Reproductive Health Hazards in the Workplace: Selected Aspects of Reproductive Health Hazards Regulations

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REPRODUCTIVE HEALTH HAZARDS IN THE WORKPLACE

staff Papem
Selected Aspects of Reproductive Health Hazards Regulations (Appendix and Technical Notes on the Regulatory Process)

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October 3, 1985

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85.3-1 Contents of a request for health hazard evaluation.

Each request for health hazard evaluation shall contain:

(a) The requester’s name, address, and telephone number, if any.

(b) The name and address of the place of employment where the substance or physical agent is normally found.

(c) The specific process or type of work which is the source of the substance or physical agent, or in which the substance or physical agent is used.

(d) Details of the conditions or circumstances which prompted the request.

(e) A statement, if the requester is not the employer, that the requester is:

   (1) An authorized representative or an officer of the organization representing the employees for purposes of collective bargaining; or

   (2) An employee of the employer and is authorized by two or more employees employed in the same place of employment to represent them for purposes of these Acts (each such authorization shall be in writing and a copy submitted with the request for health hazard evaluation); or

   (3) One of three or less employees employed in the place of employment where the substance or physical agent is normally found.

(f) A statement indicating whether or not the name(s) of the requester or those persons who have authorized the requester to represent them may be revealed to the employer by NIOSH.

(g) The following supplementary information if known to the requester:

   (1) Identity of each substance or physical agent involved;

   (2) The trade name, chemical name, and manufacturer of each substance involved;

   (3) Whether the substance or its container or the source of the physical agent has a warning label; and

   (4) The physical form of the substance or physical agent, number of people exposed, length of exposure (hours per day), and occupations of exposed employees.
Technical Note #1: Coverage Under the OSH Act

Covered Employers and Employees

Definitions of "employer" and "employee". OSH Act § 3(5) defines "employer" as a "person engaged in a business affecting commerce who has employees, but does not include the United States or any State or political subdivision of a State." Section 3(4) defines "person" as "one or more individuals, partnerships, associations, corporations, business trusts, legal representatives, or any organized group of persons." Based on these two broad definitions, the Act applies to an estimated 5 million workplaces and 75 million employees. Unlike the National Labor Relations Act and Title VII of the Civil Rights Act of 1964, OSHA coverage is not based on volume of business or number of employees. The duties imposed by § 5(a) of the Act apply to "each employer."

To be covered by the Act, an employer must have employees. All employees are covered under the Act, regardless of their title, status, or classification. Thus, the Act applies to maintenance workers, supervisors, plant managers, "silent partners," stockholders, an employer’s family members, and even the company’s vice-president and president. The affected individual must be an employee at the time of the alleged violation and it is not necessary that he or she be an employee at the time of the citation or hearing.

OSHA’s regulations on "special" employers. The Secretary of Labor has issued interpretive regulations that indicate whether certain types of employers will be considered by the Secretary to be within the Act’s coverage. Two of these categories are especially relevant to reproductive hazards in the workplace. Agricultural employers employing one or more employees are considered to be covered by the Act, although members of the immediate family of a farm employer are not considered employees. Domestic household employers who employ in their own residences persons performing household tasks such as cleaning, cooking, and caring for children are not considered to be subject to the requirements of the Act.

6. Id. at 1975.4(b)(2). See C.R. Burnett & Sons, 9 O.S.H. Cas. (BNA) 1009 (1980) (residences of migrant workers in temporary camps are subject to regulation under the Act). But see Frank Diehl Farms v. Secretary of Labor, 696 F.2d 1325 (llth Cir. 1983) (the Act only covers housing that is a condition of employment).
Interstate commerce requirement. Congress’ power to pass the OSH Act was based on its authority to act under the commerce clause to the Constitution, and the OSH Act is based on the congressional finding that workplace injuries and illnesses place a burden upon interstate commerce. The Act was therefore written to apply only to employers who are “engaged in a business affecting commerce.” The Act defines commerce as “trade, traffic, commerce, transportation, or communication among the several states, or between a state and any place outside thereof ....”

Generally, the courts interpret the Act’s definition of interstate commerce very broadly. On one occasion, the Occupational Safety and Health Review Commission held that an employer who was merely clearing land in preparation for grape production was not presently engaged in a business affecting commerce. The Ninth Circuit reversed, finding it “insignificant” that, at the time of the hearing, grapes had been neither planted nor harvested: “The effect on interstate commerce nevertheless exists.” In another case, it was held that an employer is engaged in a business affecting commerce if it does business with other employers that are engaged in interstate commerce. In that case, the Second Circuit held that a building maintenance service company was engaged in a business affecting commerce because it supplied services to a group of companies engaged in interstate commerce and because it used supplies produced out of state. Similarly, the Tenth Circuit held that it is irrelevant whether the employer itself was engaged in commerce so long as its relationship to commerce was more than minimal. Commerce was based on the use of out-of-state supplies.

Exemption for State and Local Governments. Section 3(5) expressly excludes state and local governments from the definition of employer, but this provision has been narrowly interpreted. Consequently, employers with a contractual or other relationship with a State or political subdivision have been unsuccessful in their attempts to be excluded.

Even though State employees are excluded by virtue of § 3(5), if a State has an approved State plan under § 18, the State plan must cover all employees of public agencies of the State and its political subdivisions.

State Plans

According to § 2(b)(11), one of the express purposes of the Act is to encourage State participation in safety and health regulation. Section 18 permits States to assert jurisdiction over job safety and health matters by submitting a plan for OSHA approval. The States, however, are not required to submit a State plan.

Federal OSHA sets the minimum acceptable safety standards in order to ensure that covered employees will be adequately protected and to maintain some semblance of uniformity among the States. Nevertheless, the Federal standards merely serve as starting points for State programs; the Act does not require that State plans be identical to Federal OSHA. There is no requirement that approved State plans contain a general duty clause, though several State plans have provisions similar to a general duty clause.

