance the "win-win" (for regulated industries and their workforces) character of OSHA's compliance requirements in many cases and support the achievement of greater hazard reduction.

Thus, OSHA in no way seems to be pushing regulation to its limits of technology.[5]

OSHA ran into tremendous industry resistance to a proposed ergonomics standard. Congress actually repealed the standard under recently new congressional authority, and OSHA ultimately withdrew the standard. However, OSHA has made it clear the employer has obligations to protect workers from ergonomic hazards under the general duty clause and that enforcement activity will be applied in appropriate situations. The Review Commission upheld OSHA's authority to use the general duty clause in these circumstances. OSHA also experienced political difficulty in establishing standards for secondary tobacco smoke (environmental tobacco smoke) as part of its concern for indoor air quality. OSHA issued a proposed rule in 1994, but action is yet to be taken.

The Clinton administration's record on worker protection was not impressive. No new health standards for chemicals had been issued. The two standards that were issued for 1,3-butadiene and methylene chloride had actually been proposed in the Bush administration prior to Clinton's. In the first George W. Bush administration, OSHA not only withdrew the proposed ergonomic standard, it also withdrew its plans for issuing a rule on metal-working fluids. OSHA does plan the promulgation of some new standards and the review/reconsideration of standards more than 10 years old as required by the Regulatory Flexibility Act. After a successful court challenge, in 2004, OSHA finally issued a proposed revision of its 8-hour exposure limit for hexavalent chromium, lowering the standard to $1\mu g/m^3$ from the previous 33-year-old standard of 52 $\mu g/m^3$, thus preventing 350 excess cancers annually. A peer review for a risk assessment for silica exposure was scheduled for February 2005, but, as of mid-2005, a proposed rule was not yet scheduled. Initial action on beryllium was scheduled for early 2005, but no action has yet been taken. In addition, a rule was planned for requirements for employers to pay for personal protective equipment. Four older standards are also being reviewed: lock-out/tag-out, ethylene oxide, cotton dust, and grain-handling facilities. Also under consideration for revision is a rule for the Process Safety Management of Highly Hazardous Chemicals, to add other reactive chemicals to the rule and to bring it more in line with the EPA's Risk Management Plan. As provided by the Small Business Regulatory Enforcement Fairness Act, the effects of revisited standards on small business must be assessed, and that assessment is now reviewable by the circuit courts of appeals.

With only enough inspectors to inspect 2 percent of the 6 million worksites covered by the OSHAct each year, OSHA has historically used a variety of targeting schemes to decide which sites get inspected. Nearly half of the inspections are reserved to respond to worker complaints, referrals from other agencies, or reports of major or fatal incidents. Begun in mid-2003, OSHA's Site-Specific Targeting (SST) Inspection program selects workplaces with high lost-workday injury and illness rates for inspections from self-reported survey data of about 80,000 employers (mainly mid-sized or larger employers with the lower cutoff at about 40 employees). Lost-workday injury and illness rates are dominated by injuries, and workplace exposures to harmful substances are acknowledged to be grossly underreported, thus biasing the strategy. Out of the approximately 35,000 inspections OSHA conducts each year, about 3,000 are SST-based. Further, based on the 2003 survey of recorded injuries and illnesses, OSHA contacted about 13,000 high-hazard sites, notifying them that their injury rates are above average (usually greater than twice the average) and advising them to seek safety consultations and that they would be targeted for random inspections. Those with four times the national average would be targeted for "wall-to-wall inspections." These 13,000 worksites contribute approximately 20 percent of the 3 million (reported) lost-workday cases annually. In addition to the national targeting strategy, special emphasis programs for specific hazards in selected industrial sectors are conducted at the regional level.

In the current antiregulatory climate, OSHA has, as have other regulatory agencies, shifted toward more voluntary initiatives, including the use of expert advisors, outreach, compliance assistance, consultation, and partnering with industry, trade unions, and workers. OSHA has designated Special Emphasis Programs and Initiatives on silicosis, mechanical power press injuries, lead in construction, nursing home accidents, and workplace violence. These programs and initiatives target a specific occupational hazard or industry and combine outreach and education with enforcement. OSHA has issued to its field staff a Directive on Strategic

