chapter 7

The Regulatory Process

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INTRODUCTION

Several Federal agencies have regulated substances based on deleterious health effects that include reproductive harm. While the Occupational Safety and Health Administration is the primary regulator of hazardous occupational exposures, occupational health issues are addressed by several other agencies as well. Each of these other agencies regulates industrial hazards in an area defined by either occupational category (e.g., the Mine Safety and Health Administration for mine workers) or type of exposure (e.g., the Environmental Protection Agency for pesticides).

This chapter addresses the issue of Federal Government regulation of workplace exposure to known and suspected reproductive health hazards. The activities of relevant Federal agencies are discussed, especially those of the occupational Safety and Health Administration, the Environmental Protection Agency, and the Nuclear Regulatory Commission.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION AND RELATED AGENCIES

Prior to 1970, occupational safety and health regulation was nonexistent in a majority of States and consisted of a patchwork of sometimes inconsistent laws in the rest. Congress, concerned with the human and economic costs of occupational injuries and illnesses, enacted the Occupational Safety and Health Act of 1970 (OSH Act) to "assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources." Passage of national legislation concerned with workplace hazards brought occupational safety and health coverage to more than 75 million working Americans.[3] The OSH Act resulted in the creation of three agencies to deal with occupational safety and health issues on a national level: the Occupational Safety and Health Administration (OSHA), the National Institute for Occupational Safety and Health (NIOSH), and the Occupational Safety and Health Review Commission (OSHRC).

OSHA

OSHA is a regulatory agency within the Department of Labor. It sets mandatory health and safety standards, inspects workplaces to ensure compliance with those standards, and proposes penalties and abatement plans for employers found to be violating health and safety standards. OSHA also monitors the performance of State agencies operating State occupational safety and health plans under the OSH Act. In addition, OSHA provides education and consultation services to the public, workers, and employers, mostly through grant activities. OSHA is headed by a presidentially appointed Assistant Secretary of Labor for Occupational Safety and Health, to whom the Secretary of Labor has delegated authority under the OSH Act.

NIOSH

NIOSH conducts research and related activities leading to the development of criteria or recommendations for OSHA'S use in setting health and safety standards. These activities include research designed to identify and evaluate workplace hazards, research concerning measurement tech-

[1] U.S. Congress, Office of Technology Assessment, Preventing Illness and Injury in the Workplace (1985).
[2] 29 U.S.C. § 651ff.
[3] See generally U.S. Congress, Office of Technology Assessment, Preventing Illness and Injury in the Workplace (1985).

niques and control technologies, and education of health and safety professionals. NIOSH is part of the Centers for Disease Control (CDC) of the U.S. Public Health Service (PHS), which is within the Department of Health and Human Services (DHHS). NIOSH is headed by a Director appointed by the Secretary of HHS for a term of 6 years.

The separation of research and regulatory standard-setting into NIOSH and OSHA is controversial. While defended by some as a way of keeping scientific activities neutral, it has also been said to lead to inefficiency and duplication, and the activities of the two agencies have been criticized as insufficiently coordinated.[4] (See box 7A.)

OSHRC

OSHRC is an independent, quasi-judicial review board whose duties are limited to reviewing OSHA citations issued to employers charged with violating OSHA standards. In deciding these cases, however, OSHRC decides the nature and scope of many employer obligations concerning employee health and safety. OSHRC is composed of three members, appointed by the President with the advice and consent of the Senate, for staggered terms of 6 years.

Exemptions From OSHA Jurisdiction Due to Jurisdiction of Another Agency

Most workers are covered by the OSH Act. (A detailed description of covered employers and employees appears in a staff paper available from OTA.) Section 4(b)(1) of the Act provides that the statute does not apply to:

> . . . working conditions of employees with respect to which other Federal agencies . . . exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety and health.

Although Congress intended to avoid duplication or conflict among Federal agencies that regulate safety and health, there have been many questions as to which working conditions are exempt from application of the OSH Act, what the limits of exemptions are, and what the procedural implications of exemptions are. (The legal principles governing exemption from OSHA jurisdiction are discussed in detail in a staff paper available from OTA.)

Recent Commission decisions suggest a three-part test to determine whether OSHA is preempted from exercising jurisdiction by virtue of 4(b)(l):

1. The working condition is covered by another Federal act exclusively directed at employee safety and health or more generally directed at public safety and health, and employees directly receive the protection the act is intended to provide.
2. The other Federal agency has exercised its statutory grant of authority.
3. The other Federal agency has acted in such a manner as to exempt the cited working conditions from OSHA jurisdiction.

Relevance to Reproductive Health Hazards

There are two principal ways in which the issue of $ 4@)(l) preemption may be relevant to OSHA'S regulation of reproductive health hazards. The first involves OSHA'S attempt to promulgate standards covering working conditions regulated by another Federal agency. For example, in 1973, OSHA issued an emergency temporary standard (ETS) for exposure to 21 organophosphorous pesticides.s The standard required employers to warn employees of pesticide hazards, set field reentry times, and prescribed sanitation and medical services and first aid. In 1974, the Fifth Circuit stayed and then vacated the ETS on the ground that no "grave danger" existed, as required by $ 6(c).'

After the Fifth Circuit's decision, OSHA held hearings on a new permanent pesticide standard. Eventually, OSHA discontinued its rulemaking and acceded to the position of the Environmental Protection Agency (EPA) that OSHA was preempted from regulating pesticides because of EPA's authority under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).[7] In a subsequent law-

[4] N. Ashford, **Crisis in the workplace: Occupational Disease and Injury (1976).**

[5] 38 **Fed. Reg. 10,715 (1973).**

[6] Florida **Peach Growers Association v. U.S. Department of Labor, 489 F.2d 120 (5th** Cir. **1974).**

[7] See **B. Mintz,** OSHA: **History, Law and Policy 105 (1984).**

Box 7A.—Interagency Relations

In researching the status of relations between OSHA and NIOSH, which are integral to the rulemaking process for reproductive and other health hazards, a number of interviews were conducted with present and former OSHA and NIOSH officials.

Certain patterns emerged from their responses. Present officials tended to be positive about interagency relations. Former officials were largely negative about both past and present relations. High-ranking officials were more positive about interagency relations than were their subordinates.

The interviews focused on four main subject areas: institutional concerns, funding and personnel, priorities and policies, and interagency programs.

Institutional Conce—-Perceptions of the missions of NIOSH and OSHA differ. A close working relationship between the assistant secretary of labor for OSHA and the NIOSH director during the Carter Administration was criticized for ostensibly jeopardizing the agency's image as a neutral research body.s The former NIOSH director, while upholding the scientific accuracy of NIOSH research, responded that the goal of both agencies is to protect workers, and that "the law never says that NIOSH has to be neutral."

Reagan Administration officials favor the clear separation of research and regulation. A former assistant secretary of labor for OSHA in the Reagan Administration contends that NIOSH'S role is, and should be, limited to research, a view shared by the current NIOSH director. NIOSH and OSHA have consequently discontinued the practice of publishing joint statements and hazard alerts, which had been seen as having greater impact on the public due to having been issued by both agencies.

Interaction between the agencies may be hampered by their differing levels in the bureaucracy, according to a former NIOSH director. OSHA'S head functions directly under the Secretary of Labor, whereas the director of NIOSH is responsible to the director of CDC, who is responsible to the Assistant Secretary for Health, who reports in turn to the Secretary of HHS.

Other officials disagreed, and the current NIOSH director suggested that NIOSH'S '(insulation" maybe advantageous in that it frees the Institute's director to work exclusively on science while other officials tend to the regulatory burdens.

A former OSHA chief and a NIOSH director who served under both Democratic and Republican administrations expressed concern that funding for complementary programs can be jeopardized when NIOSH and OSHA budget requests are reviewed by different budget examiners at the Office of Management and Budget (OMB). The current NIOSH director does not consider this to be a problem, however.

Funding and Personnel-It is widely agreed that personalities have an important effect on the interagency relationship. Exchanges of personnel and other joint programs can improve the relationship, a Carter Administration OSHA head believes, but opponents tend to view such efforts as "entanglement ."

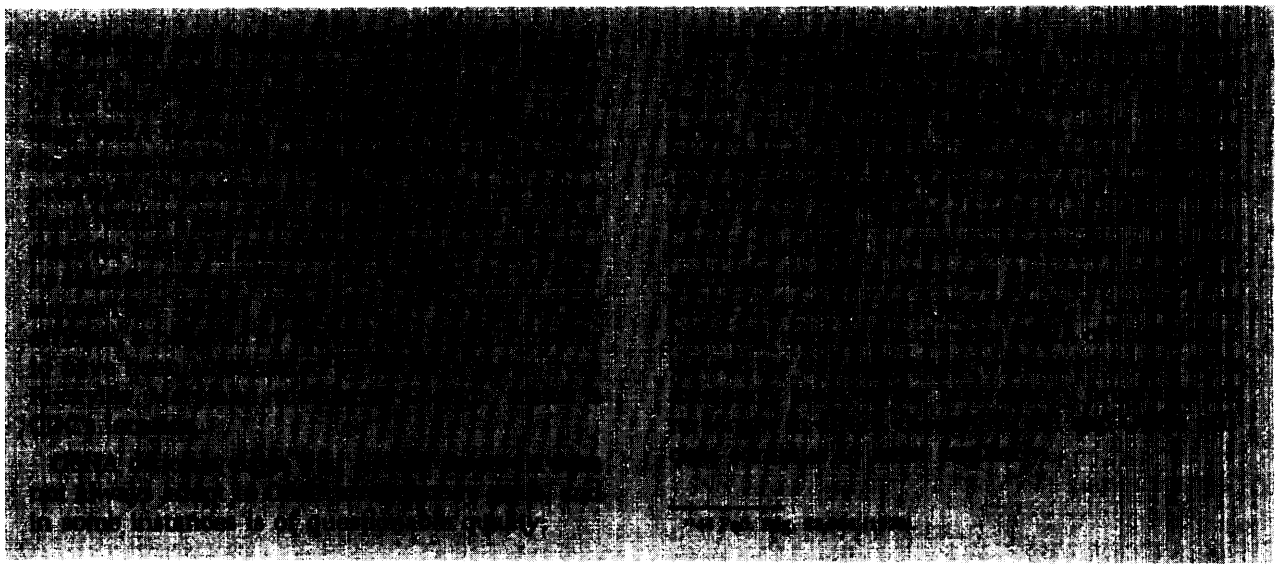
The most common criticism of current OSHA-NIOSH relations is that reductions in technical personnel at OSHA limit the agency's capacity for in-depth review of NIOSH'S work. (OSHA'S Directorate of Health Standards Programs has only one toxicologist, two epidemiologists, and no physicians, although the Directorate of Technical Support has additional personnel).[8] OSHA'S present lack of technical expertise, according to a NIOSH official, renders OSHA-NIOSH relations "close to nonexistent at the working level."

An OSHA official agrees that chronic personnel shortages impair the agency's ability to perform technical reviews. The only full-time occupational physician at OSHA, he has been aided by in-house physicians on interagency assignments, by four residents (who serve 2-to 4-month residencies), and by expert consultants when needed. However, the residency program may be in jeopardy. A senior OSHA official, who acknowledges that NIOSH generates more technical material than OSHA can handle, doubts that more technical staff is the answer. In his view, more lawyers, more administrators, and more staff are required all the way up the line.l"

[6]See U.S. Congress, Office of Technology Assessment, Preventing Illness and Injury in the Workplace (1985).

[8]According to the Administrative Officer of OSHA's Directory of Health Standards, as of Aug. 1, 1984, OSHA had 25 professionals in the Health Standards Directory (includes health scientists and industrial hygienists), compared with a high of 40 in March 1981. There are presently two epidemiologists and one toxicologist; this compares with the 1979 high of five to six epidemiologists and one toxicologist.

[10]The decline in scientific and nonscientific personnel at OSHA between March 1979 and October 1983 is documented in a recent report of the General Accounting Office. 14 O.S.H. Rep. (BNA) 281 (1984).



suit brought by a farmworker group to compel OSHA to issue a pesticide standard, the D.C. Circuit held that OSHA was indeed preempted under $ 4(b)(l) by virtue of the Federal Environmental pesticide Control Act (FEPCA) (which revised FIFRA).[12] Thus, OSHA was not permitted to issue a standard for a class of hazards that EPA was authorized to regulate.

The second way in which $ 4(b)(1) maybe relevant to OSHA'S regulation of reproductive health hazards involves attempts by OSHA to prohibit allegedly discriminatory reproductive health policies of employers. In *American Cyanam~d, *3* a case discussed more fully later in this chapter, the employer was cited under $ 5(a)(l) (the general duty clause, discussed below) after five women employed in the lead pigments department submitted to surgical sterilization in order to retain their jobs. In granting the employer's motion for a judgment in its favor, the Commission administrative law judge (ALJ) held, among other things, that $ 4(b)(1) precludes OSHA from exercising authority because the employer's fetal protection policy is possibly an unfair labor practice under the National Labor Relations Act and possibly sex discrimination under Title VII of the Civil Rights Act of 1964. Although the Commission subsequently affirmed the ALJ's decision on other grounds, the plain language of $ 4(b)(I) would seem to preclude the ALJ's interpretation. Neither the National Labor Relations Board nor the Equal Employment Opportunity Commission are agencies which "exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health." The Commission's decision was affirmed on other grounds by the U.S. Court of Appeals for the District of Columbia.

Congressional Appropriations Limitations

Beginning with fiscal 1977, Congress has restricted some specific aspects of OSHA enforcement by attaching limitations to OSHA appropriations bills and continuing resolutions. Five of these limitations are relevant to OSHA regulation of reproductive health hazards in the workplace,

First and most importantly, OSHA is prohibited from inspecting workplaces with 10 or fewer employees in industries with threedigit Standard Industrial Classification (SIC) injury and illness rates below the national lost workday injury rate for manufacturing (currently 3.4 per 100 employees).[14] The SIC codes and the injury rate are both

[12] Organized Migrants in Commun. Action, inc. v. Brennan, 520 F.2d 1161 (D.C. Cir. 1975). See Comment, Interpreting OSHA's Preemption Clause: Farmworkers As A Case Study, 128 U. Pa. L. Rev. 1509 (1980).

[13] American Cyanamid co., 9 C). .H. Cas. (BNA) 1596 (1981) aff'd, Oil, Chemical &L Atomic Workers International Union v. American Cyanamid Co., 741 F.2d 444 (D.C. Cir. 1984). A second case against Cyanamid, brought by female employees, is discussed in ch. 8.

[14] See OSHA Instruction 2.51B (1984).

determined by the Bureau of Labor Statistics. The injury rate is updated annually. There are several exceptions to the limitation, and inspections are still permitted in the following instances: in response to complaints, for failure to correct, for willful violations, to investigate accidents, for imminent dangers, for health hazards, and to investigate discrimination complaints.

Second, OSHA is prohibited from inspecting workplaces for 6 months after a State inspection is performed in States with approved plans, except for investigation of employee complaints and fatalities, special studies, and accompanied monitoring visits.

Third, OSHA is prohibited from assessing penalties for first-instance nonserious violations of any employer unless the inspection discloses 10 or more violations. OSHA is still permitted to issue citations that prescribe an abatement date for these violations, and second-instance violations of any nature can carry a penalty.

Fourth, farms, ranches, orchards, and related operations with 10 or fewer employees at one time during the past year, except those with migrant labor camps, are exempt. Members of a farm employer's immediate family are not considered employees.

Finally, no penalties maybe assessed against an employer with 10 or fewer employees who had a prior onsite consultation and had made good faith efforts to abate the violative conditions prior to the inspection.

OSHA'S Authority to Regulate the Employment Relationship Due to Reproductive Hazards

Medical Removal Protection and Rate Retention

One possible way of addressing the problem of reproductive health hazards in the workplace is for OSHA to regulate the permissible range of an employer's options relating to employee exposure. For example, OSHA might promulgate a standard prohibiting an employer from excluding only women (or men) from areas where there is exposure to known or suspected reproductive or developmental hazards; that is, abortifacient, mutagenic, teratogenic, or embryo-fetotoxic substances. The promulgation of such a regulation would raise the legal issue of whether OSHA had exceeded its statutory authority.

Although the courts have not addressed the issue of OSHA'S authority to promulgate a standard prohibiting exclusionary employment practices, some analogous issues have arisen in cases involving medical removal protection (MRP) and rate retention (RR). MRP is simply the removal of employees from further hazardous exposure to a toxic substance until it is medically advisable to return. RR requires that the removed employee's wages and benefits be maintained during the period of removal.

MRP and RR provisions in OSHA health standards have become increasingly stringent, For example, the vinyl chloride standard (promulgated in 1974) provides for MRP, but not RR[15] The asbestos standard (promulgated in 1972) provides for MRP for employees for whom respirators are ineffective, but RR is required only if there is an available position[16] The cotton dust standard **(promulgated in 1978), however, squarely raised the issue of OSHA authority by requiring RR for certain employees.** [17] The Supreme Court, without deciding the issue of whether OSHA could impose MRP and RR requirements at all, struck down this RR provision because OSHA "failed to make the necessary determination or statement of reasons that its wage guarantee requirement is related to the achievement of a safe and healthful work environment."[18]

[15] 29 CFR § 1910.1017(k)(5) (1984).
[16] Ibid. at § 1910. Idol.
[17] The cotton dust standard, 29 CFR § 1910.1043 (1984), allowed reliance on the use of respirators to protect employees from exposure to cotton dust during the 4-year interim period given employers to install engineering controls. (After 4 years, respirators were not allowed except in limited cases.) One part of the respirator provision required employers to give employees unable to wear a respirator (because of facial irritation, severe discomfort, or impaired breathing) the opportunity to transfer to another position, if available, where the dust level meets the standard's permissible exposure limit (PEL). When such a transfer occurs the employer must guarantee that the employee's wages and benefits are maintained.
[18] American Textile Manufacturer's Institute, Inc. v. Donovan, 452 U.S. 490, 537-38 (1981). Rather than explaining the RR provision as being essential in ensuring that workers would seek needed MRP, OSHA had stated that the "goal of this provision is to minimize any adverse economic impact on the employee by virtue of the inability

The Court's most instructive statement on the permissible scope of OSHA rulemaking is the following:

> Because the Act in no way authorizes OSHA to repair general unfairness to employees that is unrelated to achievement of health and safety goals, we conclude that OSHA acted beyond statutory authority when it issued the wage guarantee regulation. [19]

When OSHA subsequently promulgated its revised lead standard in 1978, it included an even broader MRP and RR provision.[20] When an employee is removed in any way, the employee retains his or her earnings rate, seniority, and benefit levels for up to 18 months and on return must be restored to his or her original job status.

Unlike its statement of reasons accompanying the cotton dust standard, the lead standard contained detailed findings of the need for RR, OSHA found that "unless workers were guaranteed all their wage and seniority rights on removal, they would resist cooperating with the medical surveillance program that determined the need for removal, since they reasonably might fear being fired or sent to lower paying jobs if they revealed dangerously high blood-lead levels."[21] This rationale was upheld by the D .C. Circuit .[22]

The D.C. Circuit's opinion contains a footnote with particular relevance to the issue of MRP and reproductive health hazards:

> Amici representing public interest law organizations and California State labor agencies have argued that MRP is not only legally valid under the OSH Act, but is legally required by Title VII of the Civil Rights Act of 1964, 42 U.S.C. $ 2000(e) et seq. (1976 & Supp. H 1978). They argue that without MRP employers will discriminate against fertile women—to whom lead exposure poses an even greater threat than it does to other workers-by excluding them from all lead-exposed jobs at the outset.
>
> A review of an OSHA proceeding, however, is not the place to address hypothetical Title VII questions, and in any event we think fertile women can find statutory protection from such discrimination in the OSH Act own requirement that OSHA standards ensure that no ***employee will suffer*** **material** impairment of health. " 29 U.S.C. $ 655(b)(5) (1976) (emphasis added).[23]

The cotton dust and lead cases suggest that OSHA may promulgate health standards that provide for medical removal and rate retention, so long as any rate retention requirement is related to the achievement of a healthful work environment, rather than to redress unfairness or discrimination.

When read together, the cotton dust and lead cases suggest the following about OSHA regulation of reproductive health hazards:

1. OSHA has the statutory authority to protect the sexual and reproductive health of male and female workers. The reproductive functions of these workers include the ability to produce healthy offspring, OSHA therefore has apparent authority to protect embryos/fetuses from workplace hazards.

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to wear a respirator." Id. at 538 (quoting 43 Fed. Reg. 27,387 (1978)). The Court dismissed DSHA'S statement of the importance of encouraging employees to disclose symptoms of disease as unacceptable "post-hoc rationalizations." Id. at 539.

[19] 452 U.S. at 540 (footnote omitted).

[20] The current version of OSHA's lead standard is at 29 CFR § 1910.1025 (1984).

[21] 43 Fed. Reg. 54,442-46 (1978).

[22] United Steelworkers of America v. Marshall, 647 F.2d 1189 (D.C. Cir. 1980), cert. denied sub nom. Lead Indus. Assn. Inc. v. Donovan, 453 U.S. 913 (1981), In this case, the D.C. Circuit upheld the validity of the MRP and RR provision. The lead industry had argued that Congress did not intend to have MRP and RR under OSHA because the Act is silent on this subject, while the Coal Mine Health and Safety Act of 1969 (CMHS Act), passed the year before OSHA, contained an MRP provision, The court rejected this argument, noting that the CMHS Act covered a single industry and was drafted with much greater specificity than OSH Act. The lead industry also argued that the provision violated § 4(1)) (4)'s prohibition on OSHA interfering with workers' compensation. Although acknowledging the "seriousness" of this argument, the court noted the limited duration and scope (e.g., there is no payment for medical expenses) of RR benefits, and indicated that the group of workers to benefit from this provision will become increasingly smaller as the PEL is lowered. "We conclude that though MRP may indeed have a great practical effect on workmen's compensation claims, it leaves the state schemes wholly intact as a legal matter, and so does not violate $ 4(b)(41." 647 F.2d at 1236. Finally, the court rejected the argument that MRP and RR violates the national labor policy of allow'-ing all substantive provisions of labor management relations to be left to collective bargaining. Simply because earnings protection is a mandatory subject of bargaining and could be adopted through collective bargaining does not mean OSHA has no authority to mandate such a program. The Supreme Court refused to hear the case, thereby allowing the D.C. Circuit's decision to stand.

[23] 647 F.2d at 1238 n, 74 (emphasis in original).

2. OSHA could promulgate a single permissible exposure level that protects male workers, female workers, and embryos/fetuses from a hazardous substance, so long as the standard met all of the requirements of $$ 3(8) and 6(b)(5), such as "significant risk" and technological and economic feasibility.
3. OSHA might be precluded from promulgating a regulation directed only at prohibiting the exclusion of all women from exposure to reproductive health hazards. Such rulemaking could be held to be preempted by Title VII, pursuant to $ 4(b)(l), or might be considered to be an ultra vires attempt "to repair general unfairness unrelated to achievement of health and safety goals, " as held in the cotton dust case, However, OSHA can allow the exclusion of men and women under a specific standard addressing health and safety goals (e.g., lead standard).
4. OSHA could probably enact a regulation prohibiting an employer from making sterilization of current employees (male, female, or all employees) a condition of continued employment. Although the ***American Cyanamid*** case (see note 13) held that the general duty clause does not implicitly prohibit such employer practices, an explicit regulation might do so. Valid health and safety goals would seem to include prohibiting both exposure to sterilizing agents and "voluntary" sterilization in order to retain employment. Note that an employment policy requiring that all employees be sterilized would not violate Title VII because both sexes are treated equally. It is less clear whether OSHA has the authority to promulgate a regulation prohibiting an employer from hiring only employees who had been sterilized or were otherwise incapable of reproduction. Such a regulation might be upheld based on the same considerations as are applicable to current employees.
5. The promulgation of an OSHA standard prohibiting an employer from refusing to hire fertile women would entail elements of both considerations 3 and 4. The legality of such rulemaking may ultimately turn on the state of the factual record developed at the rulemaking, including evidence as to whether prohibiting the employment of fertile women causes women to become sterilized .24

Employer and Employee Duties

OSHA imposes duties on both employers and employees. Employers are required: 1) to comply with OSHA standards, and 2) to generally provide employment free from recognized hazards. Employees are also required to comply with OSHA standards, though final responsibility for employee compliance rests with the employer. These duties are discussed below.

