



Risk in Perspective

The Role of Significant Risk in OSHA Reform

"Without a significant-risk doctrine, the amount of protection provided by OSHA to workers at risk will not be maximized."

Congress is now considering reauthorization of the Occupational Safety and Health Administration (OSHA) in the U.S. Department of Labor. Among other duties, OSHA is responsible for promulgating permissible exposure limits (PELs) for chemicals that will protect workers from material impairment of health. An important issue that has been raised is the proper criteria to be used by OSHA in determining whether workers are exposed to "significant risk," thereby justifying some form of protective regulatory action. This issue of RISK IN PERSPECTIVE critically examines the development of OSHA's significant-risk doctrine and suggests factors that should be considered in refining the doctrine in new legislation.

In the 1970's, OSHA was criticized for misallocating its scarce resources toward regulation of slight risks while neglecting large risks. Critics argued that OSHA could accomplish more risk reduction for workers if the agency used quantitative risk assessment to allocate its scarce resources to reduction of significant risks.

The Supreme Court Intervenes

OSHA resisted adopting a significant-risk doctrine throughout the 1970's. In its proposed generic cancer policy of 1977, OSHA took the position that worker exposures to all carcinogens should be reduced to the lowest feasible levels, regardless of the size of the cancer risks faced by workers.

Why Focus on Significant Risks?

Although many workers are exposed to chemicals that have been shown to cause adverse health effects in humans and laboratory animals, OSHA has limited resources to devote to worker-protection rules. These scarce resources include OSHA's small team of scientists, engineers, and policy experts as well as OSHA's limited political capital. The technical resources of the National Institute for Occupational Safety and Health (NIOSH) are helpful to OSHA, but they are also quite modest in size. In the last fifteen years, the budgetary resources provided by Congress to OSHA and NIOSH have actually been reduced significantly. A recent report by the AFL-CIO documented how Congress has historically dedicated fewer resources to occupational health and safety than to environmental protection.

The key turning point was the Supreme Court's decision in the 1980 benzene case. A plurality of the Court, led by Justice John Paul Stevens, rejected OSHA's position, holding that OSHA must establish that an occupational risk is "significant" before taking steps to reduce or eliminate the risk. Later, in a landmark case involving worker exposure to cotton dust, a majority of the Supreme Court led by Justice William Brennan affirmed the significant-risk doctrine while rejecting a role for benefit-cost analysis in the setting of permissible exposure limits under the "feasibility" language of the Occupational Safety and Health Act of 1970.

In the benzene and cotton-dust cases, the Supreme Court indicated that it was OSHA's responsibility to develop criteria for determining which risks are significant, and then apply these criteria in the context of specific chemicals. The Court recognized that the determination of significant risk requires a mixture of scientific and policy judgments. In discussing the magnitude of worker risks, Justice Stevens opined that a reasonable person might regard a lifetime cancer risk of 1 in 1,000 as significant enough to justify risk-reduction activities yet regard a risk of 1 in 1,000,000,000 as trivial. In a concurring opinion, Justice Powell emphasized that significant risk

L. Green



John D. Graham
Center Director

L. Green



March Sadowitz
Research Specialist

In the current budgetary environment, dramatic increases in federal funding for occupational health are unlikely. Even if Congress were to increase by ten-fold or more the resources dedicated to occupational health and safety, OSHA and NIOSH would still not be able to eliminate all risks to workers from the thousands of chemicals used in commerce each day. Given the inevitability of scarce resources, it makes sense for OSHA and NIOSH to focus their energies on significant risks.

determinations are ultimately judgmental and should not be regarded as a "mathematical straightjacket."

Since 1981 the federal courts have taken seriously the significant-risk doctrine. For example, OSHA recently attempted to promulgate PELs for 428 chemicals in a single rulemaking. A federal court rejected this initiative, in part because OSHA had not made a significant-risk determination for each chemical.

In several rulemakings in the 1980's, OSHA began to fashion a significant-risk doctrine. Progress was slow because OSHA initiated few rulemakings, usually only after labor unions persuaded federal judges that OSHA was not addressing the needs for new permissible exposure limits for chemicals such as benzene, formaldehyde, and ethylene oxide. On the basis of several recent rulemakings, it appears that OSHA has established 1 in 1,000 as a numerical threshold for determining which lifetime cancer risks to workers are significant.

