OSHA's Current Analytic Procedures 2

Before the project's principal findings are discussed (in chapter 3), it is essential to review OSHA's principal procedures for setting standards. The associated steps and requirements are extensive. As rulemakings now work, the agency's examinations of control technologies and regulatory impacts are prepared chiefly in response to the particular tasks delegated by these regulatory procedures.

ELEMENTS OF OSHA'S PERMANENT STANDARDS

Health Standards

OSHA's health standards address exposures to hazardous materials and agents, such as chemicals capable of causing cancer (or other chronic health effects), poisons, severe noises, or vibrations. In the language of section 6(b)(5) of the OSH Act, such "toxic materials or harmful physical agents" are specially treated, and the Secretary of Labor is directed to promulgate standards "which most adequately assure, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard ... for the period of his working life."

Standards that the agency promulgates under this authority typically involve several kinds of compliance provisions. A requirement for employers to limit worksite exposures to a specified level or below is usually central—a "permissible exposure limit" (PEL) usually reflecting a time-weighted average exposure over a full workshift of 8 hours (TWA8) or a "short term exposure limit" (STEL) spanning a far shorter period (often 10 to 15 minutes). Such a requirement may require an employer to install new or improved engineering controls or to use substitute materials, to modify existing work practices (to remove workers from contaminated areas or limit the length of time they are exposed), to implement new administrative procedures (such as job rotation)—or often to use some mix of these various avenues for control.

Other kinds of compliance provisions can include establishing ongoing programs to monitor workplace exposure levels and to provide exposed employees with periodic medical surveillance examinations, establishing plans to be used in emergency exposure circumstances, and providing employees with up-to-date informa-

tion about the extent of workplace risks and training in hazard-reducing work practices.

Typically, the most extensive changes an affected establishment will have to undertake for compliance will relate to lowering worksite exposure levels. Here, modifications to existing production equipment, processes, and procedures may need to be made. Nonetheless, PEL or STEL provisions are intrinsically performance objectives, where employers are free to achieve the specified limits through whatever means they deem most economical. However, in keeping with industrial hygiene practice and the agency's long-standing policy, OSHA's health standards have continued to insist on the primacy of feasible engineering controls to lower exposure levels, rather than, say, fitting employees with personal respirators and protective clothing on a full-time basis.[1]

Safety Standards

OSHA's safety standards address workplace hazards "capable of causing immediately visible physical harm." Examples include ordinary industrial equipment that may, through sudden movement, cut, crush, or otherwise injure a worker, or industrial processes whose normal operation, when combined with other worksite circumstances, could yield catastrophic incidents such as explosions or electrocutions. OSHA's setting of safety standards comes under the general guidance of the OSH Act's section 3(8) for all permanent standards, to require "conditions, or the adoption or use of one of more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment."

The specific features of safety rulemakings vary with the nature of the hazard. Generally, however, the kinds of provisions incorporated include those such as engineering specifications for equipment; work practices that seek to minimize the prospect for serious accidents; inspection and maintenance programs; advance planning for emergency situations; employee training and hazard communications; and, on occasion, formal certifications by external parties of the designs, installation, and operational adequacy of the equipment and work practices involved.

OSHA's past safety standards have often included quite specific requirements for equipment and procedures. In recent years, however, the agency has sought whenever possible to establish provisions on a performance basis, leaving employers with flexibility in choosing the means to comply.

RULEMAKING REQUIREMENTS AND INFLUENCES

As a matter of principle, OSHA has substantial policymaking discretion, with the latitude to defer to its own technical expertise in setting standards. Nonetheless, the agency's promulgation of rules is subject to considerable review and influence by various actors outside the agency. Indeed, as a general rule, OSHA's rulemakings need to be supported by an extensive presentation of evidence and rationale, and, along the way to promulgation, must be responsive to significant comments and submissions to the record by stakeholders and other interested parties. Arguably, OSHA faces rulemaking requirements among the most demanding of all federal agen-

[1] Industrial hygiene's "hierarchy of controls" places engineering controls at the top of the priority ladder, reflecting a conclusion (on good professional practice and risk reduction grounds) that workplace hazards should be removed at the source when at all possible. In parallel, OSHA's "methods of compliance" policy, first adopted by the agency from national consensus standards in 1971, has required that employers primarily use feasible engineering controls to achieve PELs. Nevertheless, this priority has been a matter of significant debate over the years with some segments of industry, wherein the flexibility to substitute respirators and/or personal protective equipment providing equivalent protection to engineering or work practice controls has been sought—and argued (by these proponents) to often provide a more cost-effective method of control.

cies with health, safety, and environmental regulatory responsibilities.[2]

Some of this circumstance stems from the various legal requirements incumbent on the agency. As the proponent of a rule or an order, OSHA must provide a demonstration in advance of promulgation that an intended rule is reasonably necessary, and refer to a documented record in doing so. As specified by the OSH Act, the agency is required to conduct rulemakings through a more demanding, hybrid version of the "informal" procedure specified by the Administrative Procedures Act.[3] Furthermore, should a challenge be mounted to a standard after promulgation, the agency's determinations must be capable of withstanding a "substantial evidence" review[4] by the courts—rather than the less demanding "arbitrary and capricious" level of review normally specified for "informal" agency rulemaking procedures by the Administrative Procedures Act.[5]

In addition, since the mid-1970s, the OSH Act has been the subject of numerous judicial interpretations—arising, for the most part, in the course of challenges mounted by stakeholders dissatisfied with newly promulgated standards. These decisions have generally been far-reaching for the agency's rulemaking procedures. Among other effects, this evolving body of case law has mandated or refined various substantive determinations the agency is obliged to make in support of rulemakings, notably, confirmation of the significance of the hazard being addressed and the technological and economic feasibility of the compliance provisions specified. Box 2-1 provides a further discussion of the essential features of these decisions as they affect OSHA's analytical activities.

[2] For a useful discussion of this point with citations, see Sidney A. Shapiro and Thomas O. McGarity, "Reorienting OSHA: Regulatory Alternatives and Legislative Reform," *Yale Journal on Regulation*, 6 (1989), pp. 4–12. Also, an OTA working paper prepared for this project compares OSHA's procedures to decisionmaking by other federal regulatory agencies with health and safety responsibilities and by OSHA-equivalent organizations abroad: David Butler, "OSHA's Brethren—Safety and Health Decisionmaking in the U.S. and Abroad," Office of Technology Assessment, U.S. Congress, Washington, DC, September 1995.

[3] As specified by the Administrative Procedures Act, "informal" rulemakings are conducted through informal notice and comment procedures, akin to a legislative process. By contrast, "formal" rulemaking operates chiefly through judicial procedures, such as swearing of witnesses, taking of depositions, and cross-examination. Congress specified essentially an "informal" procedure for OSHA with a legislative-type public hearing. But to assure the effective participation of concerned stakeholders and a just rulemaking, OSHA's procedures allow for cross-examination and specify keeping a verbatim transcript of the proceedings.

[4] The U.S. Supreme Court has interpreted substantial evidence to consist of "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion" (*Consolo* v. *Federal Maritime Commission*, 383 U.S. 607, 619-20, (1965)). Nonetheless, the courts have repeatedly recognized that OSHA's standard setting involves legislative-type decisions, which are by nature not entirely reducible to determinable facts and often must engage imperfect and contradictory information. Under these circumstances, the courts have generally been deferential to agency actions, construing "substantial evidence" to involve the presentation of pertinent factual evidence, capable of supporting the rationale used by the agency in reaching its conclusions. Such evidence must be the best available, but it does not have to approach scientific certainty. See Kent D. Strader, "OSHA's Air Contaminants Standard Revision Succumbs to Substantial Evidence Test," *University of Cincinnati Law Review*, 92 (1993): 358–365.

[5] Some analysts argue that contemporary reviewing courts applying "hard look" scrutiny to agency actions have, as a practical matter, removed much of the intended difference between the "arbitrary and capricious" and "substantial evidence" levels of review (see Shapiro and McGarity, 1989, p. 9 and footnote 50). Nonetheless, the circumstance remains that OSHA is subject to a high standard of review and, because of the considerable threat of post-promulgation challenge, must generally go the extra mile to assemble an exceptionally strong rationale and supporting record for its regulatory actions.

BOX 2-1: Court Decisions Affecting OSHA's Conduct of Rulemakings

Health Standards

Significant Risk. In a 1980 decision, the U.S. Supreme Court (in *Industrial Union Dept.* v. *American Petroleum Institute*, 448 U.S. 607) concluded that OSHA could regulate a substance only after making a threshold finding (capable of meeting a "substantial evidence" test) that a significant risk of harm existed and that the standard would eliminate or reduce that risk. Several subsequent U.S. Court of Appeals decisions refined the evidentiary basis for such determinations. In light of these directions, OSHA's normal initial step in a health rulemaking is to verify that a significant risk exists and that a new/revised standard will reduce it. Scientific evidence from quantitative risk assessments is the usual foundation for this finding—although, the courts have made it clear that a positive determination can be made, if necessary, on less conclusive evidence (e.g., the weight of expert testimony or opinion), as long as it is applicable to the situation that causes the risk. Furthermore, once the agency makes a significance determination, it must then act to eliminate the hazard—or at least reduce it to the extent feasible.