8. The Commission’s decision is reported at Les Mares Enterp., Inc., 3 O.S.H. Cas. (BNA) 1015 (1975).
The standards prescribed for covered employers may be more stringent under a State plan. In addition, States may issue standards in areas not covered by Federal OSHA. Under § 4(b)(l), the Act does not apply to working conditions regulated by other Federal agencies which are exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety and health." Where Federal OSHA is preempted by another agency under § 4(b)(l) the States may, but are not required to, maintain a similar exemption. (See chapter 7 and Technical Note #2.)

The Act preempted, at least temporarily, all State job safety and health legislation except for those in areas not covered by Federal OSHA standards. In accordance with the constitutional doctrine of Federal supremacy, the States are precluded from enacting or enforcing any conflicting law. Under § 18(b), if the Secretary determines that a State has promulgated standards comparable to OSHA's and has an enforcement plan meeting the criteria of § 18(c), jurisdiction may be ceded back to the State.

The Act leaves the choice of submitting a plan to the individual State. If a State does not submit a State plan, it is precluded from enforcing Stat laws, regulations, or standards relating to issues covered by Federal OSHA standards. This preclusion, however, does not extend to a State's enforcement of a law or standard directed to an issue upon which there is no OSHA standard in effect. An "issue" is defined as "an industrial or hazard grouping contained in any of the subparts to the general industry standards." Boilers and elevators are two issues over which OSHA has not promulgated standards and, therefore, over which State enforcement is not preempted.

States without approved plans also retain jurisdiction in three other areas. First, States may enforce standards, such as State and local fire regulations, which are designed to protect a wider class of persons than employees. Second, States may conduct consultation, training, and safety information activities. Third, States may enforce standards to protect State and local government employees. Connecticut and New York have State plans covering only State and local government employees.

The effect of a State plan is to transfer jurisdiction from Federal OSHA to the State. This transfer process, however, takes place gradually. While a State plan is in the "developmental" stage, State and Federal OSHA have concurrent jurisdiction. If a State plan does not cover an "issue," Federal OSHA will not be preempted as to that issue. The Federal Government also retains jurisdiction over areas of exclusive Federal jurisdiction, such as many Indian reservations, even if they are located in a State with an approved State plan.

There are presently 23 jurisdictions with approved State plans for private and public sector employees and two State plans covering only State and local government employees.

When Federal OSHA promulgates a new standard or modifies an existing standard the jurisdictions with their own plans are required to adopt a comparable standard. For emergency temporary standards, the States have thirty days to adopt a State emergency temporary standard; for permanent standards, the States have six months to adopt the Federal standard or "an at-least-as-effective equivalent."  

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Technical Note #2: Exemption from OSHA Jurisdiction

Coverage by Other Federal Statutes: In Northwest Airlines, Inc., 1 the Commission held that there are four categories of § 4(b)(1) cases, depending on the purpose of the other regulatory statute:

- cases involving statutes concerned solely with employee safety and health (e.g., mine safety cases);
- cases where another agency has acted to regulate employee safety and health, but the statutory authority serving as the basis of the agency’s actions pertains to matters other than employee safety and health (e.g., actions pursuant to General Services Administration and Department of Defense procurement statutes);
- cases where an agency is empowered by statute to regulate an aspect of public safety and health, and its regulations directed toward that end incidentally affect the working conditions of employees in a manner unrelated to the statutory purpose (e.g., regulation of meat processors under the Wholesome Meat Act);
- cases where a statute authorizes an agency to regulate an aspect of public safety or health, and certain employees directly receive the protection the statute is intended to provide (e.g., Department of Transportation Motor Carrier Safety Regulations).

The Northwest decision strongly implies that there will be preemption in the first and fourth categories, but no preemption in the second and third categories. The effect of the decision is to expand the number of statutes giving rise to preemption by including statutes designed to protect public safety and health where employees also receive direct protection.

Actual Exercise of Authority by Other Agency. The exercise of statutory authority involves both the prescribing and the enforcing of standards or regulations. In Northwest, the Commission upheld the validity of the somewhat unusual regulatory scheme whereby the Federal Aviation Administration (FAA) enforces company maintenance manuals regulating the working conditions of airline ground maintenance personnel. According to the Commission, the employer’s maintenance manuals had the force of law because there was statutory authority for the FAA to regulate working conditions. In rejecting OSHA’s argument that there should be preemption only for regulations produced by a Federal agency, the Commission stated that "the fact that a procedure is not ideal is no reason to reject it entirely...."

A related legal issue is whether an agency’s notice of proposed rulemaking is sufficient to preempt OSHA jurisdiction pursuant to § 4(b)(1).

In Consolidated Rail Corp., 2 the Commission held that a Federal Railway Administration (FRA) policy, in a statement that was the end result of a long deliberative

2. 10 O.S.H. Cas. (BNA) 1577, petition for review dismissed, No. 82-3302 (3rd Cir. 1982).
process, including advance public notice and agency investigation, preempted OSHA from enforcing standards dealing with hazards over which the FRA, in its policy statement, claimed authority.

The Commission has long held that for preemption to exist under § 4(b)(1), the other agency’s regulations need not be similar or equally stringent. Recent cases, however, also have held that § 4(b)(1) "does not permit the Commission to oversee the adequacy of another agency’s enforcement efforts." It is possible that the Commission would find § 4(b)(1) preemption even where the other agency undertook no enforcement activity whatsoever.

Other Agency has Acted to Exempt Entire Industry. In the leading cases of Southern Railway v. OSHRC,4 and Southern Pacific Transportation Co. v. Usery,5 the Fourth and Fifth Circuits affirmed the Commission and rejected the contention of the railroads that § 4(b)(1) provides the railroads with an industry-wide exemption. The courts based their decisions on a literal reading of the term “working conditions,” used in § 4(b)(1), and an inquiry into the statutory objectives of OSHA. According to the Fourth Circuit, an industry-wide exemption would result in unregulated working conditions for thousands of workers, which would “utterly frustrate the legislative purpose.”

The view that there are no industry-wide exemptions under § 4(b)(1) was for wed in numerous Commission and judicial decisions.8 In Dillingham Tug & Barge Corp.,9 however, the Commission overruled prior decisions and held that § 4(b)(1) “in certain circumstances” can create industry-wide exemptions. According to the majority opinion, without industry-wide exemptions, employers may have an unreasonable burden to determine the requirements of two sets of regulations.