The OSH Act is enforced solely by the Federal Government and, in States with approved plans, by those States. Specifically, OSHA inspects workplaces for compliance with OSHA standards and workplace, and may issue citations to noncompliant employers. There is no private right of action to enable employees to obtain enforcement of OSHA standards or the general duty clause as to their employers.

Compliance with Standards-Section 5(a)(2

Section 5(a)(2) of the Act provides simply that each employer "shall comply with occupational safety and health standards promulgated under this Act. " Whether an employer has complied with the Act is not determined by the number of accidents that have taken place. Furthermore, the occurrence of an accident does not always mean there has been a violation.[25] Even the occurrence of hazardous conduct is not per se evidence of a violation .26 Conversely, the absence of an accident does not mean there was no violation-it may only reflect the employer.'s good fortune .[27] Even a serious violation does not require any ac-

[24] M Rothstein, The **Regulation** of Reproductive Haza **Ids** Under OSHA **(Aug. 1984) (unpublished report),**

[25] **B & B** Insulation, Inc. v. OSHRC, 583 F. 2d 1364, 1372 & n.17 **(5th** Cir. **1978); Ryder Truck Lines, Inc.** v. Brennan, 497 F.2d **230, 233 (5th** Cir. **1974); Lebanon Lumber Co., 1 (). S.11,** Cas. (BNA) **1165 (1973).**

[26] National Realty &. **Construction** Co. v. OSHRC, 489 F 2d 1257, **1266** (D.C.Cir. **1973).**

[27] A.E. Burgess **Leather** Co. v. OSHRC, **.576** F.2d **948,** 951 (lst Cir. 1978); **Arkansas-Best Freight System, Inc.** v. OSHRC, 529 F.2d **649, 655 (8th** Cir. **1976); General Electric Co.,** 7 O.S.H. Cas. (BNA) **2183 (19801;** Kroehler **Manufacturing (:0., 6** O.S.H. **Cas.** (BNA) **2045 (1978),**

tual death or physical injury.[28] The Act seeks to prevent injury and illness by eliminating hazardous conditions.

Environmental Monitoring. -The employer is responsible for conducting periodic atmospheric tests to determine the presence and concentration of hazardous substances that are addressed by OSHA standards. The standards differ on the frequency of the testing, but even the most stringent requirements have been upheld.

OSHA'S health standards often rely on the concept of an ***action level.*** For example, in the ethylene oxide standard, OSHA established a one part per million (ppm) 8-hour time-weighted average (TWA) as the exposure limit. The action level was set at 0.5 ppm. When initial monitoring reveals exposures below the action level, no further monitoring is required unless there is a change in production, process, or control. If exposures are above the action level, exposures must be monitored twice per year. Monitoring may be discontinued, however, if two consecutive measurements, taken at least 7 days apart, show exposures below the action level. If exposures go above the TWA, more frequent monitoring is required as well as reductions in exposure levels. These requirements are summarized in the following table:

Exposure scenario	*Required monitoring activit.v*
Below the action level	No monitoring required
At or above the action level, but at or below the TWA	Monitoring exposures two times per year
Above the TWA	Monitor exposures four times per year

The action level attempts to provide a margin of safety, so that it is unlikely that a minor fluctuation in atmospheric concentration would result in an exposure exceeding the TWA. It requires that employers with exposures approaching the TWA keep close measurements to ensure that the TWA is not exceeded, while removing the burden of continuous environmental monitoring from employers with only slight exposure levels. The main problem with the use of the action level concept is that it eliminates important protections for workers whose exposures are below the action level. For example, in the Benzene case, the Supreme Court was critical of OSHA for not requiring monitoring and medical testing of employees exposed below the action level:

> By doing so, [OSHA] could keep a constant check on the validity of the assumptions made in developing the permissible exposure limit, giving it a sound evidentiary basis for decreasing the limit if it was initially set too high. Moreover, in this way it could ensure that workers who were unusually susceptible to benzene could be removed from exposure before they had suffered any permanent damage.

A similar problem exists under the lead standard, which established a permissible exposure limit (PEL) of 50 micrograms of lead per cubic meter of air averaged over an 8-hour work day and an action level of 30 micrograms. An employer's duty to supply protective clothing, change rooms, showers, and other hygiene facilities and practices is contingent on the exposure level being above the action level .30 However, an action level that is sufficient to protect the worker may not be sufficient to protect a child exposed to the worker's contaminated clothing.

Biological Monitoring. -OSHA health standards may require the biological monitoring of exposed employees to measure the body's uptake of toxic substances. For example, the lead standard requires that the employer provide blood sampling and analysis for lead and zinc protoporphyrin levels for each employee with lead exposure at or above the action level. This monitoring is required at least every 6 months .31

Medical Surveillance.-OSHA's ***22*** health standards regulating toxic substances require a variety of medical procedures. In general, employers must conduct preplacement examinations, a physician must furnish employers with a statement of suitability for employment in the regulated area, the employer must conduct periodic (usually annual) examinations, and in some instances the employer must conduct examinations at termination of employment. The failure to conduct these required medical examinations may lead to the issuance of OSHA citations and the assessment of penalties.

OSHA medical surveillance programs have two primary purposes: 1) to give the employee notice of any adverse health effects that he or she may

[28] Brennan v. Butler Lime & Cement CO., 520 F.2d 1011, 1017 (7th Cir. 1975).

[29] Industrial Union Department v. American petroleum Institute, 448 U.S. 607, 658 (1980) (footnotes omitted).

[30] 29 CFR § 191o.1o25QJ, (i) (1984).

[31] Id. at § 1910.1025(j)(2).

have suffered so that proper medical attention may be obtained and precautionary measures taken, and 2) to provide OSHA and NIOSH with data for research purposes .32 (The mechanics of medical surveillance programs are discussed in Appendix C-l.)

Controls / Other Requirement& -OSHA health standards attempt to reduce exposure through a variety of control strategies, such as engineering controls, work practice controls, personal protective equipment, and administrative controls .33

The General Duty Clause-Section S(a)(1)

Section 5(a)(l) of the Act, the general duty clause, provides that each employer "shall 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 to his employees."

The general duty clause was enacted to cover serious hazards to which no specific standard applies. Because the general duty clause was designed to augment rather than supplant standards, citation under $ 5(a)(l) is improper where a specific standard is appropriate.[34] During the first few years of the Act's existence, the general duty clause was used to prohibit hazardous conduct while specific standards were being promulgated or before a standard's effective date .35 Subsequently, however, the general duty clause has been used for peculiar violations not covered by specific standards.[3G]

The most distinctive and significant element of general duty clause violations is that they are limited to "recognized hazards." The recognition requirement serves to ensure that cited employers have at least constructive knowledge of the existence of specific hazardous conditions. In this way, Congress sought to eliminate the unfairness of assessing first-instance civil penalties based on such a sweeping and broadly worded provision .37

A hazard is considered recognized: 1) if it is common knowledge in the employer's industry, or 2) if the employer had actual or constructive knowledge of the hazardous condition. Recognition thus may be established either objectively or subjectively .[3s]

Industry Recognition of Hazard. -In addition to expert testimony, the Commission and courts have held that other sources may be used to prove industry recognition of a hazard. State[39] and local[40] laws, American National Standards Institute[41] and National Fire Protection Association[42] standards, industry publications ,43 and manufacturer's warnings[44] all have been used to dem-

[32] B. Mintz, OSHA: **History, Law, and** Policy **131 (1984).**

[33] Depending **on the working conditions, employers may have a wide range of other duties, such as providing showers and changing rooms, protective clothing, and laundry facilities. Employers also may be obligated to post warning signs and give detailed warnings to their employees. Finally,** OSHA **standards require that all health hazard emergencies be reported. For example, carcinogen exposure must be reported to** OSHA **within 24 hours. See, e.g., 29** CFR § **1910.1003(f)(2) (1984). Radiation exposure must be reported immediately** by **phone or telegram and a written report must be filed within 15 days. 29** CFR § **1910.96(1) (1984).**

[34] **s+ Brisk waterproofing Co., 1** O.S.H. Cas. (BNA) **1263 (1973).** See **S. Rep.** No. **1282, 91st** Cong., **2d** sess. **9, 10, reprinted in 1970 U.S. Code** Cong. & **Ad. News 5177, 5185-86.**

[35] See **American** Smelting **& Refining** Co. v. OSHRC, 501 F.2d 504, **512 (8th** Cir. **1974).**

[36] See, e.g., Marquette Cement **Manufacturing** Co., **3** O.S. **H.** Cas. (BNA) **1928 (1976), vacated, 568** F.2d **902** (2d Cir. **1977) (employee crushed by falling bricks); Richmond Block, Inc.,** 1 O.S.H. Cas. (BNA) **1505** (1974) **(employee killed while cleaning inside of cement mixer); Southern Soya Corp., 1** O.S.H. Cas. (BNA) **1412 (1973) (employees suffocated by cave-in of stored cottonseed),**

[37] **The case of American** Smelting **& Refining Co. v.** OSHRC, **501** F.2d **504 (8th** Cir. **1974), concerned the issue of whether recognized hazards are limited to those detectable through the senses or whether they extend to hazards only detectable through instrumentation. The Eighth Circuit reviewed the legislative history of the general duty clause and found of considerable importance the fact that Congress changed the wording from '<readily apparent hazards," used in an earlier version of the bill, to "recognized hazards." Moreover, the court pointed out that the ameliorative purpose of the Act would be subverted by a narrow construction of "recognized hazards," "[T]o limit the general duty clause to dangers only detectable by the human senses seems to us to be a folly. . Where hazards are recognized but not detectable** by **the senses, common sense and prudence demand that instrumentation be utilized." Id. at** 511.

[38] **In National** Realty **& Construction CO.** v. OSHRC, **489** F.2d 1257 (D.C. Cir. **1973), a landmark § 5(a)(1) case, the** D.C. **Circuit held that whether a hazard is recognized** by **an industry is determined by the "common knowledge of safety experts who are familiar with the circumstances of the industry or the activity in question." Ibid. at 1265** n.32. **The Commission has followed National Realty and also has held that the expert testimony of a compliance officer about industry practice may be used to show that a hazard was recognized.** Beaird-Poulan, 7 O.S.H. Cas. (BNA) **1225 (1979);** Cormier Well **Service, 4** O.S.H. Cas. (BNA) **1085 (1976).**

[39] **Ford** Motor **Co., 5** O.S.H. Cas. (BNA) **1765 (1977);** Sugar Cane **Growers Coop., 4** O.S.H. Cas. (BNA) **1320 (1976);** M.A. **Swatek & Co., 1** O.S.H. Cas. (BNA) **1191 (1973).**

[40] **Williams Enterprises, Inc., 4** O.S.H. Cas. (BNA) 1663 (1 **976).**

[41] St. Joe Minerals Corp. v. OSHRC, **647** F.2d **840, 845** n. 8 **(8th** Cir. **1981); Betten Processing Corp., 2** O.S.H. Cas. (BNA) **1724 (1975).**

[42] Cargill, **Inc.,** 10 O.S.H. Cas. (BNA) **1398 (1982).**

[43] R.L. **Sanders Roofing** Co., **7** O.S.H. Cas. (BNA) **1566 (1979), rev'd, 620** F.2d **97 (5th** Cir. **1980).**

[44] Young Sales Corp., **7** O.S.H. Cas. (BNA) **1297 (1979),** aff'd. **mem., No. 79-1612** (D.C. Cir. **1980).**

onstrate that a hazard was recognized by the employer's industry. It is essential that the referenced industry is the appropriate one.[45] All industries do not necessarily recognize the same hazards and a citation maybe vacated on this basis.[4G]

Employer Knowledge of Hazard.–An employer's knowledge that a condition is hazardous does not depend on the occurrence of prior accidents .47 Moreover, employer knowledge encompasses both actual and constructive knowledge. Thus, employer knowledge has been found on the basis of correspondence, industry meetings, and publicized accidents;[48] warnings given to supervisors by an independent engineering firm and at least one of its own employees;[48] the employer's use of fences, warning lights, and requiring passes to the area;[50] and the employer's taking some measures to protect exposed employees.

Companies and industries thus have little incentive to participate in epidemiologic studies of workers exposed to possible occupational health hazards. Such studies can be used to establish the existence of a "recognized hazard, " thereby creating for companies a legal duty to abate the hazard under the general duty clause. These studies can also be used to support tort liability (chapter 10) and workers' compensation (chapter 9) claims. Without industry cooperation, however, it is difficult for academic and government researchers to learn more about occupational health hazards.

In ***National Realty,*** the D.C. Circuit outlined the Secretary of Labor's burden of proving a violation of the employer's general duty. The Secretary must prove: 1) that the employer failed to render its workplace free of a hazard that was 2) recognized, and 3) causing or likely to cause death or serious physical harm, and 4) that the citation has specified the particular steps the cited employer should have taken to avoid citation and that these measures are feasible and have a likely utility .[52]

The General Duty Clause and Reproductive Health Hazards.—There are two possible ways in which $ 5(a)(l) may be relevant to reproductive hazards in the workplace. First, employers could be issued citations under $ 5(a)(l) and ordered to abate working conditions that are harmful to the reproductive health of workers or their offspring. The Secretary of Labor, however, would have two difficult hurdles to overcome in proving such a violation. To begin with, citation under $ 5(a)(l) requires the hazard to be recog-

[45]See R.L. Sanders **Roofing Co. v.** OSHRC, **620 F** .2d **97 (5th** Cir. **1980) (Commission erred in looking to construction industry rather than roofing industry).**

[46]See, e.g., H-30, **Inc.** V. Marshall, **597** F.2d **234** (10th Cir. 1979).

[47]St. **Joe** Minerals Corp. **v.** OSHRC, **647** F.2d **840, 845 n. 7 (8th** Cir. **1981). Cf. Magma Copper Co. v. Marshall, 608** F.2d **373 (9th** Cir. **1979) (where recognition is based on employer knowledge the Secretary has the burden of demonstrating that the employer's safety precautions were unacceptable in its industry).**

[48]Atlantic Sugar Association., **4** O.S.H. Cas. (BNA) 1355 **(1976).**

[49]St. **Joe Minerals Corp.** v. OSHRC, **647** F.2d **840, 845 (8th** Cir. **1981).**

[50]General **Electric Co., 10** O.S.H. Cas. (BNA) **2034 (1982).**

sl~~h_e_li_n_g-Pittsb_u_gh Steel Corp., 10 O.S.H. Cas. (BNA) **1242 (1981).**

Some recent decisions of the Commission, Litton Systems, Inc., 10 O.S.H. Cas. (BNA) **1179 (1981), and courts of appeals, Donovan v.** Missouri **Farmers Association, 674** F.2d **690 (8th** Cir. **1982); Continental Oil Co. v.** OSHRC, **630** F.2d **446 (6th** Cir. **1980), cert. denied, 45o U.S. 965 (1981), have inferred employer knowledge from the** obvious **nature of the hazard. For example, in one case, the Commission found an "obvious" hazard where the employer refueled gasoline-powered trucks indoors in the vicinity of open-flame heaters. Eddy's Bakeries Co., 9** O.S.H. Cas. (BNA) **2147 (1981).**

[52]National Realty **& Construction CO. v.** OSHRC, **489** F.2d 1257 (D.C. Cir. **1973).**

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nized by the employer or its industry. For newly discovered or suspected-but-unproven repro ductive health hazards, it may be difficult to prove that they were actually or constructively recognized as hazardous. Thus, the general duty clause is unlikely to be a substitute for an emergency standard under $ 6(c) as an interim measure until section $ 6(b) rulemaking is completed.

The other problem with using the general duty clause to cite employers for hazardous conditions is that the clause cannot be used unless there is no applicable standard under $ 5(a)(2). For example, if a standard had a PEL of 10 ppm and the data showed that there were still reproductive health effects at exposures below the PEL, the general duty clause could not be used. The Commission has held that citation under $ 5(a)(l) is improper where the applicable standard is inadequate, because this would amount to a circumvention of the rulemaking process .53

OSHA'S enforcement guidelines[54] also provide that the general duty clause may not be used to require an abatement method not set forth in a specific standard. For example, if a standard provides for engineering controls but not medical surveillance, $ 5(a)(l) may not be cited to require medical surveillance.

A second possible use of the general duty clause, to prohibit exclusionary employment practices, has already been attempted unsuccessfully. In ***American Cyanamid Co.,*** the only case to address this issue,[55] the Commission was faced with the question of whether the employer's policy, which excluded from certain employment women aged 16 to 50 who had not been surgically sterilized, constituted a "hazard" under $ 5(a)(l). Five women employed in the lead pigments department submitted to surgical sterilization in order to retain their positions. A majority of the Commission held that "Congress did not intend the Act to apply to every conceivable aspect of employer-employee relations and that due to its unique characteristics this condition of employment is not a hazard within the meaning of the general duty clause." "Hazard" was defined to mean processes and materials that cause injury and disease by operating directly on employees as they engage in work or work-related activities. The Commission's decision was affirmed by the D.C. Circuit.[56]

In dissent, one Commissioner charged that the sterilizations resulted from a condition of employment imposed by the employer, and therefore should be considered a hazard subject to the general duty clause. Moreover, he cautioned that "[the exclusion of fertile women from **Certain emp**loyment invites employers to exclude other highly susceptible groups from employment when the effect varies among the exposed classes of individuals."

Even if an ernployer's reproductive health hazards policy were held to be within the purview of the general duty clause, it is not clear that a violation could be found. AS discussed earlier, citation under $ 5(a)(l) is inappropriate if a specific standard applies. An argument could be made that the "hazard" is not the employer's policy, but exposure to the hazard, specifically, lead. The employer's policy is simply the employer's attempt to deal with exposure to the hazard, Therefore, citation under the general duty clause is arguably precluded because of the existence of a standard dealing with lead that does not prohibit the employer's policy.

Another question is whether the Secretary would be able to prove all the necessary elements of a general duty clause violation. Specifically, the Secretary must specify the particular steps that the cited employer should have taken to avoid citation and to demonstrate the feasibility and likely utility of those measures. Simply ordering the return of the women to the toxic environment will not correct the problem of reproductive health hazards. Finally, an order directing the company to end its exclusionary policies would be prospective only and would not help the women already excluded or who had undergone sterilization.

Employee Duties.—Section 5(b) provides that "[elach employee shall comply with occupational safety and health standards and all rules, regula -

[53]Daniel International, Inc., 10 O.S. **H.** Cas. (BNA) 1557 (1982).

[54]OSHA **Instruction CPL** 2.50 **(1982).**

[55]American Cyanamid Co., 9 O.S **H.** Cas. (BNA) 1596 (1981), aff'd, **Oil, Chemical & Atomic** Workers **International** Union v. **American** Cyanamid **Co.,** 741 F.2d 444 (D.C. Cir. 1984).

[56](i

tions and orders issued pursuant to this Act which are applicable to his own actions and conduct." Nevertheless, OSHA has no power to fine or otherwise sanction disobedient employees.[57] (A staff paper available from OTA discusses the leading case establishing this principle.)

Final responsibility for employee compliance with OSHA'S requirements rests with the employer. Therefore, employers must take every measure possible to ensure employee compliance, including the sanctioning of recalcitrant employees.

According to OSHA regulation, disciplinary measures taken by employers solely in response to employee refusals to comply with appropriate safety rules and regulations are not considered discrimination in violation of $ 11(c) of the Act.[5a] In fact, many collective bargaining agreements specifically require employee adherence to safety and health standards.

Decisions of the Commission have continued to hold that concerted employee refusal to comply is not a defense to a valid citation.[Sg] Employers have been found in violation even where a union contract prohibited employer discipline without going through the union foreman'" and where prior attempts to enforce the standard had resulted in work stoppages up to 5 days long.'* Since concerted employee refusal to comply with safety and health standards is not protected activity under the Act, employer disciplinary action is not prohibited.[fiz]

Procedures for Promulgation of Standards

Section 6(b) provides that any promulgation, modification, or revocation of OSHA standards must comply with specific rulemaking procedures.'s Pursuant to $ 6(b)(2), the Secretary is required to publish a notice of proposed rulemaking in the Federal Register and must allow 30 days after publication for interested parties to submit written data or comments. As a practical matter, OSHA usually allows at least 90 days for the submission of data or comments. [G4]

OSHA usually schedules a public hearing when a proposal is issued, even though under $ 6(b)(3) a hearing is not required unless requested. Most of the testimony time is used to question witnesses.[G5] OSHA also produces its own witnesses and questions them.[G,]

Hearings on proposed standards are of increasing importance, both in allowing interested persons an opportunity to present their views and in developing the record for subsequent judicial review. This may account for the great length of the hearings. For example, OSHA'S first asbestos rulemaking hearing took 4 days and resulted in a record of 1,100 pages. The hearing on OSHA'S carcinogens policy took 2 months and had a record of 250,000 pages.[G7]

After the hearing is completed, the presiding administrative law judge usually gives the parties 30 days to submit additional data and 30 days after that to submit post-hearing briefs.Ga According to $ 6(b)(4), the final standard (or a determination that no new standard is needed) must be issued within 60 days after the end of the comment period. For a variety of reasons, OSHA has rarely been able to meet this deadline.

[57] Atlantic & Gulf Stevedores, Inc. V. OSHRC, 534 F.2d 541, 553 (3d Cir. 1976).
[58] 29 CFR § 1977.22 (1984).
[59] Reinhardt's plumbing & Heating, Inc., 5 O.S.H.Cas.(BNA)1743 (1977); T. Clark & Son, 4 O.S.H.Cas.(BNA) 1913 (1976).
@Theodore D. Bross Line Construction Co., 3 O.S.H.Cas.(BNA) 1935 (1976).
[61] Weyerhaeuser Co., 3 O.S.H.Cas.(BNA)1107 (1975).
[62] 29 CFR § 1977.22 (1984).
[63] OSHA rulemaking procedures appear at 29 CFR pt. 1911 (1984).
[64] B. Mintz, OSHA: History, Law and Policy 63 (1984).
[65] Id
[66] Id. at 64.
[67] Id. at 62.
[68] Id. at 65.
[69] In National Congress of Hispanic American Citizens v. Usery, 554 F.2d 1196 (D.C. Cir. 1977), rev'g 425 F. Supp. 900 (D.D.C. 1975), the plaintiff sought an order requiring the Secretary to promulgate various agricultural standards. The district court granted summary judgment for the plaintiff and held that the timetable for promulgating standards in § 6(b) was mandatory. On appeal, the D.C. Circuit reversed, holding that the timetable was not mandatory because: 1) the Secretary was given discretion under §6(g) to "alter priorities and defer action due to legitimate statutory considerations"; and 2) inasmuch as the Secretary can decide not to issue a standard, "there is no sense in proceeding completely through the rulemaking process . . . only to end up with the Secretary issuing a notice that the standard is not adopted. " On remand, the district court ordered the Secretary to complete development of a field sanitation standard as soon as possible and to submit a timetable for completion of the standard to the court within 30 days. National Congress of Hispanic American Citizens v. Marshall, No. 2142-73 (D.D.C. 1978). The D.C. Circuit again reversed. National Congress of Hispanic American Citizens v. Marshall, 626 F.2d 882 (D.C.Cir. 1979).