Technological Feasibility. Reviewing courts have generally interpreted the "to the extent feasible" stipulation of the OSH Act's section 6(b)(5) to contain separate technological and economic components. On the technology side, OSHA must establish a general presumption (within the limits of best available evidence, capable of satisfying a substantial evidence level of review) that the typical firm in an affected industry will reasonably be able to develop and install the necessary engineering and work practice controls in most of its operations. This can be done by pointing to technology already in use. Nevertheless, the agency is not restricted to presently available technology. It can set a standard at a level achievable only by the most advanced plants in an industry or one that forces the development and diffusion of new technology. Here, certainty is not necessary, but the agency must provide a substantial evidence finding that the necessary technology has been conceived and is reasonably capable of experimental refinement and distribution within the standard's deadlines by companies acting vigorously and in good faith. (Decisions by both the U.S. Supreme Court and U.S. Court of Appeals were instrumental in defining these principles. See particularly *Society of the Plastics Industry* v. *OSHA*, 509 F.2d, 1301, 1309 (1975); *USWA* v. *Marshall*, 647 F.2d, 1189 (1980); *American Textile Manufacturers* v. *Donovan*, 452 U.S. 490 (1981); *Building and Construction Trades Dept., AFL-CIO* v. *Brock*, 838 F.2d 1258 (1988)).

Economic Feasibility. Similarly, the courts have concluded that OSHA must demonstrate (again, on a best available evidence basis, capable of substantial evidence review) that a standard is generally economically feasible for each regulated industry (or, potentially, for specific segments therein, if such segments are particularly vulnerable to the ramifications of the standard). In this, the agency must prepare a sound estimate of compliance costs and show that the standard will not cause massive economic dislocations within, or imperil the existence of, affected industries. Nevertheless, an economically feasible standard can be financially burdensome, can affect profit margins adversely, and need not guarantee the continued viability of individual firms that historically have lagged other regulated firms in providing safe places of employment. (See particularly *Industrial Union Dept.* v. *Hodgson*, 499 F.2d 467 (1974); *USWA* v. *Marshall*, 647 F.2d, 1189 (1980); *American Textile Manufacturers* v. *Donovan*, 452 U.S. 490 (1981)).

(continued)

BOX 2-1: Court Decisions Affecting OSHA's Conduct of Rulemakings (Cont'd.)

Benefit-Cost Balancing. In 1980, the U.S. Supreme Court, in *American Textile Manufacturers* v. *Donovan* (452 U.S. 490), directly addressed the use of benefit-cost analysis in establishing OSHA's health standards. The court concluded with the agency that section 6(b)(5) of the OSH Act precluded benefit-cost analysis as a direct basis—because Congress had placed the benefit of worker health above all other considerations save those making attainment unachievable, had considered health and safety protections as a reasonable cost of business, and had required feasibility analysis (to limit the prospect of regulatory overstretch). The Court's guidance in this area supersedes the executive order requirements that intended standards necessarily reflect a reasonable benefit-cost relationship. Nevertheless, as a practical matter, OSHA prepares estimates of regulatory costs and benefits—and often discusses their relationship in reviewing its economic feasibility findings.

Safety Standards

Significant Risk. OSHA has drawn much the same conclusions about the courts' guidance on this matter for safety standards as it has for health standards, that is, section 3(8) of the OSH Act requires, prior to promulgation, a threshold finding that significant risks are present in the workplace and can be eliminated or reduced by a change in practices. Thus, in this regard, the agency generally approaches a safety standard much the same as a health standard, and makes a significance determination as an initial rulemaking step.

Technological and Economic Feasibility. OSHA must make threshold determinations in both of these areas, just as for a health standard. The same burdens of proof prevail: general presumptions of feasibility for each affected industry (or relevant segments thereof), best available evidence, capable of withstanding a substantial evidence level of review by the courts.

Benefit-Cost Balancing. The U.S. Supreme Court's 1980 decision in *American Textile Manufacturers* v. *Donovan* (cited earlier) addressed the use of benefit-cost analysis only in health standards and left open the relevance of this method in safety rulemakings. More recently, though, in *International Union, UAW* v. *OSHA*, 938 F.2d 1310 (1991), the District of Columbia Circuit court (addressing various challenges to OSHA's 1989 Hazardous Energy Sources ["lockout-tagout"] safety standard) indicated concern that OSHA's interpretation of the OSH Act vis-à-vis the procedures for safety rulemakings could lead to very costly and minimally protective standards. The court expressed the view that safety standards restricted only by "feasibility" provided unreasonably broad discretion to OSHA. The court remanded the agency's interpretation of its procedural requirements for further consideration and suggested that benefit-cost analysis (though not the only acceptable approach) was consistent with the language of section 3(8) (the portion of the OSH Act that governs setting safety standards). OSHA's response to this matter to date (see 59 *Federal Register* 4427-4429) has been to argue that a technologically and economically infeasible standard would *a fortiori* not meet the "reasonably necessary or appropriate" threshold of section 3(8) and to strongly affirm the adequacy of its existing process for safety standards. (These procedures include a significant risk finding, technological and economic feasibility determinations, evidence and rationale capable of withstanding a substantial evidence review by the courts, the need to consider all serious comments on the record and specify cost-effective measures, but not a benefit-cost test.) Nonetheless, this is a matter that may not yet be resolved, and could well further gravitate toward a need for more systematic consideration of the balance of benefits and costs in future safety standard rulemakings.

SOURCE: Summarized by OTA from various OSHA rulemaking preamble materials in the *Federal Register*; Kent D. Strader, "OSHA's Air Contaminants Standard Revision Succumbs to Substantial Evidence Test," *University of Cincinnati Law Review* 92 (1993): 358-365; and other sources.

Presidential orders have added to the analytical requirements for a rulemaking. Nearly every administration since President Ford's in 1974 has issued an executive order mandating that federal regulatory agencies prepare comprehensive regulatory impact analyses to support rulemakings. The broad purpose of these orders has been to assure due consideration of the expected costs and benefits of new regulations and, since the early 1980s, to expand the role of White House and Executive Office of the President oversight in federal agency rulemaking.[6]

Additional requirements for analysis derive from congressional legislation subsequent to the OSH Act. The 1980 Regulatory Flexibility Act (5 U.S.C. 60 *et seq.*) requires that OSHA examine the economic impacts of its standards on "small entities" (i.e., small businesses, organizations, governmental jurisdictions) and demonstrate that a significant or unnecessary burden will not result.

Finally, beyond these formal requirements, there is also the day-to-day reality that the agency's regulatory mission is often exceedingly controversial and involves stakeholders with widely diverging interests. There are often substantial differences among affected parties' assessments of the need to enhance a level of protection, the likely efficacy of new compliance measures in reducing existing risks, and the attendant economic benefits and costs. The threat that those dissatisfied with an action will seek post-promulgation redress and a reshaping of the outcome through the courts is considerable and is a circumstance that has arisen frequently in OSHA rulemakings (particularly with respect to health standards). Beyond the statutory and technical considerations, the agency's policymaking invariably faces the challenging task of accomplishing the health and safety mission delegated to it by Congress and striking a workable balance among competing stakeholder interests.

[6] In general, these orders have reflected the desire that agencies clearly consider economic costs and alternative policies in their rulemakings and that adequate opportunity be provided for public comment on agency assumptions and findings. President Ford's E.O. 11821 in 1974 required an "inflation impact statement" to assure consideration of the possible inflationary effects of a regulation, where significant impacts on costs, productivity, competition, or the supply of important products and services were expected. (E.O. 11949 in 1976 extended the period of applicability of this mandate, and also renamed the required analyses "economic impact statements.") In 1978, President Carter replaced the Ford executive orders with his own E.O. 12044, requiring preparation of a "regulatory analysis" for all "major" rules (i.e., those expected to impose an annual effect of $100 million or more on the economy or give rise to a major increase in costs or prices for individual industries, levels of government, or geographic areas), showing that alternative policy approaches had been considered, and explaining the agency's policy choice. In 1981, President Reagan replaced the Carter order with E.O. 12291, which similarly mandated preparation of a "regulatory impact analysis" for all "major" rules (defined in most respects along the lines of the Carter order) but required more elaborate attention to expected costs and benefits, the consideration of policy alternatives (including nonregulatory means of achieving policy goals), and the net benefit and cost-effectiveness of potential new regulations. The Reagan order also substantially enlarged OMB's role in overseeing the regulatory impact assessment process and monitoring the preparation of potential regulatory actions. (A second order, E.O. 12498, issued four years later, authorized OMB's involvement at an earlier stage in the rulemaking process.) President Clinton's E.O. 12866 in 1993 replaced both of the Reagan orders, introduced a number of significant changes in the procedures for regulatory planning and executive oversight of rulemakings, but retained a requirement for the preparation of a formal "assessment" for any "significant regulatory action" (defined similarly to "major" in the Carter and Reagan orders) that considered the potential costs and benefits of the intended action and the policy alternatives available (including non-regulatory means).