If there is no industry-wide exemption, then it must be decided whether specifically cited working conditions are exempt from OSHA jurisdiction. This has proven to be another difficult issue. In Southern Railway, the Fourth Circuit defined “working conditions” to mean “the environmental area in which an employee customarily goes about his daily tasks.” Under this broad definition, larger areas of the workplace would be exempt. By contrast, in Southern Pacific, the Fifth Circuit defined “working conditions” to include both “surroundings” (such as general premises of toxic liquids) and “hazards” (a location, a category of items, or a specific item).11 Under this more

5. 539 F.2d 386 (5th Cir. 1976), cert. denied, 434 U.S. 874 (1977).
6. 539 F.2d 338.
flexible definition, OSHA coverage would be broader and therefore the exemptions to coverage more limited.

Proponents of the Fifth Circuit definition argue that it prevents gaps in coverage of employees, while proponents of the Fourth Circuit definition argue that it gives employers greater notice of what conditions are covered by each agency. The Commission’s current position on this issue is not clear, but the courts are clearly split, with the First Circuit adopting the Fifth Circuit definition and the Third Circuit adopting the Fourth Circuit definition.  

11. 539 F.2d at 390.
Technical Note #3: Employee Duties

In the leading case of Atlantic & Gulf Stevedores, Inc. v. OSHRC, the employer was cited for a violation of § 5(a)(2) because employees were working without hard hats. The employer contended that the employees refused to wear hard hats, despite its strenuous efforts to obtain compliance. Specifically, the employer had furnished the hard hats and encouraged their use at regular safety meetings, posted hard hat signs at the worksite, used payroll envelope stuffers advocating wearing hard hats, and placed hard hat safety messages on employee hiring tapes. Furthermore, there was evidence that the employer believed that employees would engage in wildcat strikes or walkouts if the employer attempted to enforce the standard by discharging employees who refused to comply.

In affirming the Commission’s finding of a violation, the Third Circuit held that the Secretary could insist that during collective bargaining the employer retain the right to discipline disobedient employees. The court, however, rejected the position that employees were subject to direct sanctioning under the Act by the Secretary or by cease and desist orders of the Commission.

To lessen the harsh results of its holding, the court suggested several remedies available to employers faced with employee refusals to comply. First, because safety and health is a mandatory subject of bargaining, the employer can insist to the point of impasse upon the right to discipline disobedient employees. Once established, this contract right may be enforced by a suit under § 301 of the Labor-Management Relations Act. Second, should employee discipline or discharge produce a work stoppage, injunctive relief would be available if the parties have a no-strike and arbitration clause. Third, where an injunction cannot be obtained or arbitration fails to vindicate an employer’s action, the employer can still apply for a variance. Fourth, the employer could file a petition for modification of abatement. In I. T. O. Corp. v. OSHRC, the First Circuit specifically endorsed the Third Circuit’s rationale in Atlantic & Gulf.

1. 534 F.2d 541 (3d Cir. 1976).
3. For criticism of the court’s approach, see M. Rothstein, Occupational Safety and Health Law 148-49 (2d ed. 1983).
4. 540 F.2d 543 (1st Cir. 1976).
Technical Note #4: Judicial Review of OSHA Standards

The validity of OSHA standards may be reviewed by the courts in two ways. First, any party adversely affected by a standard may obtain pre-enforcement review by filing a petition for review within sixty days of a standard’s promulgation. Pursuant to § 6(f), these petitions may be filed in the United States court of appeals for the circuit in which the party resides or has its principal place of business. A copy of the petition must be forwarded to the Secretary of Labor by the clerk of the court.

The second method of review, available to any person adversely affected or aggrieved by a final order of the Commission, is filing a petition for review pursuant to § n(a). Petitions for review under § 11(a) must also be filed within sixty days in a United States court of appeals for the circuit in which the violation is alleged to have occurred, for the circuit in which the employer has its principal office, or in the District of Columbia Circuit.

Filing a petition for judicial review under § 6(f) does not delay the effective date of a standard, nor does a § 11(a) petition stay a final order of the Commission. A reviewing court, however, may grant a stay. In judicial review under either section of the Act, the Secretary’s determinations in promulgating a standard are conclusive if supported by “substantial evidence” in the record considered as a whole.

Section 6(f) specifically provides for judicial review of standards in the United States courts of appeals. Section 8(g), which authorizes OSHA to promulgate necessary rules and regulations, is silent on the issue of judicial review and therefore, under the Administrative Procedure Act the district courts are the proper forum for initial review of regulations. Consequently, it is important to determine whether the Secretary has promulgated a “standard” or a “regulation.”

In Louisiana Chemical Association v. Bingham, the Fifth Circuit held that although the promulgating agency’s characterization of a rule is a relevant factor, it is not necessarily determinative. According to the court, Congress conceived § 6 of the Act to address specific and already identified hazards, not as purely administrative efforts designed to uncover violations of the Act and discover unknown dangers. Applying this test, the access to exposure and medical records rule is a regulation aimed primarily at possible detection of significant risks not yet covered by standards. Therefore, it is a regulation, reviewable in a district court, rather than a standard, reviewable in a court of appeals.

Section 6(f) permits the party challenging the standard to file for judicial review in the United States court of appeals for the circuit in which the party resides or has its principal place of business. Considering the national scope of OSHA standards and the number of parties adversely affected by a standard, there is ample opportunity for forum shopping. Indeed, the ability of affected industries to obtain judicial review in a sympathetic court is one of the major impediments to OSHA rule making according to a number of individuals interviewed. Employee representatives may also seek review in a sympathetic court.

1. The discussion of judicial review is based largely upon M. Rothstein, Occupational Safety and Health Law 89-97 (2d ed. 1983).
2. 5 U.S.C. § 702.
3. 657 F.2d 777 (5th Cir. 1981).
A second, related problem concerns the “race to the courthouse” that invariably occurs when two or more parties are seeking review in different circuits. Under 28 U.S.C. § 2112(a), if there are two or more filings in different courts of appeals to review the same administrative order, venue will lie in the court of the first filing.

