

SETTING OCCUPATIONAL EXPOSURE LIMITS: ARE WE LIVING IN A POST-OEL WORLD?

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Setting limits for safe exposure to toxic agents in the workplace is a complex process involving science, law, and policy. Development and use of occupational exposure limits (OELs) transcends national interests and international borders. Even though OELs have a lengthy history, and they form the cornerstone of most occupational risk assessment and risk management plans, their effectiveness in protecting worker health is increasingly being questioned.

To better understand the current state of the OEL-setting process both in the United States and internationally, we need to understand what OELs are; how they are used in the workplace; how OELs are developed and why there are so many different OEL-setting entities; how often they are updated; whether OELs are effective; and whether there are newer approaches which are more effective in protecting worker health than traditional ones that use OELs.

I. OCCUPATIONAL EXPOSURE LIMITS

The concept of OELs dates back to 1886 when Germany became the first country to introduce them to aid in the assessment and management of risks posed by the new industrial workplace.¹ In the intervening 119 years, the processes for developing, setting, and using OELs have become widespread throughout the developed world. Despite their prominent historical status, the process of developing and setting OELs has been criticized as overly complex and excessively lengthy.² And questions have

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1. D. Henschler, *The Concept of Occupational Exposure Limits*, 101 SCI. TOTAL ENV'T. 9, 9-16 (1991).

2. JOHN MENDELOFF, *THE DILEMMA OF TOXIC SUBSTANCE REGULATION: HOW OVERREGULATION CAUSES UNDERREGULATION* 134 (1988).

been raised about how many industrial end users actually utilize OELs.³

Generally speaking, an occupational exposure limit represents the concentration of a toxic agent above which it is not safe for a worker to be exposed. Said another way, OELs are representations by the OEL-setting body that no scientific evidence exists to suggest exposure to a toxic agent will be injurious to workers if they are exposed to the agent at levels below the OEL for their working life.⁴

A. *Functional Categories*

Four functional types of OELs exist, which, depending on the OEL-setting entity that developed the OEL, are referred to by different names.

1. Daily Exposure Limit

The most common type of OEL describes a time-weighted average (TWA) concentration measured over an average workday, i.e., eight to ten hours. Measured on a daily basis, this type of OEL is designed to protect workers against the adverse health effects arising from exposure to a toxic agent over a worker's working life, i.e., thirty to forty years.

2. Short-term Exposure Limit

A second type of OEL is a short-term exposure limit (STEL). A STEL—often a fifteen-minute TWA concentration—is designed to protect workers against the adverse health effects arising from exposure to an agent that can harm a worker quickly.⁵

3. Ceiling Exposure Limit

A ceiling OEL is a concentration of a toxic agent that should not be exceeded at any time during the workday. A TWA and a STEL do permit limited excursions above their limits if the average over their specific time frame (eight to ten hours for a TWA limit or fifteen minutes for a STEL) is

3. M.D. Topping et al., *Industry's Perception and Use of Occupational Exposure Limits*, 42 ANNALS OF OCCUPATIONAL HYGIENE 357, 360–61 (1998). In this study, where 1000 users of chemicals were interviewed, the results showed that in making decisions on what control measures to use most users rely heavily on information from manufacturers and suppliers as opposed to OEL information from OEL-setting entities. *Id.*

4. Dennis J. Paustenbach, *Occupational Exposure Limits*, in ENCYCLOPEDIA OF OCCUPATIONAL SAFETY AND HEALTH 30.27, 30.30 (Jeanne Mager Stellman ed., 4th ed. 1998).

5. Gordon C. Miller & Dennis R. Klonne, *Occupational Exposure Limits*, in THE OCCUPATIONAL ENVIRONMENT 21, 24 (Salvatore R. DiNardi ed., 1997).

below the exposure limit.⁶ In contrast, a ceiling value should never be exceeded at any time.

4. Emergency Chemical Exposure Limit

A fourth type of exposure limit is called an IDLH value. An IDLH value refers to a condition which is “immediately dangerous to life or health.” IDLH values are set by the National Institute for Occupational Safety and Health (NIOSH), a component program of the Centers for Disease Control and Prevention in the United States Department of Health and Human Services. IDLH values are airborne concentrations which may cause lethal, permanent, or escape-impairing effects via inhalation or ocular exposure.⁷ The chief purpose of establishing an IDLH exposure concentration is to ensure that the worker can successfully escape a situation in the event that failure of the worker’s respiratory equipment occurs.