ANALYTICAL CONTENT AND METHODS

In light of these various guidelines and requirements, OSHA normally conducts a rulemaking along a well-defined logical path. In the case of health standards, the principal steps are to (as OSHA describes them): 1) demonstrate that the substance/hazard to be regulated poses a significant risk to workers; 2) identify which if any of the regulatory policy alternatives being considered will substantially reduce the risk; 3) identify the most protective control requirements that are both technologically and economically feasible for the affected industries; and 4) identify the most cost-effective way to achieve this risk reduction objective.[7]

The agency articulates something quite similar for safety standards: 1) demonstrate that the proposed standard will substantially reduce a significant risk of material harm; 2) confirm that the required compliance actions are technologically feasible for the affected industries (in the sense that the protective measures required already exist, can be brought into existence with available technology, or can be created with technology that can reasonably be developed); 3) show that the new costs arising from these actions are economically feasible for the affected industries to bear (in the sense that industry can absorb or pass on the costs without major dislocation or threat of instability); and 4) demonstrate that the standard is cost-effective (in the sense that it employs the least expensive protective measures capable of reducing or eliminating significant risk).[8]

As the rulemaking process is (and has for some time been) organized to work, OSHA defines a target exposure level (e.g., a PEL) that provides an appropriate degree of protection, on health/safety grounds and with reference to "significant risk" considerations.[9] Such determinations are generally based on findings and risk modeling methods from the various scientific fields that comprise the discipline of Quantitative Risk Assessment (QRA).[10] The agency's conclusions on this matter are normally discussed in detail in the "preamble" sections published (in the *Federal Register*) along with the proposed and final versions of permanent standards.

Assessments of technological and economic feasibility are conducted in light of this target exposure level (or range of levels, if a single point has not been specified). These determinations, along with the additional analyses needed to satisfy the executive order-mandated regulatory impact analysis and Regulatory Flexibility Act requirements, are documented in "Regulatory Impact and Regulatory Flexibility Analysis"

---

[7] See, for example, Department of Labor, Occupational Safety and Health Administration, "Occupational Exposure to Bloodborne Pathogens—Final Rule," *Federal Register* 56: 64034, Dec. 6, 1991.

[8] See, for example, Department of Labor, Occupational Safety and Health Administration, "Electric Power Generation, Transmission, and Distribution; Electrical Protective Equipment—Final Rule," *Federal Register* 59:4427, Jan. 31, 1994.

[9] As discussed earlier in Box 2-1, in setting permanent standards, OSHA is obligated to make a threshold determination (through substantial evidence) that a "significant risk" of harm exists and that new/revised compliance requirements can eliminate or reduce the risk. The U.S. Supreme Court's decision in *Industrial Union Dept. v. American Petroleum Institute* established the "significant risk" test in 1980. (For a further discussion, see Strader, 1993, pp. 365–373.) The Court did not, though, specify the "bright line" dividing significant from non-significant levels of risk. In rulemakings since the early 1980s, and based on an interpretation of Justice Steven's opinion in the case, OSHA has placed this "line" at a marginal risk of about one in a thousand over a full working lifetime. Some critics argue, however, that this level is not sufficiently protective, noting that other agencies such as EPA have been regulating to risk levels as stringent as one in a million. (See, for example, AFL-CIO, Department of Occupational Safety and Health, "The Workplace: America's Forgotten Environment—A Comparison of Protections Under U.S. Workplace Safety and Environmental Laws," Washington, DC, April 1993.) In fact, the Court only gave rough guidance in this matter, by recognizing that one in a thousand risk was "certainly significant" and that one in a billion was certainly not. Some critics view OSHA's choice of the least stringent level in this range as evidence of a policy objective to set comparatively relaxed standards that limit the economic burdens imposed on employers.

[10] For background on the issues and methods involved, see U.S. Congress, Office of Technology Assessment, *Researching Health Risks*, OTA-BBS-570 (Washington, DC: U.S. Government Printing Office, November 1993), pp. 45–66, or National Research Council, *Science and Judgment in Risk Assessment* (Washington, DC: National Academy of Science Press, 1994). A useful example of the current application (and complexities) of these methods to OSHA rulemakings is the recent health standard for cadmium, 57 *Federal Register* 42108-42210, Sept. 14, 1992.

reports, published in preliminary and final forms (also summarized in the *Federal Register*) to accompany proposed and final rules.

The agency's regulatory impact/regulatory flexibility assessments are multifaceted analyses, which, since the early 1980s, have normally focused on the following matters:

- *Identification and characterization of affected industries*. Here, the incidence of the hazard is mapped across industry, identifying those sectors and occupational groups with existing conditions and material uses that create exposures relevant to the intended rulemaking. The resulting profiles are typically quite detailed—usually distinguishing industries at a 3- or 4-digit Standard Industrial Classification (SIC) level and according to relevant occupational subgroups.[11]

The key results include estimates of the number of affected establishments and workers in each industry, existing exposure levels, and the frequency of health/safety effects. Background information on the basic business and process features of each affected industry is also normally assembled at this time. (OSHA's typical findings on these topics are illustrated in box 2-2, drawing on material from the 1992 health standard for cadmium.)

- *Technological feasibility of compliance*. On this matter, the principal task is demonstrating, for each affected industry, a general presumption that the compliance steps required by the various provisions of the intended standard involve control measures that are reasonably available, that is, they are either in the marketplace currently or can be developed/implemented consistent with the court's guidelines on "feasibility" (as outlined in box 2-1).

Normally this exercise involves detailed consideration of the existing production processes and work practices, along with the controls and programs for hazard prevention already in place. Depending on the specifics of the compliance provision examined, this analysis may focus on controls already successfully applied by establishments in the industry, or look more widely—to approaches in other industries, to experiences in industries/establishments outside the United States, or to emerging technologies not yet commercially available. (A further description of the agency's approach to this task is in box 2-3.)

By the time of the final rule, the discussion of technological feasibility is usually tightly focused on the specific provisions being promulgated. Earlier in the rulemaking, however, the examination of varying policy options is often wider (say, to examine the means and feasibility of achieving exposure ceilings at differing levels of stringency).

- *Anticipated benefits from regulation*. As part of the rationale for a rulemaking and to comply with executive order-mandated "regulatory impact analysis" requirements, OSHA normally provides quantified estimates of the principal health and safety benefits (on an annualized basis) that it expects to result from compliance (e.g., avoided cancer deaths, avoided cases of chronic illnesses, avoided permanent disabilities, avoided injuries involving lost work days).

Typically, these estimates are built up from detailed, industry-by-industry analyses, using the

[11] The information used for these tasks varies by the standard and the industries involved. However, recurring sources include data from OSHA's Integrated Management Information System (IMIS—which chiefly contains the field data collected during the agency's inspection and enforcement efforts) and from the record of prior rulemakings (some of which may have involved large-scale survey efforts collecting data on exposures, in place production processes, and control measures already used); data from other federal agencies, including the National Institute of Occupational Safety and Health (particularly from the Institute's Health Hazard Evaluations), Environmental Protection Agency (such as information from the Toxic Release Inventory), and the Department of Commerce (particularly from the various periodic surveys of manufacturers); original research conducted for the rulemaking, such as site visits to establishments in affected industries or large-scale industry surveys; and information submitted to the rulemaking docket, such as self-reports provided by individual establishments, surveys prepared by industry representatives, or research findings provided by various experts. OSHA normally assembles a substantial record of data on these matters. But often the best available information is incomplete, and working estimates must be prepared from what is available.

risk assessment findings and estimates of pre- and post-promulgation compliance levels. For the most part, the estimates are presented in physical terms (i.e., deaths, diseases, injuries avoided), as the agency has historically been reluctant to specify a particular monetary value for a statistical life saved or injury avoided. On occasion, however, the physical units are infor- really monetized in the course of discussing the findings.

BOX 2-2: An Illustration of OSHA's Industry Baseline and Control Option Characterizations—1992 Cadmium Standard

Industry sector [a,b]	Existing circumstances	Additional controls for compliance
Nickel-cadmium batteries *6* plants. 1,500 potentially exposed workers, Average exposure level is 73 μ g/m³ in "high" group, 14 μ g/m³ in "low" group, SECALs	Local exhaust ventilation (LEV), automation, enclosure, housekeeping practices in place—but used to varying extent. Respirators standard practice in high-exposure areas. All processes pose challenges for compliance through engineering and work practice controls alone—but difficulties are greatest in plate making and plate preparation,	Further exposure reduction through expanded use of current practices. Additional steps include modifications in materials procedures, upgrade of hygiene practices, improved information and training. But continued respirator use is likely to be necessary in some high exposure process areas.
Zinc/cadmium refining *5* plants. 1,350 potentially exposed workers. Average exposure level is 91 μ g/m³ in "high" group, 6 μ g/m³ in "low" group. SECAL	Hoods and baghouses exist in many process operations. Challenges for compliance through engineering and work practice controls alone in some areas: cadmium refining, casting, melting, oxide production, and sintering.	Added/improved LEV, mechanization of material transfer, added enclosures, centralized vacuum cleaning, clean air islands, revised work practices, improved housekeeping (vacuuming, damp mopping, added cleanup prior to maintenance). But continued respirator use is likely to be necessary in some high exposure process areas.
Cadmium pigments *4* plants. 100 potentially exposed workers. Average exposure level is 130 μ g/m³ in "high" group, 23 μ g/m³ "low" group, SECALs	Some controls in place, but use of ventilation systems generally limited. Large extent of batch production limits dedicated production lines. All processes pose challenges for compliance through engineering and work practice controls alone-but difficulties are greatest in calcining, crushing, milling, and blending.	Extensive expansion of ventilation systems, enclosure of process equipment, added central vacuuming equipment, adjusted work practices, improved housekeeping. Continued respirator use is likely to be necessary in some high-exposure process areas.
Dry color formulators *700* plants. 7,000 potentially exposed workers. Average exposure level is 10 μ g/m³	LEV, general ventilation, good housekeeping practices (vacuuming, damp mopping) are already in place. But batch nature of operations yields intermittent, variable exposure levels and frequent cleaning is required.	Added/improved general ventilation and LEV, dust collection systems, central vacuuming. But continued/ expanded respirator use—particularly during cleaning and maintenance, and other intermittent activities such as weighing out pigments.