In Industrial Union Department v. Bingham, the D.C. Court of Appeals held that a petition to review the benzene standard was timely filed in the D.C. Circuit after the standard was disclosed to industry and labor representatives, but before the standard was filed with the Federal Register. Nevertheless, “in the interest of justice,” the court ordered the case transferred to the Fifth Circuit, where “the first petition was filed subsequent to the disclosure of the agency decision to the public.”

After the decision in Industrial Union Department, OSHA promulgated a regulation that indicated that standards are “issued” when they are published in the Federal Register. Although the regulation gave all parties the same starting time, it did not end the “race to the courthouse.” Indeed, even with a uniform starting time, problems of varying sorts have arisen. For example, in United Steelworkers of America v. Marshall, a conflict developed involving two challenges to OSHA’s lead standard. When OSHA “issued” its standard on November 13, 1978, the Steelworkers immediately filed a petition for judicial review in the Third Circuit at 8:45 a.m. EST. At precisely the same time, 7:45 a.m. CST, the Lead Industries Association filed a petition in the Fifth Circuit. In ruling on the venue question, the Third Circuit refused to go beyond the official notations of the time of filing to determine if one petition had been filed seconds before the other petition. The court declared that “unlike race tracks,... courts are not equipped with photoelectric timers, a d we decline the invitation to speculate which nose would show as first in a photo finish.” The court then ordered that the proceeding be transferred to the D.C. Circuit, which was deemed “obviously a convenient forum” because a petition to review an EPA lead standard had recently been filed by the industry in that court.

Section 6(f) grants the right to seek judicial review to “any person who may be adversely affected by a standard.” There have been no OSHA cases decided on the issue of how adversely affected a person must be in order to challenge a standard. In Fire Equipment Manufacturers Association v. Marshall, however, the Seventh Circuit held that a trade association and manufacturers of fire protection equipment did not have standing to challenge an amendment to OSHA’s fire protection standard. The industry petitioners claimed they were “adversely affected” because the new standard would result in a loss of profits and competitive disadvantage. In rejecting the argument, the court held that “[t]he profits of manufacturers of fire fighting equipment are not within the zone-of-interests protected or regulated by the Act.”

Section 6(f) provides that in judicial review of new OSHA standards “[t]he determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole.” Thus, although the substantial evidence test is

4. 570 F.2d 965 (D. C. Cir. 1977).
5. Id. at 972.
7. 592 F.2d 693 (3d Cir. 1979).
8. Id. at 695.
9. Id. at 698.
10. 679 F.2d 679 (7th Cir. 1982), cert. denied, 103 S. Ct. 728 (1983).
11. 679 F.2d at 682.
generally used in adjudicatory proceedings or formal rule making, it also applies to OSHA standards promulgation, which is informal rulemaking. The Act’s anomalous use of the substantial evidence test resulted from a legislative compromise. The Senate bill provided for informal rulemaking, while the House version required formal rule making and the use of the substantial evidence test.

The courts have had considerable difficulty in applying the substantial evidence test in viewing OSHA standards. In Associated Industries v. U.S. Department of Labor, the Second Circuit held that the substantial evidence test must be applied to policy determinations as well as findings of fact. The court suggested, however, that the difference between the substantial evidence test and the "arbitrary and capricious" test may be largely semantic. This view has been shared by the Fifth Circuit.

The D.C. Circuit has taken a somewhat different approach and considers that the substantial evidence test provides for "more rigorous scrutiny" on the arbitrary and capricious test. Industrial Union Department. Hodgson, the D.C. Circuit found it "impossible" to apply the substantial evidence test to the Secretary’s policy determinations. The court indicated it would analyze the Secretary’s rulemaking to determine whether it had been performed "in a manner calculated to negate the dangers of arbitrariness and irrationality in the formulation of rules for general application in the future."

Despite slightly different tests in the various courts of appeals, the courts of appeals have been in agreement on the general standards of review of policy decisions. Judicial review of policy decisions will be limited to determining whether the Secretary’s

12. Formal rulemaking involves adjudicatory hearings, including the right to submit oral evidence and to conduct cross-examination. Informal rulemaking involves notice and an opportunity to submit comments. See Note, Judicial Review under the Occupational Safety and Health Act: The Substantial Evidence Test as Applied to Informal Rulemaking, 1974 Duke L.J. 459.
15. 487 F.2d at 349-50.
16. See American Petrol. Inst. v. OSHA, 581 F.2d 493, 497 (5th Cir. 1978); synthetic sub nom. Industrial Union Dept. v. American Petrol. Inst., 448 U.S. 607 (1980); Florida Peach Growers Ass'n v. United States Dept. of Labor, 489 F.2d 120, 128-29 (5th Cir. 1974). See also Texas Indep. Ginners Ass'n v. Marshall, 630 F.2d 398, 404 n.22 (5th Cir. 1980) (rejecting assertion that substantial evidence test can be used only for factual determinations and noting that use of this test for policy considerations impracticable).
18. 499 F.2d 467 (D.C. Cir. 1974).
action is consistent with the statutory language and purpose, 21 whether the policy judgment is reasonably related to factual matters supported by substantial evidence, 22 and whether there are adequate explanations for the assumptions underlying predictions or extrapolations and of the bases for resolving conflicts and ambiguities. A standard will be remanded only if there are "nagging questions" about the rationale for the Secretary’s particular choices. 24

The Supreme Court also has been troubled in its search for the most appropriate standard by which to review the complex scientific and policy issues involved in OSHA rulemaking. 25 It has indicated, however, that it will give deference to the courts of appeals’ determinations of whether there is substantial evidence.

In American Textile Manufacturers Institute, Inc. v. Donovan, 26 the Supreme Court held that, because the Act places responsibility for determining substantial evidence questions in the courts of appeals, the Supreme Court will intervene only in the rare instance when the substantial evidence standard was misapprehended or grossly misapplied by the court of appeals.