The final form of a standard may differ from the original proposal. Changes in a standard often reflect the comments and criticisms of interested parties as well as further agency deliberation and thus are to be encouraged. Nevertheless, the argument has been raised that where the final standard differs from the proposal, interested persons have been denied an opportunity to comment on the standard in its final form.[70]

Final OSHA standards typically contain detailed preambles, the standard itself, and any appendixes. A common format is as follows [71]

1. an introductory discussion of the substance being regulated, its uses, and toxic properties;
2. a description of the background and history of the rulemaking proceeding;
3. a summary of the record and a discussion of the major issues raised by the proceeding—for health standards, this includes the extent of the risk from exposure to the substance, the PEL, and economic and technological feasibility;
4. a discussion of the specific provisions of the standard, section-by-section, including an explanation of why the particular provision was adopted and others were rejected;
5. a statement, as appropriate, on OSHA compliance with Executive orders on regulatory analysis, the National Environmental policy Act,[73] and the Regulatory Flexibility Act;[74] and
6. the text of the standard.

The validity of OSHA standards maybe reviewed by a Federal appellate court if a petition is filed by an adversely affected party either before or after issuance of an OSHA citation. (Judicial review of OSHA standards is discussed in detail in a staff paper available from OTA.)

possible Modification to Rulemaking Process

There is widespread agreement that the OSHA rulemaking process is slow, cumbersome, a drain on resources, and extremely adversarial .[75] In 1975, former Secretary of Labor John Dunlop attempted to expedite the process by using negotiations between the steel companies and unions to reach a consensus on a standard for coke oven emissions, "This effort failed, and Dunlop's approach was greeted with considerable hostility.'

In 1983, OSHA enlisted the services of neutral third-party mediators to facilitate a labor-industry agreement on revision of the existing benzene standard. Industry representatives from the Chemical Manufacturers Association, Rubber Manufacturers Association, American Iron and Steel Institute, and the American Petroleum Institute held a series of mediation sessions with union representatives from the AFL-CIO; United Steelworkers; Oil, Chemical, and Atomic Workers; and United Rubber Workers. Although it is not clear as yet whether mediation will be a success in the benzene standard, the use of mediation has prompted a discussion of the use of alternative dispute resolution techniques in OSHA rulemaking .[77]

[70] Taylor Diving & Salvage Co. v. U.S. Department of Labor, 599 F.2d 622 (5th Cir. 1979); Daniel International Corp. v. OSHRC, 656 F.2d 925 (4th Cir. 1981).

[71] See B, Mintz, OSHA: History, Law and Policy 71 (1984).

[72] Exec. Order No. 12,291, 46 Fed. Reg. 13,193 (1981). See M. Rothstein, Occupational Safety and Health Law 71 (2d ed. 1983).

[73] 42 U.S.C. §§ &I. &II (1976 & Supp. V 1981); 29 CFR §§ 1999.1 to .8 (1984). See M. Rothstein, Occupational Safety and Health Law 70-71 (2d ed. 1983).

[74] 5 U.S.C. §§ 601.612 (1982).

[75] See, e.g., Comptroller General of the United States, Report to Congress, Delays in Setting Workplace Standards for Cancer Causing and Other Dangerous Substances (1977); General Accounting Office, Report to the Senate Committee on Labor and Public Welfare: Slow Progress Likely in Development of Standards for Toxic Substances and Harmful Physical Agents Found in Workplaces (1973).

[76] B. Mintz, OSHA: History, Law and Policy 88 (1984) (footnote omitted).

[77] Three senior OSHA officials were optimistic about mediation and thought that it could shorten the rulemaking process (both the hearing and comment period) and ease the resource drain of standards-setting. One thought that the best chance for success might be with chemicals that had not been the subject of prior regulation and where the positions of the parties had not hardened. He favored mediation to reach a draft standard and then allowing the public to comment.

Other former OSHA officials interviewed for this report were skeptical about mediation, perhaps as a result of OSHA's experience in 1975. One cautioned that it would be inappropriate to have the mediation take place too far along in the rulemaking process. Another former OSHA official, while agreeing that consensus is important, questioned whether OSHA can or should delegate its statutory responsibility to protect the public interest. Specifically, she questioned whether the unions can be expected to represent the views of all workers, including nonunion employees. A current OSHA official countered this argument by asserting that the regular comment period protects against this danger and permits comments by all concerned individuals.

Even those individuals who have doubts about mediation emphasize the need for labor-management cooperation. One former OSHA head recommends that labor and management attempt to reach agreement on key issues, while another former OSHA official notes that joint statements, stipulations of fact, and other agreements help the rulemaking process, but adds that such agreements are difficult to reach within the present rulemaking framework.

Emergency Temporary Standards

Section 6(c)(1) provides that if the Secretary determines that employees are "exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards," an emergency temporary standard (ETS) may be issued. These standards are effective immediately upon publication in the Federal Register without conforming to the detailed rulemaking requirements that apply to permanent standards. Under $ 6(c)(3), an ETS may remain in effect for only 6 months; thereafter, the Secretary must promulgate a permanent standard under $ 6(b). In this event the ETS serves as the proposed rule.[78]

An emergency temporary standard must be based on the existence of a grave danger[79] and the need for a standard to protect workers from the danger.

Although emergency temporary standards need not be promulgated in accordance with the detailed procedures of $ 6(b), certain procedural requirements must be complied with. One of these requirements is a statement of reasons, which must indicate:

1. the data in the record on which the ETS principally relies,
2. why those data suffice to show that the substances covered by the standard are harmful and pose a grave danger of exposure to employees, and
3. why the particular standard is necessary for the protection of employees.[a]*

An ETS may be amended in the same manner as it was originally issued, according to the Fifth Circuit

[78] See 29 CFR § 1911.12 (1984).

[79] According to the Third Circuit, the Act does not require an absolute certainty of the deleterious effect of a substance, but there must be evidence showing "more than some possibility" of a grave danger'. Dry Color Manufacturers' Association v. U.S. Department of Labor, 486 F.2d 98, 104 (3d Cir. 1973). The dissent, however, contended that the purpose of the Act would be best effectuated by holding that even a scintilla of evidence can support an ETS. Id. at 110 (dissenting opinion).

The Fifth Circuit rejected the suggestion that deaths must occur before the issuance of an ETS. Nevertheless, the court held that there must be a danger of "incurable, permanent, or fatal consequences to workers, as opposed to easily curable and fleeting effects on their health. . . ." Florida Peach Growers Association v. U.S. Department of Labor, 489 F.2d 120, 132 (5th Cir. 1974).

In many instances, the only scientific research on a hazardous substance before promulgating an ETS will be animal studies. The application to humans of data extrapolated from animal studies of carcinogens was specifically accepted by the Third Circuit. Synthetic Organic Chemical Manufacturers' Association v. Brennan, 503 F.2d 1155 (3d Cir. 1974), cert. denied, 420 U.S. 973 (1975); Dry Color Manufacturers' Association v. U.S. Department of Labor, 486 F.2d 98 (3rd Cir. 1973). See generally McElveen and Eddy, Cancer and Toxic Substances: The Problem of Causation and the Use of Epidemiology, 33 Clev. St. L. Rev. 29 (1984); Comment, Judicial Attitudes Towards Legal and Scientific Proof of Cancer Causation, 3 Colum. J. Envtl. L. 344 (1977).

[80] The Third Circuit noted that the purpose of § 6(c)(1), to provide immediate protection, allows the Secretary to assume that employee exposure is occurring at any workplace containing the proscribed hazardous substance and where the corrective measures required by the ETS are not in effect. If the workplace is as safe and healthful without compliance with the letter of the ETS, the employer must resort to the variance procedures of § 6(d). Dry Color Manufacturers' Association v. U.S. Department of Labor, 486 F.2d at 102-03 n.3. Cf. Taylor Diving & Salvage Co. v. U.S. Department of Labor, 537 F.2d 819 (5th Cir. 1976) (stay of ETS granted where there was probability of success on merits of attack on standard and the likelihood of issuance of variance too uncertain to eliminate possibility of irreparable injury),

[81] In Dry Color Manufacturers' Association v. U.S. Department of Labor, 486 F.2d 98 (3d Cir. 1973), OSHA attempted to promulgate an ETS concerning exposure to 14 chemicals said to be carcinogens. The only statement of reasons was a conclusion, finding the chemicals to be carcinogens and reciting the need for a standard. The Third Circuit held that the statement of reasons was inadequate because it failed to meet the three-part test described in the text. The dissent in Dry Color, however, argued that preparing an exhaustive statement of reasons would be time-consuming and would render the ETS mechanism ineffective. Thus, it was suggested, all that should be required is notice of the Secretary's reason for issuing the ETS and access to the scientific data on which the Secretary relied. 486 F.2d at 110 (dissenting opinion). See also Synthetic Organic Chemical Manufacturers' Association v. Brennan, 506 F.2d 385 (3d Cir. 1974), cert. denied, 420 U.S. 973 (1975); Florida Peach Growers Association v. U.S. Department of Labor, 489 F.2d 120 (5th Cir. 1974); Associated Industries v. U.S. Department of Labor, 487 F.2d 342 (2d Cir. 1973).

[82] In Florida Peach Growers Association v. U.S. Department of Labor, organizations representing farmworkers contended that the Secretary exceeded his authority by summarily amending an ETS without using the modification procedures of § 6(b). The Fifth Circuit disagreed, observing that adherence to § 6(b) procedures could easily consume the entire 6-month life of the ETS. 489 F.2d 120 (5th Cir. 1974).

Not surprisingly, both present and former OSHA officials interviewed for this report were dismayed by the court's decision and its implications. A former OSHA Chief stated: 'You can kiss ETSS goodbye. They are not a viable option for the foreseeable future." Another former OSHA Chief did not agree that emergency standards are dead, citing DBCP, but cautioned that unless there were "hot new data" it would be best to use an ETS onIy for new hazards. Other former officials noted the problem of trying to persuade a reviewing court to uphold OSHA'S use of an ETS to lower the PEL of a current standard, pointing out that even emergency standards for new hazards, such as hyperbaric diving, had been struck down.

Those interviewed stated that the record overwhelmingly supported issuance of the asbestos standard. According to an OSHA health standards official, IF there is no grave danger for asbestos, there is no grave danger for anything. The health effects of asbestos are 10 times worse than the rest of the substances combined." He added that, other than tobacco smoke, there were more epidemiological data on asbestos than any other substance of which he was aware. A former OSHA chief expressed a similar view. 'The asbestos ETS was the best piece of work the agency had ever done–by far." A former DOL official reasoned that ETS challenges are difficult cases for the courts to decide on an emergency basis and that they are reluctant to order any capital expenditures when the life of the standard is only 6 months. In her view, Congress would need to amend $ 6(c)'s "grave danger" language to make the ETS provision effective. In the meantime, two former OSHA heads agree that pursuing an ETS now would be a waste of the agency's limited resources in the sense of its very limited probability of being upheld.

Table 7=1.-Judieial Review of OSHA Emergency Temporary Standards

Standard	Date of enactment	Result	Reference
asbestos (1)	1971	Not challenged	
organophosphorous pesticides	1973	Vacated	Florida Peach Growers Association v. Department of Labor, 489 F.2d 120 (5th Cir. 1974)
14 carcinogens	1973	12 upheid	Dry Coior Manufacturers Association v. Department of Labor, 488 F.2d 98 (&t Cir. 1973)
vinyl chloride	1974	Not challenged	
commercial diving	1976	Stayed	Tayior Diving & Salvage Co. v. Department of Labor, 537 F.2d 819 (5th Cir. 1976)
benzene	1977	Stayed	Industrial Union Department v. Bingham, 570 F+2d WM (D.C, Cir. 1977)
DBCP	1977	Mot chaliengpd	
acrylonitrile	1978	$tey refused	Vktron v. C)SHA, 0 Q.S.H. Oaa. (BNA) 1483 @th W. 1$?8)
asbestos [11]	1983	Stayed	Asbestos Information Assookttlon v. OSHA, 72? F.2d 416 (&h Cir. 1$84)

SOURCE: Offloe of Technology Awe$amnt.

Box 7B.--The Problem of Emergency Temporary Standards

On November 4,1983, O)SHA promulgated an ETS for asbestos that lowered the permissible exposure limit (PEL). The ETS "emergency" was based on a new quantitative risk assessment showing that reducing the PEL for 6 months would save 40 to 80 lives. A group of asbestos products manufacturers sought judicial review of the ETS in the Fifth Circuit.

In ***Asbestos Information Association v. OSHA,*** ***the*** Fifth Circuit held that the ETS was invalid and stayed its enforcement. The central theme of the court's analysis focused on whether OSHA had proven the need to adopt an ETS rather than mod. ifying the existing standard after notice-and. comment rulemaking. The court pointed out that:

> . . . the plain wording of the statute **limits us to** assessing the harm likely to accrue, or the grave danger **that the ETS may alleviate, during the 6-** month period that is the life of the stimdard.

One reason for publishing the ETS, according to OSHA, was to set in motion the process of promulgating a new permanent asbestos standard. The court was wary of permitting $ 6(c) rulemaking to substitute for $ 6(M rulemaking.

The court rejected the asbestos manufacturers' argument that an ETS may not be issued unless it is based on new information. A "heightened awareness" based on new extrapolations certainly could justify the Secretary's action. Nevertheless, the benefits of the ETS must outweigh its costs. While it rejected the industry argument that the costs were excessive, the court was unconvinced of the accuracy of OSHA'S estimate of the benefits.

Rather than rely on animal data, OSHA performed a detailed quantitative risk assessment and developed a dose-response curve from epidemio-Iogical studies of exposed workers. This assessment was made specifically to satisfy the "significant risk" requirement of the Supreme Court's ***Benzene*** decision[s] and the "grave danger" **language of S *6(c).*** The Fifth Circuit was troubled by the possibility of inaccuracy in using risk assessment for a 6-month exposure period.

> **[Although** risk assessment analysis is an extremely useful tool, especially when used to project lifetime consequences of exposure, the results of its application to a small slice of time are speculative because the underlying database projects only long term risks. . . . Applying the risk assessment process to a period of 6 months, **one-ninetieth of OSHA'S estimated working lifetime,** only magnifies those inherent uncertainties.

Moreover, as the court had previously noted, the mathematical extrapolations had not been the subject of "peer review.

Finally, the court held that, even assuming OSHA'S projected benefits would accrue from the ETS, OSHA failed to prove that an ETS–''the most dramatic weapon in its enforcement arsenal''-is necessary to achieve the projected benefits.~ Specifi" cally, OSHA had failed to enforce its current standard and could reduce exposures through enforcement and expeditious $ **6(b)** rulemaking.

The court's opinion is subject to a variety of criticisms. Simply stated, the court is requiring OSHA to do the impossible. If the ETS were not accompanied by quantitative risk assessment of the expected benefits, undoubtedly the court would have held the ETS to be invalid. OSHA, however, performed a detailed risk assessment based on epidemiological evidence and calculated the number of lives expected to be saved. Differences of opinion over mathematical models should not obscure the fact that under any model a substantial number of lives would be saved by the :ETS. It is never possible to predict precisely the effects of exposure on thousands of workers—nor is such evidence required. As the Supreme Court stated in the ***Benzene*** **case:**

> OSHA is not required to support its finding that a significant risk exists with anything approaching scientific certainty. Ahhough the Agency's findings must be supported by substantial evidence, . . . a reviewing court [is required] to give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge.s~

Furthermore, the court's discounting of numerous reputable studies because of a lack of opportunity for public comment is antithetical to the express purpose of $ 6(c).

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[s]**727 F.2d 415 (5th Cir. 1984).**
%.1. **at** *422.*
[s]**Id. at** *423.*
[s]**Id. at 423-24.**
[s]**Industrial** Union Department v. American **Petroleum Institute,** 448 U.S. *607 (1980).*
[s]**727** F.2d at *425-26.*
[s]**Id.** at 421 **n.15.**
[s]**Id.** at 426.
[s]**Id. at** 427,
[s]**Industrial** Union Department v. American Petroleum Institute, 448 U.S. *607, 8S6 (1980).*

As box 7B demonstrates, OSHA has had a difficult time in the courts of appeals in challenges to its ETSS. This is particularly true in the Fifth Circuit, which has refused to uphold the ETS for pesticides, commercial diving, or asbestos.

Hazard Identification

The existence of health hazards is brought to OSHA'S attention in three primary ways: 1) NIOSH brings its research to OSHA'S attention, 2) advisory committees or consultants recommend health standards, and 3) citizens, labor unions, or companies petition OSHA or NIOSH for action. A discussion of NIOSH research appears in chapter 6. Advisory committees and citizen petitions are discussed below. (A detailed discussion of OSHA priorities in risk assessment and risk management appears in Appendix C.2.)

Standards Advisory Committees

Section i'(a) of the Act established a National Advisory Committee on Occupational Safety and Health (NACOSH) to advise the Departments of Labor and DHHS on matters related to the Act.[93] The Federal Advisory Council on Occupational Safety and Health (FACOSH) was established in 1974 to advise the Secretary of Labor on occupational safety and health matters relating to Federal Government employees.[94]

Between **1971 and 1976,** most of the major health standards proposals were based on advisory committee recommendations. Since 1977, advisory committees have not been used to make recommendations. This change was based on detailed requirements for advisory committees mandated by OMB and the Carter Administration's effort to reduce the number of advisory committees. Instead, OSHA has used consultants to assist in the research and drafting of various parts of OSHA standards.[95]

Citizen Petitions

Section 6(b)(1) of the Act contemplates that information about the need for a new standard may be presented by "an interested person, a representative of any organization of employers or employees, a nationally recognized standards-producing organization, the Secretary of Health and Human Services, the National Institute for Occupational Safety and Health, or a State or political subdivision. . . ." The Secretary's regulations also provide that "any interested person may file . . . a written petition for the promulgation, modification, or revocation of a standard.

Some citizen petitions have been granted by OSHA. For others, OSHA'S refusal to issue an ETS or begin rulemaking on a permanent standard was sometimes followed by a court proceeding in which the petitioners sought to compel issuance of the standard. In some instances, such as pesticides, cotton dust, and labeling, the mere filing of the lawsuit may have been a substantial factor in issuing the standard more quickly.[97] In other instances, protracted litigation was necessary and had a mixed record of success for the petitioners.[98]

[93] NACOSH is a permanent committee comprised of 12 members, 4 appointed by the Secretary of HHS and 8 appointed by the Secretary of Labor. The membership is comprised of representatives of management, labor, the public, and the occupational safety and health professions. NACOSH's basic purpose is to study all relevant material, consider possible alternatives, and weigh the feasibility of proposed standards.

[94] FACOSH is a permanent body, but is subject to renewal every 2 years. Exec. Order No. 12,196, 45 Fed. Reg. 12,769 (1980). The 16 members of FACOSH are appointed by the Secretary of Labor and serve staggered 3-year terms. Eight members are representatives of Federal agencies and eight members are representatives of Federal employee labor organizations.

[95] B. Mintz, OSHA: History, Law and Policy 65 (1984). Some present and former OSHA officials have differing views on the efficacy of advisory panels. An OSHA health standards official recommended amending the advisory panel language in the Act to eliminate the requirement of having representatives of various interest groups, and replace these members with independent and disinterested individuals. In his view, a panel of independent scientists could provide the peer review of technical documents needed by the agency. A former OSHA chief conceded that NACOSH has been "under-used and too political," but he still believes that it could perform the peer review function if it was seriously regarded by the Assistant Secretary of Labor for OSHA. Another former OSHA chief believes the committees are important, need not be nonpolitical, and benefit by having industry and employee representatives.

[96] 29 CFR § 1911.3 (1984).

[97] B. Mintz, OSHA: History, Law and Policy 197 (1984).

[98] Regardless of the merits of a citizen petition, the courts are extremely reluctant to order the issuance of a standard, particularly an ETS. The decision to issue a standard commits the agency to a substantial expenditure of resources and is often at the expense of other, arguably more important, rulemaking. Thus, in Public Citizen Health Research v. Auchter, the D.C. Circuit held that the district court erred in ordering OSHA to issue an ETS for ethylene oxide. 702 F.2d 1150 (D.C. Cir. 1983). While ruling that the district court "impermissible substituted its evaluation for that of OSHA" in ordering the issuance of an ETS within 20 days, the court or-

Strategy for Hazard Exposure Control

Engineering Controls and Personal Protective Equipment

In its report, Preventing Illness ***and Injury in the Workplace,*** OTA examined the concept of "hierarchy of controls, in which the basic tenet is to control the hazard as close to the source as possible. In general, the order of controls is described as: engineering controls, work practice controls, and personal protective equipment. Sometimes administrative controls are included at the same order as either engineering controls or work practice controls. But in all cases, personal protective equipment is listed as the control of last resort. The problems of personal protective equipment arise out of: 1) limitations in performance; 2) difficulties in evaluating their performance; and 3) problems and burdens associated with their use, and the physical burdens they create. 100

Engineering controls have the advantage of being easier to monitor to determine performance, are more reliable, enhance the development of new control and production technology, and do not create employee burdens. The main advantage of personal protective equipment is that it is usually significantly less expensive than engineering controls.

In February 1983, OSHA issued an advance notice of proposed rulemaking, stating its intention to reexamine its policy of giving priority to engineering controls In comments submitted to OSHA, employers and trade associations supported a change in OSHA policy to allow personal protective equipment to substitute for engineering controls. Comments from NIOSH, health and safety professionals working for universities and government agencies, and labor unions supported a continuation of OSHA'S preference for engineering controls, In the preamble to the ethylene oxide standard, OSHA specifically restated the agency's policy of favoring the hierarchy of controls approach. (A discussion of the legal aspects of technological feasibility of OSHA health standards appears in Appendix C.3.)

Medical Removal Protection

OSHA'S statutory authority to use medical removal protection (MRP) as a strategy for control was discussed earlier in this chapter. Assuming such authority exists, the next question is whether MRP is a viable strategy for control of reproductive health hazards.

The starting point for considering this issue is OSHA'S lead standard. The standard set a PEL of 50 micrograms per cubic meter of air averaged over an 8-hour period and an action level of 30 micrograms. In addition, employees with blood-lead levels at or above 50 micrograms per 100 grams of whole blood (or who have symptoms of lead disease) are subject to medical removal.

In its preamble to the final lead standard, OSHA indicated that:

> To minimize the risk of genetic damage, menstrual disorders, interference with sexual function, lowered fertility, difficulties in conception, damage to the fetus during pregnancy, spontaneous miscarriage, stillbirth, toxic effects on the newborn, and problems with the development of the newborn or developing child, blood-lead levels should be kept below 30pg/100 g in both males and females exposed to lead who wish to plan pregnancies.[102]

Despite this language, the standard's PEL and MRP requirements contemplate that when full compliance is achieved the average blood-lead levels of workers will be 35 p.g. '03 The OSH Act feasibility requirement, however, prevented OSHA from promulgating a stricter standard. Reproductive effects were to be minimized, according to OSHA, by the action level, medical surveillance, and employee education. 105 Moreover, the stand-

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dered OSHA to expedite its rulemaking. **Id. at 1153. In** UAW v. **Donovan, the district court, in refusing to order** OSHA **to issue an ETS on formaldehyde, stated: "Judicial review of an** OSHA **decision not to regulate is 'extremely narrow.' Reversal of** OSHA's **decision here thus requires the exceptional to exist from both 'substantive' and 'judicial review' perspectives." UAW** v. Donovan, **45 OS. H. Rep.** (BNA) **2017** (D.D.C. July **12, 1984).**

[99] U.S. Congress, Office **of** Technology **Assessment, Preventing Illness and** Injury **in the Workplace (1985).**

[100] Id .

[101] 48 Fed. **Reg. 7474 (1983).**

[102] Fed. Reg. **52,960 (1978).**

[103] Id. **at 52,966,**

[104] I d

[105] Id.

ard's medical surveillance guidelines suggest that "the physician might recommend special protective measures or medical removal for an employee who is pregnant or who is planning to conceive a child. . .

Can optional MRP under the lead standard prevent reproductive harms? Is optional or mandatory MRP for pregnant workers or for male and female workers attempting to parent children a feasible control strategy? The experts interviewed for this report were doubtful about MRP for a variety of reasons.