(continued)

BOX 2-2: An Illustration of OSHA's Industry Baseline and Control Option Characterizations—1992 Cadmium Standard (Cont'd.)

Industry sector[a,b]	Existing circumstances[c]	Additional controls for compliance
Cadmium stabilizers 5 plants. 200 potentially exposed workers. Average exposure level is 116 µg/m^3 in "high" group, 3 µg/m^3 in "low" group. SECAL	Some LEV/baghouse control exists in dry process operations; little control present in wet process operations. Challenges for compliance through engineering and work practice controls alone in some areas: cadmium oxide charging, crushing, drying, and blending.	Added/improved LEV, installation of centralized vacuum systems, containment and enclosure improvements, automated material handling systems. Continued respirator use is likely to be necessary in some high-exposure process areas.
Lead smelting/refining 4 plants. 400 potentially exposed workers. Average exposure level is 43 µg/m^3 in "high" group, 3 µg/m^3 in "low" group. SECAL	Industry is already employing engineering controls to the extent feasible—because of the OSHA lead standard. Respirators used substantially in high-exposure areas. But particular challenges for compliance based on engineering and work practice controls alone in sinter, blast furnace, baghouse, and yard areas.	Some incremental improvements in ventilation and enclosure equipment. Marginal expansion of employee protection programs (hygiene, medical removal, etc.) Many of the requirements of the revised cadmium standard overlap existing requirements. Existing respirator use is expected to continue.
Cadmium plating 400 plants. 1,200 potentially exposed workers. Average exposure level is 35 µg/m^3 in "high" group, 2 µg/m^3 in "low" group. SECAL	Electroplaters make up 90 percent of this industry—adequate ventilation systems (LEV, hoods over material handling areas) are generally in place, and exposure levels for most are already below the PEL. Mechanical platers make up the rest of industry—ventilation systems are fairly widely in place, but exposure levels are well above the PEL, and apparent challenges are posed for full compliance based on engineering and work practice controls alone.	For mechanical platers: improved ventilation equipment, partial enclosures, better work practices and housekeeping procedures, increased respirator use during some operations.
Electric utilities 4,000 plants. 37,000 potentially exposed workers. Average exposure level is 1 µg/m^3.	Employee exposures generally arise during intermittent inspection or maintenance activities associated with electrostatic precipitators, fly ash conveyance, and boiler outages—and not during ordinary operations. Respirators are already standard practice.	Some additional engineering and work practice controls may be useful, e.g., wash downs of fly ash prior to boiler maintenance, fans or ventilation systems during maintenance operations. But respirators are likely to remain the mainstay of protection, due to intermittent and unpredictable nature of exposures.
Iron & steel 120 plants. 40,000 potentially exposed workers. Average exposure level is 2 µg/m^3.	"Best adequately demonstrated" technological systems for continuous emission reductions are generally in place in the industry—largely because of extensive EPA regulations. Respirator use is common in high-exposure areas. Job/process classifications with greatest risk for above PEL exposures include leaded steelmaking, work on air pollution control systems, maintenance activities.	Modest expansion of respirator use.

(continued)

BOX 2-2: An Illustration of OSHA's Industry Baseline and Control Option Characterizations—1992 Cadmium Standard (Cont'd.)

Industry sector[a,b]	Existing circumstances[c]	Additional controls for compliance
Other general industry 50,000 plants. 365,570 potentially exposed workers. Average exposure levels for the 10 occupational classes range from 0.4 to 6.0 µg/m^3.	Extent of existing controls varies widely across the many industries in this analysis group.	Generally applicable steps are improved general dilution ventilation, LEV for close capture of dusts and fumes, process enclosure (e.g., sealed panels, equipment covers, enclosed conveyors, glove boxes), separation/isolation of processes, improved work practices (to reduce generation of airborne cadmium and risks of exposures to high levels), additional cleanup prior to maintenance activities. In some cases it may be possible to shift to other materials or processes. Respirators are likely to be necessary in some situations.
Construction 10,000 plants. 70,000 potentially exposed workers. Average exposure level is 0.5 µg/m^3.	Construction activities are often intermittent and of short duration with unpredictable exposures. Activities may not involve fixed workplace and frequently occur in circumstances where engineering controls are not feasible. Respirators are widely used.	In some applications, shifts to products without cadmium. Feasible engineering and work practice controls include: portable hoods, exhaust ventilation, fans, enclosures, tools and work practices capable of minimizing exposures. Some further increase in the already substantial level of respirator use.

[a]The rulemaking identified nearly 100 industries as subject to compliance requirements under the new standard. However, for purposes of the analysis, these were grouped into the 11 sectors identified below in the table.

[b]The exposure levels listed are all TWA8.

[c]The descriptions above are summaries of the more detailed industry characterizations on which OSHA based its control and impact analyses.

[d]The final rule specified a uniform TWA8 PEL of 5 µg/m^3. However, in six industries, where feasibility limits were judged to exist, one or more so-called separate engineering control air limits (SECALs) were established (addressing specific production areas), allowing employers to achieve the PEL through application of a wider number of control measures (e.g., personal respirators along with engineering and work practice controls).

SOURCE: Summarized by OTA from U.S. Dept. of Labor/OSHA, Office of Regulatory Analysis, Final Cadmium Rule, 57 *Federal Register* 42224-42330, Sept. 14, 1992.

BOX 2-3: OSHA's Approach To Demonstrating Technological Feasibility

OSHA's consideration of applicable technological measures for hazard control arises chiefly in the course of providing adequate evidence of the general feasibility of an intended standard's compliance requirements across the industries identified as affected. In light of the procedural guidelines from the courts, such an analysis is normally conducted industry by industry (i.e., at a 3- or 4-digit SIC level of detail).

In the case of *health standards*, most of the effort is usually directed toward showing that suitable control measures are available (or can reasonably be developed within the compliance timeframe of the standard) so that an intended PEL can generally be achieved across an affected industry. Other provisions (medical surveillance, emergency planning, workforce training, and the like) may involve a technological component, but achievability is usually not a matter of debate.

As OSHA's rulemaking process is now organized to work, "significant risk" considerations define the target level for hazard reduction. Feasibility analysis proceeds in a "serial" way based on this determination, that is, engineering controls or substitution options are considered first (in keeping with industrial health's "hierarchy of controls" and OSHA's policy priority). If added control measures or substitutes that reduce exposures to (or below) the target level can be identified, then the analysis moves on to the economic feasibility test. Should some residual significant risk remain beyond the full application of such controls, however, work practice and administrative measures are considered. As a last resort, respirators and other personal protection equipment are factored in, if necessary.

Safety standards vary widely in the technological content of their provisions. (For example, the 1992 Process Safety Management standard primarily involved safety audit and other procedural requirements. But the 1987 Grain Handling Facilities standard involved various process equipment improvements and a major expansion in some housekeeping activities.) Nonetheless, the major issues and demonstration tasks are essentially the same as those for health standards.

The analyses for both kinds of standards have a number of common features:

- The consideration of potential means of control normally begins from a fairly detailed description of the industry baseline—the mix of production processes and equipment running in a typical plant, the work practices used, level of hazards experienced, and control measures already in place. Also, where scale effects and/or functional differences among the various subgroups of establishments in an industry are relevant considerations, the industry is often disaggregated into a number of stylized "model" plants for separate treatment.
- The primary focus of the analysis is demonstrating feasibility. As a general rule, the agency does not seek to identify and evaluate all possible control measures available to address the hazard or to define the frontier of maximally feasible hazard control.
- The agency's analyses tend to emphasize those measures whose engineering applicability, effectiveness of control, and cost characteristics can be well documented in the rulemaking record, that is, already commercially evident technologies with a clear track record are the preferred basis for feasibility determinations (because they can less easily be contested later in court). Where such obviously feasible measures cannot be identified or where a standard is deliberately technology forcing, OSHA must look more widely to analogous measures in other industries or to measures yet to be developed. Such measures can provide an adequate basis for a standard, as long as the agency can make a substantial evidence case that the necessary technology can be sufficiently refined and distributed within the standard's deadlines (see discussion in box 2-1, presented earlier).

(continued)

BOX 2-3: OSHA's Approach To Demonstrating Technological Feasibility (Cont'd.)

- Finally, the analysis process does *not* generally seek to forecast expected behaviors. The establishments that make up an affected industry are not, for the most, examined from the standpoint of the control options perceived to be available or the nature of the incentives at play that influence the selection of one kind of compliance strategy over another.

To comply, some (perhaps, even many) of an affected industry's establishments will adopt the control measures on which the agency's feasibility determination is based. (These measures are, after all, identified by OSHA because of their workability and usually are, by the ranking procedures employed, low-cost options among the set of feasible measures identified.) However, other establishments may well decide that it is more advantageous from a business standpoint to accelerate the turnover of plant equipment in order to adopt a new generation of production technologies (deriving, perhaps, productivity and product quality improvements at the same time as providing enhanced health/safety risk protections). Alternatively, some establishments may also choose to pursue opportunities for innovation with the prospect of yielding new technologies with a superior combination of production and hazard control characteristics. However, a reasonable estimate of the mix of behaviors among these various responses that one could expect to see post-promulgation is not something that can readily be discerned from OSHA's present analysis process—and actually involves a more complex and extensive analytical effort than what OSHA routinely performs in the context of feasibility demonstration.

SOURCE: Office of Technology Assessment, based on discussions with OSHA staff and review of various rulemaking docket materials.