[O]ur inquiry is not to determine whether we, in the first instance, would find OSHA’s findings supported by substantial evidence. Instead, we turn to OSHA’s findings and the record upon which they were based to decide whether the Court of Appeals "misapprehended or grossly misapplied" the substantial evidence test. 27

27. 452 U.S. at 523.
CERCLA, also known as Superfund, was enacted in December 1980. It provides the
government with the authority and funding to take action against actual and threatened
releases of hazardous substances, "and to recover cleanup costs and natural resource
damages from the responsible parties. Unlike most other federal environmental statutes,
CERCLA employs liability, rather than "command and control" regulation, as the
incentive for pollution control.

The Act establishes a $1.6 billion fund, generated over a five-year period by a tax
on petroleum and chemical feedstocks (87.5 percent) and by governmental appropriations
(12.5 percent). The purpose of the fund is to provide “up-front” financing of cleanup
costs and resource damages where responsible parties are uncooperative, unknown, or
insolvent. The liability provision of the Act (§ 107) is intended to ease the ability of the
government to sue for the recovery of fund monies expended.

At the core of CERCLA is the National Contingency Plan (NCP).2 This plan
includes: 1) a list of priority sites to be addressed by the government; 2) the rules setting
priorities among sites; and 3) the cleanup procedures to be followed. In general, all
governmental actions under CERCLA must be consistent with the NCP. Failure to
follow the NCP may jeopardize the ability of the government to recover its cleanup costs
from responsible parties.

With one exception (see section below on “Pollutants or Contaminants”), CERCLA
does not explicitly refer to reproductive health hazards. However, the statutory
language clearly can be interpreted to embrace reproductive health hazards. And as
discussed below, Congress intended EPA to consider such risks in its decisionmaking. The
most important statutory sections bearing on EPA’s ability to control reproductive health
hazards under CERCLA deal with:

- the definition of hazardous substances,
- the setting of “reportable quantities,”
- the definition of “pollutants or contaminants,” and
- the ranking of sites according to the risks they pose.

Section 101(14): Definition of Hazardous Substances

CERCLA primarily addresses “hazardous substances,” which comprise a broader
category of chemicals than hazardous wastes. Section 101(14) of the Act defines
“hazardous substance,” in part, by cross-referencing other federal pollution control
statutes.4

In all, over 600 specific substances are covered. However, for the following three reasons, an indeterminate number of chemicals and chemical risks, including reproductive health hazards, may actually be considered “hazardous” substances under CERCLA: 1) the cross-referencing of other EPA statutes in CERCLA means that when a new chemical is regulated in specified ways under these other laws, it automatically becomes a CERCLA hazardous substance; 2) EPA’s definition of hazardous wastes under the Resource Conservation and Recovery Act, included under CERCLA, is itself open-ended. Thus any wastes that are considered ignitable, corrosive, reactive, or toxic, according to EPA-specified tests, are automatically considered hazardous. 5 While waste chemicals posing reproductive health hazards do not necessarily meet the RCRA definition of hazardous waste, hazardous wastes may include wastes presenting reproductive risks. And, 3) EPA has the authority to designate additional substances as “hazardous” under § 102 of CERCLA. EPA is considering numerous other chemicals as “candidates” for such a designation. 6 These candidates include a wide variety of chemicals that may pose reproductive health hazards, such as:

1) 600 pesticide active ingredients;
2) listed hazardous constituents of RCRA hazardous wastes;
3) chemicals recommended for priority consideration under § 4(e) of TSCA;
4) substances within a broad group of chemicals regulated by other agencies; and
5) substances for which EPA “has demonstrated some concern.” 7

A. any substance designated pursuant to section 311(b)(2)(A) of the Federal Water Pollution Control Act,
B. any element compound, mixture, solution, or substance designated pursuant to section 102 of CERCLA,
C. any hazardous waste having the characteristics identified under or listed pursuant to section 3001 of the Solid Waste Disposal Act (but not including any waste the regulation of which under the Solid Waste Disposal Act has been suspended by Act of Congress),
D. any toxic pollutant listed under section 307(a) of the Federal Water Pollution Control Act,
E. any hazardous air pollutant listed under section 112 of the Clean Air Act, and
F. any imminently hazardous chemical substance or mixture with respect to which the Administrator has taken action pursuant to section 7 of the Toxic Substance Control Act. The term does not include petroleum, including crude oil or any fraction thereof which is not otherwise specifically listed or designated as a hazardous substance under subparagraphs (A) through (F) of this paragraph, and the term does not include natural gas, natural gas liquids, liquefied natural gas, or synthetic gas usable for fuel (or mixtures of natural gas and such synthetic gas).

7. Id. at 23,603-04.
On its face, therefore, the CERCLA definition of “hazardous substance” does not suggest a major role for the Act in addressing reproductive health hazards in the workplace. However, by cross-referencing other statutes that may target such risks, and by its open-ended nature, CERCLA’S definition of a “hazardous substance” may clearly include numerous reproductive health hazards within its ambit. In keeping with this implicit statutory emphasis, EPA has considered reproductive health hazards in implementing CERCLA. (See section below on “Reportable Quantities,” § 102). Moreover, as is also discussed below, legislative authority to control reproductive risks explicitly appears in another provision of the Act (see section on “Pollutants and Contaminants,” § 10).

Section 102: Setting and Adjusting Reportable Quantities

Section 102 of CERCLA requires EPA to set a “reportable quantity” (RQ) for each hazardous substance. A release in excess of the RQ by a vessel or facility triggers a requirement to notify the government.

Where a hazardous substance already has an RQ under the Clean Water Act, that number is considered the RQ for purposes of CERCLA, unless EPA adjusts this figure. EPA has published a list of “adjusted” RQ’s under CERCLA. In making these adjustments, EPA has stated that it will consider six primary criteria: 1) aquatic toxicity, 2) mammalian toxicity, 3) ignitability, 4) radioactivity, 5) carcinogenicity, and 6) other toxic effects. Reproductive health hazards are explicitly included among the “other toxic effects” to be weighed by the Agency in adjusting RQ’s.

Section 104(a): Definition of Pollutants or Contaminants

Under § 104(a) of CERCLA, EPA is authorized to take action, where the parties responsible will not address a chemical problem, when there is a release or a substantial threat of a release into the environment of:

1) a hazardous substance; or

2) a pollutant or contaminant which may present an imminent and substantial danger to the public health or welfare.