In many ways, lead is one of the best substances for medical removal because the effects of lead are largely reversible with discontinuation of exposure. But MRP as a reproductive health hazards control strategy, even for lead, is not entirely satisfactory. A NIOSH epidemiologist points out that there is a "rebound effect" of blood-lead levels after removal or chelation, where the levels will often go back up, without further exposure, after an initial drop. In addition, because of low calcium levels during pregnancy, lead stored in bones and other tissues may reenter the bloodstream. Finally, MRP would not prevent mutagenic effects that may have already occurred.

Although some individuals interviewed said that, in some situations, MRP could be a valuable strategy to use for substances other than lead, others expressed great reluctance to use MRP, mostly because of a lack of research on reproductive health hazards,

OSHA Reproductive Health Hazard Regulations

OSHA has only regulated three substances on the basis of their potential hazard to human reproductive health: DBCP, lead, and ethylene oxide, as discussed below.

DBCP

DBCP (1,2-dibrorno-3+hloroProPane) k a liq-uid pesticide. In July 1977, workers at the Occidental Chemical Co. in Lathrop, California, noticed a pattern of infertility among DBCP workers. When tests were performed by Donald Whorton at the University of California, 14 of 38 workers tested had significantly reduced sperm counts. No OSHA standard governing DBCP existed at that time.

In August 1977, the workers' union (OCAW) petitioned OSHA to issue an ETS for DBCP with a PEL of one part per billion (ppb). In September 1977, OSHA issued an ETS for DBCP, establishing an 8-hour TWA of 10 ppb and a 15-minute ceiling level of 50 ppb. Based on evidence that DBCP was a carcinogen as well as a gametotoxin, in March 1978, OSHA issued a permanent standard lowering the 8-hour TWA to 1 ppb, with no ceiling limit. Neither the ETS nor the permanent standard was challenged in court.

In addition to regulating the permissible airborne concentration of DBCP, the standard also prohibited dermal and eye contact, required exposure monitoring, established a respirator program, and provided for protective clothing, change rooms, and showers. The medical surveillance section of the standard provides for preplacement and annual examinations, which must include at least the following:

1. a medical and occupational history, including reproductive history;
2. a physical examination, including examination of the genito-urinary tract, testicle size, body habitus, and a determination of sperm count;
3. collection of a serum specimen, with the following determinations made by radioimmu - noassay techniques utilizing National Institutes of Health specific antigen or one of equivalent sensitivity:
   a. serum follicle stimulating hormone,
   b. serum luteinizing hormone (LH), and
   c. serum total estrogen (females); and
4. any other tests deemed appropriate by the examining physician.

The standard also provides for employee information and training as well as signs and labels.

[106] 29 CFR § 1910.1025 app. C (1984).

[107] D. McCaffrey, OSHA and the politics of Health Regulation 108 (1982).

[108] 42 Fed. Reg. 45,536 (1977).

[109] 43 Fed. Reg. 11,514 (1978) (codified at 29 CFR § 1910.1044 (1984)).

[110] 29 CFR § 1910,1044(m)(2) (1984).

In June 1979, the Environmental Protection Agency's Pesticide Advisory Committee recommended suspension of DBCP under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) because research by EPA and others demonstrated that DBCP caused cancer, harmful testicular effects, and genetic mutations in laboratory animals .[111]

EPA Administrator Doug Costle signed the notice of the order of emergency suspension for DBCP in July 1979, thereby beginning the 5-day period during which DBCP registrants could request administrative hearings on the order.[112] The hearings were held in October 1979. Extensive testimony was received, a significant portion of which supported EPA's original assessment of $42 million in production losses to growers. As a result of the cancellation hearings, EPA decided to suspend all uses of DBCP, with the exception of its use in Hawaiian pineapple fields, where residues were found not likely to occur given the method of DBCP application.[113] EPA's hearing concluded that "the immediate suspension of all uses of all registrations of pesticide products containing DBCP is necessary to prevent an imminent hazard. ''n' In April 1981, EPA reached an agreement with the producers of the pesticide and canceled further administrative hearings. In that agreement, the Agency affirmed its 1979 decision banning DBCP for all uses except on Hawaiian pineapples.[115] OSHA'S regulation of workplace exposure now has little relevance, except for those situations in which EPA granted exemptions for the use of DBCP.[117]

In January 1985, EPA published a notice of its intent to cancel registration of DBCP used to fumigate Hawaiian pineapple fields, after finding DBCP contamination of groundwater. The ban goes into effect in 1987.

[111] For studies supporting suspension, see **44 Fed. Reg. 65,135 (1979).**
[112] Chem. Reg. Rptr. (BNA) 577 (July 20, 1979).
[113] See **44 Fed. Reg. 65,135 (1979) (final suspension order).** See also Chem. Reg. Rptr. (BNA) 1285 (Oct. 26, 1979) (cancellation hearings).
[114] Quoted in Chem. Reg. Rptr. (BNA) 1285 (Oct. 26, 1979).
[115] 46 Fed. Reg. 19,592, 19,596 (1981); Chem. Reg. Rptr. (BNA) 7 (Apr. 3, 1981).
[116] Exemptions can be granted under FIFRA Section 6d(C)(A), 7 U.S.C. § 136d(e)(A) (1982), if the Administrator determines that a use "will not have unreasonable adverse effects on the environment."
[117] Envtl. Health Newsletter, Oct. 1, 1982, at 3-4.
[118] 50 Fed. Reg. 112 (1985).

Lead

Unlike the DBCP standard, which was promulgated largely because of the negative reproductive consequences of exposure, the lead standard was promulgated primarily to prevent other health problems (e.g., neurological disorders), Indeed, as discussed previously, the standard as promulgated is not sufficient to ensure that there will be no reproductive damage caused by exposure to lead, although it does attempt to minimize reproductive harms in several ways. These include medical removal provisions to protect workers wishing to have children.

The standard's medical surveillance section requires that a medical history be taken and must include a history of any reproductive problems. It provides that medical examinations, "if requested by an employee, shall include pregnancy testing or laboratory evaluation of male fertility."[119] The standard further provides that the employer must furnish a medical examination or consultation if the employee notifies the employer of a desire to obtain advice concerning the effects of current or past exposure on his or her ability

[119] 29 CFR § 1910.1025(j)(3) (ii) (1984).

Photo credit: Pemina Meisels

Although the use of personal protective equipment is essential to many occupations, engineering, administrative, and work practice controls are given higher priority in efforts to limit hazard exposure.

to produce a healthy child. A final relevant provision of the standard requires the employer to inform all exposed employees about the medical surveillance program, "including information concerning the adverse health effects associated with excessive exposure to lead (with particular attention to the adverse reproductive effects on both males and females)

Ethylene Oxide (EtO)

EtO is a clear, colorless gas that is used primarily as a chemical intermediate in the production of pesticides and as a sterilant and fumigant for hospital equipment. Because of EtO's use both as a pesticide as well as in nonfarm occupational settings, a controversy arose because the substance's use could be potentially regulated both by EPA under FIFRA and by OSHA under the OSH Act.

In 1978, citing multi-test studies demonstrating the mutagenic properties of EtO, EPA published a notice of Rebuttable Presumption Against Registration (RPAR) and placed EtO under special review,[122] The agency solicited comments on the action from registrants of the EtO pesticides and other interested parties. Pursuant to FIFRA, it requested that registrants submit data concerning the benefits of the compound that would justify its continued registration, as well as any further data on adverse health effects.

A number of studies released in 1981 and 1982, which showed additional evidence of the adverse effects of EtO, further fueled the controversy .[123]

In January 1981, the Public Citizen Health Research Group and the American Federation of State, County, and Municipal Employees petitioned OSHA to force the agency to issue a new permissible exposure level for Et0.1[24] They urged OSHA to establish an emergency temporary standard until a final regulation could be promulgated. The petition was denied and the group sued OSHA.1[25] In January 1983, the U.S. District Court for the District of Columbia required OSHA to issue an emergency temporary standard by June 1983.126 Additionally, it rejected OSHA'S initial contention that EPA's actions precluded OSHA from taking regulatory action .127

A panel of the U.S. Court of Appeals for the District of Columbia overruled the lower court decision 2 months later.1[28] The panel decided that the lower court had "impermissible substituted its evaluation for OSHA's,'and rejected the order requiring an emergency standard, Nevertheless, the D.C. Circuit directed OSHA to expedite completion of its ongoing rulemaking on EtO and within 30 days to promulgate a notice of proposed rulemaking. However, the Court affirmed the lower court's decision on the question of jurisdiction over EtO. It stated:

> An easy question to *resolve . . . is* the Assistant Secretary's assertion that "there is a serious question as to OSHA'S jurisdiction over hospital employees engaged in EtO sterilization activities, " because of EPA's regulation of the chemical under the pesticide statute (the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. $5136-136y). OSHA, as the district court pointed out . . . has dealt with exposure to EtO for over a decade and has committed itself to eventual replacement of its dated standard. We agree entirely with the district court's conclusion that OSHA is not disabled from issuing an EtO standard in "areas-such as the health care industry—whereas EPA has apparently exercised minimal, if any,

[120] Id .
[121] Id. § 1910. 1025(j) (1)(v)(D).
[122] 43 Fed. Reg. 830 (1978).
[123] The '<Bushy Run Study," released in February 1981, demonstrated that EtO caused cancer in laboratory animals at dosages as low as 10 ppm. Snellings, 1981, Final Report: Ethylene Oxide, Two Year Inhalation Study, Bushy Run Research Center Submission to EPA, Pittsburgh, PA.
In March 1982, a Johnson & Johnson study was released which showed chromosomal damage to hospital workers engaged in sterilization procedures using EtO. Preliminary report of Pilot Research Chromosome Study of Workers at Sites Where Ethylene Oxide Gas is Utilized as a Sterilant. Unpublished report available from Dr. J. Paul Jones, Director of Health Sciences, Johnson& Johnson, New Brunswick, NJ (1982).
In November 1982, the Hemminki study demonstrated a significantly higher rate of spontaneous abortion among hospital nurses using EtO in sterilizers. Hemminki, K., Mutinen, P., Saloniemi, I., Neimi, M. L., and Vainis, H., Spontaneous abortions in hospital staff engaged in sterilizing instruments with chemical agent. BRI. MED. I. *285: 1461-63 (1982).*

[124] Public Citizen Health Research Group v. Auchter, 554 F. Supp. 242, 245 (D.D.C. 1983).
[125] Public Citizen Health Research Group v. Auchter, 554 F.Supp. 242 (D.D.C. 1983).
[126] Id. at 251.
[127] Id. at *250.*
[128] Public Citizen Health *Research* Group v. Auchter, 702 F.2d 1150 (D.C.Cir. 1983).
[129] Id. at 1156-57.
[130] Id. at 1159.

> regulatory authority in an overlapping manner.[131]

In April 1983, OSHA published a Notice of Proposed Rulemaking for EtO that proposed to reduce the permissible 8-hour time-weighted average for EtO from 50 to 1 ppm. *[32] A specific short-term exposure limit for EtO was not proposed, although comments on the issue were solicited.

In spite of OSHA'S proposal, EPA published a Notice of Revised Labeling for Certain pesticides containing EtO in April 1984.[133] EPA stated in that notice that:

> . . . the evidence of the mutagenicity of EtO has continued to accumulate and the Agency believes that EtO poses a mutagenic risk to exposed humans. . . . New evidence also augments the concern that EtO may produce adverse reproductive effects.[134]

The notice makes clear that the agency considers the use of EtO in hospitals to be a pesticidal use, and states:

> (T)he changes contained in this notice are limited to hospital and health care facility use. . . . (T)he Agency decided to focus on this use first because hospital and health care facility workers are the single largest group of workers exposed to EtO and are believed to be occupationally exposed to the highest levels of Et0.1[35]

EPA proposed product label changes requiring modifications in workplace design and practice in hospitals and health care facility to control exposure to EtO.

The 1984 Federal Register notice also addresses the progress of the special review on ethylene oxide that EPA initiated in 1978.[136] It states that EPA "intends to pursue the comprehensive evaluation of all EtO data and, upon completion of this evaluation, to issue a Preliminary Notice of Determination Concluding the RPAR [Special Review] Process ."[137] The rationale supplied by EPA for the interim label changes was "because it will take additional time to develop the final position on all EtO uses and it is evident" from available information that exposure limitations should be implemented as soon as practical.[138]

EPA also completed a review draft health assessment for ethylene oxide under the Clean Air Act in April 1984.*[39] Although the assessment was initially developed for evaluating EtO as a hazardous air pollutant under $112 of the Clean Air Act, the scope of the assessment was expanded to address multimedia impacts. EPA concluded on the basis of its draft review that ethylene oxide produces developmental toxicity in laboratory animals when conducted at or near maternal toxic doses (maximum tolerated dosages), and produces adverse reproductive effects and testicular atrophy at levels lower than those which produce general toxicity. It also concluded that EtO may cause spontaneous abortions to hospital personnel in occupational settings and is capable of causing gene mutations.

Still under the D.C. Circuit court order to produce a permanent standard, OSHA published a final standard consisting of an 8-hour TWA occupational exposure level for EtO of 1.0 ppm and an action level of 0.5 ppm in June 1984.[140] Reportedly under pressure from the Office of Management and Budget, OSHA sidestepped the issue of a short-term exposure level by saying it would consider the issue at a later time. The Public Citizen Health Research Group immediately filed suit, claiming that OSHA had violated the court settlement by failing to propose a short-term exposure level.

On the same day that OSHA published its standard, EPA withdrew the labeling standard it had proposed in April 1984.[142] The rationale for the

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131 1, at 1156 n.23. In another late unrelated action concerning EPA's consideration of EtO, the Natural Resources Defense Council (NRDC) and the AFL-CIO filed suit against EPA in May 1983 charging that the Agency had conducted ex-parte meetings with industry to terminate RPARs for certain pesticides, including EtO. The groups charged that the public had been illegally excluded from the decisionmaking process. This contention is presently being reviewed in settlement negotiations.

132 48 Fed. Reg. 17,284 (1983).

133 49 Fed. Reg. 15,628 (1 984).

134 I d

135 Id.

136 I d.

137 It is unclear how this process may affect future EPA regulatory action on EtO.

138 49 Fed. Reg. 15,628 (1 984).

139 EPA-600/8-84-009A (April 1984).

140 49 Fed. Reg. 25,734 (1984).

141 Occupational Health and Safety Letter, at 5 (June 22, 1984).

142 49 Fed. Reg. 25,675 (1984).

action was that EPA did not want to preempt OSHA'S ability to set a comprehensive (long- and short-term) standard for exposure to EtO in hospitals and health care facilities. The agency stated:

> Since the issuance of the notice, substantial concern has been raised over the possibility that adoption of the requested labeling changes, which are intended to affect workplace design and practice in hospitals and health care facilities, might have a preemptive effect on OSHA'S ability to set comprehensive EtO standards. EPA has determined that it would be prudent to withdraw its April 18, 1984 notice and the associated requests that registrants submit revised labeling for pesticide products containing EtO. **143**

According to one union lobbyist, union pressure was responsible for persuading EPA to withdraw the labeling standard because the union believed that the proposal would interfere with OSHA'S issuance of a short-term exposure limit for EtO and with implementation of the standard.[14]A An EPA staffer with responsibility for the special **review** of EtO said that the agency was unsure of whether or not it would take further action on EtO. 145

In response to an order from the U.S. Court of Appeals for the District of Columbia, in August 1984, OSHA presented a sworn affidavit in Federal district court stating that it would complete a rulemaking on a short-term exposure limit for EtO by December 1984.[146] In December of that year, OSHA informed the district court that adoption of a short-term exposure limit for EtO was not warranted by the available evidence and was therefore not appropriate for inclusion in the final standard. 147 The statement of reasons was published in January 1985.[148]

The current OSHA standard not only lowered the PEL, but included other measures designed to protect the reproductive health of workers. Some of these measures are identical to the lead standard's requirements, and some are slightly different. As in the lead standard, employers must provide a medical examination or medical consultation for employees desiring information about the effects of current or past exposures on the ability to produce a healthy child. *49 As with lead, the medical history also includes a reproductive history, The physical examination must also give particular attention to the reproductive sys - tem. pregnancy and fertility testing must be provided if the employee so requests, but only if the physician concurs in the need for testing. The preamble to the standard explains that the purpose of requiring the physician's concurrence for pregnancy or fertility testing is to avoid "abusive or frivolous" requests, although OSHA cited no evidence of such abuses under the lead standard.

The ethylene oxide standard requires the use of warning signs and labels, which must clearly note that ethylene oxide is a cancer hazard and a reproductive hazard. Employees also must be given training and information concerning ethylene oxide use, including the substance's potential for reproductive harm.

Other Reproductive Health Hazards

OSHA standards have set PELs for a number of other known or suspected reproductive health hazards, including benzene, cadmium, mercury, and ionizing radiation. The scientific evidence relating to these agents is discussed in chapter 4. **No** efforts have been specifically addressed to preventing reproductive harms from exposure to these hazards. (Most of these standards are those adopted under section 6(a) of the OSH Act when OSHA was first created.)

An OSHA official has observed that regulation of reproductive hazards is constrained by the paucity of studies on reproductive health effects of substances found in the occupational setting:

> We're no better off today in terms of studying reproductive health hazards than we were

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[143] Id. at 25,675.

[144] Personal communication with **Jordan** Barab, AFCSME (Sept 10, 1984)

[145] Personal communication with Ann **Barton,** Deputy Division **Director,** Hazard Evaluation Division, EPA (Sept **11, 1** 984).

[146] **"W;hcnl.** Reg. Rptr. (BNA) 608 (Sept 14, 1984)

[147] 4 () S .H.Rep. (BNA) 563 **(Jan. 3,** 1985).

[148] 50 Fed. Reg. **&I** (1985). The Public Citizen Health Research Group **has** filed **suit** challenging OSHA's decision **to** exclude a **short-term** exposure **limit** for EtO **t** rom OSH **1,4 final** EtO **standard.** Public Citizen Health Research Group v Row **hind,** Nos. **84-12.52,** 84-1392 (D.C. Cir filed January 1985)

[149] 29 CFR § 1:11(), **1047(j)(2)** (i)(E) **(1984).**

[150] Id. at § 1910.1 **047(j)** (2)(ii)(A **)(1)**

[151] Id **at § 1:) lo. 1047(** (j)(2)(ii)(A)(2).

[152] d. at § 1910. **1047(j**)(2)(ii)(B).

> in the 1950s. However, in terms of regulating hazards, we're worse off because we've done little or nothing to contain substances shown to be teratogenic to humans exposed in the occupational setting.

A former NIOSH director, agreeing that the toxicology has not been well developed, added that "traditional teratological studies strengthened the stereotype of the exclusively maternal role in the transmission of reproductive health harms. "

Several of the NIOSH criteria documents submitted to OSHA have identified reproductive health hazards appropriate for regulatory action. These hazards include antimony,[153] carbon disulfide,[154] ethylene thiourea,[155] polychlorinated biphenols (PCBs),[156] and nitrous oxide.[157] Formaldehyde[158] and ethylene dibromide (EDB),[159] the subjects of recent citizen petitions, have also been linked with reproductive health harms.

Generic Standards

As discussed in this report, the promulgation of new OSHA standards is a long costly, and difficult process. In reviewing OSHA standards, the courts insist on procedural regularity, a showing of significant risk, the use of the "best available evidence, " proof of material impairment, demonstration of technological and economic feasibility, and substantial evidence of other crucial elements. These requirements, along with budget and personnel problems, legal challenges, policy shifts at OSHA, and other factors have resulted in very few new standards being promulgated.

There have been only 10 successful permanent rulemaking actions since 1971, resulting in 22 health standards. The bulk of OSHA health standards remain the outdated (1968) American Conference of Government Industrial Hygienists' threshold limit values adopted by OSHA in 1971. The standards contain mostly PELs, with no requirements for environmental monitoring, biological monitoring, or medical surveillance. Hundreds of new chemicals are being introduced into industry each year, but few new standards are being promulgated. The agency is always "playing catchup." For example, in 1977 OSHA lowered the PEL for the pesticide DBCP when it was shown that DBCP was a gametotoxin and carcinogen. The pesticide often used as a substitute for DBCP is EDB, a potent carcinogen that also has been linked to a variety of reproductive health harms. OSHA is now examining restrictions on exposure to EDB.

During the Ford and Carter Administrations, OSHA attempted to promulgate health standards on a "generic" basis. That is, OSHA sought to establish a regulatory framework for rulemaking on an entire class of substances or hazards on a single occasion.[160] It was hoped that such an approach would result in more efficient and expeditious promulgation of standards. The '(standards completion project, " begun in 1974, was a generic rulemaking project that attempted to update the original health standards package. The generic carcinogen policy developed criteria and procedures for regulating carcinogenic substances. Both efforts failed: the standards completion project was abandoned and the generic carcinogen policy, still pending in the courts, is still in effect but has not been relied on by the current Administration. Although generic-type rulemaking has produced the access to employee exposure and medical records standard and the hazard communication standard, there have been no further efforts to promulgate generic standards,

The broad array of reproductive health hazards to be regulated raises the question of whether it is possible or desirable to promulgate a generic reproductive health hazards standard. A former OSHA Director, who considers it possible, recommends coordinating various regulatory agencies (e.g., OSHA, EPA, Mine Safety and Health Administration, Consumer Product Safety Commission, Food and Drug Administration) and starting with a less controversial generic standard before moving to reproductive health hazards. A former NIOSH chief agrees with the idea of beginning with a simpler generic standard, such as skin irritants, but points out the difficulties of propos-

[153] NIOSH No. 78-216.
[154] NIOSH No. 78.166,
[155] NIOSH No. 77-140.
[156] NIOSH No. 77-156.
[157] NIOSH No. 78-144.
[158] NIOSH No. 77-225.
[159] NIOSH No. 76-149.

[160] For a further discussion, see B, Mintz, OSHA: History, Law, and Policy 82-86 (1984).

ing a generic standard for reproductive health hazards given the paucity of information. Three other high-ranking officials also support the idea of a generic approach to reproductive health hazards.

A key issue in using such an approach is deciding on the quantity and quality of data needed before specific standards can be issued. One NIOSH official stated that "we need to protect workers on the basis of toxicological studies, rather than waiting for epidemiological data, " while another questioned whether we know enough about the physiological processes of reproductive health harms to use a generic approach.

EEOC and OFCCP proposed Interpretive Guidelines on Employment Discrimination and Reproductive Health Hazards

OSHA'S attempts to regulate reproductive health hazards have invariably raised employment discrimination issues. For example, in the ***American Cyanamid*** case,[161] discussed earlier, OSHA unsuccessfully attempted to use $ 5(a)(l) to prohibit an employer's policy of excluding all fertile women from working where there was exposure to lead.

In January 1980, the Equal Employment Opportunity Commission (EEOC) and the Department of Labor's Office of Federal Contract Compliance Programs (OFCCP) issued joint Proposed Interpretive Guidelines on Employment Discrimination and Reproductive Health Hazards .l[G2] The Guidelines, issued pursuant to Title VII of the Civil Rights Act of 1964 and Executive Order 11,246, were proposed to address the fact that:

> ... an increasing number of employers and contractors . . . are initiating policies excluding all women of childbearing capacity from certain jobs because of exposure to hazardous substances or conditions .*G[3]

The Proposed Guidelines would have permitted the "temporary emergency exclusion" of only male, female, or pregnant employees under limited circumstances where there is proof of a hazard to one sex or to the future offspring of one sex, but not to the other sex and where no other alternatives were available. The Guidelines did not, however, address the issue of how the emergency exclusion would be triggered. For example, there was no discussion of whether an employer could have required women employees to take periodic pregnancy tests.

The Guidelines would have prohibited altogether any reproductive health hazard policies applicable to only one sex. Facially neutral policies that have an adverse impact on one sex were to be justified "in accordance with relevant legal principles." (Presumably, this meant establishing a business necessity or job-relatedness defense, as discussed in chapter 8.)

The proposal evoked widespread controversy. In January 1981, the Proposed Guidelines were withdrawn largely, according to a former chairperson of the EEOC, as a result of a lack of consensus on the scientific evidence received in response to the proposal, without which it was considered virtually impossible to issue a final regulation dealing with this complex and controversial subject.