OSHA's analyses also often identify one or more kinds of direct expenses that are anticipated to be avoided as a consequence of the hazard-reducing effects of the standard (e.g., reduced insurance premiums or lower costs for company-provided medical treatments). While these are tangible benefits of the regulation, OSHA's normal practice with such effects is to categorize them as avoided costs and net them against the estimated compliance spending. (Boxes 2-4 and 2-5, based on material from the 1992 Process Safety Management standard, illustrate the agency's benefits estimation process.)

- *Costs of compliance*. Often a considerable proportion of the overall analytical effort is devoted to identifying where compliance entails new costs for establishments in affected industries and preparing quantified estimates of this incremental spending. The agency now usually reports these figures on a pre-tax and annualized basis, spanning a time horizon dictated by the compliance terms of the standard and the depreciable life of the equipment and control actions involved.[12]

[12] The components of incremental compliance costs can include capital investments in new production equipment or controls, one time "sunk costs" required to establish required programs, and periodically recurring expenses such as for operations and maintenance. OSHA's normal procedure is to amortize capital investments and one-time costs over some appropriate recovery period (dictated by the specifics of the equipment and actions involved) and then add these as annualized figures to the estimated recurring costs. Where avoided costs (e.g., reduced insurance premiums because of reduced risk) are identified, they are quantified and netted out.

Typically, this is a detailed computational exercise, conducted provision by provision, and industry by industry.[13] In most cases, the calculations assume industry-wide adoption of the predominant technologies and control steps identified in the "feasible technology" analysis described earlier.[14] The calculations are also usually prepared to reflect the extent of pre-existing compliance with the new provisions prevailing across the industry—although, this aspect of the estimation process is often hampered by the absence of adequate field data pertaining to the existing baseline. (As an illustration, box 2-6 summarizes the compliance cost calculations for one of the industries regulated under OSHA's 1992 cadmium standard.)

Like the examination of feasible technologies, the version of compliance cost estimates published with the final rule is generally tightly focused on the provisions actually promulgated. But at earlier stages in the rulemaking, figures on several competing policy alternatives are often presented for review and comment.

- *Economic impacts*. The main objective of this portion of the rulemaking analysis is to demonstrate a general presumption of the financial feasibility of the compliance-related spending for each affected industry. Generally, this task is addressed by considering the ability of the typical establishment in the industry to either pass through or absorb these added costs. Analytically, the estimates of annualized compliance costs are compared with current figures on the industry's annual sales and annual profitability; these findings are supplemented by a discussion of the fundamental competitive and other economic forces driving the industry. (Box 2-7 provides a more detailed discussion of the agency's approach to these determinations. Box 2-8 illustrates the analytic results, drawing on the 1992 cadmium standard.)

[13] To put this task in perspective, OSHA's 1992 health standard for cadmium (57 *Federal Register* 42104) had 13 major compliance provisions and spanned almost 100 affected industries, with about 65,000 establishments and 525,000 potentially exposed workers. The 1991 standard for process safety management (57 *Federal Register* 6356) included 14 major provisions and affected 127 industries, with around 153,000 plants and around 3 million affected workers.

[14] See box 2-3. As reviewed there, OSHA generally assumes (for any given industry) the adoption of the low-cost, feasible measures relevant to the control needs at hand. The emphasis of attention is usually placed on those measures whose applicability, effectiveness of control, and cost characteristics can be well documented in the rulemaking record (i.e., already commercially evident technologies with a clear track record).

BOX 2-4: An Illustration of the Scope of OSHA's Consideration of Expected Compliance Benefits—1992 Process Safety Management Standard

Source identified	Treatment in rulemaking analysis
Incident reduction	
Fatalities avoided/major incidents	Quantified (annual estimates, years 1–5 and 6–10)
Injuries & illnesses avoided/major incidents	Quantified (annual estimates, years 1–5 and 6–10)
Injuries & illnesses avoided/less severe incidents	Mentioned, but not quantified
Health risk reductions	
Lowered risks for long-term health effects—reduced chronic exposures to airborne toxics from improved process designs	Mentioned, but not quantified
Cost savings	
Improved employee productivity	Quantified (annual estimates, years 1–5 and 6–10)
Reduced property damage	Quantified (annual estimates, years 1–5 and 6–10)
Reduced lost production	Quantified (annual estimates, years 1–5 and 6–10)
Reduced employee turnover	Quantified (annual estimates, years 1–5 and 6–10)
Lower insurance premiums	Mentioned, but not quantified
Reduced administration	Mentioned, but not quantified
Other accident prevention costs	Mentioned, but not quantified
Other economic benefits	
Improved use of space, labor, equipment	Mentioned, but not quantified
Efficiency gains from integration of process design, construction, operation, and safety	Mentioned, but not quantified
Reduced loss of raw materials; reduced inadvertent generation of waste	Mentioned, but not quantified
Reduced minor process/equipment breakdowns	Mentioned, but not quantified
Improved product quality	Mentioned, but not quantified

NOTE: OSHA addressed a 10-year post-promulgation time horizon in preparing the regulatory impact calculations for this rulemaking. Separate calculations were prepared (across all measures) for years 1–5 and years 6–10, because some of the major compliance provisions involved a gradual phase-in and the expectations for regulation-induced reductions in fatalities and injuries/illnesses were accordingly different.

SOURCE: Summarized by Office of Technology Assessment from the preamble to the final rule, 57 *Federal Register* 6400, 6402, Feb. 24, 1992.

BOX 2-5: An Illustration of OSHA's Estimation of Cost Savings from Compliance—1992 Process Safety Management Standard

OSHA's examination of the economics of compliance by the affected industries with the PSM standard quantified four sources of associated cost savings: improvements in productivity, reductions in worker turnover, reductions in lost production, and reductions in property damage. Examples of the estimates for several selected industries (for the standard as a whole, 127 industries were so identified) appear here, followed by some descriptive comment on how the calculations were performed.

	SIC industry	Productivity improvements	Reduced worker turnover	Reduced lost production	Reduced property damage	Total cost savings	Total compliance cost[1]
		$ thousands, annually					
Years 1– 5							
1321	Natural gas liquids	1,285	344	162	674	2,465	2,900
20	Food and kindred products	12,009	3,219	7,736	25,513	48,477	35,800
22	Textile mill products	2,160	579	125	1,926	4,790	3,200
2431	Millwork	1,105	296	133	3,562	5,097	5,900
25	Furniture and fixtures	9,273	2,486	653	8,472	20,884	44,100
Years 6–10							
1321	Natural gas liquids	2,570	689	323	1,348	4,930	1,100
20	Food and kindred products	24,018	6,438	15,472	51,026	96,955	13,500
22	Textile mill products	4,320	1,158	250	3,851	9,579	1,300
2431	Millwork	2,211	593	266	7,124	10,193	2,400
25	Furniture and fixtures	18,547	4,972	1,305	16,945	41,768	18,100

[1]Reported here to provide a basis for gauging the magnitude of the estimated cost savings.

Productivity Improvements

Substantial opportunities for improvements in operational efficiencies were expected to result as a by-product of the standard's required conduct of process hazard analyses. Some of these improvements related to streamlined equipment and technology (reducing waste and inefficiency), some to enhanced standardization of operating procedures (improving worker effort per unit of production).

The rulemaking docket contained a number of instances where efficiency gains could be associated quantitatively with the implementation of process safety management procedures. OSHA concluded that 0.5 percent annual productivity gains in years 1–5 and 1.0 percent annually in years 6–10 were roughly in line with this information. This gain, in effect, reduced the number of production labor hours required for the same level of output, which yielded an economic benefit in the form of reduced payroll costs.

(continued)

BOX 2-5: An Illustration of OSHA's Estimation of Cost Savings from Compliance—1992 Process Safety Management Standard (Cont'd.)

Reduced Worker Turnover

The level of workplace health and safety risks is generally regarded as an important contributing factor in the rate of employee turnover that is experienced. Thus the reduction of risk resulting from a program such as PSM was expected to slow the pace of such turnover. And such an improvement would reduce costs, because expenses are incurred in hiring and training new employees, and some decrease or interruption in production may be experienced while new workers are screened, hired, and trained to achieve the same efficiency as the previous personnel.

For the PSM rulemaking, OSHA approximated these costs according to the wages of the departed workers. Industry by industry, the gross payroll cost of production workers (assumed to average 60 percent of all employees) was multiplied by the overall turnover rate for manufacturing (26.4 percent) and by the fraction of turnover accounted for by the existence of hazards (33 percent) to establish a worker turnover baseline. The 40 and 80 percent effectiveness rates (Years 1-5 and Years 6-10, respectively) expected for the standard were then applied to estimate the cost savings.

Reduced Lost Production

Major/catastrophic incidents will often physically damage an affected plant's final products. Raw materials used to fashion a final product may be damaged or lost, and have to be purchased anew when production ultimately resumes. Furthermore, interruptions in production can give rise to unintended physical waste, some of which may be hazardous and require costly special treatment. Also, beyond the industrial sector that is immediately affected, sudden production bottlenecks can impose higher prices (OSHA noted that a major explosion at a Phillips Corporation plant in 1989 reduced the supply of high density polyethylene by 18 percent, which, in turn, drove a sharp price increase for this product.)