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TABLE 3-3

Summary of OSHA's Four Voluntary Compliance Programs

Program and Year Established	Target Participants	Program Description	OSHA Oversight
State Consultation Program, 1975	Small businesses in high-hazard industries.	Free, usually confidential reviews of employers' worksites to identify hazards and abatement techniques.	Program operates in all states and is run by state governments, but funded mainly by OSHA.
Voluntary Protection Programs, 1982	Single worksites typically with injury and illness rates below average for their industry sector.	Recognizes worksites that have safety and health programs with specific features that exceed OSHA standards.	Employers must pass a weeklong on-site worksite review by OSHA personnel. Participants complete yearly self-evaluations. OSHA recertifies worksites every 1 to 5 years.
Strategic Partnership Program,[a] 1998	Priority for participation is given to groups of employers and employees in high-hazard workplaces, with a focus on employers working at multiple worksites.	Flexible agreements between OSHA and partners to address a specific safety and health problem.	OSHA conducts verification inspections for a percentage of partner worksites to ensure compliance with the partnership agreement.
Alliance Program, 2002	Trade and professional organizations, employers, labor unions, governmental organizations.	Agreements with organizations that focus on training, outreach, and promoting the consciousness of safety and health issues.	OSHA meets quarterly with participants to ensure progress toward alliance goals is being met.

[a] Although the Occupational health and Safety Administration (OSHA) had partnership agreements prior to 1998, the Strategic Partnership Program was not formalized until that year.
Source: General Accounting Office (GAO) analysis.

Partnerships for Worker Safety and Health. OSHA Strategic Partnerships are intended to establish cooperative efforts at improving health and safety. However, OSHA continues to favor the more voluntary initiatives of *voluntary protection programs*—which it intends to expand tenfold—and alliances discussed below. All in all, the United States stands out in its slow, if not reluctant, approach to protect workers sufficiently with all the tools at its disposal.

The GAO recently reviewed OSHA's four voluntary initiatives and concluded that OSHA had not collected the data necessary to evaluate their effectives. GAO describes the four voluntary compliance programs as follows (Table 3-3):

(Through) the Voluntary Protection Programs (VPP), the State Consultation Program, the Strategic Partnership Program, and the Alliance Program,* OSHA has extended its reach to a growing number of employers. While worksites directly involved in these programs represent a small fraction of the 7 million sites over which OSHA has authority, their numbers suggest an expansion in the number of employers the agency

* *The State Consultation and the Strategic Partnership programs are sometimes referred to by slightly different names. The State Consultation Program is also known as the Onsite Consultation Program and the Consultation Program and the Strategic Partnership Program is also known as OSHA Strategic Partnerships for Worker Safety and Health.*

is able to reach through enforcement. OSHA's four voluntary compliance programs have involved employers both directly and indirectly through trade and professional associations. These programs represent a mix of strategies designed to reach different types of employers, including those that recognize employers with exemplary safety and health practices and programs designed to address serious hazards in workplaces. The State Consultation Program—a state run, but largely OSHA-funded, program—provides consultations, usually confidentially, to small businesses in high-hazard industries and exempts worksites that meet certain standards from routine inspections. Almost 29,000 consultation visits were made in 2003 as a part of this program. The VPP recognizes employers with exemplary safety records and practices by exempting them from routine inspections. The VPP has grown substantially over the past decade and currently includes over 1,000 worksites. The Strategic Partnership Program encourages employers in hazardous industries to develop measures for eliminating serious hazards. To date, there are more than 200 partnerships. In the Alliance Program, OSHA has collaborated with more than 160 organizations, such as trade and professional associations, to promote better safety and health practices for their members. To support all of its voluntary compliance strategies, OSHA has increased the proportion of resources dedicated to them from about 20 percent of its total budget in fiscal year 1996 to about 28 percent in 2003. The agency also plans to expand its voluntary compliance programs in the future, although national and regional OSHA officials we interviewed acknowledged that doing so would be difficult given the agency's current resources. For example, OSHA plans an eightfold increase in the number of worksites for the VPP, from 1,000 to 8,000. OSHA's voluntary compliance programs have reduced injuries and illnesses and yielded other benefits, according to participants, OSHA officials, and occupational safety and health specialists, but the lack of comprehensive data makes it difficult to fully assess the effectiveness of these programs. Participants we interviewed in the three states and nine worksites we visited told us they have considerably reduced their rates of injury and illness. They also attributed better working relationships with OSHA, improved productivity, and decreased worker compensation costs to their involvement in the voluntary compliance programs. However, much of the information on program success was anecdotal, and OSHA's own evaluation of program activities and impact has been limited to date. OSHA currently does not collect complete, comparable data that would enable a full evaluation of the effectiveness of its voluntary compliance programs. For example, OSHA requires participants in the Strategic Partnership Program to file annual reports but does not collect consistent information about each partnership. The agency has begun planning but has yet to develop performance measures to use in evaluating the programs and a strategic framework that will allow it to set priorities and effectively allocate its resources.