The Proposed Guidelines contemplated active "consultation and coordination" between EEOC, OFCCP, NIOSH, and OSHA. Several present and former OSHA officials interviewed for this report had reservations about such OSHA involvement, asserting that OSHA lacked the statutory authority, resources, or expertise to become involved in discrimination claims. A former OSHA chief, who was instrumental in getting the proposed guidelines issued, disagreed. In her view, OSHA has "inherent responsibility" in this area; and should lend technical support and assistance to EEOC and NIOSH. Neither OSHA, EEOC, nor OFCCP currently plan to reconsider rulemaking in this area. However, EEOC and OSHA will continue to handle allegedly discriminatory employment policies relating to reproductive health on a case-by-case basis.

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[161] American Cyanamid co., 9 O.S.H.Cas. (BNA) 1596 (1981), aff'd, Oil, Chemical& Atomic Workers International Union v. American Cyanamid Co., 741 F.2d 444 (D.C.Cir. 1984).

[162] 45 Fed, Reg. i'514 (1980).

[163] Id

[164] 46 Fed. Reg. 3916 (1981). The EEOC's statement accompanying the withdrawal indicated that cases of discriminatory FPPs would continue to be monitored and evaluated under existing Title VII principles.

Hazard Communication Standard

In November 1983, OSHA issued its final hazard communication standard, after nearly a decade of study and proposed rulemaking. A former OSHA chief called the regulation "the single most significant and far-reaching standard ever written by this agency The regulation covers approximately 15 million workersl[G7] and is expected to cost $600 million. It requires chemical manufacturers and importers to assess the hazards of the chemicals they produce or import, and communicate that information to workers. Furthermore, distributors of hazardous chemicals must label chemical containers, and provide a material safety data sheet to customers in the manufacturing sector (SIC codes 20-39).

In January 1977, OSHA issued an advance notice of proposed rulemaking on chemical labeling.l[Gg] After receiving comments from State and local government agencies, businesses, and labor organizations in favor of apprising workers of health hazards caused by exposure to chemicals, OSHA published a notice of proposed rulemaking in January 1981.[170] The 1981 proposal was in most respects more comprehensive and costly than the regulation that was eventually enacted. The proposal would have required chemical hazard labeling on all containers (and pipes) used in the workplace, in addition to labeling by distributors who ship chemical containers to manufacturers,1[7'] and would have covered approximately 20 million workers,[172] whereas the present regulation covers roughly 15 million workers. 173

Less than a month after the rule was proposed, it was withdrawn by the Reagan Administration. Due to a growing awareness of the importance of the issue, and perhaps as a result of Federal inaction in this area, several States enacted labeling and disclosure laws. *'Q

OSHA then revised its proposal and issued another notice of proposed rulemaking. The 1983 Hazard Communication Standard is the culmination of OSHA'S activities in this area. (The coverage of employees, employers, and chemicals in the standard is described in Appendix C.4.) OSHA'S regulation notwithstanding, numerous State legislatures seeking more stringent regulation of chemical health hazards have continued to enact "right-to-know" laws. For example, New Jersey, which produces approximately 25 percent of all chemicals manufactured in the United States, 175 passed a law in 1983 that is considerably broader than the OSHA regulation.1[7G] As of April 1985, 20 States had passed such statutes (see table 7-2), and the District of Columbia, Georgia, Louisiana, Missouri, North Carolina, and Texas are considering passage of right-to-know laws.1[77] Whether these laws are preempted by the OSHA standard is under judicial review.

[165] 29 CFR $1910.1200 (1984).

[166] Chemical Right-to-Know Requirements: Federal and State Laws and Regulations on Disclosure, Special Report (BNA) 3 (1984) [hereinafter cited as BNA Special Report.]

[167] Workers' "Right. to. Know": OSHA's Hazard Communication Rule, Issue Brief IB84103, The Library of Congress Congressional Research Service, 2 (1984) hereinafter cited as CRS.] Another authority has estimated that approximately 14 million workers will be protected by the OSHA Regulation. BNA Special Report, supra note 166, at 1.

[168] Preamble to final OSHA Standard on Workplace Hazard Communication, O.S.H. Rep. (BNA) 700, 748 (Dec. 1, 1983) [hereinafter cited as BNA Preamble.]

[169] 42 Fed, Reg. 5372 (1977).

[170] 46 Fed. Reg. 4412 (1981).

[171] BNA Preamble, supra note 168, at 701. The 1981 regulation contained no employee training requirement, whereas the present OSHA regulation does.

[172] BNA Special Report, supra note 166, at 1.

[173] CRS, supra note 167 and accompanying text.

[174] By 1981, Maine, Michigan, New York, and West Virginia had enacted right-to-know laws.

[175] CRS, supra note 167, at 6.

[176] BNA Special Report, supra note 166, at 18. New Jersey's law requires that employees in nearly all workplaces be informed of the health hazards of approximately 2,000 chemicals.

[177] Status of Right-to-Know Legislation, Women's Occupational Health Resource Center News, Columbia University 1, 5 (Aug. 19S4). See also BNA Special Report, supra note 166, at 1; persona] communication, Peg Seminario, Assistant Director, Department of Occupational Safety, Health, and Social Security, AFL-CIO (Apr. 12, 1985).

Table 7-2.—States With Right-to-Know Laws

State	Effective date	State	Effective date
Alaska	1983	Michigan	1980
California	1983	Minnesota	1983
Connecticut	1983	New Hampshire	1983
Delaware	1985	New Jersey	1983
Florida	1985	New York	1980
Illinois	1984	Oregon	1984
Iowa	1984	Pennsylvania	1985
Maine	1980	Rhode Island	1983
Maryland	1984	West Virginia	1981
Massachusetts	1984	Wisconsin	1982

SOURCE: Himmelstein and Frumkin, "The Right-to-Know About Toxic Exposures," New *Eng. J.* Med. 312(1 1):668, Mar. 14, 1965.

Reproductive Health Hazards.—Chemicals posing potential reproductive health hazards are not expressly addressed by OSHA'S regulation, though they are implicitly covered. However, many State right-to-know laws explicitly discuss reproductive health hazards, *78 and some States' statutes that do not have taken the position that such hazards are implicitly covered within the State statute's definition of toxic and hazardous substances.1[78] In addition to specifically listing teratogens as a class of hazardous chemicals regulated by their laws, two States have special trade secret provisions for teratogens. Massachusetts requires that containers of chemical teratogens, the compositions of which are trade secrets, be labeled with a large "T" at the worksite. And New Jersey denies all trade secret protection to teratogens.

Similar concern about protecting workers from reproductive health hazards was expressed by Connecticut's right-to-know law, which contains a nondiscrimination provision. Connecticut's law prohibits the sterilization of employees as a condition of employment, transfer, or promotion.[180] The law also protects female employees by requiring an employer to attempt to offer to transfer pregnant employees when the employer or employee reasonably believes that continued exposure will threaten her reproductive health, or the health of her offspring. *81

Disclosure: Written Hazard Communication Program.—If a chemical manufacturer, importer, or distributor determines that a substance poses a hazard to workers, a written hazard communication program must be developed.[182] Three methods of communicating information are required by the Act: 1) labeling, 2) supplying material safety data sheets (MSDSS), and 3) employee information and training programs.

Trade Secrets.-One of the most controversial provisions of OSHA'S regulation is the section dealing with trade secrets. The standard permits chemical manufacturers or importers to withhold the chemical name and other information about the chemical from the MSDS if the manufacturer or importer believes the information is a trade secret .*[83] While the chemical name and other data may be withheld, information concerning the hazards of the chemical must be disclosed. In medical emergency situations, the employer must disclose the chemical name; in nonemergency situations, however, an employer claiming a trade secret need only disclose the identity of a substance to medical personnel if several conditions are first met. [184]

The trade secret provision of OSHA'S regulation has been subject to strong criticism. Critics maintain that too much discretion is conferred on employers in determining what constitutes a trade secret and that challenging an employer's decision to withhold information is costly, cumbersome, and time* onsuming. *[8s] Critics also contend that OSHA'S review of an employer's claim of a trade secret is too limited.1[8G]

State hazard communication Iaws regulating trade secrets vary in at least one significant way from OSHA'S regulation. Most States automatically review the determination of a trade secret made by an employ er.1[87]

Preemption. —The preemption doctrine—based on the supremacy clause of the U.S. Constitution![88]—holds that State laws which conflict with Federal laws that constitutionally regulate the same subject matter are invalid. OSHA maintains that all aspects of State right-to-know laws that have not received prior approval by OSHA are preempted by OSHA'S Hazard Communication rule, except those aspects pertaining to commu-

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[178] E.g., Alaska, **Connecticut, Illinois,** Minnesota, Maine, Massachusetts, and New Jersey expressly **mention reproductive hazards in their right-to-know** laws.

[179] Personal comm unication, Ivan Russell, M innesota OSHA **(January 1984);** Richard **Stone,** New York Bureau **of** Toxic **Substances** (January 1984).

[180] Conn. Gen. **Stat. Ann.** § 31-40h (Supp. 1984).

[181] Conn Gen. **Stat.** Ann § **46a-60** (a)(7)(E) (Supp. 1984).

[182] 29 CFR § 191 (). 1200(e) (1 984).

[183] 29 CFR § 1910.1200(i) **(1984).**

[184] 29 CFR § **1910.1200(i)(3) (1984).**

[185] CRS, supra **note 167, at 5.**

[186] Personal **communication with Peg** Seminario, **Assistant Director, Department of Occupational Safety, Health, and** Social Security **AFL-CIO (Feb. 21,** 1984).

[187] California, **Connecticut,** Illinois, **Massachusetts, Minnesota** , New **Hampshire, New Jersey, New York, and** Wisconsin **have automatic review provisions.**

[188] U .S. Const. **art,** VI, § **2.**

nity information requirements.[189] Yet constitutional concerns, State interests that the OSHA standard cannot regulate (e.g., protection of State public employees), and the language of the OSH Act itself require that a more detailed analysis of the preemption issue be undertaken by the courts.

Conclusions

The Occupational Safety and Health Administration has authority to regulate occupational reproductive health hazards in various ways. The agency can promulgate permanent health standards concerning a single hazardous substance, a group of specific substances, or even reproductive health hazards as a class, after extensive and cumbersome rulemaking proceedings that may take several years to complete. OSHA has promulgated permanent standards for only three substances—DBCP (1,2 -dibromo-3-chloropropane), lead, and ethylene oxide—that include specific guidelines for the protection of reproductive health,

As detailed in the text of this report, promulgating any new OSHA health standard is extremely difficult. It depends on a good working relationship between NIOSH and OSHA, adequate budgets and personnel for each agency, and insulation of the decisionmakers from the political pressures that invariably arise when new regulations are proposed. The rulemaking process is protracted, detailed, cumbersome, resource-draining, and adversarial. The reviewing courts have required detailed analyses of significant risk, technological feasibility and economic feasibility. The courts also have shown a reluctance to uphold the validity of emergency temporary standards, and have required, at times, precise and almost cataclysmic evidence of "grave danger. "

The prospects are unclear for new standards or more stringent modifications of existing standards to protect reproductive health. A number of problems exist. Scientific evidence concerning reproductive health hazards in the workplace is lacking, in part, because of a historical lack of interest in this field at OSHA, NIOSH, CDC, and PHS. There are also problems with methodologies for new studies, such as the need to develop better models for extrapolating animal data to humans, the ongoing problem of selection of proper controls, and the lack of large enough study populations for epidemiological studies.

The prospect of new substances being introduced at a faster rate than regulations are currently being issued has raised the question of whether a generic reproductive hazard standard is possible or feasible. Such a policy would establish the framework for regulating a variety of substances and would, presumably, allow for more efficient and expeditious standards promulgation. Although many individuals interviewed supported the idea in principle, there are potential scientific, legal, and political stumbling blocks.

OSHA may issue an emergency temporary standard (ETS), effective immediately, if it determines that employees are exposed to a "grave danger" from exposure to health hazards. No court has decided whether reproductive health problems are "grave dangers," though a recent Federal court of appeals decision suggests that only "incurable, permanent, or fatal" health consequences could support the issuance of an ETS. Since OSHA has lost several challenges in the courts of appeals to its ETSS, OSHA is unlikely to issue ETSS for known or suspected reproductive health hazards, especially in situations where the reproductive damage is temporary.

Even where no temporary or permanent health standards apply, OSHA is empowered to ensure that employers are fulfilling their general duty under the OSH Act to furnish working conditions free from '(recognized hazards" that are likely to cause death or serious physical harm. Since a hazard is considered recognized only if it is common knowledge in the employer's industry or if the employer had actual or constructive knowledge of the hazard, it may be difficult for OSHA to prove that newly documented or suspected reproductive health hazards are recognized. The general duty clause is therefore unlikely to be a substitute for an emergency temporary standard or to serve as an interim measure until a permanent standard is enacted.

It is unclear whether OSHA has authority to address the problem of reproductive health hazards

[189] Personal communication with Jennifer Silk, Health Scientist, OSHA (Mar. 29, 1985). See also CRS, supra note 167, at 6.

by regulating the employer's options relating to employee exposure, such as employment policies that exclude women from jobs involving potentially hazardous exposures. The Occupational Safety and Health Review Commission has ruled that Congress did not intend OSHA to have authority to issue a citation to an employer whose fetal protection policy excluding fertile women from certain jobs resulted in several women submitting to surgical sterilization to keep their jobs, The Commission's decision has been affirmed by the D.C. Circuit.

Even if OSHA had the authority to expedite the permanent health standard procedure or to enact ETSS without fear of being reversed in court, it is not clear that health standards for reproductive health hazards would result. This is attributable both to the difficulty of identifying these substances and to less-than-ideal working relations between OSHA and NIOSH resulting from the personal relations, policies, and perceptions of their leaders. OTA conducted interviews with many present and former OSHA and NIOSH officials to explore the agencies' relations and coordination with respect to occupational health issues in general and reproductive health hazards in particular, The institutional concerns, priorities, and policies of OSHA and NIOSH often vary considerably, with officials of each agency indicating disapproval of the priorities and policies of the other. Interagency cooperation also varies with the political philosophy of the Administration in power. Under the Carter Administration, OSHA and NIOSH developed a close working relationship, including personnel exchanges and various joint programs, though this resulted in criticism of NIOSH for allegedly abandoning its neutrality. The Reagan Administration, which believes in the clear separation of research from regulation, has discontinued some cooperative programs. Interviews revealed that a 1979 interagency agreement concerning cooperative programs between NIOSH and OSHA was unknown to many current, high-ranking OSHA officials.

In addition, OSHA has a shortage of professional technical staff to develop health standards, and this staff shortage may result in insufficient technical expertise for evaluating NIOSH'S work and taking appropriate regulatory actions. Adding technical staff would likely require additional legal and administrative staff to direct and implement a regulatory strategy for reproductive and other health hazards.

EPA AUTHORITY TO ADDRESS REPRODUCTIVE HEALTH HAZARDS

The following section describes 1): ***EPA legal authority*** to regulate chemicals and compounds that are known or suspected occupational reproductive health hazards, 2) ***EPA activities*** concerning reproductive health hazard assessment and management, and 3) an *evacuation* of EPA's activities related to the assessment and management of occupational reproductive health hazards. EPA's authority to address hazards from ionizing radiation are addressed in the section entitled ***Nuclear Regulatory Commission.***

Introduction: General Statutory Overview

The statutes that EPA administers do not explicitly address the agency's authority over occupational exposures to known or suspected reproductive health hazards except for the Federal Insecticide, Fungicide, and Rodenticide Act, Under that statute, EPA's mandate includes the protection of farmworkers.lgo In addition, EPA acts under Executive Order No. 10,831 and the Atomic Energy Act to regulate occupational exposure to ionizing radiation, although the agency does not have explicit statutory authority to do so. (This is discussed in a later section.) Despite the lack of an express mandate under the other Iaws that it administers, however, EPA has considerable authority to acquire and evaluate information concerning reproductive toxicity associated with the production, use, and release of chemicals in the

[190]This mandate was made clear by the 1 972 Amendments to the **Federal Insecticide, Fungicide, and** Rodenticide **Act,** Pub. **L.** No. **92-516, 86 Stat.** 973 **(1972),** which expressly **addressed** the **need for farm** \ vorker protections

environment, Pursuant to the Toxic Substances Control Act (TSCA), EPA also has extensive discretionary authority to regulate occupational exposures to chemicals in a variety of ways. This authority is presently being evaluated by EPA in relation to several substances, including formaldehyde, glycol ethers, and I',3' butadiene.

The following sections discuss the two most important environmental statutes that could be used to regulate or monitor reproductive health hazards from chemical compounds in the workplace: the Toxic Substances Control Act of 1976,1gl and the Federal Insecticide, Fungicide, and Rodenticide Act of 1947.[192] Following this is a description of how particular chemicals that have been associated with reproductive health hazards in the workplace have been dealt with by the current Administration. Five statutes of lesser importance to reproductive health hazards are evaluated in a staff paper available from OTA. These are:

1. the Clean Air Act of 1970, as amended; 192
2. the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (Superfund); 194
3. the Solid Waste Disposal Act, as amended by the Resource, Conservation and Recovery Act; 195
4. the Safe Drinking Water Act;1[9G] and
5. the Federal Water Pollution Control Act of 1972, as amended by the Clean Water Act of 1977.19[9]

Toxic Substances Control Act[198]

TSCA was enacted in 1976 and authorizes EPA to control risks to human health and the environment caused by the production, use, and disposal of toxic substances in the United States. This broad statutory mandate to regulate chemicals throughout their life cycle has provided EPA with a basis for proposing regulatory action affecting several known and suspected reproductive health hazards in the workplace, discussed in detail later.

The term "unreasonable risk" is pivotal to TSCA'S implementation. "Unreasonable risk" is not defined anywhere in TSCA despite the fact that the term and its variants are used more than 35 times in the Act. It is clear from various sections of TSCA, however, that EPA's finding of an '(unreasonable risk" from a specific chemical substance or mixture will depend, among other things, on the degree of human exposure to the substance, its toxicity and tendency to bioaccumuIate in the environment, its use (e.g., as an intermediary or catalyst in the production of a produ$_c$t), and the safety with which it can be disposed. With respect to the weight EPA is to accord each of these characteristics in determining the appropriate regulatory response to a chemical under TSCA, the statute states in fi 2(c) that:

> . . . [ilt is the intent of Congress that the Administrator shall carry out this Act in a reasonable and prudent manner, and that ***the Administrator shall consider the environmental, economic, and social impact of' any action*** the Administrator takes or proposes to take under this Act (emphasis added).

This method for assessing risks by weighing other costs is reinforced by the Act's legislative history. 199

Congress placed extensive discretionary authority in EPA to decide whether or not a public health hazard, regardless of its source or the type of exposure, is better controlled through the use of TSCA than through some other Federal law. It appears that nothing in the language of $ 9(a) or its legislative history imposes a barrier to EPA's discretion to decide that a regulatory action under $6 (regulatory actions) or a $7 (imminent hazard) order is the best way to protect the public health from significant risks of chemical production, use, or disposal. zoo Section 9(a), however, also allows EPA's Administrator the discretion to conclude that a risk is best prevented or reduced under another Federal law administered by some

[191] 15 U.S.C. §§ 2601-2629 (1982).
[192] 7 U.S.C. §§ 136-136y (1982).
[193] 42 U.S.C. §§ 7401-7642 (1982).
[194] 42 U.S.C. §§ 9601-9657 (1982).
[195] 42 U.S.C. §§ 6901-6987 (1982).
[196] 42 U.S.C. §§ 300f to 300j-10 (1982).
[197] 33 U.S.C. §§1251-1376 (1982).
[198] 15 U.S.C. §§2601-2692 (1982).

[199] See, e.g., S. Rep. NO. 698, 94th Cong., 2d sess., reprinted in 1976 U.S. Code Cong. & Ad. News 4491 (stating that "unreasonable" requires a balancing of risks and benefits).
[200] Conf. Rep. No. 1679, 94th Cong., 2d sess., reprinted in 1976 U.S. Code Cong. & Ad. News 4539.

other Federal agency. This discretionary decision is not subject to judicial review. [201]

If EPA concludes that another Federal law contains adequate authority to prevent or reduce a suspected or known risk to a sufficient extent, it must submit a report to the other Federal agency and publish it in the Federal Register, This report must describe the risk, including a description of the activity or combination of activities EPA believes presents the risk. It must also request the other agency to determine if the risk may be prevented or sufficiently reduced by action under its authority, as well as whether or not the activity presents an unreasonable risk. TSCA requires that the other agency respond to EPA within 90 days.

If the other Federal agency issues an order declaring that there is no unreasonable risk, or if it initiates a regulatory action, EPA may not take regulatory action under either $6 or $7 of TSCA. The Administrator can, however, continue to use his authority under $4 (Testing), $5 (Premanufacturing Notification), or $8 (Reporting and Information Gathering) to insure that more data about the substance (including its production, volume, and use) are collected. Nor does the provision appear to preclude EPA from concluding at some future time that regulator-y action is appropriate under TSCA on the basis of new studies. In addition, the Conference Report detailing $ 9's mechanisms specified "if the other agency does not take one of these actions (within 90 days) then the Administrator is permitted to act under $ 6 or $ 7 to protect against the risk. ''[202]

Section 9(b) attempts to resolve the relationship between TSCA and other environmental laws administered by EPA. It establishes a rule of thumb whereby TSCA is to be used only to the extent that the Administrator determines, in his discretion, that it is in the public interest to use TSCA instead of some other law to regulate the risk. The legislative history of this section reveals that although the determination whether to use TSCA is discretionary, Congress intended the Administrator to make a formal presentation describing why other authorities were not as appropriate as TSCA and why it is in the public interest to resort to TSCA instead of some other act. [203]

Information Gathering

Under TSCA, EPA has numerous ways of developing information about reproductive hazards. Section 4 permits EPA to promulgate testing rules prescribing standards for the development of data by the manufacturers of designated chemicals. Section 5 prohibits the manufacture of a new chemical without ***prior notification*** to EPA, such premanufacture notification (PMN) being accompanied by a minimum set of health and environmental exposure data. Section 8(a) authorizes EPA to require manufacturers to maintain records or submit reports about chemicals not subject to the PMN requirement. Section 8(b) requires EPA to compile and maintain an inventory of chemicals in production and distributed in commerce. Section 8(c) requires chemical manufacturers to maintain records of significant adverse reactions to health or the environment that cause long--lasting or irreversible damage. Section 8(d) directs EPA to promulgate rules requiring chemical manufacturers to submit to EPA copies of health and safety studies conducted by or known to the company, Under $ 8(e), a company is required to notify EPA within 15 days of obtaining information that reasonably supports the conclusion that the substance presents a substantial risk of injury to health or the environment. Finally, $ 10 requires EPA to carry out research, development, and monitoring whenever necessary to carry out the purposes of TSCA. (These provisions are discussed in detail in Appendix D. I.)