OSHA examined lost value added as an indicator of the economic value forgone in the aftermath of an incident—a measure it recognized as useful but conservative, because labor and overhead expenses were recognized, but raw materials (which may also be lost) were not. Estimates of the lost value added for the average incident (two weeks' shutdown time, on average, at minimum, based on an examination of historical incidents by an OSHA consultant) were developed industry by industry, using data from the *Annual Survey of Manufactures*, other government censuses, and private sources. A baseline level (i.e., pre-compliance) for value added lost annually was assembled by combining these figures with industry-level estimates of the number of incidents. Compliance with the standard was assumed to lower the number of incidents (in line with the aforementioned 40 and 80 percent effectiveness levels), from which a corresponding savings in value added was estimated.

OSHA went on to note that the PSM rule was also expected to prevent a large number of minor breakdowns. OSHA placed the annual economic savings of this reduction in the "tens of million" dollars. It did not, however, include this component in the savings figures reported.

Reduced Property Damage

Here, the main concern was that major/catastrophic incidents could yield significant damage to facilities and the in-place equipment.

Using analyses of historical incidents by outside consultants, OSHA estimated that average value of property damage from major/catastrophic incidents was $904,000. (OSHA characterized this as a lower bound, however, because history clearly indicated that damage ranging up to 10's of million dollars or more could arise.) This value for the average incident was then used to prepare savings estimates, industry by industry, in line with the baseline rate of incidents and the expected effectiveness of the PSM standard.

SOURCE: Summarized by Office of Technology Assessment from U.S. Department of Labor, Occupational Safety and Health Administration, Office of Regulatory Analysis, "Final Regulatory Impact and Regulatory Flexibility Analysis of the Final Standard for Process Safety Management of Highly Hazardous Chemicals," Washington, DC, 1992, pp. IV.17-IV.29.

BOX 2-6: An Illustration of OSHA's Estimation of an Affected Industry's Compliance Costs—1992 Cadmium Standard

Compliance cost estimates are often numerically extensive, but usually straightforward in concept. The figures and text here illustrate the details of these calculations for one of the industries identified as affected in the 1992 revision of the cadmium standard. (Across the entire standard, almost 100 industries were identified as affected. Similar calculations were prepared for these other industries.)

Nickel-Cadmium Batteries

The industry consists of 6 plants and has 1,500 potentially exposed workers. The average exposure for the "high" group of workers is 73 $\mu g/m^3$; that of the "low" group, 14 $\mu g/m^3$. The final rule established a uniform TWA8 PEL of 5 $\mu g/m^3$ across all affected industries. However, in the case of this sector, the usual requirement for PEL compliance principally through engineering and work practice controls was modified by a pair of "separate engineering control air limits" (SECALs)—which called for engineering/work practice controls to achieve 50 $\mu g/m^3$ in plate making and plate preparation, 15 $\mu g/m^3$ for all other processes, with respirators sanctioned to cover the excess of exposure between the SECAL and PEL (5 $\mu g/m^3$) levels.

■ **The cost of engineering controls**

	Controls per plant by size of plant				Cost per control (thousand $)			Industry costs (thousand $)				
Type of control	Small	Med	Large	Total industry-controls[1]	Capital	Ann. power & main.	Ann. labor	Total capital	Ann. capital charge[2]	Ann. power & main.	Ann. labor	Total annual industry cost (thou.$)
Local exhaust ventilation	1	5	8	29	80	8	0	2,320	377	232	0	609
Clean air islands	1	5	10	31	18	2	0	558	91	62	0	153
Central vacuum systems	1	1	2	7	15	1	7	105	17	7	49	73
Enclosure	0	3	5	17	9	0	0	153	25	0	0	25
TOTAL				84				3,136	511	301	49	861

[1]The industry consisted of 1 small plant; 4 medium plants; 1 large plant. [2]Assumes a 10% interest rate (the OMB "standardized" figure) and an amortization period of 10 years (in line with the depreciable life of the equipment involved, as defined by the tax code and standard accounting treatment).

The assumptions about the adoption of engineering controls reflected OSHA's "feasible technology" determination (described earlier), along with what available knowledge (or the most reasonable interpretation thereof) indicated about specific plant circumstances (i.e., existing exposure levels and controls, and process requirements). The unit cost figures used were the most credible values that OSHA could identify—whether from its own data, the initial estimates prepared by its contractor, figures submitted to the docket (e.g., those prepared by industry representatives or industry firms), or a reasonable synthesis of all of these. There was some controversy, however, about the assumptions used for these calculations, because several industry representatives submitted detailed analyses with findings on the options available, the likely effectiveness of controls, and costs that differed in significant ways from OSHA's preliminary estimates.

(continued)

BOX 2-6: An Illustration of OSHA's Estimation of an Affected Industry's Compliance Costs—1992 Cadmium Standard (Cont'd.)

■ **The cost of other provisions**

Provision	Annualized cost (thousand $)	Basis for calculations
Respirator use	180.0	An estimated 80 percent of production and maintenance employees would need to wear respirators full time after the implementation of feasible engineering controls. Accounting for existing use (which was substantial), the revised standard would require respirators for an additional 600 workers (i.e., 40 percent of the 1,500 potentially exposed employees). OSHA estimated the unit cost for appropriate respiratory protection at about $300 per worker. Thus the added annual cost is $300 times 600.
Exposure monitoring	16.2	The revised standard requires semi-annual exposure monitoring of "each shift for each job classification in each work area," but also allows representative samples to be taken for workers with similar exposures. Such a sampling regime is already prepared at the typical plant, but only annually. About 180 jobs would need to be monitored: an average of 10 job categories per plant, times 6 plants, times 3 shifts. OSHA estimated the unit costs at $40 per lab analysis and $1,500 per plant for the services of an industrial hygienist (or other qualified professional). Thus the incremental annual cost is $40 times 180 plus $1,500 times 6.
Medical surveillance (including operation of the "medical removal" program)	387.5	The revised standard's medical surveillance requirements involve a complex combination of various employee categories, action triggers, and types of exams. The base requirements call for annual biological monitoring, including tests for cadmium in urine, cadmium in blood, and β_2-microglobulin in urine, and for a full medical examination every two years. More frequent biological monitoring and medical exams are required if tests indicate elevated levels. Although medical surveillance was already widely done in the industry, the final rule would require most establishments to expand their programs. OSHA estimated that 300 additional medical exams would be needed (for those not currently covered plus those needing to be examined more frequently), at about $250 each (professional services plus employee wages). Tests for β_2-microglobulin were generally not currently provided; about 30 percent of the exposed workforce may be subject to more frequent biological monitoring, with 20 percent receiving semi-annual monitoring and 10 percent, quarterly monitoring. This entails an estimated 2,000 β_2-microglobulin tests annually (at $85 each including collection), 750 additional tests for cadmium in the urine (at $65 each, including collection), and 750 tests for cadmium in the blood (also $65 each). Based on these figures, the total estimated cost for incremental medical exams and biological monitoring is $342,500 annually. Regarding medical removal, OSHA estimated that on average about 3 percent of the workforce (i.e., 45 employees) may need to be removed every 5 years, at a cost of $5,000 per employee—or $45,000 on average annually for the industry as a whole.

(continued)

BOX 2-6: An Illustration of OSHA's Estimation of an Affected Industry's Compliance Costs—1992 Cadmium Standard (Cont'd.)

Hygiene facilities and protection	495.0	Most plants in this industry already comply with the work clothing and regulated areas requirements. But some modifications or expansions of lunch and shower rooms would be needed. The wages of the additional employees required to shower and change (about 300 workers) would also have to be taken into account. OSHA concluded that $200,000 in capital costs and $5,000 in annual operating costs would be a reasonable working average for the physical plant improvements. At about $900 per employee for showering on work time, i.e., 15 minutes per day, 240 days a year, at an hourly rate of $15, the cost works out to $1.2 million in capital spending (or $195,000 appropriately annualized) plus $300,000 in annual expenses.
Record-keeping and information	7.5	OSHA estimated an annual cost of $5 per employee—to cover the equipment needed and staff time. Thus, the incremental annual cost is $5 times 1,500.
Subtotal	1,086.2	Summing all the "other provisions" components above.

NOTE: OSHA drew the various figures and characterizations for these calculations from its own analyses and those of its contractor's initial assessment. The assumptions, however, were generally in line with the testimony and evidence in the rulemaking record and, for the most part, were not controversial.

■ **Total annual cost of compliance**

	thousand $	
Engineering controls	861.0	From above
Other provisions	1,086.2	From above
TOTAL	1,947.2	

SOURCE: Summarized by Office of Technology Assessment from the preamble materials to the final rule prepared by OSHA's Office of Regulatory Analysis, 57 *Federal Register* 42235-42239, Sept. 14, 1992.

BOX 2-7: Economic Feasibility—OSHA's Approach To Determining It

Concept

New regulations ordinarily shift resources toward compliance goods and services and away from production activities. As part of its burden to demonstrate feasibility, OSHA must show that the costs and other economic consequences of such a redistribution will not threaten the existence or competitive structure of the affected industries.

Establishments may pass the costs of a new regulation through to their customers as increased product prices or absorb them in the form of reduced profits, or some combination of these two. In markets where customers have choices (say, for a substitute product or for the equivalent product of a competitor that may not face the same regulatory requirements), a noticeable increase in price can usually to be expected to result in a loss of product sales. Alternatively, lower profits may reduce the value of the industry's capital, firms operating at the margin may choose to exit the industry, and the desirability of new investment in the industry may be diminished.