In addition to these formal programs, OSHA conducts other compliance assistance activities, such as outreach and training activities, to aid employers in complying with OSHA standards and to educate employers on what constitutes a safe and healthy work environment.

ANALYSIS OF EPA'S PERFORMANCE AND COMMENTARY ON NEW INITIATIVES

As with OSHA, EPA has underperformed in its effort to implement the legislation under its authority.[6] TSCA is internally regarded as a "dead letter" when it comes to the regulation of toxics and continues to move slowly on the testing of chemicals. As of mid-2005, the number of significant final rules promulgated by EPA under all the legislation under its authority during the two George W. Bush administrations was 11, compared to 31 and 40 in the two Clinton administrations and 31 under the first Bush administration. In 2004, EPA withdrew 25 items from its regulatory agenda, 12 of them coming from Clean Water Act items. During the first administration of George W. Bush, there have been 90 withdrawals as of September 2004: 39 from Clean Air Act planned action. 16 from Clean Water Act actions, and 12 from RCRA actions. EPA is resource-strapped but also without determined leadership. As of June 2004, EPA failed to achieve fully 73 percent of the benchmarks announced in its December 2003 agenda.

Like OSHA, EPA has invested its efforts in voluntary and conciliatory overtures to industry. What is euphemistically called regulatory reinvention was begun (at least under that name) in the Clinton administration and continues today in evolving forms. The most prominent early example was EPA's Common Sense Initiative (CSI), wherein the agency assembled groups of interested parties to focus on regulatory issues concerning a particular industry sector, such as automobile

manufacturing, with an eye toward developing "cleaner, cheaper, smarter" ways of reducing or preventing pollution. In contrast, EPA's Project XL focused on negotiations with individual firms. Both programs have now been phased out, and the Bush administration's National Environmental Performance Track program is now occupying center stage in regulatory reinvention. This program focuses on creating partnerships with individual firms in which the firms agree to exceed regulatory requirements, implement environmental management systems, work closely with their communities, and set 3-year goals to improve continuously their environmental performance in exchange for reduced priority status for inspections, reduced regulatory, administrative, and reporting requirements, and positive public recognition.[*] The program is too new to evaluate for inclusion in this writing.

OCCUPATIONAL HEALTH AND SAFETY IN BRITISH COLUMBIA

The discussion in this chapter has focused on occupational health and safety in the United States. The system in British Columbia, Canada, is very different and provides another useful perspective. (The following is based on a 1997 analysis of that system.)

Profile of British Columbia

British Columbia is Canada's third-largest province, with 1.4 million workers of a total population of 3 million people. Thirty-seven percent of the workers are unionized, compared with approximately 15 percent in the United States. Ninety-five percent of the firms have 50 or fewer workers, and 75 percent have five or fewer workers.

Administrative Structure

In British Columbia, the occupational safety and health regulation and enforcement activities and the workers' compensation system are part of the same administrative public corporation, the Workers' Compensation Board (WCB), and both are funded by assessed premiums on employers (see Box 4-2). The WCB is administered by a panel of administrators appointed by the Minister of Labour.

The Prevention Division (formerly the Occupational Safety and Health Division) employs approximately 400 people, which would translate into 28,000 for the United States (compared with the actual number of approximately 2,000). The annual division budget would be equivalent to a U.S. $1.5 billion budget for OSHA, five times larger than the amount actually allocated in the United States.

Legal/Structural Basis

Two provincial pieces of legislation—the Workers' Compensation Act (see Chapter 4) and the Workplace Act—provide the basis for the WCB's standard-setting authority. The federal Workplace Hazardous Materials Information System serves as the basis for provincial right-to-know activities. The Panel of Administrators adopts regulations, with the assistance of a tripartite Regulation Advisory Committee, including professionals from the division, which was responsible for developing new regulations and revising older ones during the last extensive regulation review process. A Policy Bureau in the division provides advice to the Panel of Administrators concerning the final regulations. Thereafter, there is no legal mechanism to challenge the regulations in the British Columbia system. Thus, the development of regulatory policy by the courts discussed for the U.S. system does not exist in British Columbia, for all practical purposes.