Regulatory Actions[204]

Section 6 allows EPA to select from a broad range of regulatory responses to address significant human health and environmental risks from the production and use of chemicals. The range of possible actions that EPA can take through administrative rules include:

1. prohibiting the manufacture, processing, or distribution of the substance;
2. limiting the amount of such substances that

[201] Id.
[202] Id.
[203] S. Rep. No. 698, 94th Cong., 2d sess. 11 (1976).
[204] 15 U.S.C. §2605 (1982)

can be manufactured, processed, or distributed in commerce;

3. prohibiting the manufacture, processing, or distribution of the substance for a particular use;
4. limiting the manufacture, processing, or distribution of a chemical or mixture for a particular use;
5. prohibiting the use of the chemical substance or mixture in a concentration in ex - cess of that specified by the administrator;
6. limiting the concentration of the chemical or mixture in excess of levels specified by the administrator for a particular use;
7. requiring that any such substances be clearly marked with or accompanied by clear and adequate warnings and instructions with respect to their use, distribution in commerce, or disposal, or any combination of such activities (the form and content of labels may be prescribed by EPA);
8. requiring the manufacturer or processor of the substance or mixture to make and retain records of processes used in manufacturing or processing the materials;
9. requiring the manufacturer or processor of regulated substances or mixtures to monitor or conduct tests that are reasonably necessary to assure compliance with any particular rule that EPA has promulgated;
10. prohibiting or otherwise regulating the manner or method of commercial use of the chemical substance or mixture;
11. prohibiting or otherwise regulating the manner or method of disposal of such substance or mixture, or any article containing the material either by the manufacturer or processor themselves, or any persons who use or dispose of such chemical substances or mixtures or articles for commercial purposes; and
12. issuing a directive requiring manufacturers or processors of such substances or mixtures to:
    a. give notice of unreasonable risk of injury to distributors of such materials in commerce, and to the extent that it is reasonably ascertainable, to other persons in possession of or exposed to such substances and mixtures; and to
    b. replace or repurchase such substance or mixture as elected by the person to whom the requirement is directed.[205]

The administrator is also authorized by $ 6(a) to limit one or any combination of the above regulatory options to a specified geographic area. (No other environmental statute in the EPA Administrator's arsenal provides this authority.)

Imminent Hazard Authority[206]

Section 7 authorizes EPA to seek orders in the U.S. District Courts to enjoin activities in order to protect against "imminent hazards." Imminent hazards are defined under TSCA as substances or mixtures that present an unreasonable risk of death, serious illness, serious personal injury, or serious environmental harm prior to the completion of an administrative or other proceeding authorized under the bill.[207] In this sense, some reproductive health hazards would fall under the authority of this section.

public Disclosure of Data[206]

Any information obtained under TSCA that qualifies as a trade secretor as confidential business information generally may not be disclosed to the public, and special clearance is required for employees of the agency who handle this information. However, these data may be disclosed if EPA determines disclosure is necessary to protect health or the environment against unreasonable risk of injury. Regardless of any confidentiality considerations, any information filed pursuant to TSCA'S requirements is available to committees of Congress.

Data from health and safety studies are treated separately from the confidentiality protections, however, Pursuant to $ 4(b), any health and safety study must be disclosed with respect to any chemical substance or mixture that has been offered for commercial distribution or for which $4 testing or $ 5 notification has been required. [209]

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205 15 U.S.C. § 2605(a) (1982).
206 15 U.S.C. § 2606 (1982).
207 15 U.S.C. § 2606 (1982).
208 15 U.S.C. § 2613 (1 982).
209 Section 4(b) adds, however, that disclosure of health and safety studies under TSCA does not authorize the release of any data to the public that disclose processes used in the manufacturing or proc-

Citizen Suit Provisions

TSCA states that any person may petition EPA to issue, amend, or repeal a rule or an order. If the administrator denies or fails to respond to a petition within 90 days, the petitioner may commence a civil action in Federal district court to compel EPA to take the requested action. If the petitioner demonstrates that there is an adequate basis for the issuance of the rule or order requested, the court must order the administrator to initiate proceedings on the requested action,[210] unless doing so would make EPA resources unavailable to attend to more serious problems [211]

Federal Insecticide, Fungicide, and Rodenticide Act[212]

FIFRA provides a comprehensive mechanism for regulating the use, manufacture, and distribution of pesticides.[213] EPA's authority to regulate reproductive harms from occupational exposures to pesticides under this law is extensive, although not as extensive as it is under TSCA (which confers authority for regulating all uses of chemicals, not just substances used as pesticides). Another reason FIFRA is less potent than TSCA for regulating human health hazards is that the statute is primarily a registration and labeling law. Under limited instances, discussed below, EPA can also suspend and cancel the registration of products classified as pesticides if it determines that the substances are public health hazards.

Congress intended FIFRA to protect the health of farmworkers and other employees exposed to pesticides in the field and in their preparation. In passing the 1972 Amendments to FIFRA, a prime motivation was to make clear EPA's responsibility to protect farmworker health .[214] What is less clear is whether other kinds of workers, including those who dispose of wastes contaminated by pesticides, are similarly protected.

FIFRA's keystone is the registration of pesticide producers and their products. The Act prohibits distributing, selling, or receiving pesticides that are not registered with EPA. In registering a pesticide, EPA can impose restrictions on its use and require labeling to ensure that the pesticide is properly handled and applied, As part of this process, EPA is required to classify pesticides for either general use, restricted use, or a combination of the two. The classification determines who can purchase or apply the pesticide. In general, the law is intended to ensure that the pesticides do not have an "unreasonable adverse effect on the environment. " In addition, the statute sets forth procedures for the cancellation and suspen-

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essing of **chemicals, or** the **relevant proportions of** active **ingredients in mixtures.** Thus the Administrator must exclude **such information** when **releasing a** study. **No** advance **notice to the companies** who filed **this information is** necessary **for the release of health** and safety studies. To **obtain health and" safety studies, one must file a** Freedom **of Information** Act (FOIA) request.

[210] See Environmental Law Institute (ELI) **Citizen Suit** Study for **grounds of successful citizen petitions,** ELI, **Citizen Suits (** 1984). **The** most recent artion **compelled** EPA to **list** formaldehyde under **§ t(f) on the basis of animal tests that** showed **the substance to be a** potential carcinogen

[211] H.R. Rep No 1679, **94th** Cong , 2d sess. 98 **(** 1976).

[212] 7 II, S.C. §§ 136-136v (1982).

[213] The term " **pesticide**" refers to any substance or mixture **Of** substances **intended for** preventing, destroying, **repelling, or mitigating** any **pest, and** any **substance or mixture intended for** use as **a plant** regulator, defoliant, **or desiccant,** 7 **[1.** S.C. **§ 136(u) (definitions).** The **term embraces a** wide variety of biological **approaches** to the **control of' pests, including reproductive inhibitors intended to** reduce **or** otherwise alter the reproductive capacity or potential of various **organisms** and **animals,**

[214] S. **Rep, No,** 838, **92d** Cong., **2d** sess. **4063** (1972).

Photo credit: Pemina Meisels

No new chemical may be manufactured unless the manufacturer first provides EPA with exposure and toxicity data.

sion of pesticides that may result in adverse effects on the environment or an imminent hazard.

Two terms—"environment" and "unreasonable adverse effects on the environment ''—are pivotal to the use of FIFRA to protect workers from the effects of pesticides. "Environment" includes water, air, land, plants, and humans and other animals, and the interrelationships that exist among these. The phrase "unreasonable adverse effects on the environment" is defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide. '

Registration of Pesticides[217]

Generally, producers, sellers, and distributors of pesticides must apply for registration of each pesticide with EPA before marketing. The registration process places the burden on the company desiring to market the pesticide to produce the data needed by EPA to evaluate the application.[218] EPA must either approve a registration as expeditiously as possible or deny it according to procedures that give the applicant an opportunity to appeal. For those pesticides the agency decides to register, EPA must classify them for either general or restricted use on the basis of hazards associated with their use.

Regulatory Action on Applications for Registration.—EPA must grant an applicant registration for a pesticide on finding that:

- its composition warrants the proposed claims for it;
- a complete copy of the pesticide's labeling and other material comply with the Act;
- the pesticide will perform its intended function without unreasonable adverse effects on the environment; and
- when used in accordance with widespread and commonly recognized practices, th'e pesticide will not generally cause unreasonable adverse effects on the environment .[219]

Thus EPA may register a pesticide that has the potential for certain deleterious health effects as long as the risk to man or the environment is not "unreasonable. " If EPA determines that use of the pesticide in accordance with its labeling, warnings, and cautions, and in accordance with widespread and commonly recognized practice, wi!l generally not cause unreasonable adverse effects, it can be classified for general use. A pesticide may also be registered for restricted uses if EPA determines that its use may generally cause such unreasonable adverse effects as injury to the applicator unless use is restricted.

Pesticides must be re-registered every 5 years. EPA carries out specific risk/benefit analyses of chemicals suspected of causing unreasonable risks. In addition to the data submissions already described for new pesticides, applicants for reregistration or amendment of an existing registration must also submit to EPA any factual information, including unpublished studies and accident reports, regarding adverse effects of the pesticide on the environment or man that the applicant has obtained or that has come to his attention, and insofar as he is aware, has not previously been submitted to the agency .[221]

Special Review.—If, during the registration of a pesticide or through other information, EPA

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[215] 7 U.S.C. § 136(j) (1982).

[216] 7 U.S.C. § 136(bb) (1982). The latter phrase appears in several sections of the law. These include a determination by EPA of:

- whether to approve or deny an application for registration of a pesticide,
- whether a pesticide should be classified for general or restricted use,
- whether to issue a notice of intent to cancel registration or to hold hearings,
- whether to suspend a registration pending completion of cancellation procedures,
- whether to issue a final cancellation order, and
- whether a pesticide represents an '(imminent hazard. "

The relative weight to be assigned to risks and benefits of a pesticide varies with each type of determination, though there is an overriding concern expressed throughout the Act to reduce risk to public heahh.

[217] 7 U.S.C. § 136a (1982).

[218] FIFRA requires that EPA publish guidelines specifying the kinds of information required to support the registration of a pesticide. 7 U.S.C. § 136a (1982). In cases of minor uses of a pesticide, standards are to be made commensurate with the anticipated extent of use and the level of potential exposure of man and the environment to the pesticide. Furthermore, in the development of these standards, EPA must consider the economic factors of potential volume of use, extent of distribution, and the impact of the cost of meeting the data requirements on the incentives for any potential registrant to undertake the development of the required data.

[219] 7 U.S.C. § 136a(c)(5) (1982).

[220] 7 U.S.C. § 136d(a)(1) (1982).

[221] 40 CFR § 162.8(b)(2) (1984).

finds evidence that the pesticide might cause an unreasonable adverse health or environmental risk, $ 3(c)(8) authorizes the agency to initiate a "public interim administrative review process" to develop a risk/benefit evaluation for the pesticide. Under this procedure, called "special review, " or the "rebuttable presumption against registration" (RPAR) process, the Office of Pesticide Programs develops a recommendation for a regulatory position with regard to the registration, suspension, cancellation, and restrictions on the pesticide under review.

Farmworker Protection Standards

Pursuant to EPA's authority to register agricultural pesticides, it is also the primary governmental body with responsibility for overseeing and regulating health risks of these products to farmers and farmworkers.[222] When EPA is exercising this responsibility with respect to a particular class of chemicals, OSHA is preempted from taking action.[223]

EPA first published worker protection standards for agricultural pesticides in May 1974.[224] These rules:

- prohibited applying pesticides when workers who are not wearing protective clothing were in the area being treated,[225]
- prohibited worker reentry until '(sprays have dried or dusts have settled," and
- listed harvest intervals for certain pesticides [226]

In August 1984, EPA published an advanced notice of rulemaking stating that it intended to revise these standards within 12 months .227 The summary of the notice lists the following areas that EPA intends to consider under its $ 3(a) authority, including:

1. expanding the scope of the regulations, including the categories of workers, work activities, and pesticide uses to which the regulations would apply;
2. revising reentry times;
3. revising the protective clothing provisions;
4. revising the standard for warnings; and
5. imposing other types of safety requirements .[228]

EPA also stated that it will consider using new methods to implement and enforce standards .[229]

The current standards give no attention to special subgroups of workers who may be particularly vulnerable to reproductive effects from exposure to pesticides. EPA's 1974 proposal would have defined farmworkers to include children under 12 years of age, who are viewed as being particularly vulnerable to certain types of reproductive health hazards. However, the inclusion of this subpopulation "who might be in the field at any time for any reason" was strongly protested by growers and their associations[230] and therefore dropped as an element in the regulations. In addi -

[222] S Rep. No. 838, 92d Cong., 2d sess. 14 (1972). The Senate Committee on Agriculture and Forestry Report on the Amendments stated that EPA pesticide registration authority encompassed worker protection:

> The Committee believes there can be no question but that the trill (FEPCA) requires the Administrator to require that the labeling and classification of pesticides be such to protect farmers, farm workers, and others coming in contact with pesticides or pesticide residues

[223] In 1975, the U.S. Court of Appeals for the District of Columbia ruled in organized Migrants in Community Action v. Brennan that EPA has authority to provide protection for farmers and farm \ \ orkers from the adverse effects of pesticides, and that where EPA was exercising this authority, OSHA was preempted from issuing standards on its own. 520 F.2d 1161 (D.C. Cir. 1975). See EPA interpretation at 49 Fed. Reg. 32,605 (1984). This suit arose from citizen suit petitions to compel OSHA to issue permanent standards governing field reentry time for 21 organophosphate pesticides for which OSHA had issued emergency temporary standards in 1973. 38 Fed. Reg 10,715 (1973). Publication of emergency standards under OSHA started the 6-month period within which the agency must issue final standards. However, during this period, EPA had indicated its intention to publish standards and had signed a memorandum of agreement with OSHA to this effect. 39 Fed. Reg. 9457 (1974). The Court held on this basis that OSHA was preempted from taking action with regard to this class of chemicals by EPA's action.

[224] 39 Fed, Reg. 16,888 (1974) (codified at 40 CFR pt. 170 (1982)). The 1974 standards define '(farmworker" or '(worker" as "any person or persons engaged in agricultural hand labor in the field, " 39 Fed. Reg. at 16,890; 40 CFR § 170.2(b). This term encompasses workers who might come in contact with pesticides during transportation, storage, application, or after the product has been applied.

[225] Fed. Reg. at 16,890; 40 CFR § 170.2(c).

[226] "Harvest intervals" or "reentry" times were set for 12 substances which precluded unprotected workers from reentering a field treated with pesticides for specified periods ranging between 24 and 48 hours.

[227] 49 Fed. Reg. 32,605 (1984); 40 CFR § 170.3(b)(2) (1984) (intervals specified). Farmworker organizations and some EPA officials believe that the 1974 standards provide inadequate protection for field laborers, particularly against reproductive hazards and other health concerns. See 49 Fed, Reg. 32,605 (1984).

[228] 49 Fed. Reg. at 32,605.

[229] Id. at 32,605, 32,608. EPA enforcement authority is presently limited to instances when it can show that a product has been used inconsistently with its labeling

[230] See 39 Fed. Reg. 889 (1974).

tion, the standards provide no specific precautions with respect to protection for pregnant farm laborers and there is no evidence in the summary of comments received that reproductive harms to pesticide applicators received more than cursory attention.

Use of Restricted Pesticideszs[1]

Section 4 authorizes EPA to prescribe standards for the certification of applicators of pesticides subject to restricted use under $3. By means of this provision, EPA can minimize exposure to designated toxicants, including substances that may be reproductive health hazards, by requiring that persons who mix and apply the substances be certified. A certified applicator must demonstrate practical knowledge of application techniques, environmental factors, and pesticide toxicity, through written examinations and in some cases performance testing.[232]

Cancellation and Reregistration of pesticides2ss

The provisions of $6 may be directly relevant to the detection and removal of pesticides from the market that may expose workers to possible reproductive health hazards. Section 6(a) requires EPA to automatically cancel a pesticide's registration after 5 years unless a request for continuance of the registration is submitted and approved. Section 6(b) authorizes EPA to cancel pesticides that cause unreasonable adverse effects on the environment or man. Finally, $6 provides EPA with authority to suspend the registration of a pesticide immediately to prevent an "imminent hazard, " (These provisions are discussed in Appendix D.2.)

Storage, packaging and Disposal of Pesticideszaa

Section 19 of FIFRA authorizes EPA to establish procedures and regulations for the safe storage, packaging, and disposal of pesticides. EPA must accept for disposal, on request of the owner, any pesticides for which registration has been been canceled. General precautions for the handling of pesticide wastes have been promulgated by EPA.[235] Chemicals associated with reproductive health hazards do not appear to be handled differently than other toxic wastes.

EPA Implementation of Reproductive Health Hazard Control Programs

The foregoing discussion indicates that EPA has clear authority under both TSCA and FIFRA to regulate certain types of occupational exposures to reproductive health hazards and to collect information about the potential reproductive effects of various substances as a basis for regulatory action. It is also clear that under a wide variety of other statutory programs (see staff paper available from OTA), the agency may accumulate data and assess a substance's potential for developmental health effects, mutagenicity, and other reproductive impacts associated with human and environmental exposure in the three environmental media. The following sections present an overview of what EPA has done in the area of reproductive hazard assessment and management. This information was primarily developed from discussions with EPA staff members. Finally, relevant interagency relationships, particularly between EPA and the Occupational Safety and Health Administration, the Food and Drug Administration, and the Consumer Protection and Safety Commission are described.

As was discussed earlier, EPA has statutory authority to regulate chemicals on the basis of developmental effects, as well as on the basis of other more subtle reproductive and sexual impacts. EPA receives and analyzes test data of these health effects under TSCA and FIFRA, and routinely performs risk assessments based on these characteristics. Although it appears that carcinogenic characteristics of a chemical generally provide a more compelling basis for regulation by EPA than do reproductive health effects, this emphasis may change, particularly with the development and acceptance of short-term tests. According to several EPA officials, EPA regulates

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231 7 U.S C. § 136(b) (1982).
232 40 CFR §171.4 (1984).
233 7 U.S.C. § 136d (1982).
234 7 U.S.C §136q (1 982).
235 40 CFR pt. 165 (1984).

chemicals on the basis of carcinogenicity more often than for reproductive effects because of the assumption that chemicals that cause reproductive health effects generally also have positive indicators of carcinogenicity. The problem with reproductive health hazards, as has been pointed out in congressional testimony,[23G] is that regulation on the basis of carcinogenicity is generally inadequate to protect against the deleterious reproductive effects that may occur at lower dosages.

There are, however, some prominent examples of EPA actions taken on the basis of reproductive health effects alone. The regulatory activity surrounding several of these chemicals where occupational exposure was involved is discussed below. It should be noted that all of the final actions based on reproductive health effects have occurred pursuant to FIFRA. Several important actions involving occupational exposures to chemicals under TSCA are also pending in EPA.

EPA Actions Under FIFRA

Dibromochloropropane (DBCP).—[See discussion of EPA and OSHA regulation of this nematocide in the section entitled OSIYA ***I?e~roductive Health Hazard Regulations.]***

Ethylene Oxide (EtO).–[See discussion of EPA and OSHA regulation in the section entitled ***OSHA Reproductive Health Hazard Regulations.]***

Oryzalin.—In November 1979, the International Chemical Hazards Union petitioned EPA under FIFRA to ban the production and use of the herbicide Oryzalin based on anecdotal evidence of high rates of birth defects in the offspring of workers involved in the production of Oryzalin at a plant in upstate New York. During a 1%-year period of the pesticide's production, not one of the worker's wives had experienced a normal pregnancy.[237]

In March 1980, EPA decided not to regulate Oryzalin, based on its review of a series of developmental studies performed by Eli Lilly, whose subsidiary produced Oryzalin. Analysis of eight other plants involved in the production of the pesticide showed no statistically significant rate of birth defects. Although one developmental test on laboratory rabbits produced evidence of teratogenesis,[23s] replication of the test produced no effect, and EPA judged it to be an insufficient basis for regulation.[23g] The agency concluded that production methods at the upstate New York plant were less protective than in other plants, allowing greater exposure to the chemical.[240] EPA officials were denied entrance into the plant to test this hypothesis, because they did not have legal authority for inspections of working places under either TSCA or FIFRA.[241] While the agency agreed to do further monitoring of Oryzalin (along with OSHA and NIOSH), EPA officials concluded at that time that they did not have the authority to regulate the production of pesticides, only their use .[242]

Cyanazine.—EPA has recently undertaken a special review of cyanazine, a herbicide marketed under the trade name of Bladex,[243] after the agency found that cyanazine causes developmental effects in laboratory animals. As a result of these studies, EPA has concluded that female agricultural workers who apply, load, or mix the herbicide may be exposed to unsafe levels of the substance.

EPA determined that a dietary risk of adverse effects of cyanazine as a result of traces found in agricultural products was insignificant. The agency is currently undertaking an analysis of potential adverse effects of the herbicide on drinking water, however.

Because of the effects on laboratory animals, the agency has required that warning labels be placed on the herbicide notifying users of these potential effects. Furthermore, because of the possibility of ground or surface water contamination,

[236] Relationship of Exposure to Toxic Chemicals to Reproductive Impairment, Hearings Before the Subcommittee on Investigations and Oversight of the House Committee on Science and Technology, 97th Cong., 2d sess. 25-26 (1982) [statement of Dr. Jeane Manson, University of (Cincinnati Medical School),

[237] See Relationship of Exposure to Toxic Chemicals to Reproductive Impairment, Hearings Before the Subcommittee on Investigations and Oversight of the House Committee on Science and Technology, 97th Cong., 2d sess. 122.128, 142-145 (1982) (statements of Dr Gordon F. Hueter, Director, Health Effects Laboratory, and Dr Ed Johnson, Director, Office of Pesticides, EPA).

[238] Id. at 123.

[239] Id

[240] Id. at 126,

[241] Id.

[242] Id

[243] 50 Fed. Reg. 14,151 (1985).

labels must be placed on cyanazine advising applicators not to use the substance in permeable soils or where water is near the surface.

During the special review of cyanazine, EPA will receive evidence and determine what final action to take, including whether to issue a final notice to propose regulations to reduce the risks associated with cyanazine or issue a notice of an intent to cancel the herbicide.[244]

Nitrophen (TOK).—Regulation of the herbicide nitrophen, marketed under the trade name of TOK, was considered by EPA based almost solely on the teratogenic risks to female farmworkers .245 In 1980, however, the company that produced the compound voluntarily withdrew it from the market. The company intended to develop safe uses for the chemical and return it to the market, but laboratory tests performed by both the agency and the company could find no level at which the compound did not have a teratogenic effect. In 1983, EPA requested that the company proceed with cancellation of the product, "in light of the determination that nitrophen presents a substantial teratogenic risk and a potential oncogenic and mutagenic risk without economic benefits ."[24G] The company agreed to the cancellation, and EPA completed cancellation proceedings in 1984.

Agency Actions Under TSCA

The Glycol Ethers.–EPA published an Advanced Notice of proposed Rulemaking (ANPR) to regulate two glycol ethers and their acetates in the Federal Register in January 1984 pursuant to its authority in $ 6 of TSCA .[247] The notice stated:

> A number of animal studies indicate that adverse reproductive and fetotoxic effects are associated tvith these chemical substances at concentrations to which humans may be exposed. EPA is concerned about both short-term and chronic exposure of pregnant women, either as workers or as household consumers, to these chemical substances. EPA is also concerned about the exposure of males to these substances, both from short-term and chronic exposure. EPA has also made a preliminary review of the toxicity of some potential substitutes for these four ethers, and while some exhibit toxic effects, they appear to be of less concern than the effects of the glycol ethers that are the subject of this ANPR.[248]

According to an EPA official, this is the first regulatory action under TSCA based solely on reproductive health hazards.[248] The Advanced Notice of Proposed Rulemaking followed earlier reports that the Office of Toxic Substances had been '(actively pursuing regulation" of six chemicals, including glycol ethers, that are used as intermediaries in the production of plastics. °These same reports also indicated that EPA had been attempting to coordinate regulation of glycol ethers with the Consumer product Safety Commission (CPSC) and OSHA.[251] However, CPSC rejected the notion of a coordinated effort with EPA and had determined earlier to take no action on the group of compounds used commonly as solvents in household products and paints.[2SZ] As a result, publication of the notice was a unilateral action by EPA, and does not refer to cooperative regulation of glycol ethers with other agencies.

This use of TSCA to control glycol ethers based on their potential reproductive effects in the workplace, though still at a pre-regulatory phase, has provoked some controversy within the agen-**Cy.Z53 The** Reproductive Effects Assessment Group (REAG) refused to approve the risk assessment performed by the Office of Toxic Substances when it came to the office for review because it employed what REAG considered to be questionable uses of dose-response relationships in its risk assessment .254 Despite these conflicts, officials from both offices believe that EPA will undoubtedly regulate glycol ethers based on their reproductive effects. A partial ban on some uses is apparently being considered.