Typically, the most important determinant of a regulated industry's pricing flexibility is demand elasticity, that is, the extent of change in demand for a product changes with increases (or decreases) in its price. Where demand is relatively inelastic, producers can increase prices without losing sales. But where demand is elastic, the opposite circumstance is true. Numerous factors influence demand elasticity, including the availability of a substitute product, the importance of the product in customers' budgets, the degree of customers' technological or contractual dependence on the product, and the relative importance of price and nonprice attributes of the product.

Analysis and Data

OSHA's examination concerns the financial and economic impacts of compliance, with particular attention to changes in prices and profits. But consideration is also given to the effects on industry output, competition, employment, and international trade.

A first look at feasibility is gleaned by examining the maximum potential impacts on prices and profits. This is quantified by calculating both the ratio of estimated compliance costs to the industry's current revenues, and the ratio of compliance costs to the industry's current (pre-tax) profits. The former ratio reflects the situation that would arise if demand is price inelastic and compliance costs are fully passed on to customers as increased product prices. The latter ratio reflects the situation where demand is price elastic and compliance costs are absorbed by the industry as reduced profits. In most cases, these ratios reflect extreme circumstances, with the likely reality lying somewhere between. But they provide a useful perspective on how large the price and profit effects might be if the worst impacts prevail.

The figures used for these comparisons are straightforward. The compliance cost estimates are the annualized figures discussed earlier. Data on the industry's annual revenue and profits (usually for the most recent year available) are drawn from a variety of sources, including from the U.S. Department of Commerce's *Annual Census of Manufactures* and the financial press (Dun & Bradstreet, DIALOGUE, Dow Jones, etc.). Financial data on individual companies, which may have been submitted to the rulemaking docket, are used also, but OSHA indicates its normal practice is to first verify such figures through comparison with published sources.

OSHA then combines these ratios with other, and often more qualitative, information on the dynamics of the industry—demand growth rates, apparent demand elasticity, competitive considerations (both domestic and international), etc.—to draw its overall conclusions about feasibility. Obviously, where the ratios alone suggest that compliance costs are a small share of both revenues and profits, there is little evidence of a threat to the industry's existence.

SOURCE: Summarized by Office of Technology Assessment from OSHA discussion materials; see also the preamble to the Cadmium Final Rule, 57 *Federal Register* 42265, 42326, Sept. 14, 1992.

BOX 2-8: An Illustration of OSHA's Economic Feasibility Determinations—1992 Cadmium Standard

Industry sector[a]	Estimated average annual cost, per affected establishment	Expected economic impacts and feasibility rationale[b]
Nickel-cadmium batteries 6 plants. 1,500 potentially exposed workers. Average exposure level is 73 µg/m^3 in "high" group, 14 µg/m^3 in "low" group. SECALs[c]	$324,500	The final version of the standard may impose palpable costs for this industry (including reduced profitability). But these effects should not be substantial, compared with the other forces already operating in the market. Demand for Ni-cad batteries is strong and growing, and a 1 percent increase in revenues would completely offset the compliance costs, without reduction in profits. But the prospects for recouping compliance costs by raising prices are limited—as foreign competition is strong and there appears already to be enough production capacity outside the United States to satisfy current global demand. The standard is not expected to yield overall changes in production or result in plant closures. But the consequences for new investment or job creation is unclear.
Zinc/cadmium refining 5 plants. 1,350 potentially exposed workers. Average exposure level is 91 µg/m^3 in "high" group, 6 µg/m^3 in "low" group. SECAL	$344,600	By 1989, the U.S. had gone from near self-sufficiency to a net import reliance of 62 percent—as the result of environmental regulation, labor costs, and other factors. Nonetheless, the effects of the revised cadmium standard would be completely overshadowed by the basic forces in this industry. Cadmium is a necessary by-product of zinc refining, and decisions about its production are not made independent of conditions in the zinc market—indeed, cadmium revenues are usually considered a credit (or negative cost) by zinc refiners. The incremental costs of the standard are only a small fraction of present revenues and return on equity. Cadmium refining operations are currently conducted with extensive use of respirators and would have to continue to do so with or without the revised standard. The incremental compliance costs would be a very minor factor in investment decisions and are unlikely to greatly influence the survival of the industry in the United States.
Cadmium pigments 4 plants. 100 potentially exposed workers. Average exposure level is 130 µg/m^3 in "high" group. 23 µg/m^3 "low" group. SECALs	$118,400	Cadmium pigments are more expensive than other types of pigments. But overall demand is relatively inelastic, because of superior coloring features and chemical properties. (However, U.S. and foreign environmental regulations currently provide incentives to substitute away from cadmium pigments. And where their unique properties are not essential, the use of cadmium pigments has been declining.) Imported pigments reportedly sell for 15 to 30 percent less than comparable domestic products, but U.S. producers have maintained their share (70 to 80 percent) of the market. Compliance with the new standard would increase production costs for U.S. producers, but the associated changes in prices and profits would be relatively small. These changes would be overshadowed by more fundamental industry forces—price changes in raw materials and labor, tighter environmental restrictions at home and abroad, changes in the basic pattern of demand.

(continued)

BOX 2-8: An Illustration of OSHA's Economic Feasibility Determinations—1992 Cadmium Standard (Cont'd.)

Industry sector[a]	Estimated average annual cost, per affected establishment	Expected economic impacts and feasibility rationale[b]
Dry color formulators 700 plants. 7,000 potentially exposed workers. Average exposure level is 10 µg/m^3.	$10,500	Cadmium pigments are essential in many applications, and thus demand is inelastic. Only a slight increase in prices is needed to recoup compliance costs, and these should not result in plant closures, generally threaten the viability of the formulator industry, or produce adverse impacts in other industries. However, compliance costs can be expected to vary among establishments, depending on the type of technology used and the extent of existing exposure controls. And competition may limit the ability of some producers to raise prices to fully offset these new costs.
Cadmium stabilizers 5 plants. 200 potentially exposed workers. Average exposure level is 116 µg/m^3 in "high" group, 3 µg/m^3 in "low" group. SECAL	$187,100	Demand is inelastic. The dominant, almost exclusive market for cadmium stabilizers is for the production of flexible PVC compounds—and the stabilizers themselves account for only a small share of the cost of the compound. No good substitutes currently exist for cadmium stabilizers, imports currently make up an insignificant fraction of domestic supply, and domestic suppliers have generally similar cost profiles. Manufacturers should be able to raise prices sufficiently to recover compliance costs without major reductions in profits or sales volumes. The new standard poses no apparent threats to the industry's viability or competitive stability, should not result in plant closures, and would have only negligible influence on new investment decisions.
Lead smelting/refining 4 plants. 400 potentially exposed workers. Average exposure level is 43 µg/m^3 in "high" group, 3 µg/m^3 in "low" group. SECAL	$70,700	Many of the requirements of the revised standard overlap existing requirements (e.g., for control of lead and arsenic exposures) and do not create new burdens. The compliance costs imposed represent only a modest increase in exposure control costs and a marginal expansion of employee protection programs already instituted. Lead smelters and refiners should be able to absorb these new compliance costs—about equivalent to one new employee—into operating expenses.
Cadmium plating 400 plants. 1,200 potentially exposed workers. Average exposure level is 35 µg/m^3 in "high" group, 2 µg/m^3 in "low" group. SECAL	$2,000	Over 90 percent of establishments in this industry are electroplaters, generally with low exposures that will require minimal or no additional expense to comply with the new standard. The costs of compliance are primarily concentrated in mechanical plating—the other 10 percent of establishments. But demand for this more expensive and specialized service is relatively inelastic and should not be significantly affected. A price increase of about 10 percent would be needed to offset the estimated compliance costs for these establishments. Nevertheless, the cost of plating components generally is only a small fraction of the cost of final products (such as automobiles), and an increase in the cost of plating would translate into only a small increase in final product cost. Most of the affected establishments are small businesses that may need technical assistance in complying.

(continued)

BOX 2-8: An Illustration of OSHA's Economic Feasibility Determinations—1992 Cadmium Standard (Cont'd.)

Industry sector[a]	Estimated average annual cost, per affected establishment	Expected economic impacts and feasibility rationale[b]
Electric utilities 4,000 plants. 37,000 potentially exposed workers. Average exposure level is 1 µg/m^3.	$600	Implementation of the new standard would not involve new programs or large changes in procedures. The employees affected are already covered by the existing standards for lead and arsenic. The expected compliance costs are vanishingly small in comparison with the industry's revenues and operating income. There will be no significant impact on electricity demand, prices, production, or installed generation capacity.
Iron & steel 120 plants. 40,000 potentially exposed workers. Average exposure level is 2 µg/m^3.	$13,700	The value of blast furnace and basic steel industry shipments in 1989 exceeded $64 billion; new capital expenditures exceeded over $3 billion. The prospects for continuing future profitability are strong. The industry is subject to environmental and other regulations that impose costs far greater than the costs of meeting the new cadmium standard. The new standard represents a minimal increase in total regulatory burden and involves provisions consistent with requirements imposed by existing regulations. The standard will not threaten the industry's existence, reduce its competitiveness, or cause its contraction.
Other general industry 50,000 plants. 365,570 potentially exposed workers. Average exposure levels for the 10 occupational classes range from 0.4 to 6.0 µg/m^3.	$3,200	The new standard affects only a small part of the workforce in these industries and a limited number of activities. The standard's probable effect will be mixed—a combination of increased prices and reduced profits in the affected industries. But the estimated compliance costs are quite small by comparison to overall revenues and profits and are unlikely to affect the viability of existing establishments. The overall effect—on prices, output, etc.—would be largely undetectable.
Construction 10,000 plants. 70,000 potentially exposed workers. Average exposure level is 0.5 µg/m^3.	$1,100	Compliance costs would be incurred on a per-project basis, varying according to the size of the project, but would generally not require large capital expenditures. These cost increases, estimated to be only about 2 percent of the industry's current revenues, would in most cases be passed through to customers.