Enforcement

Historically, British Columbia standards have not been technology forcing. For example, until 1993 the lead standard permitted exposures up to 150 $\mu g/m^3$, compared with the U.S. standard of 50 $\mu g/m^3$. First-instance citations (mandatory citations on discovery of violations) exist only for a few, mostly safety, violations. There is pressure to include specific chemical exposures and failure of the employer to provide an adequate health and safety program/health and safety committee in the list of violations requiring first-instance citations. The Prevention Division can and does impose penalty assessments; criminal penalties are rarely issued. Labor participates in the WCB's enforcement and appellate process in a significant way.

Inspection activity is targeted by a combination of industry hazard classification, payroll, compensation claims, and inspector experience through a rational targeting system called WorkSafe. The

[*] *Approximately 350 firms have joined the program from a diverse cross-section of the economy. In contrast to Project XL, regulatory flexibility seems to relate to discretionary activities of agency inspection and reporting policies rather than to extensive exclusion of individual firms from mandatory regulatory provisions. See <http://www.epa.gov/performancetrack>.*

construction and logging industries are targeted for special attention because of their high-hazard nature and poor claims experience. The Prevention Division places serious emphasis on its data collection and analysis activities, which appear to be more useful than those of OSHA and the Bureau of Labor Statistics. Accident reporting, which is being computerized, increasingly provides the information needed to focus prevention activities, such as the cause of the accident, rather the cause of the injury. The Prevention Division is implementing the Diamond Project, which, like OSHA's Cooperative Compliance Program, is based on the Maine 200 Program, and seeks to shift responsibility to firms and workers when justified by a good record of occupational injuries (and diseases).

Consultation

Most inspection activity results in warnings and corrective orders rather than monetary penalties on the employer. Some consultation and technical assistance is usually rendered by the inspector at the time of the inspection or closing conference. The division provides engineering guidance and advice to employers in the form of technical bulletins and on-site consultation. The WCB also has an active first-aid certification program for workplace-based first-aid attendants, which is required by law. The WCB does not charge a fee for consulting advice or laboratory assistance/analysis.

Worker Participation

Workplace safety and health programs are required to be provided by all employers with a workforce of 50 or more employees (5 percent of the firms). For especially hazardous industries, the programs are required for employers with a workforce of 20 or more employees. Joint workplace safety and health committees are considered an essential part of these programs. There is pressure to expand the number of firms required to have such a program. Workers complain that they need more authority in the functions of the safety and health committees. They also complain of the inadequacy of the antidiscrimination provisions of the current law/structure, such as in relation to the right to refuse hazardous work.

Comment

Features of the British Columbia system suggest possible U.S. OSHA reforms, such as mandatory health and safety programs and committees, greater recognition of occupational disease, a streamlined standard-setting process, and a linkage of compensation and prevention activities. The period since 1970 has revealed both the strengths and weaknesses of the U.S. system, including the need to strengthen the connection between OSHA and the EPA through the OSHAct, TSCA, and the safety provisions of the Clean Air Amendments.

OCCUPATIONAL HEALTH AND SAFETY IN THE EUROPEAN COMMUNITY

Occupational health and safety legislation in individual European countries is in a great deal of flux after the formation of the European Community (EC), now the European Union (EU). (The following is based on a 1998 analysis.) The Single European Act establishing the EC was enacted in 1987. Article 118A of the act addresses employment, working conditions, and occupational health and safety and provides a streamlined legislative process for the development of health and safety directives and minimum health and safety standards affecting approximately 150 million people. The EC directives have the force of law and set down general principles for the protection of workers. However, individual countries are obligated to adopt national legislation implementing these principles, with important technical details concerning enforcement and administration left to the EC member states. Thus, programs may be expected to differ considerably among countries in the near future, although these differences may narrow as European integration becomes a reality. Therefore, it may be some time before innovations in health and safety regulatory approaches can be evaluated and serve as models for OSHA reform in the United States. Nevertheless, the EC experience may be important for the United States because (a) with the formation of a North American Free Trade Zone, the problems of harmonization of legislation may be similar; (b) the EC will be an important force in occupational safety and health; and (c) the EC will be a major trade competitor. The recent agreement between the EC and the European Free Trade Association countries to set up a free trade area means that the EC safety and health legislation is applicable in 19 countries in Europe.

Legal and Structural Basis

Regulatory activity within the EC can include regulations, decisions, directives, resolutions, and recommendations, varying from commitments in

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principle to legally enforceable mandates on the Member States. The European Commission, aided by expert groups, makes formal proposals to the EC Council of Ministers. The council, in consultation with the Economic and Social Committee and the European Parliament, adopts, rejects, or modifies the proposals and issues directives by a qualified majority vote of 54 of a total of 76. Individual member states can maintain or introduce more stringent measures for the protection of working conditions than those contained in the directives.