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[244]Id

[245]Personal communication with Harry Chitik, **office** of **Pesticide Programs, EPA (Sept.** 8,1984).

[246]Chem. Reg. Rptr. (BNA) 141 (May 4 , 1984).

[247]49 Fed Reg. 2921 (1 984).

[248]Id ,

[249]Personal communication with Harry Teitelbaum, **Office of** Toxic **Substances,** EPA **(Sept. 20,** 1984).

[250]Chem. **Reg.** Rptr. (BNA) 1301 **(Jan. 1,** 1983).

[251]Id

[252]Personal communication with Harry Teitelbaum, **Office of** Toxic **Substances,** EPA **(Sept. 20, 1984).**

[253]Personal communication **with Peter** Voytec, **Reproductive Effects Assessment Group, Office of Research** and **Development,** EPA **(Sept. 20, 1984).**

[254]Personal communication with Harry Teitelbaum, **Office** of **Toxic Substances, EPA (Sept. 20,** 1984).

Industry opposes EPA's regulation of glycol ethers, claiming that the agency lacks sufficient data on these chemicals' uses, exposures, benefits, and suspected risks.[255] In addition, industry representatives believe that EPA should defer regulation of glycol ethers to OSHA because that agency is responsible for regulating workplace hazards.[256]

C)ther Actions

A summary of EPA actions under TSCA and FIFRA based on information from EPA's February 1984 Status Report of Chemical Activities appears in table 7-3. It shows the number of chemicals that EPA has looked at or is looking into under the authority of the two acts based on mutagenic, developmental, and reproductive effects, single or in any combination. Listing of these chemicals based on any of these effects in EPA's data base does not necessarily preclude their listing in another category of effects, such as carcinogenicity. Therefore, reproductive effects may not be the sole basis for the EPA actions described.

Interagency Jurisdictional Issues

EPA's activities concerning reproductive health hazards to workers, as illustrated by the ethylene oxide and glycol ethers cases, suggest a growing tension between EPA and OSHA on jurisdictional issues. EPA's increased willingness in the past several years to rely on the use of TSCA, with its very broad mandates to regulate not only the initial manufacture of chemical substances, but also their use and disposal, has created a potentially volatile situation between the two agencies.

In an effort to resolve some of the more outstanding political issues that EPA's actions over recent months have created, EPA and OSHA are considering a comprehensive Memorandum of Understanding for controlling workplace exposures giving EPA broad discretion as to whether or not it will refer chemicals to OSHA. Until this Memorandum is formalized, EPA has completed an intra-agency memo outlining interim policy for referring actions to OSHA and other agencies. The document states that EPA will use TSCA $ 9(a) to refer a chemical problem to OSHA as soon as: 1) there is credible evidence that the chemical poses an unreasonable risk, and 2) EPA has reason to believe that the problem would be most effectively or efficiently addressed under the provisions of the OSH Act, or the Mine Safety and Health Act (MSH Act). It also states that referral will be made where occupational exposures are at issue, or where the exposure could be most effectively addressed by workplace standards. These statements are simply a reiteration of TSCA'S language. According to the memo, however, EPA will not refer a chemical to OSHA when "too much of the exposure lies beyond the reach of the OSH Act and MSH Act" and where "a full or partial ban on the production or use of the chemical, or other remedies uniquely available under $ **6** of the TSCA, provide the most effective or efficient remedy."

This approach has been criticized by industry groups and by OMB, both of whom claim that $ 9(a) of TSCA should not be used to preclude OSHA from exercising its authority over workplace exposures. However, a letter from three members of the Senate Environment and Public Works Committee endorsed this approach, saying that the provision "does not preclude action under TSCA merely because another agency also has the authority to respond ."[257]

[255]Chem. Reg. Rptr. (BNA) 5 (Apr. 6, 1984).

[256]Personal communication with **Sanford** Gaines, Assis tant General Counsel, **Chemical** Manufacturers **Association** (Oct. 27, 1984).

[257]Chem. Reg. Rptr. (BNA) 276-277 (June 1, 1984).

Table 7.3.–EPA Actions Under TSCA and FIFRA Based on Mutagenicity, Developmental, and Reproductive Effects[a]

TSCA		FIFRA	
Testing	250		
Preliminary/ preregulatory	120	Preliminary/regulatory assessment	2
Summary review	18	Cancellation/ban	14
Ban	0	Other/DCI	42
Notice	5	Risk documentation/ assessment	6
Special review	96		

[a]Four substances listed under both **Acts are not included**

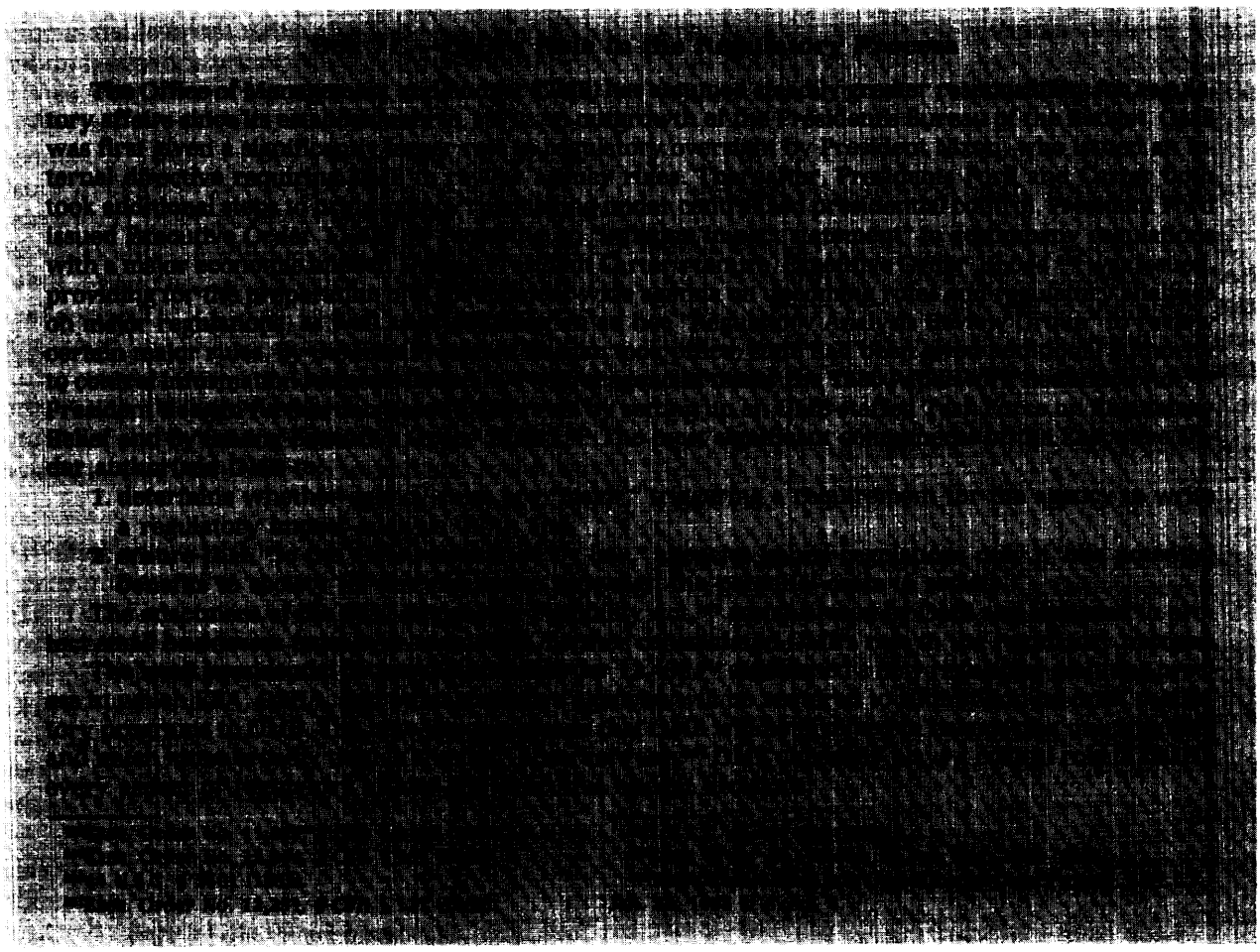
SOURCE Adapted by Environmental Law Institute from Information provided by the U S Environmental Protection Agency

Qualitative Analysis of EPA Management of Reproductive Health Hazards

Many of the EPA officials interviewed for this report stated that there had been very little activity within EPA to regulate chemicals with reproductive effects. Some felt that EPA has become more seriously involved in this area, but that this was a fairly recent development. Only a few individuals were knowledgeable about EPA's efforts to use its existing authority under environmental statutes to examine occupational exposures to chemicals with known or suspected reproductive effects.

There was virtual agreement among interviewees that EPA tends to look first at chemicals based on their potential to cause cancer. They believed this to be largely a result of statutory authority, congressional pressure, and public phobia about carcinogenic chemicals. There was disagreement among interviewees, however, concerning whether regulating a particular chemical based on its carcinogenic risk provided sufficient protection to people from the reproductive health hazards of some substances. (A discussion of EPA risk assessment activities appears in chapter 6.)

Many public interest groups and some government officials expressed reservations about EPA's willingness to use its authority to protect workers. Some charged that EPA's inactivity in this regulatory area was due to the agency's lack of a mission to protect public health in the process of regulating chemicals. Many others, however, expressed doubts about EPA's authority to regulate occupational exposures and its leaders' willing-



ness to insert themselves into this politically "hot" area, given OSHA'S current reticence on the issue. Several officials and other interviewees expressed high regard for EPA's current emphasis regarding several proposed actions under TSCA and FIFRA to regulate significant occupational and consumer reproductive health hazards,

Inter- and Intra-agency Coordination

Interviewees inside and outside the agency noted that the management of reproductive health hazards in the workplace could benefit from improved inter- and intra-agency coordination, EPA officials noted that there was little formal coordination between other program offices and REAG with respect to how chemicals associated with reproductive effects are evaluated. A workgroup on teratology has recently been established in the agency, but beyond this group, communication with other officials is on an informal basis. There was also a lack of formal communications with other agencies. This may be remedied by a newly organized Intra-agency Risk Management Council now under the Cabinet Council and its subcommittee on reproductive health hazards, but few interviewed thought there was real hope for this forum providing meaningful communication channels among agencies. In addition, some thought that a formal Memorandum of Understanding between EPA and OSHA would probably not cure strained relationships between the agencies due to the use of TSCA for regulating occupational hazards.

Future of Reproductive Health Hazard Program at EPA

Several interviewees suggested that EPA had essentially failed to regulate reproductive health hazards to farmworkers despite a strong statutory mandate under FIFRA and that EPA is generally unresponsive to the special working conditions of farmworkers, who may be exposed to greater quantities of toxic substances than any other work force in the country as a result of "spray drift" and lack of clean drinking water. Since many farmworkers do not have laundry facilities, they often wear pesticide-laden clothing for days at a time, including in their homes. Most farmworkers do not have drinking water facilities in the field, so they rely on irrigation ditches as a source of water. These ditches are commonly used to transport a mixture of water and pesticides. While no studies have directly determined the causes of reproductive difficulties some farmworkers are experiencing, several interviewees claim there is a "high index of suspicion" relating it to pesticides in drinking water. None of these individuals was optimistic that EPA's current attempt to address some of these problems by revising worker standards will be successful.

Many people who are encouraged by EPA's interest in reproductive health hazards from chemicals are generally not optimistic about whether this interest can provide a solid foundation for regulating chemicals on the basis of their potential to cause deleterious reproductive effects. Many believe that the basic science in this area is seriously deficient. Lacking a sufficient scientific data basis, the proposed risk assessment guidelines, one person stated, may be putting the cart in front of the horse.

Another related theme that emerged during the interviews was curiosity, and general despondency, about the future of these programs under new EPA leadership. The importance of the publication of the reproductive risk assessment guidelines for public comment before January 1985 was stressed by several people. Interviewees seemed to believe that former Administrator Ruckelshaus' leadership was fundamentally responsible for placing emphasis on reproductive effects as an issue and in the agency's present willingness to challenge OSHA'S jurisdiction in this area.

Conclusions

The Environmental Protection Agency has made significant strides within the last several years toward developing its institutional expertise and authority for regulating occupational exposures on their potential to induce deleterious reproductive effects. However, it is also apparent that while the statutory authority for regulating these health risks undeniably exists under the Toxic Substances Control Act, and to a more limited extent under the Federal Insecticide, Fungicide and Rodenticide Act, there are some substantial scientific, institu-

tional, and political uncertainties that may militate against EPA assuming a larger role than it now has in regulating occupational reproductive health hazards.

One of the most important problems confronting EPA (and any other agency) in regulating reproductive health hazards appears to be scientific. The "state-of-the-art" for assessing hazards or risks for different types of reproductive effects is only beginning to evolve.

There are also institutional constraints on EPA's ability to regulate reproductive health hazards effectively. First, it is not clear whether EPA's collection of data on reproductive health hazards is sufficiently systematized to provide a regular and consistent data base for assessing chemicals across the board for their reproductive effects. The new FIFRA regulations will, for the first time, require manufacturers and processes of pesticides already registered by EPA to submit information on these products' potential for reproductive effects. In addition, information collected on the reproductive health effects of new and existing chemical compounds under TSCA may not be uniformly available to other program offices, including the Office of Pesticide Programs. The agency may also be legally prohibited from sharing this information with OSHA, except in certain instances such as TSCA $9 referrals. Finally, there seems to be a notable dependence on EPA's part to rely on informal relationships between professionals within the agency and with health professionals in the private sector to stay abreast of current university studies and publications on the reproductive effects of chemicals and scientific assaying techniques. These communication channels are based, at least in part, on EPA employees' membership in scientific societies as well as former professional and collegial associations. These techniques, while consistently important in scientific communities in private institutions as well as in the government, are sufficiently personal in nature that they may not necessarily become part of the institutional memory of the agency when important staff professionals leave EPA.

The third largest area of concern is political constraints on EPA's ability to regulate occupational health hazards in general, and reproductive health hazards in particular. Although EPA has moved to regulate such chemicals as ethylene oxide, formaldehyde, and glycol ethers, all of which may have potential reproductive effects in humans but that are nonetheless used widely in the workplace, there is a perception among the EPA staff working on these actions that this is the result of EPA's recent leaders' willingness to use TSCA and FIFRA to take the initiative to manage these hazards. The memorandum outlining EPA's position on the future Memorandum of Understanding to be consummated between EPA and OSHA concerning EPA's authority to use TSCA for occupational exposures, for example, demonstrates very little willingness by EPA to yield its jurisdiction over these hazards to OSHA. In the situation involving EPA's proposal to regulate ethylene oxide use in hospitals on the basis that the compound was registered under FIFRA as a pesticide, the same aggressiveness appears evident. According to interviewees, the agency relented only when convinced by public interest groups of the importance of letting OSHA proceed in setting workplace exposures so as not to run afoul of the holding, in ***Organized Migrants in Community Action v. Brennan,***[265] that EPA's actions could preempt OSHA if it moved to regulate the chemical even though EPA did not have the clear authority or resources to inspect or enforce EPA regulations.

Yet, EPA has indicated that it will refer two other chemicals, 4',4' methyene dianiline and I'3 butadiene, over which EPA and OSHA share potential jurisdiction, to OSHA under $9 of TSCA, since it believes OSHA can most effectively regulate human exposures to these chemicals. EPA has not yet formally referred these chemicals. The agency is currently preparing regulatory packages for referring methyene dianiline and 1'3 butadiene to OSHA as well.

[265] 520 F.2d 1161 (D.C. Cir. 1975).

NUCLEAR REGULATORY COMMISSION (NRC)

Despite early awareness of the hazards of occupational exposure to radiation,[266] a Federal regulatory response was belated. The development of nuclear technology during World War 11 and dramatic demonstration of its biological destructiveness did not immediately elicit a Federal response to protect health. Rather, the Atomic Energy Act of 1946[267] showed congressional preoccupation with maintaining both secrecy and the Government monopoly on nuclear technology. The Act made no substantive statement on public or occupational health .[268]

Congress modified this course with the Atomic Energy Act of 1954.[269] Intent on finding peaceful uses of atomic energy, Congress encouraged private participation in the development of nuclear technology. The result was a substantial growth in the use of radioactive materials in industry and Government coupled with increasing use of X-rays and radioisotopes in medicine, leading to a corresponding increase in the size of the work force exposed. In 1960, crude estimates indicated that approximately 440,000 workers were exposed. By 1970, the number had grown to an estimated 775,000, an increase of 80 percent in 10 years By 1980, about 1.3 million workers were being exposed to radiation. Of these, 44 percent were exposed in medicine, 23 percent in industries not part of the nuclear fuel cycle, 16 percent in Government, 11 percent in the nuclear fuel cycle, and 6 percent in miscellaneous occupations.[270]

Congress had anticipated this trend; the 1954 Act represented the first substantive Federal involvement in protecting the health of workers exposed to radiation. Under this Act, the Atomic Energy Commission (AEC) was charged with the duty to enact regulations to protect health,[272] and in 1957, it issued its first Standards for Protection Against Radiation.[273] In 1959, the Federal Radiation Council was established to advise the President on radiation matters affecting health, and in 1960, it promulgated the first Federal Radiation Guidance for occupational exposure to radiation.[274] The Council was abolished in 1970, when the Environmental Protection Agency was created, and its functions were transferred to the new agency.

Today, no single agency regulates radiation exposure of workers; Federal responsibility, which is dispersed among five executive departments, one independent commission, and two agencies, by diverse statutory provisions, operates under the unifying force of Federal radiation protection guidance administered by EPA. However, by 1980, a major review had found "inconsistencies of jurisdiction and regulatory programs. . ." and "confusion . . . from inconsistencies in ways in which regulatory agencies and the public regard and interpret data . . . [and] what the policy should be."[275] The primary authority for the regulation of occupational exposure to ionizing radiation in the nuclear industry rests with the Nuclear Regulatory Commission (NRC), the successor agency to AEC. In the medical and industrial communities, EPA's authority is shared with OSHA and the States.

The Energy Reorganization Act of 1974 created NRC and abolished AEC.[276] AEC had been given the sometimes conflicting roles of both promoting and regulating nuclear technology. The reorganization established NRC as an independent commission that inherited only AEC'S regulatory responsibilities .[277]

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[266] See, e.g., historical review in J. Serwer, The Rise of Radiation Protection, 1896-1935, Report to Brookhaven National Laboratory, BNL-, 22,279 (December 1976)

[267] 42 U.S.C. §§ 2011-2296 (1982).

[268] W. Wood, Nuclear Safety: Risks and Regulation, American Enterprise Institute, (1983)

[269] 42 U.S.C. §§ 2011-2296 (1982).

[270] A.W. Klement et al., Estimates of Ionizing Radiation Doses in the U. S.: 1060-2000, EPA, ORP/CSD 72-1 (1972).

[271] S. Kumazawa, D. Nelson & A.C.B. Richardson, Occupational Exposure to Ionizing Radiation in the United States: A Comprehensive Summary for the Year 1980 and a Summary of Trends for the Years 1960-198.1, of ffice of Radiation Programs, EPA (1984). See also L. Sagan Radiation and Human Health, vol. 4, No. 7 EPRI J. (September 1979)

[272] 42 U.S.C., § 2201(b) (1982).

[273] 10 CFR pt 20 (1958).

[274] 25 Fed. Reg. 4402 (1960).

[275] Report of the Task Force on Occupational Radiation Exposure Regulations, U.S. Radiation Policy Council (1980).

[276] 42 U.S.C. §§ 5801-5891 (1982).

[277] See discussion in W.C. Wood, Nuclear Safety: Risks and Regulation, American Enterprise Institute (1983). See also 10 CFR pt. 1 (1984).

NRC's authority is conferred by three statutes: the Atomic Energy Act of 1954,[278] the Energy Reorganization Act of 1974,[279] and the Uranium Mill Tailings Radiation Control Act of 1978.[280] The Commission's regulatory power is derived principally from the authority previously held by AEC, since all licensing and rulemaking functions of AEC conferred by the Atomic Energy Act were transferred to NRC by the Energy Reorganization Act. As a result, NRC's jurisdiction over human exposure to radiological hazards pertains to exposures to "source, byproduct and special nuclear material NRC's regulatory jurisdiction runs with all materials included in these categories. However, NRC authority is limited to NRC-licensed activities. Furthermore, NRC's regulations are subject to EPA environmental radiation protection standards for air and water, which have been established for all components of the nuclear power cycle and for all emissions to air from any other licensed operation.

If a material is reactor-produced (e.g., Americium used in smoke detectors) or is a source material (e.g., uranium used in ceramic dyes or thorium used in welding rods), then NRC may regulate the workplace in which it is used, under some circumstances. Thus, NRC with its comprehensive control over nuclear power plants, also finds smoke detector and ceramic manufacturing plants within its jurisdiction.[282] Regulated workplaces may include nuclear power reactors; reactor fuel producers; uranium milling; and all industrial, manufacturing, medical and pharmaceutical facilities that use controlled materials.

The Uranium Mill Tailing Radiation Control Act[283] extended NRC's authority by expanding the definition of "byproduct material" to include uranium and thorium mill tailings. Congress recognized the radiological hazard posed by tailings and directed NRC to subject this class of byproduct to appropriate regulatory control, under standards established by EPA, to protect health and the environment.

NRC implements its statutory authority in three main ways: licensing proceedings, rulemaking, and regulatory guides. NRC also has the authority to relinquish some of its regulatory power to State radiation control programs (Agreement States). In addition, States may establish standards, applicable to all NRC licensees, that are more restrictive than those set by EPA under the Clean Air Act.

Important elements of nuclear safety regulation have developed through NRC licensing proceedings. NRC has authority to regulate by license most aspects of nuclear technology. Atomic Energy Act materials are therefore licensed on a cradle-to-grave basis; licenses are necessary to distribute, possess, use, transport, and dispose of nuclear material. Nuclear production and utilization facilities also undergo extensive licensing procedures in two steps: at the construction permit stage and at the operating permit stage. The NRC staff reviews safety aspects at each stage. At the end of the process, a license may be issued with whatever restrictions are determined necessary for the safe operation of the plant. Throughout the process, there is a strong presumption that the facility can be made acceptably safe; NRC has never denied an operating license to a constructed nuclear facility.[284] In all licensing proceedings, NRC establishes minimum criteria requisite to the issuance of a license,[285] and can condition the license on terms that force the licensee to comply with all NRC rules, regulations, and orders.[286]

NRC also has broad authority to promulgate ***regulations*** that govern licensee activities, and many regulations have been adopted by NRC to resolve safety and occupational exposure issues on a generic basis, applicable to all licensees .287

Regulatory guides are also issued by NRC to describe acceptable methods of compliance with NRC regulations. While not legally binding, the expense for the licensee of demonstrating alter-

[278] 42 U.S.C. §§ 2011-2296 (1982).
[279] 42 U.S.C. §§ 5801-5891 (1982).
[280] 42 U.S.C. §§ 7901-7942 (1982).
[281] 42 U.S.C. § 2014 (1982).
[282] Senate Committee on Goverment Affairs, Study on Federal Regulation: Regulatory Organization, S. Dec. No. 91, 95th Cong., 2d sess. (1977).
[283] 42 U.S.C. §§ 7901-7942 (1982).
[284] W.C. Wood, Nuclear Safetv: Risks and Regulation, American Enterprise Institute (1983). "
[285] 42 U.S.C. §§ 2073, 2093, 2111 (1984).
[286] 42 U.S.C. §§ 2201(b), 2233 (1 984).
[287] See 10 CFR pts, 19, 20 (1984).

native means of compliance makes acceptance of the NRC methods practical. The guidelines are so detailed that licensees often have little leeway for developing alternative methods of promoting safety .[288]

NRC has the authority to relinquish specific regulatory powers to a State by written agreement, but it may not delegate its responsibility for special nuclear materials in quantities sufficient to form a critical mass,[zag] for the production or operation of nuclear facilities, [zgo] for the export or import of nuclear materials or facilities,[2g1] or for certain disposal methods of nuclear materials. [zgz] Before entering an agreement with a State, the Commission must determine that the State radiation protection program is sufficiently compatible with that of the Commission [293]

All licensees are governed by NRC's occupational exposure regulations contained in 10 CFR Parts 19 and 20. Since NRC Agreement States must have compatible regulations, these States effectively implement the 10 CFR Parts 19 and 20 regulations. In 1983, NRC had agreements with 26 States, which had issued about 13,200 radioactive material licenses. This represented approximately 64 percent of all licenses issued in the United States.[2g4]

Few NRC actions relevant to radiation and reproductive health have been tested by judicial review. (A discussion of those actions that have been reviewed appears in a staff paper available from OTA.)