The definition of a “hazardous substance” has been discussed above, and incorporates by reference many reproductive health hazards. The definition of “pollutant or contaminant,” however, is more explicit in addressing reproductive risks. Section 104(a)(2) of CERCLA states:

For the purposes of this section, “pollutant or contaminant” shall include, but not be limited to, any element, substance, compound, or mixture, including disease-causing agents, which after release into the environment and upon exposure, ingestion, inhalation, or assimilation into any organism, either directly from the environment or indirectly by ingestion through food chains, will or may reasonably be anticipated to cause death, disease, behavioral abnormalities, cancer, genetic

10. Id. at 23,562.
mutation, physiological malfunctions (including malfunctions in reproduction) or physical deformations in such organisms or their offspring (emphasis added).

The definition of a “pollutant or contaminant,” therefore, is much broader than the definition of “hazardous substance.” The principal practical distinction between the two terms relates to EPA’s ability to recover cleanup costs and resource damages from responsible parties. Under § 104 EPA can take action against both “hazardous substances” and “pollutants or contaminants.” But the Government can only recover cleanup costs and resource damages from responsible parties with respect to releases of hazardous substances. Cleanup costs and resource damages resulting from releases of pollutants or contaminants (unless they are also considered hazardous substances) must be paid for by the Superfund.

THE SOLID WASTE DISPOSAL ACT, AS AMENDED BY THE RESOURCE CONSERVATION AND RECOVERY ACT (RCRA)

The Resource Conservation and Recovery Act (RCRA), enacted in 1976 as an amendment to the Solid Waste Disposal Act, reflects Congressional concern over the mounting problems with the disposal of solid and hazardous wastes. The act requires EPA to regulate hazardous wastes from cradle to grave, thereby governing the treatment, storage, transportation, and disposal of hazardous wastes which have adverse effects on health and the environment.

Section 3001(a): Identification of Hazardous Wastes

Section 3001 describes the criteria for the identification and listing of hazardous wastes. Specifically, the act directs State and Federal regulators to take into account “toxicity, persistence, and degradability in nature, potential for accumulation in tissue, and other related actors such as flammability, corrosiveness, and other hazardous characteristics.”

While the RCRA statutory language does not specifically address reproductive hazards, the regulation of hazardous wastes provides some protection from hazards to reproduction. Moreover, EPA has considered reproductive risks in its RCRA regulations. One of EPA’s criteria for listing wastes as hazardous is whether the waste contains:

any of the toxic constituents listed in Appendix VIII [of the RCRA rules] unless, after considering [a variety of listed factors], the Administration concludes that the waste is not capable of posing a substantial present or potential hazard to human health or the environment when improper treated, stored, transported or disposed of, or otherwise managed...

In turn, EPA’s rules on listing the constituents in Appendix VIII state:

16. RCRA, Sec. 3001(a).
Substances will be listed on Appendix VIII only if they have been shown to have toxic, carcinogenic, mutagenic or teratogenic effects on humans or their life forms. (Wastes listed in accordance with these criteria will be designated Toxic wastes)\(^{18}\) (emphasis added).

EPA’s original approach toward toxic wastes, including reproductive health hazards, was to bring them into the RCRA regulatory scheme if they possessed certain broad characteristics. In its final rules on hazardous waste identification, EPA explained its shift to a listing approach toward toxic wastes:

EPA is not fully confident that it can suitably define and construct testing protocols for the characteristics of organic toxicity, carcinogenicity, mutagenicity, teratogenicity, bioaccumulation potential, phytotoxicity, radioactivity and infectiousness, and is consequently relying on the listing mechanism to bring wastes exhibiting these properties into the system. One negative aspect of this change in approach is that it shifts to EPA the primary burden for identifying, analyzing and evaluating these wastes with the result that it may take longer to achieve full regulatory coverage. This negative aspect is substantially offset however, by the greater flexibility and assurance which the listing approach provides, especially when accompanied by the delisting procedure\(^ {19}\) (emphasis added).

In addition to controlling reproductive health hazards through the hazardous waste identification process, EPA may be able to regulate exposure to reproductive health hazards under RCRA by exercising its abatement authority, under § 7003. Section 7003 authorizes the Administrator to bring suit against any person involved in the generation, transport, or disposal of hazardous waste which "may present an imminent and substantial endangerment to health or the environment.\(^ {20}\) Specifically this provision might be used to abate risks posed by the disposal of chemicals on-site. Reproductive health hazards at a waste site presumably could constitute such an “endangerment,” allowing EPA to obtain judicial relief. These disposal practices may also present occupational exposure, but it is unclear whether authority under RCRA would provide a cause of action in such an instance.

**SAFE DRINKING WATER ACT (SDWA)**\(^ {21}\)

The Safe Drinking Water Act (SD WA) is designed to ensure that safe, disease-free drinking water is delivered by public water systems nationwide. The Act was passed largely in response to increasing concern over long-term exposures to low levels of carcinogens in water, coupled with news of several outbreaks of acute disease caused by waterborne organisms. The goal of providing safe drinking water at the consumer’s tap is to be achieved by national standards implemented and enforced through a State-Federal regulatory mechanism. States are encouraged to assume primary responsibility (or “primacy”) for implementation, enforcement, and monitoring of national guidelines and standards. EPA also issues health advisories on drinking water contaminants. While the SDWA does not expressly address reproductive health hazards, various programs under the Act may be designed to address the issue of general health concerns. In addition, the programs may be of direct relevance in establishing farmworker safety programs.

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The SDWA does not explicitly address reproductive health hazards. However, in setting National Interim Primary Drinking Water Regulations, EPA has occasionally considered reproductive effects. For example, in establishing recommended maximum contaminant levels (MCL's) for volatile synthetic organic chemicals (VOC's), EPA noted some reliance on evidence of mutagenicity to suggest that a chemical may also be a carcinogen:

Many carcinogens are capable of altering DNA; chemically induced alteration of DNA in germinal cells can also cause mutable changes, or mutations; thus, when a chemical shows a positive response in short-term mutagenicity tests, there is a concern that it could also be a carcinogen.

