



Risk in Perspective

OSHA's Program for Updating the Permissible Exposure Limits (PELs): Can Risk Assessment Help "Move the Ball Forward?"

It is time to put a science-based approach to worker protection ahead of "politics as usual."



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In February 1996, the Occupational Safety and Health Administration (OSHA) proposed to establish an ongoing mechanism for updating Permissible Exposure Limits (PELs), the legal limits on the concentration of industrial chemicals allowable in the air of American workplaces. This, in and of itself, would not have generated much interest but for the fact that virtually all occupational health professionals are convinced that many PELs are outdated. Perhaps as many as 400 of the current 630 PELs deserve revision while another 200 new chemicals warrant being added to the list. Due to this state of affairs, not all American workers have enjoyed the level of protection against airborne contaminants that was intended by those who in 1970 wrote and shepherded the Occupational Safety and Health Act.

Fortunately, it appears that the "planets may now be aligned" such that labor, industry, and OSHA may be able to work together to resolve this issue. Health professionals have had nearly twenty years of experience in refining the craft of health risk assessment and thus it is now feasible to bring together science, regulatory policy, and fiscal reasonableness in a sound plan.

This issue of **RISK IN PERSPECTIVE** describes the historical backdrop regarding the origin of the PELs, why they have been "frozen in time," and how OSHA can use health risk assessment tools to establish a lasting program for adjusting these limits in response to important advances in scientific information. Some of the impediments to initiating this program and a few radically different alternative approaches are discussed. Lastly, some of the challenges that

OSHA might face as it attempts to adopt some of the advice that has been offered in a few recent major risk assessment guidance documents are discussed.

The Origins of PELs

In 1970 OSHA created the first PELs by adopting the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs)®, as allowed by Congress, and health professionals applauded the Agency for putting "teeth" into what were previously only recommendations to the regulated community. At the time, it was expected that the PELs would be routinely and regularly updated as new toxicological and epidemiological information became available. To the surprise of many, few PELs have been updated over the past 25 years and those that have been changed have often involved a time consuming, costly, and litigious fight between the regulated community, the Agency, and organized labor. For example, by 1988 only 13 rules for 26 hazardous substances had been promulgated.

Recognizing that its PELs were significantly outdated, in 1988 OSHA proposed to change 420 of them. The subsequent PELs, promulgated in 1989, were based on recent scientific information and all but one of them was lowered (i.e., made more strict). However, legal challenges to the standard by numerous labor and industry groups were heard in the Eleventh Circuit Court of Appeals in 1992 and the Court overturned OSHA's PELs. The court indicated OSHA should perform quantitative analyses of risk for non-cancer endpoints (where possible), offer more extensive discussion of the

health evidence for each substance, and prepare more careful feasibility analyses of the new PELs. Consequently, the Agency was obligated to revert back to enforcing the limits established in the early 1970s. However, states retain the right to maintain or promulgate lower limits.

OSHA'S New PROPOSAL

In July 1995, OSHA indicated that it sought to establish an ongoing mechanism for updating the PELs and solicited ideas from stakeholders about the criteria to be used by OSHA when selecting chemicals as targets for new PELs. In February 1996, the Agency published a specific list of substances that it was slating for rulemaking. In that notice, OSHA also announced that a public meeting would be held so that interested stakeholders could participate in the process by submitting oral and/or written comments. OSHA, and its Director of Health Standards, Dr. Adam Finkel, were generally applauded for offering all parties the opportunity to do "what makes sense" (e.g., establish PELs which are consistent with current scientific knowledge). After all, the 1968 TLVs were generally based on toxicological data collected before 1965; in contrast, the vast majority of toxicological and epidemiological studies that would form the basis for PELs have been conducted since then.

OSHA identified twenty different chemicals as candidates for rulemaking (see Table I). It indicated that the chemicals selected were based on six criteria: the inherent toxicity of the substance, the number of workers exposed or the amount produced, uses or prevailing exposure levels, the severity of the adverse effect, the availability of information needed to conduct a thorough risk assessment, and the potential for risk reduction. The Agency also noted that "administrative consideration and professional judgment were also factored into the decision making." The Agency stated that although the chemicals were selected "on the basis of relatively objective criteria," it was not to be concluded that these were the only chemicals which required new PELs or that these were necessarily the highest-risk substances.