Until 1988, EC directives, such as those dealing with occupational exposure limits for vinyl chloride, lead, asbestos, and benzene, were very detailed and prescriptive. STELs were also specified. After Article 118A was enacted, a more general Framework Directive 89/391/EEC "on the introduction of measures to encourage improvements in the safety and health of workers at work" was issued. This directive is the centerpiece of EC health and safety policy and establishes the guiding principles on which more specific directives are issued. There are now seven so-called daughter directives to the Framework Directive. Directive 90/394/EEC addresses carcinogens at work. Directive 88/642/EEC addresses risks related to exposure to chemicals and physical and biological agents at work and has led to some 27 indicative limit values (ILVs), which are advisory only. The enforcement of those limits is left to the individual regulatory systems and styles of the various member states. Nevertheless, there is a preferred hierarchy of control for "dangerous substances and products." In order of preference, these are substitution of dangerous substances by safe or less dangerous ones, the use of closed systems or processes, local extractive ventilation, general workplace ventilation, and personal protective equipment.

Other EC directives address biological agents, asbestos, video display terminals, work equipment, personal protective equipment, and handling of loads. In 1988, the European Parliament adopted a Resolution on Indoor Air Quality, which is receiving attention for development into a directive.

All commission proposals are submitted to the Advisory Committee on Safety, Hygiene and Health Protection at Work, composed of representatives of employers, workers, and governments. Initially, an expert scientific group evaluates all scientific data relevant to protecting workers from a particular substance. The commission makes a proposal and solicits Advisory Committee opinion. The Technical Progress Committee votes on the proposal. The limit values may be adopted as indicative values by commission directive. If the exposure limits are mandatory, they are adopted by the Council of Ministers as directives pursuant to Article 118A. Compared with the United States, relatively few health standards have been established, reflecting the slowness of the tripartite process of participatory standard setting envisioned by the EC.

The Framework Directive applies to all sectors of employment activity, both public and private. However, it excludes the self-employed and domestic workers. Employers have a general "duty to ensure the safety and health of workers in every aspect related to the work" (Article 5.1). Among the employer's specific duties are (a) to evaluate risks in the choice of work equipment, chemicals, and design of the workplace; (b) to integrate prevention into the company's operations at all levels; (c) to inform workers or their representatives of risks and preventive measures taken; (d) to consult workers or their representatives on all health and safety matters; (e) to train workers on workplace hazards; (f) to provide appropriate health surveillance; (g) to protect especially sensitive risk groups; and (h) to keep records of accidents and injuries.

Enforcement

Labor inspectorates in each member state have the responsibility to ensure employer compliance with health and safety requirements. However, beyond broad principles and duties, the EC directives are often advisory, and not many specific requirements are enforceable through EC channels. Attempts to place binding obligations on national governments to establish the necessary institutional elements to support proper implementation of safety and health regulations, such as health and safety technical centers, have been unsuccessful. The commission established a Committee of Senior Labor Inspectors in 1982 to facilitate information exchange to encourage coordination of policy. The commission also established the European Agency for Safety and Health at Work in Bilbao, Spain.

The commission does have the authority to bring action against a member state for failure to adhere to EC directives, but the commission does not yet have the institutional capacity to monitor compliance effectively. Action against a member state has never been brought, however, even though some countries have not adopted national legislation to

conform with specific mandatory exposure limits, such as for noise. No uniform policy on enforcement of standards, such as first-instance citations or penalty levels, exists, and it is likely that intercountry variations will be allowed.

Worker Participation

The Framework Directive calls for "the informing, consultation, balanced participation . . . and training of workers and their representatives" to improve health and safety at the workplace (Article 1.2). The directive gives workers the rights to consult in advance with their employers on health/safety matters, to be paid for safety activities, to communicate with labor inspectors, and to exercise the right to refuse dangerous work. Safety committees are not explicitly addressed by the directive, although many European countries have required them in transposing the directive into national law. Similarly, joint decision-making is not mandated but may occur in practice.

Comment

The health and safety policy of the EC is evolving. Although the general principles declared in EC legislation and specific directives are laudable, it remains to be seen what course implementation will take and how much variation will continue to exist among the different member states. European regulatory systems tend to be more advisory. On the other hand, they are also more participatory, inviting decision making on a tripartite basis.

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