In addition, EPA specifically noted the VOC mutagenicity data on trichloroethylene, tetrachloroethylene, 1,1,1 trichloroethane, carbon tetrachloride, vinyl chloride, benzene, and 1,1 dichloroethane. Perhaps even more importantly, in addition to setting MCLS, EPA often issues informal health advisory on drinking water contamination. Called “Suggested No Adverse Response Levels” (SNARLS) these advisories are frequently based, in part, on reproductive effects. While not enforceable standards, SNARLS are often relied upon by governmental officials charged with protecting drinking water. They could thus be used for providing technical guidance for establishing enforceable drinking water standards for water supplies used by farmworkers. (See discussion below).

FEDERAL WATER POLLUTION CONTROL ACT (FWPCA)

The Federal Water Pollution Control Act (FWPCA) is a comprehensive statute intended to clean-up the nation’s surface waters. The FWPCA sets water quality and use goals and deadlines for achieving them, as well as detailing major programs to achieve these goals.

The Act rarely addresses reproductive health hazards explicitly. An exception is in granting or modifying the application of certain effluent limitations to a particular point source. A brief examination of EPA’s use of effluent limitations for toxic chemicals is illustrative of how the agency can (and occasionally does) reach reproductive health hazards under the FWPCA.

EPA is required under the Act to issue technology-based effluent guidelines and limitations for water pollutants. EPA must establish effluent guidelines and limitations for conventional pollutants, and special requirements governing toxic pollutants and certain other discharges."

24. Id. at 24,340.
25. Id. at 24,341.
26. Id.
27. Id. at 24,342.
28. Id.
29. Id. at 23,343.
30. Id.
In regulating toxic pollutants, EPA is required to take into account:

- the toxicity of the pollutant,
- its persistence, degradability,
- the usual or potential presence of the affected organisms in any waters,
- the importance of the affected organisms,
- and the nature and extent of the toxic pollutant on such organisms.

Not infrequently, EPA does consider reproductive health hazards in regulating toxic pollutants under the FWPCA. For example, in denying an industry petition to remove certain substances from EPA’s toxic pollutant list, PA specifically cited data on the potential reproductive effects of such chemicals. Thus, even in the absence of statutory language on reproductive health hazards, a number of provisions in the FWPCA can readily be interpreted to authorize EPA control of such risks.

**THE CLEAN AIR ACT**

Congress passed the Clean Air Act in 1977 with the intent of protecting and enhancing "the quality of the nation’s air resources so to promote the public health and welfare and the productive capacity of its population." Although the act does not explicitly provide for control of reproductive hazards, its broad mandate to protect public health and welfare can also be construed as protection against such hazards.

Section 109: The National Ambient Air Quality Standards

Section 109 directs the Administrator to prescribe national ambient air quality standards (NAAQS) for each of the designated criteria pollutants. The legislative history of the Clean Air Act does not reveal any specific Congressional intent to control reproductive hazards in particular. However, there does not appear to be any limitation on the use of this provision for setting NAAQS to protect reproductive health because of the section’s broad language respecting the protection of public health and welfare. Nevertheless, it is most unlikely that a worker could rely on EPA’s ability to set NAAQS for governing workplace exposures since it is very clear from the Act itself that it was intended to prevent health risks from outdoor “ambient” exposures of chemicals.

One aspect of the development of the NAAQS may be important to workers who suspect that they have been exposed to a reproductive hazard, however. The criteria documents assembled and periodically revised by EPA, and subject to extensive peer review within EPA and by its Clean Air Scientific Committee, consider occupational exposures to the criteria pollutants as one indicator of what the NAAQS should be. They also bring together and assess in vivo and in vitro toxicological studies which may include multi-generational mutagenicity studies and others affecting target reproductive organs. This information may be of help in establishing legal causation in actions to recover compensation for injury or to enjoin certain types of occupational exposure. The main limitation, however, is that these documents are only available for the criteria pollutants: 1) ozone/oxidants, 2) sulfur dioxide, 3) nitrogen oxides, 4) total suspended particulate, 5) carbon monoxide, and 6) lead. A standard for short-term exposures to NO\(_x\) is currently being developed within EPA which treats reproductive

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33. 46 Fed. Reg. 2265, 2271, 2278 (1981) (the substances were ethylbenzene, dichlophenol, 2,4,5 trichlorophenol, and pentachlophenol (phenol)).
hazards from exposure to the compound. That standard probably will not be proposed in
the near future. In addition, the lead criteria document that is presently being revised
addresses many reproductive characteristics of lead transfer to the fetus and infant.

Section 112: NESHAPs

Under § 112, particularly dangerous air pollutants are subject to more rigorous
regulatory requirements than are the conventional "criteria" pollutants. Congress
intended § 112 to allow stringent, uniform and relatively quick federal regulation of
substances that pose risks of particularly serious illness at relatively low concentrations
in the ambient air through the establishment of national emission standards for hazardous
air pollutants (NESHAPS). The Act defines a hazardous air pollutant as a substance
which, in the judgment of the Administrator, "causes, or contributes to, air pollution
which may reasonably be anticipated to result in an increase in mortality or an increase
in a serious irreversible or incapacitating reversible illness." 38

Because this section deals more explicitly with hazards to human health than other
sections of the Clean Air Act and because it was designed to respond to trace amounts of
air pollutants, NESHAPs are more likely to be used to regulate any noncriteria air
pollutants that are considered to be reproductive hazards. The legislative history of the
Clean Air Act amendments shows that Congress was cognizant of the effects of at least
four substances on reproduction, and it singled out the occupational reproductive hazards
of vinyl chloride in its discussion of this section.

Sections 202 to 211: Mobile Sources 39

Section 202 directs the Administrator to establish standards for motor vehicle
emissions "which in misjudgment cause or contribute to, air pollution which may
reasonably be anticipated to endanger public health and welfare." 40 This section does
nonspecifically govern reproductive hazards but neither are there any limitations placed
on the definition of the meaning of endangerment of public health and welfare.
However, pursuant to these sections EPA proposed a ban on lead in gasoline, in part
based on studies demonstrating the fetal toxicity of lead, and is considering regulatory
action on benzene, another potential reproductive hazard to which workers are exposed
in relatively high concentrations. The health assessment documents preparedly EPA on
these actions may provide information on hazards to these chemicals.