In that notice, OSHA also requested comments from the public on several risk

assessment issues: (1) the appropriateness of relying on maximum likelihood estimates or other statistical approaches to estimating the potency of cancer-causing substances, (2) procedures to address variations in human susceptibility to a toxicant's effects, (3) the proper selection of interspecies scaling factors, and (4) criteria for evaluating the adequacy of data for conducting physiologically-based pharmacokinetic modeling. All these topics have been debated for many years, not only within OSHA but at EPA, FDA and, to a lesser degree, CPSC.

The Agency also requested comments on approaches to setting exposure limits for non-carcinogens. OSHA noted that historically the "safety-factor" approach had been used but that the "benchmark dose" method had gained sufficient recognition to justify consideration. OSHA did not appear to support one approach over the other, but acknowledged that it was time to deal squarely with the scientific issues surrounding the quantitative evaluation of the possible risks of exposure to non-carcinogens in the workplace.

On a more policy-related issue, the Agency requested comments on "the determination of significant risk." That is, how might OSHA differentiate those risks which are plainly acceptable from others which are clearly unacceptable? It noted that, heretofore, predicted lifetime fatality risks higher than 1 in 1,000 were often considered to be significant, even though many PELs for carcinogens appeared to pose risks as great as 1 in 100, while those as small as 1 in 10,000,000 were always accepted to be negligible. Apparently, the main reason OSHA raised this issue was not because of its concern about the cancer risks predicted by various low-dose models, but rather because it was curious about the proper risk criteria to adopt for the non-cancer endpoints (e.g., incidence of 1 in 1,000 for marginal liver toxicity or eye irritation).

The Agency also requested comments on its first list of substances to be regulated, an issue that proved to be quite controversial.

STAKEHOLDER CONCERNS

In late February 1996, OSHA held a public meeting in Washington to discuss its proposal. What occurred was alarming to

many occupational health professionals yet it may be characteristic of the journey that agencies will take when they involve stakeholders in the rulemaking process. The surprise was that in spite of the fact that virtually every organization that presented testimony to the Agency claimed that the PELs needed to be updated, not one group was completely supportive of OSHA's proposal! Further, no group offered an alternative approach. For those who have embraced the lofty and perhaps idealistic suggestions of the recent report of the Commission on Risk Assessment and Risk Management, it probably represented a sobering reminder of the difficulties of bridging the gulf between groups with conflicting agendas. The concerns of the various stakeholders can be grouped into seven themes.

First, they wanted to know why certain chemicals were on the initial list of twenty and others were not. In particular, although the regulated community was not necessarily dissatisfied with the selection criteria, they wanted to understand the exact methodology and specific parameters used in the ranking formula.

Second, concern was expressed that stakeholders had not been brought into the process prior to assembling the list and that this was contrary to many of the recent recommendations of the National Academy of Sciences and other scientific bodies involved with risk assessment. Although agencies are just now learning to what lengths they are expected to go to identify and involve stakeholders, it would appear that OSHA probably met much of its obligation when it asked for input in its July 1995 announcement in the *Federal Register*.

Third, specific industries questioned the rationale for having "their" chemicals on the initial OSHA list. They generally claimed that the Agency was unaware that current levels of occupational exposure to their particular chemicals were quite low, thus not deserving attention, or they expressed a view that another chemical (which was typically not one of commercial interest to them) should have been first placed on the list.

Fourth, other stakeholders claimed that the Agency had failed to consider the technical

feasibility of meeting lower exposure levels for the major users of the listed chemicals. Although it was probably premature for OSHA to consider this issue, the dry cleaning industry offered one view which illustrated its concern. Specifically, it claimed that workplace risk reduction would be more cost-effective from the standpoint of engineering controls if OSHA had chosen a chemical like ethylene dichloride (EDC), rather than perchloroethylene (PCE), which is used in thousands of small businesses. The rationale was that only a handful of sources emitted huge amounts of EDC and that the cost of reducing these emissions was negligible compared with trying to control 30,000 or more small dry cleaning establishments.

Fifth, scientists within the regulated community expressed concern that OSHA had not put sufficient weight on recent biological or epidemiological data when establishing its list of twenty chemicals. It was claimed that if OSHA had considered these issues, then several chemicals on the list would no longer be considered a significant risk at the concentrations found in most workplaces.