Other Regulatory Authority

Several other agencies have statutory authority to set and enforce standards for worker exposure to radiation. The most important of these is the overall Federal guidance provided by the Environmental Protection Agency, In 1970, EPA was directed by ***Reorganization Plan Number 3*** to assume the functions of the former Federal Radiation Council to "advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all Federal agencies in the formulation of radiation standards. . . ,"[295] Under this authority, EPA studies the hazards of exposure to radiation and formulates guidance for use by other agencies.[296] All Federal regulations are consistent with this guidance.[2g7] In the case of occupational exposure, this guidance includes numerical limits on the exposure of workers. This guidance, which was last issued in 1960, has recently been reviewed and new recommendations are in the final stage of review by Federal agencies.

Although NRC and the States are not bound by EPA guidance, they have, as a policy matter, always adhered to Presidential directives such as the Federal Radiation Guidance. While EPA does have the authority to establish regulatory standards for public health and environmental protection from all radioactive materials, this jurisdiction applies to environmental releases to areas outside the facilities regulated by NRC in the case of Atomic Energy Act materials. [298]

The existence of EPA's Federal Guidance role provides uniformity to worker protection from ionizing radiation, because several other agencies are also responsible for regulating occupational exposure to radiation. This complicated jurisdictional picture would otherwise result in a piecemeal approach to radiation safety. The Department of Energy, the Department of Defense, and the Department of Labor have regulations designed to indirectly limit certain exposures by regulating sources of exposure. The Department of Health and Human Services and the Department of Transportation indirectly regulate exposures.

NRC Relations

NRC regulations do not explicitly address reproductive health, although it can be inferred from their structure and content that NRC

[288] A Review of NRC Regulatory processes and Funct [00S, Advisory Committee on Reactor Safeguards, N. R.C. (1977).
[289] 42 U.S.C. § 202 1(b)(3) (1984).
[290] 42 U.S.C. § 2021(cN 1) [1984).
[291] 42 U.S.C. § 202 1(c)(2) (1984).
[292] 42 U.S.C. § 2021(c)(3)(4) (1984).
[293] 42 U.S.C § 2021 (d)(1)(2) (1984).
[294] Annual Report: 1983, U.S. Regulator Commission (1983).
[295] Reorg. Plan No. 3 of 1970, 3 CFR § 1072 (1966-70 compilation), reprinted in 5 U.S.C. app. at 1132 (1982).
[296] d
[297] Radiation Protection Guidance for Federal Agencies, 25 Fed. Reg. 4402 (1970).
[298] Memorandum of Understanding, AEC-Licensed Facilities, 38 Fed. Reg. 24,936 (1973).

considered some aspects of reproductive health.[299] For example, the regulations deal with the sensitivity of youth, the various risks associated with cumulative dose, and the susceptibility of the gonads. No regulations deal directly with the protection of the embryo/fetus, although a nonbinding regulatory guide advises women to minimize exposures while pregnant. Thus, the NRC regulations must be carefully disassembled to determine their implicit application to the reproductive health of workers, and their adequacy for protecting reproductive health.

At the outset, it is instructive to understand the philosophical underpinnings of Federal regulation of occupational exposure. The regulation of radiation exposure encompasses two concepts: the ***linear dose-response assumption*** and the ***"as-low-as-reasonably-achievable" (ALARA) assumption.***

Current analytic methods are not sensitive enough to define the pathological effects of chronic exposures to low levels of radiation. As stated in an NRC Regulatory Guide, "at the relatively low levels of occupational exposure in the United States, it is difficult to demonstrate correlations between exposure and effect, ''300 In the absence of such evidence, the assumption is now made that there is no threshold dose below which radiation damage will not occur. Most authorities have therefore adopted the conservative hypothesis of a ***linear relationship between dose and biological effect*** even at very low doses. This means that each increment of radiation, however small, is currently assumed to inexorably result in an increment of health risk. This assumption determines Federal approach to the formulation of occupational radiation standards.

NRC espouses the "ALARA principle," which holds that despite the permissiveness of its standards, actual exposures should be kept "as low as reasonably achievable, " and therefore at or below the level permitted by the standard.[301] This may be implemented in the design of facilities or through use of work practices that minimize unnecessary exposure.

These concepts are manifest in Part 20. The purpose of the regulation is to control the possession, use, and transfer of licensed material so that the total dose to a worker does not exceed the prescribed dose limit, The licensee is required to:

> . . . make every reasonable effort to maintain radiation exposures . . . as low as is reasonably achievable. The term "as low as is reasonably achievable" means as low as is reasonably achievable taking into account the state of technology, and the economics of improvements in relation to the benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to the utilization of atomic energey in the public interest ,[302]

Three main sections of Part 20 are germane to reproductive health: 1) permissible doses, levels, and concentrations; 2) precautionary procedures; and 3) records, reports, and notification. (These are discussed in Appendix E.)

Applicability to Reproductive Risks

NRC has promulgated standards that implicitly account for many of the known reproductive sensitivities, and that represent what the Commission believes to be acceptable levels of risk. While both the International Commission on Radiation Protection (ICRP) and the National Council on Radiation Protection and Measurements (NCRP) have recommended lower occupational dose limits for fertile and pregnant women, criticism of these recommendations has prevented NRC from adopting differential exposure limits. Critics cite male reproductive susceptibility and

[299] NRC regulations for protecting workers are set forth in 10 CFR pts. 19, 20 (1984). Part 19 establishes requirements for notices, instructions, and reports by licensees to employees who are exposed to radiation. Required procedures include instructions to the workforce concerning radiologic health protection, as well as reports to individual workers detailing their exposure. Part 20 defines permissible doses, levels, and concentrations to which employees can be exposed, and outlines precautionary procedures, including radiation surveys and personnel monitoring. Compliance with both parts 19 and 20 is a mandatory condition of all NRC licenses.

[300] Instruction Concerning Risk From Occupational Radiation Exposure, Regulatory Guide 8.29 and Value/Impact Statement, Office of Standard Development, Nuclear Regulatory Commission (1981).

[301] See discussion in Biological Effects of Ionizing Radiation, Report Nos. 1, 2, & 3, Advisory Committee on the Biological Effects of Ionizing Radiation, National Academy of Sciences (1972, 1977, 1981).

[302] 10 CFR pt. 20, § 20. 1(c) (1975).

carcinogenicity as supporting lower exposure limits for both sexes.

In 1984, the ICRP recommended that women of reproductive capacity should be employed only under conditions where the annual dose is unlikely to exceed 1.5 rein, delivered at an even rate. This would exclude any special permission to allow exposure up to 3 reins per quarter, as provided by NRC regulations previously discussed. It would also prevent high rates of exposure (i.e., exposure to the 3 rem quarterly limit in less than 3 months). The ICRP believed that these exposure conditions would keep the embryonic dose below 0.1 rem per month during the critical period of organogenesis. Once a pregnancy is diagnosed, ICRP also recommends that the women's exposure should be controlled so that the accumulated dose to the fetus during the remaining term does not exceed 0.5 rem, the upper limit for annual exposure of the general population .[303]

In 1971, the NCRP recommended that the dose to the fetus from occupational exposure of the mother not exceed a total of 0,5 rem over the period of gestation. This recommendation was similar to the then-current recommendation of the ICRP (1 rem). A statement accompanying the recommendation stated:

> The need to minimize exposure of the embryo and fetus is paramount. It becomes the controlling factor in the occupational exposure of fertile women. In effect, this implies that such women should be employed only in situations where the annual dose accumulation is unlikely to exceed 2 or 3 reins and is acquired at a more or less steady rate. In such cases, the probability of a dose to the fetus exceeding 0.5 rem before a pregnancy is recognized is negligible. Once a pregnancy is known, the actual approximate dose can be reviewed to see if work can be continued within the framework of the limit set above. . . . For conceptual purposes, the chosen dose limit essentially functions to treat the unborn child as a member of the public involuntarily brought into controlled areas. The NCRP recommends vigorous efforts to keep exposure of an embryo or fetus to the very lowest practicable level.[304]

In response to early ICRP and NCRP recommendations, the predecessor agency to NRC published proposed amendments to 10 CFR Parts 19 and 20 in 1975 that were designed to incorporate the "intent" of then+ current ICRP and NCRP recommendations. It did not propose to amend the dose-limiting sections of the regulations, which would have resulted in differential standards for men and women. The proposed amendments would only require licensees to provide instructions to all workers that include information about the biological risks to embryos and fetuses exposed to radiation, and would require that women be advised of the need to keep exposures of the fetus to the very lowest practicable level during the entire gestation period.[305] These amendments were not adopted. While recognizing the greater radiosensitivity of the fetus, NRC did not believe a reduction of exposure limits for all workers was "practicable":

> Reduction of the dose limits for all radiation workers in order to avoid discrimination against women does not appear practicable. Such a reduction in the dose limits would cost the nuclear industry large sums of money in the application of design and engineering changes and, in some cases, the employment of additional workers in order to accomplish essential work within the reduced individual dose limits. The latter could even result in a net increase in total man reins of exposure .306

NRC also believed that actual exposure of pregnant women was currently within the NCRP recommendation, making adoption of the proposed changes unnecessary. It made this finding on the basis of mandatory licensee reports for 1973, which showed that 29,169 workers received measurable doses averaging 0.73 rem per year, and that 3,435 workers had exposures in excess of 2 reins, in industries believed to have the greatest worker exposures. NRC also assumed that many working women were not fertile, and that only a small portion of the fertile women being ex -

[303] 1 4 Annals of the International Commission on Radiation Protection, No. 1 (1984).

[304] Review of the NCRP Radiation Dose Limit for Embryo and Fetus in Occupationally Exposed Women, Report No. 53, National Council on Radiation Protection and Measurements (1977).

[305] 40 Fed. Reg. 800" (1975).

[306] 40 Fed. Reg. 799 (1 975).

posed would become pregnant. The Commission concluded that:

> . . . the continued implementation of ALARA in its licensing and enforcement process . . . will result in further reduction in radiation doses, and may make specific adoption of the NCRP recommendation regarding additional limitation on exposure of fertile women of minor effect.[307]

The impact of the proposed amendment on women's privacy and employment opportunities also figured in NRC's informal decision to reject amending its regulations. The proposed amendment was instead made into an appendix to ***Regulatory Guide Number 8.13.*** The Guide instructs NRC licensees to instruct all workers about the biological risks to embryos and fetuses from radiation, and to advise women of the need to minimize exposures while pregnant, The Guide is nonbinding but considered persuasive.

A salient feature of NRC's exposure regulations is the failure to control the ***rate of exposure.*** While the regulations limit a worker's dose to a maximum of 3 reins per quarter, they do not prevent that exposure from being attained in minutes. It does not appear that the rate of exposure increases the risk for adult workers; 3 reins is believed to carry the same probability of genetic damage whether attained in minutes or in weeks. However, the failure to restrict the rate of exposure has two important implications for reproductive health. First, an acute exposure that coincides with the sensitive stages of embryonic or spermatogenic development can have a severe health effect even though the pregnant woman or prospective father may be well within the 3-rem-perquarter dose limit. Second, NRC's failure to restrict the rate of exposure makes possible the use of ***temporary workers*** as a means of meeting exposure limits and circumventing the ALARA mandate.

Draft recommendations that would revise current Federal Radiation Protection Guidance would delete the 3 reins per quarter limit in favor of a 5 reins per year whole-body dose equivalent limit, believed to be sufficient to protect against the risk of lethal cancer and prompt genetic effects (those in the first two generations). It would also explicitly limit exposure of the fetus to 0.5 rem, and would recommend avoidance of variation above the uniform monthly exposure rate that would satisfy this limiting value. The draft recommendations state, as a matter of policy, that conformance to the limiting value for the unborn should be achieved without economic penalty or loss of job opportunity and security to workers. They also recommend that employees exposed to radiation be instructed as to the genetic and fetal health risks of exposure. These recommendations are expected to be transmitted to the President for approval in late 1985.

[307] 40 Fed. Reg. 800 (197.5).

Temporary Workers[308]

A principal purpose for regulating occupational exposure to radiation should be the minimization of genetic risk to the population. This goal may be jeopardized if NRC licensees continue to be permitted to hire, quickly expose, and dismiss

[308] Attention was first focused on the issue of temporary workers through investigations of a reprocessing and waste storage facility which was plagued by design defects and frequent breakdowns that resulted in high occupational exposures. During its 6-year history, the company employed about 170 full time workers, but in 1971 alone, 991 temporary workers were used. House Committee on Government Operations, West Valley and the Nuclear Waste Dilemma, H. ft. Rep. No. 755, 95th Cong., 1st sess. (1977). Thirty percent of the occupational radiation exposure accrued to temporary workers, each of whom had less than one day's employment in the facility, Temporary workers would often receive a full quarterly dose in one day's work. Wages for less than 1 percent of the plant total went to temporary workers. R.W. Kates and B. Braine, The Locus of Benefits and Risks of West Valley Nuclear Wastes, Center of Technology, Environment, and Development, Clark University (1982). Some believe that this is unfair:

> Whether a worker receives his quarterly maximum of 3 reins in 3 months or in 3 minutes may make no biological difference. But if, as is generally assumed, every exposure carries some discrete risk of genetic damage or illness, then the full-time worker who earns 3 months' pay for 3 months' radiation benefits considerably more than the worker who accepts the same risk—knowingly or not—for half a day's pay. Gillette, Transient Nuclear Workers: A Special Case For Standards, Science 125 (Oct. 11, 1974).

This argument does not consider the fact that a nuclear worker's wages are based on the amount and type of labor as well as the amount of exposure, however. The typical temporary worker is paid substantially more, on an hourly basis, than other nuclear workers with similar skills, and this differential probably represents the market price of the difference in radioactive exposures.

The company discussed above represents an extreme case. But the employment of temporary workers as a means of meeting exposure standards is a permanent, prevalent, and growing nuclear industry practice. M .H. Melville, The Temporary Worker in the Nuclear Power Industry: An Equity Analysis, Center for Technology, Environment, and Development, Clark University (1981). See also 1984 Nuclear Power Safety Report, Public Citizen (1984).

large numbers of temporary workers, also known as "sponges" or "jumpers. "

> Jumpers are unskilled, short-term employees who expose themselves to quick doses of relatively high radiation for relatively high pay, often for only minutes of work. Chosen at the '(body shop" for their small size, which enables them to crawl through the 18-inch-wide passageways of mammoth steel reactor pressure vessels, they may do no more than turn a bolt. But in a workplace giving off as many as 25 reins an hour of radiation, it must be done in seconds .[30g]

The ALARA admonition does not make clear whether that concept requires ***individual*** exposures or ***work force population*** exposures to be as low as reasonably achievable when a choice between the two must be made. Industry's use of large numbers of temporary workers to perform tasks resulting in high exposures results in many workers being exposed to radiation (high population exposure), but to lower levels per capita than if a smaller number of permanent workers performed these tasks (high individual exposure). Although NRC regulations do not explicitly state which of the two types of exposures is preferable, high population exposure is implicitly preferred by the NRC regulations, since individual exposures are expressly limited while population exposures are not.

The use of large numbers of temporary nuclear workers may represent a public reproductive health problem, since brief but relatively high exposures to radiation may affect the workers' ability to parent healthy children if the reproductive safety threshold is relatively low. The Bulletin of Atomic Scientists has also expressed concern:

> The fact that many nuclear power plants are finding it necessary to solve the individual exposure problem of repair work in persistently high radiation areas by hiring temporary employees to spread out the dose has increased the overall cancer and genetic risks to the population, which is exactly what we should try to avoid.

Concerned about temporary workers, NRC analyzed the mandatory annual reports filed by nuclear power companies. The reports showed several thousand employees had been hired and terminated more than once in 1977. The indicated periods of employment were less than 90 days in about half of the cases. In an effort to monitor these employees, NRC focused on '(transient workers)" those employees hired and terminated by two or more employers in one quarter. NRC believes this class to be the most mobile and therefore the most vulnerable to overexposure.[312]

Between 1973 and 1977, the number of nuclear power workers exposed to measurable levels of radiation tripled to reach 71,904. Although the average level of exposure declined from 0.87 to 0.74 person reins per year, an eightfold increase occurred in the number of transient workers, from 157 to 1,311. The average exposure for these workers fell from 0.89 to 0.52 person reins per year.[313] Nevertheless, distributing small doses over an enlarged worker population may have effects on reproductive health in the Nation.

NRC's narrow definition of transient workers represents only a fraction of the temporary work force. When defined simply as the class of workers hired on any basis other than permanent, estimates of the size of the temporary work force are 18 times that of NRC's "transient workers. " Under this definition, there were 23,520 temporaries in 1977, which represented 35 percent of the monitored work force. These workers received 47. s percent of the radiation dose.[314]

The use of temporary workers presents a profound ethical question. Since a worker is part of the human gene pool, his dose is genetically significant for the entire population. Therefore, when a worker receives a radiation dose to the gonads, the worker and society are both harmed.

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[309] Nuclear Plants Hiring stand-ins to Spare **Aides Radiation Risks,** N.Y. **Times,** July 16, **1979,** at 1,

[310] K.Z. Morgan, Cancer and Low-Level Ionizing Radiation, The Bulletin of Atomic Scientists, 30 (September 1978).

[311] Occupational **Radiation Exposure, Tenth Annual Report,** 1977, **Office of** Management **and Program Analysis, Nuclear Regulatory Commission (1978).**

[312] M.H. Melville, **The** Temporary Worker **in the** Nuclear Power **Industry:** An **Equity Analysis,** Center **for Technology, Environment, and Development, Clark University (1981). See also 1984 Nuclear Power Safety Report, Public Citizen (1984).**

[313] M.H, Melville, **'rhe** Temporary Worker **in the** Nuclear Power **industry: An** Equity Analysis, Center **for** Technology, Environment, and Development, Clark University **(1981),**

[314] I d

Given the linear dose-response assumption, genetic injuries are proportional to the dose received. A large dose to a limited number of workers can therefore have less effect on future generations and the entire society than small doses distributed across a larger work force. NRC regulations permit the widespread practice of hiring temporary workers; this practice defeats the purpose of radiation health protection. (A discussion of radiation regulation in Europe appears in a working paper available from OTA.)

Conclusions

NRC regulations[315] for protecting worker health do not explicitly address reproductive health, but manifest various reproductive health concerns in that they provide for special protection for the gonads and for various health risks to reproduction that arise from cumulative dose. No provisions deal with fertility, pregnancy, or protection of the embryo/fetus per se. However, NRC Regulatory Guide 8.13 provides information on risks. In developing its standards for worker protection, NRC employs a linear dose-response assumption. Furthermore, NRC requires its licensees to do more than merely comply with its standards, namely, to make every reasonable effort to maintain radiation exposures "as low as reasonably achievable" (the ALARA concept).

The exposure of regular employees (whole body; head and trunk; active blood-forming organs; lens of eye; or gonads) is limited to between 1.25 and 3 reins per calendar quarter, depending on the worker's accumulated lifetime dose from prior occupational exposures. Thus, employees are limited to 5 reins of radiation exposure per year. Workers under 18 years of age are more stringently protected, with the maximum dose to the minor's gonads set at 0.125 rem per calendar quarter.

In addition, NRC requires employers who have been licensed to handle radioactive materials to conduct various precautionary procedures, which also serve to safeguard reproductive health. These include periodic surveys of radiation hazards, use of personal monitoring equipment by workers, demarcation of restricted areas, maintenance of records of radiation surveys and personnel exposure, and furnishing of general instructions and individual exposure data to workers.

NRC standards are uniformly applied, irrespective of worker sex. NRC mandates no special protections for the fetus. The International Commission on Radiation Protection (ICRP) has recommended that women diagnosed as being pregnant be employed only where the annual dose is unlikely to exceed 1.5 reins, and not be permitted to receive the maximum 3 reins per quarter NRC regulations now provide for workers without records of prior occupational exposures. They further recommend that fetal protection should be "broadly comparable with that provided the general public" (i.e., 0.5 rem), and that substantial irregularities in the *rate* of exposure not occur. This would keep the fetal dose below 1 rem during the critical period of organogenesis.[316] The National Commission on Radiation Protection (NCRP) has recommended a protective limit of 0.5 rem for occupational exposure of women during the entire period of gestation. Controversy over these proposals exists.

NRC has not adopted these recommendations. According to its formal statement, it does not believe the recommendations are practicable, in that they would result in high costs for the nuclear industry and the employment of additional workers, which could even result in a net increase in total man reins of exposure. It has also provided further reasons: that actual exposure of pregnant women meets the NCRP recommendation; that the ALARA concept works to further reduce actual doses; and that the recommendations, if adopted, would lead to intrusions into the privacy of female workers and sex discrimination in violation of Federal law by their employers, NRC has, however, issued an appendix to one of its regulatory guides, which asks NRC licensees (employers) to instruct workers about risks to a fetus from radiation, and to advise women of the need to minimize exposure when pregnant.

Nor has NRC controlled the *rate of" exposure* by regulatory action. This means that a pregnant

[315] 10 CFR pts. 19, 20 (1984).

[316] 14 Annals of the International Commission on Radiation Protection, No. 1 (1984).

woman, who may be well within the 3-rem-per-quarter dose limit for previously exposed workers, may be permissibly exposed to this quarterly limit in a matter of minutes. Such a focused exposure may coincide with the sensitive stages of embryonic development and have severe health effects.

NRC's silence on acute exposure with high dosage has also led to widespread use of temporary workers in industry as a means of meeting exposure limits while keeping individual doses relatively low over time. By 1977, temporary workers represented 35 percent of the work force in the nuclear power industry alone, with these workers receiving an estimated 47.5 percent of the total work force radiation dose.[317] Although quarterly dose limits are generally adhered to by the employers of temporary workers, temporary workers without occupational dose records are permitted to receive the higher doses of up to 3 reins per quarter, and, in practice, may receive this dose in a very short period of time (minutes), thereby endangering the embryo/fetus, as noted above. The distribution of small doses across an enlarged work force that tends to involve younger, temporary workers has resulted, and could have a greater impact on future generations than would a large dose to a smaller number of permanent workers .[318]

NRC authority, while preempting State law on matters involving health and safety regulations, does not preclude tort actions or workers' compensation by injured workers, under State law. Thus NRC licensees are subject to NRC standards and NRC license provisions, but may also be subject to private claims for compensatory and punitive damages by injured employees, their spouses, and their children, under circumstances that differ from State to State.

Finally, the factual basis for NRC regulatory actions on health issues has not been adequately tested in the courts. The Federal courts have repeatedly deferred to NRC expertise and discretion, and have failed to probe NRC technical findings and assumptions in affirming NRC regulatory decisions. Tort suits against the NRC have also failed to provide for accountability, since the courts have barred such suits on the grounds that NRC is exempt from Federal tort claims because its actions fall within the "discretionary function" exception of the Federal Tort Claims Act.[319]

[317] M.H. Melville, The Temporary Worker in the Nuclear Powrer Industry: An Equity Analysis, Cent& for Technology, Environment, and Development, Clark University (1981), See also 1984 Nuclear Power Safety Report, Public Citizen (1984).

[318] K.Z. Morgan, Cancer and Low-Level Ionizing Radiation, The Bulletin of Atomic Scientists 30 (September 1978).

[319] 28 U.S.C. § 2680(a) (1982). See Dalehite v United States, 346 U.S. 15 (1953).