Although OSHA's choice of 1 in 1,000 as a benchmark of significant risk is based on Justice Stevens' opinion, it is not clear that the number has been applied in the manner that Stevens intended. While Stevens thought risks greater than 1 in 1,000 could reasonably be regarded as significant, he did not suggest that risks less than 1 in 1,000 are necessarily insignificant. Indeed, his only comment on insignificance was that a risk less than 1 in 1,000,000,000 would surely be regarded as insignificant. Stevens was silent about the significance of risks that fell between 1 in 1,000 and 1 in 1,000,000,000.

Factors Missing from OSHA's Significant-Risk Doctrine

As Congress considers refinements to the significant-risk doctrine, they should go beyond a simple numerical criterion and encourage OSHA to address several important scientific and policy considerations.

First, judgments about significant risk should reflect concern about the *size of the exposed population* as well as the magnitude of individual risk. An individual risk level of 1 in 10,000 might reasonably be considered insignificant by OSHA if 10 or fewer workers are exposed, but should certainly be considered significant if 1 million or more workers are exposed. While the affected workers might regard such risks as significant (regardless of their numbers), OSHA has a broad public health mission to pursue. Since the fixed costs of any agency rulemaking are substantial, OSHA's significant-risk doctrine should be refined to give some priority to occupational hazards that affect large numbers of workers.

Second, judgments about significant risk should take into account *the severity of the adverse health*

effect. A risk level of 1 in 1,000 might be regarded as significant when fatal cancer is the expected endpoint. The same probability of subtle immunological dysfunction might not be regarded as significant.

Finally, judgments about significant risk should take account of the *scientific quality of the evidence* used to calculate risk. For example, a risk level of 1 in 10,000 that is calculated based on observation of working populations might be regarded as significant since the scientific inference is well supported. In contrast, an estimated risk that is ten times larger (1 in 1,000) might be regarded as insignificant if it is based on extrapolation of tumor responses from one strain of rodents that has tested positive only at the maximum tolerated dose, especially if scientists believe that the mechanisms of tumor induction in rodents are unlikely to be applicable to humans. As risk assessment methods improve, it may ultimately be feasible to incorporate these scientific considerations directly into numerical estimates of risk.

Skeptics of the significant-risk doctrine may be concerned that a strong role for risk assessment at OSHA will produce "paralysis by analysis." It is important to remember, however, that the paralysis at OSHA observed in the 1980's was generated by a lack of political will to regulate, not by the inherent complexity of risk assessment. As the political will to protect workers through regulation is rejuvenated, it will become increasingly important that OSHA's resources are targeted at the most significant risks.

Conclusion

A strong case can be made that the scientific and financial resources available to OSHA and NIOSH should be expanded considerably. Yet even if more resources are provided, it will still be necessary and appropriate for OSHA to implement a serious significant-risk doctrine. Without a significant-risk doctrine, the amount of protection provided by OSHA to workers at risk will not be maximized.

When Congress works to reauthorize the Occupational Safety and Health Act, it should give consideration to refining the significant-risk doctrine espoused originally by Justice John Paul Stevens in 1980. A sound significant-risk doctrine would call for OSHA to make explicit policy judgments based on consideration of key factors stipulated by the Congress. It seems reasonable that these factors should include the level of risk to the exposed worker, the severity of the adverse health effects of concern, the size of the exposed population of workers, and the quality of the scientific inference about risk. The explicitness of the criteria for determining significant risk will facilitate public participation, congressional oversight, and judicial review.

Harvard Center for
Risk Analysis
Harvard School of
Public Health
718 Huntington Avenue
Boston, Massachusetts
02115

617 432-4497



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Further Reading

Alon Rosenthal, George M. Gray, and John D. Graham, "Legislating Acceptable Cancer Risk from Exposure to Toxic Chemicals," *Ecology Law Quarterly*, vol. 19, pp. 269-363, 1992.

John D. Graham, Laura C. Green, Marc J. Roberts, *In Search of Safety: Chemicals and Cancer Risk*, Harvard University Press, Cambridge, MA, 1990.

Peer Reviewers

Milton C. Weinstein, Ph.D.
George M. Gray, Ph.D.