Sixth, it was claimed that workers would be better served to have chemicals which were not currently regulated by OSHA to be the highest priority. For example, there are more than 200 chemicals for which there are TLVs but no PELs. Worse yet, there are another 300 or more chemicals routinely found in commerce for which there is no guidance.

Lastly, the view was expressed that even though stakeholders need to be involved in the "standard-setting process," their involvement should not be a license or opportunity to stall the regulatory process. Specifically, organized labor expressed concern that arguments about which 20 chemicals should or should not be the first to be tackled could last for years and that the fact that nearly 500 PELs needed revision could be easily forgotten during protracted discussions!

WHERE DO WE GO FROM HERE?

It is not surprising that when OSHA "opened its door," a large number of comments were received. Undoubtedly, some of

these were positive, while others were critical of the process. Nonetheless, history has shown that, in the main, this iterative process of proposal, critique, compromise, and revision produces a better and more effective approach. Because no group has yet objected to the need for the initiative, the challenge now facing OSHA is "how can we move the ball forward?"

It seems that two major options are available; work with stakeholders to strengthen the existing proposal or attempt a completely different approach. If the proposed approach is to be pursued, the tool of health risk assessment needs to be the cornerstone upon which it is built. Since the courts have indicated that risk assessment should be a tool that is used to help guide us toward promulgating "measured and reasonable" regulations, it is clear that some of the lessons learned over the past twenty years need to be incorporated into the process.

The four reports or guidance documents which OSHA undoubtedly evaluated when it developed its proposal include *Science and Judgment in Risk Assessment* by the National Research Council, the draft report of the Commission on Risk Assessment and Risk Management under the Clean Air Act, *Understanding Risk: Informing Decisions in a Democratic Society* by the National Research Council, and EPA's *Draft Guidelines for Carcinogen Risk Assessment*. All of them contain common threads which support OSHA's conceptual approach. For example, each document places emphasis on a) moving away from default options in risk assessment (where feasible), b) insuring that policy judgments do not constrain the ability of scientific information to inform decision making, and c) insuring that stakeholders have ample opportunity to participate in the process. Consistent with the suggestions embodied in these reports, and in an attempt to prevent gridlock, OSHA might consider adopting some of the following ideas in response to the public's comments:

First, right or wrong, it is clear that the stakeholders perceived that they had not been adequately involved in developing the process by which OSHA planned to revise the PELs. The Agency should consider holding one or two workshops with repre-

sentatives of the labor unions, trade associations, and other stakeholders to carefully dissect its current proposal, discuss others, and identify the preferred path. If these parties carefully assess the other possible approaches, as described in the following section of this text, it is possible that they will conclude that OSHA's current proposal may be more reasonable than originally perceived.

Second, the prospect of a "list" of chemicals seems to bother everyone. To some extent, there is a general mistrust of any process wherein a certain chemical is targeted for regulation while another is not. One way to prevent this from being the focus of attack would be to drop the list entirely. Instead, the Agency might present a generic formula for different toxicological effects for calculating "preliminary" PELs for various classes of chemicals (e.g., carcinogens, irritants, and CNS depressants). Then, when consensus is reached on the formulae, the information on the various chemicals need only be put in to the "master equations," which would yield a comprehensive list of PELs for hundreds of chemicals. Following generation of such a list, OSHA would then need to resolve its statutory requirements for cost-effectiveness and technical feasibility.

Third, the lack of transparency in OSHA's process for selecting the initial chemicals reinforced the perception that some special interest groups were more effective than others in preventing their chemicals from "getting listed." This issue needs to be hit "head on" by the Agency. There seems no better way than to share publicly the data and analyses that supported the Agency's proposal. OSHA should then encourage technical comments on this information. After having assembled up-to-date information that is "more or less" accepted by stakeholders, the Agency should then publish several different algorithms for establishing a priority list. This list would subsequently be shared in the *Federal Register* with the initial list of "pilot chemicals."

Fourth, the "cat and mouse" atmosphere that pervades regulatory initiatives requires that OSHA describe the scientific approach it plans to use to quantify risk for both the cancer and non-cancer causing agents; otherwise, the process could result in gridlock.