SOURCE: Summarized by Office of Technology Assessment from U.S. Dept. of Labor/OSHA, Office of Regulatory Analysis, Final Cadmium Rule, 57 *Federal Register 42224-42330*, Sept. 14, 1992.

NOTES: [a]The rulemaking identified nearly 100 industries as subject to compliance requirements under the new standard. However, for purposes of this analysis these were grouped into the 11 sectors identified in the table. [b]Not shown here, but an essential consideration in the findings, are the ratios of estimated annual compliance costs to, first, annual revenues and, then, annual (before tax) profits that OSHA calculated for each industry. [c]The final rule specified a uniform TWA8 PEL of 5 µg/m^3. However, in 6 industries, where feasibility limits were judged to exist, so-called separate engineering control air limits (SECALs) were established, allowing employers to achieve the PEL through application of a wider number of control measures (e.g., personal respirators along with engineering and work practice controls).

To satisfy Regulatory Flexibility Act requirements, a similar analysis—one that distinguishes small establishments from the larger organizational entities in the industry—is performed. And, in keeping with the executive order mandate, there is generally some discussion of the

potential magnitude of the economic impacts expected to ripple through to the larger economy—for example, on the general level of prices, levels of employment in affected sectors, effects on trade and competitiveness, and so on.[15]

- *Assessment of "nonregulatory alternatives."* Finally, the agency's regulatory impact documents now routinely include a section discussing why the market itself or other non-governmental interventions have not provided, and are unlikely to provide, the level of workplace health and safety protections envisaged by the standard. This discussion responds to a stipulation of the executive order-mandated regulatory analysis process and a practical need to address the "Why regulate?" question.

IMPLEMENTATION

Principal responsibility for the conduct of the agency's control technology and regulatory analyses is vested in OSHA's Office of Regulatory Analysis (ORA), located in the agency's Directorate of Policy (see figure 2-1). Nonetheless, other agency offices also contribute; these include the Health Directorate and Safety Directorate, which often provide some analytic support to ORA on matters related to workplace exposures and control technologies; the Department of Labor's Office of Regulatory Economics and Economic Policy Analysis, which in the past has reviewed OSHA's regulatory analysis documents and provided technical advice on economic regulatory issues; and the Department of Labor's Office of the Solicitor, which extensively reviews OSHA's regulatory analyses, vis-à-vis compatibility with statutory requirements.

OSHA continues to rely substantially on outside contractors (usually, expert consultants or consulting firms with expertise variously in fields related to engineering, economics, and industrial health) to conduct the necessary regulatory analysis research.[16] OSHA has also sought to draw, where possible and relevant, on the expertise and research of other federal agencies, particularly that of the National Institute of Occupational Safety and Health (NIOSH).[17]

The physical production of the analyses of control technology and regulatory impacts varies by the specifics of rulemaking and the affected industries. Nonetheless, most draw on a wide variety of information sources[18] and are produced and completed through a process that evolves over the course of a rulemaking and is open to substantial external review and comment.

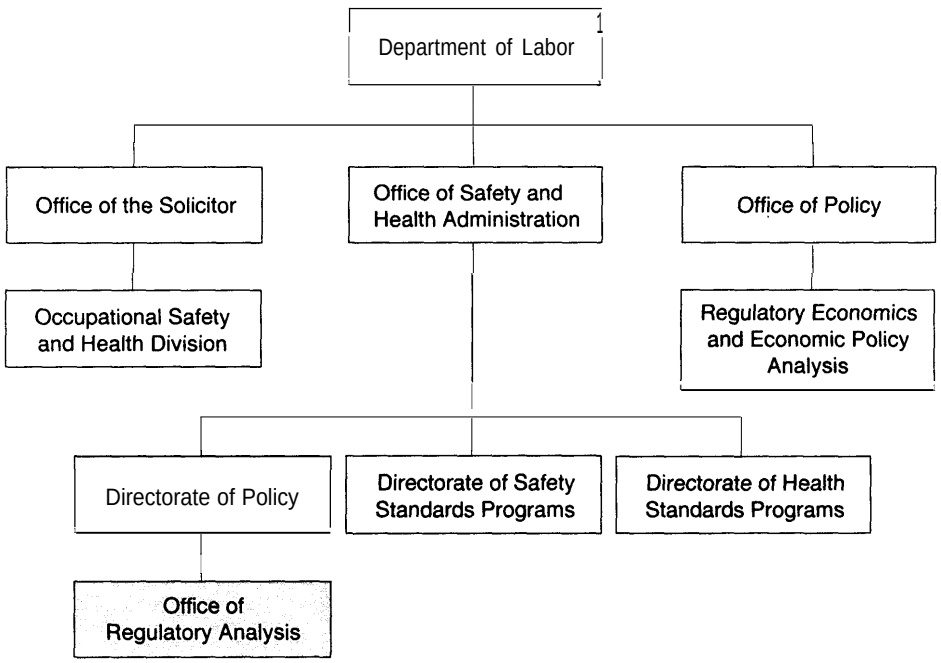
[15] Much of this kind of analysis has been performed by the agency on a more-or-less qualitative (though, nonetheless, informed) basis. However, the economic impact analysis for the 1978 cotton dust standard—which was anticipated, at least in the early stages of the rulemaking, to entail comparatively large compliance costs—did rely on simulations from a large-scale input/output model of the U.S. economy.

[16] Nonetheless, final responsibility for the content of a feasibility/regulatory impact analysis resides with OSHA. The preliminary version of the analysis report may well closely reflect the contractor's findings and conclusions. But the final version is usually substantially revised by OSHA—to reflect the opinions and data received from the hearings and comment period, any new analytical studies completed, and attendant changes in findings and conclusions.

[17] NIOSH is the principal federal agency with responsibility to conduct and disseminate research on occupational safety and health. NIOSH is formally a part of the Department of Health and Human Services. The staff is predominated by professionals with expertise in the areas of epidemiology, industrial hygiene, other health sciences, and engineering. NIOSH often makes recommendations to OSHA (in the form of "Criteria Documents" or other formal statements) concerning safety and health standards.

[18] As is perhaps apparent from the few illustrative examples provided in the chapter, the typical feasibility/impact assessment relies on and is documented through an extensive array of calculations, data points, and expert analytical judgments—documentation that in most cases defies brief summary. Generally, the kinds of information sources that play key roles include materials on health, safety, control engineering, and various economic matters published by the government, industry, and independent experts; field data from visits to selected establishments in affected industries and industry survey data (where available in the literature or from previous studies, or prepared specifically for the rulemaking by OSHA or interested parties); and expert judgments from various knowledgeable analysts.

FIGURE 2-1: Where OSHA's Regulatory Analysis Work is Conducted within the Department of Labor



SOURCE: Office of Technology Assessment, 1995.

Normally, a rulemaking is begun when OSHA issues an Advance Notice of Proposed Rulemaking (ANPR), inviting the submission of data, opinions, and other information (including that related to potential control options, compliance costs, and other regulatory impacts) from stakeholders and knowledgeable commentators.[19] In parallel with or soon thereafter, OSHA usually commissions one or more outside contractors (typically, consulting firms with expertise in the areas of economics, engineering, and industrial health or specialized knowledge about the affected industries) to prepare initial studies covering the full spectrum of the feasibility and regulatory impact issues just outlined. The agency then prepares a proposed standard and a preliminary regulatory impact/regulatory flexibility assessment reflecting these studies and the comments and other material available in the rulemaking record. Prior to publication, the agency is required to submit the proposed standard and the supporting regulatory impact analysis to OMB for review.

Subsequently, public hearings are held (usually announced in a Notice of Proposed Rulemaking, NOPR), wherein stakeholders, those with relevant expert knowledge, and other interested parties can comment and/or submit additional information related to the proposed content of the standard and the preliminary feasibility and regulatory impact findings. OSHA then uses these comments and other materials, along with any further studies/analyses that it may deem necessary, to resolve the final content

19 While an ANPR is the normative first step, **OSHA** does not always issue one. For example, the rulemaking leading **to** the 1992 cadmium health standard formally began in 1989, under a court-ordered deadline to quickly issue a proposed standard and move expeditiously to a final rule. Nonetheless, an ANPR is not the only way that preliminary opinions and information pertaining to a potential rulemaking can be gathered. In the cadmium case, the need for a standard had been a matter of consideration and debate by OSHA and the industrial health community since the early 1970s and much documented material already existed at the time the rulemaking commenced (see 57 ***Federal Register 42106,*** Sept. 14, 1992).

of the permanent standard and complete its regulatory impact/regulatory flexibility findings. The flow of these outside comments, recommendations, and new information (which can include new industry survey data or substantial technical analyses) is frequently quite heavy[20] and can lead to significant refinements and revisions in the OSHA's preliminary findings and policy decisions. Prior to publication, OSHA must again submit the final rule and the supporting regulatory impact analysis to OMB for review.

[20] Substantial comments and submissions from stakeholders, experts, and other interested parties in the many hundreds, if not the thousands (yielding many testimony transcript and other written pages) are typical for the agency's rulemakings. Some of these may be elaborate and detailed arguments—reflecting significant independent data collection and analysis—which take issue with OSHA's findings and determinations.