Section 303: Imminent Hazard Authority 41

This section empowers the Administrator to take civil action against a source or
combination of sources that is imminently and substantially endangering human health
the appropriate State or local authorities have not taken action, empowers the Administrator to issue an order against the alleged offender if it is not
practicable to assure prompt protection of the health of persons solely by
commencement of such a civil action. 43 Presumably, this authority could extend to the
emergency control of an outdoor air pollutant that is allegedly causing reproductive
hazards, although Congress did not specifically address the issue in the legislative
history.

41. 42 U.S.C. § 7603.
42. 42 U.S.C. § 7603(a).
43. Id.
Technical Note #6: Judicial Review of NRC Actions

Few NRC actions relevant to radiation and the reproductive health of workers have been tested by judicial review or tort litigation, and the reported decisions all indicate considerable judicial deference to the NRC on the technical aspects of its decisions. Thus, judicial accountability on the technical (e.g., health, science, risk analysis) aspects of NRC decisions has been minimal.

A recent example of judicial deferral to the Commission’s decisions is the decision in Baltimore Gas & Electric Co. v. Natural Resources Defense Council, Inc. At issue was a determination by NRC, in the face of great scientific uncertainty, that the storage of high-level nuclear wastes would have no significant environmental impact. The U.S. Supreme Court found the Commission’s zero-release assumption to be within the bounds of reasoned decision-making and reversed the 1) C. Circuit’s requirement of greater consideration of possible environmental consequences. Justice O’Connor described the judiciary’s role in the judicial review of NRC decisions:

A reviewing court must remember that the Commission is making predictions, within its area of special expertise, at the frontiers of science. When examining this kind of scientific determination, as opposed to simple findings of fact, a reviewing court must generally be at its most deferential.2

This is consistent with prior court decisions which repeatedly manifest extreme judicial deference to NRC decisions on technical, health, and safety issues in the handling of radioactive materials. While NRC’s occupational exposure standards have apparently not been directly challenged in court, other NRC standards and provisions for health and safety (usually licensing actions) have been judicially reviewed. The court decisions all demonstrate a judicial reluctance to question the technical or factual basis for Commission actions.

Federal court deference to NRC actions extends back to Crowther v. Seaborg,3 decided in 1970. In that case, the AEC proposed permitting an atmospheric release of radioactive gas to be created by an underground nuclear explosion. Although predicted exposures to individuals in the general population were well below AEC’s standard of 0.5 rem/year, plaintiffs sought to enjoin the release. Extensive expert testimony was used to attack the validity of AEC’s standard in an attempt to prove that scientific evidence indicated a high risk of chromosomal aberrations in the general public to be exposed, and that health science studies supported a ten-fold reduction. The Federal district court found the radiation protection standards, reached by AEC or NRC use of a cost-benefit analysis approach, to be reasonably adequate to protect life, health, and safety. In its opinion, characterized by deference to the AEC, the court stated:

The law provides a strong presumption of validity and regularity when administrative officials decide weighty issues within the specific area of their authority and the burden is on the plaintiffs to overcome this presumption.

All that is required to establish the reasonableness of the decision setting a standard under the statutory directive to protect health and safety is that it be made carefully in light of the best of available scientific knowledge.4

2. Id. at 2256.
While NRC's occupational radiation standards have not been directly challenged, it is reasonable to assume that the same judicial affirmation of expertise granted NRC's general population standards would be provided NRC'S occupational radiation standards. Actions to hold NRC liable under various tort theories have been filed against the agency for alleged personal injuries. But these have failed to result in judicial scrutiny of NRC technical expertise. These attempts must be analyzed from an understanding of the Federal Tort Claims Act of 1946.\(^5\) The Act abrogated the Federal Government's immunity from tort liability. However, the Act preserved federal immunity with respect to acts or omissions which fall within the “discretionary function” of an agency. Claims by employees for radiation injury against NRC have consistently failed due to the discretionary function exception.

Under the Atomic Energy Act, Congress gave NRC extensive discretion to deal with matters relating to health and safety. Pertinent language is contained in 42 U.S. C. § 2051.(a):

> The Commission is directed to exercise its powers in such manner as to ensure the protection of health and the promotion of safety during research and production activities. The arrangements made pursuant to this section shall contain such provisions (1) to protect health, (2) to minimize danger to life or property, and (3) to require the reporting and to permit the inspection of work.

*Blaber v. United States*\(^6\) involved an action under the Federal Tort Claims Act for personal injury and for death resulting from a thorium explosion at a facility under contract with the AEC. The court barred the suit by finding that AEC's duty to issue health and safety regulations was a discretionary function.

> ... when the Commission decides the extent to which it will undertake to supervise the safety procedures of private contractors, it is exercising discretion at one of the highest levels. Decisions of this kind are therefore within... [its] discretionary function [under the Federal Tort Claims Act.\(^7\)]

In *Bramer v. United States,*\(^8\) the plaintiff was injured by a radiation leak at a laboratory operated by a university under contract with the AEC. The contract had delegated responsibility for health and safety programs to the university. The contract also recognized that the work was dangerous. The plaintiff sued the AEC on the non-delegatable duty doctrine; the common law theory that delegation of inherently dangerous activities does not shield the delegator from liability. The court barred the suit on the grounds that the AEC was not bound by the non-delegatable duty doctrine, due to the discretionary exemption of the Federal Tort Claims Act.

\(^4\) 312 F. Supp. at 1234.
\(^6\) *Blaber* v. United States, 332 F.2d 629 (2d Cir. 1964).
\(^7\) Id. at 631.
These examples of failed tort actions demonstrate, as do the examples of deferential judicial review, that the NRC’s technical bases for its final actions and operational activities have not been adequately examined by the courts. Thus, the courts have not provided for technical accountability because of NRC’s alleged expertise and scope of discretion.