B. Legal Categories

From a legal perspective, OELs can be divided into two major classes. First, there are OELs that create no legal duties with which an employer must comply. These OELs represent recommendations only. In the United States, both a governmental agency, NIOSH, and a non-governmental professional membership entity, the American Conference of Governmental Industrial Hygienists (ACGIH), establish the majority of OELs that fall into the recommended OEL category.⁸

Examples of these recommended OELs are (1) a recommended exposure limit, or REL, established by NIOSH,⁹ and (2) a threshold limit value, or TLV, established by the ACGIH.¹⁰ Other examples of recommended OELs include Workplace Environmental Exposure Levels (WEELs) which are established by the American Industrial Hygiene Association (AIHA), for chemicals “when no legal or authoritative limits exist.”¹¹ In the absence of authoritative recommended OELs, various

6. *Id.*

7. NAT’L INST. FOR OCCUPATIONAL SAFETY AND HEALTH, DEP’T OF HEALTH AND HUMAN SERVS., DOCUMENTATION FOR IMMEDIATELY DANGEROUS TO LIFE OR HEALTH CONCENTRATIONS (1994), available at <http://www.cdc.gov/niosh/idlh/idlh-1.html>.

8. Miller & Klonne, *supra* note 5, at 26.

9. NAT’L INST. FOR OCCUPATIONAL SAFETY AND HEALTH, DEP’T OF HEALTH AND HUMAN SERVS., NIOSH POCKET GUIDE TO CHEMICAL HAZARDS (2003).

10. AM. CONFERENCE OF GOVERNMENTAL INDUS. HYGIENISTS, STATEMENT OF POSITION REGARDING THE TLVS AND BEIS (2002), available at <http://www.acgih.org/TLV/PosStmnt.htm>.

11. AM. INDUS. HYGIENE ASS’N, WORKPLACE ENVIRONMENTAL EXPOSURE LEVELS

industry groups often establish their own OELs.¹²

Second, there are those OELs which, by virtue of their adoption under the rulemaking authority of the Occupational Safety and Health Act (OSH Act) of 1970¹³ by the Occupational Safety and Health Administration (OSHA), or under the authority of the Mine Safety and Health Act (MSH Act) of 1977¹⁴ by the Mine Safety and Health Administration (MSHA)—both agencies of the U.S. Department of Labor—are legally binding on a covered employer. Even though these legally enforceable OELs may represent the exact numerical value as that of their recommended OEL counterparts, their names change to connote their new legal status. A NIOSH REL, or an ACGIH TLV, becomes a permissible exposure limit (PEL) when adopted by OSHA or MSHA.

II. PURPOSE

Whether recommended or mandatory, it is important to keep in mind that an OEL is a means to an end, and not an end in itself. The end is the prevention of work-related injury and illness.

As tools to achieve injury and illness reduction in American workplaces, OELs are used to (1) convey information to both employers and workers about the occupational health risks of work-related exposures; (2) provide guidance to occupational safety and health professionals (e.g., industrial hygienists, occupational physicians, and safety engineers) tasked with creating working environments in which workers' health is protected from the harm that excessive exposure to toxic agents can cause; (3) aid in the determination of which respirator should be selected to protect against a particular workplace chemical hazard;¹⁵ and (4) serve as a legally enforceable requirement under the OSH and MSH Acts.¹⁶

As legally enforceable requirements, employers' compliance with

COMMITTEE (2002), available at <http://www.aiha.org/Committees/html/weelcom.htm>.

12. Dennis Paustenbach & R. Langner, *Corporate Occupational Exposure Limits: The Current State of Affairs*, 47 AM. J. OF INDUS. HYGIENE 806, 810–11 (1986).

13. Williams-Steiger Occupational Safety and Health Act of 1970, 29 U.S.C. §§ 651–678 (2000).

14. Mine Safety and Health Act of 1977, 30 U.S.C. §§ 801–962 (2000).

15. An OEL can be useful in the selection of appropriate respiratory protection. For example, by dividing the expected exposure concentration of a chemical or physical agent by the OEL, one can determine the minimum Assigned Protection Factor (APF) a respirator must have in order to provide adequate protection. See 29 C.F.R. § 1910.134.

16. Sec. 654(a)(2) of the Occupational Safety and Health Act states that “each employer . . . shall comply with occupational safety and health standards promulgated under this [OSH] Act,” 29 U.S.C. § 651 et seq. (2005); and 30 U.S.C. § 803 (2005) states that the Federal Mine Safety and Health Act of 1977 applies to “[e]ach coal or other mine, the products of which enter commerce, or the operations or products of which affect commerce, and each operator of such mine.”

PELs is assessed by regulatory agencies like OSHA and MSHA during enforcement inspections. If a compliance officer finds levels of a toxic agent in excess of the PEL, an employer can be issued a citation carrying a civil penalty under either the OSH or the MSH Acts.

Aside from the use of mandatory OELs by government, occupational safety and health professionals use both mandatory and recommended OELs as risk assessment and risk management tools. Most safety and health professionals would say that OELs have successfully served as primary tools in workplace disease prevention for over fifty years and are an essential part of any firm's risk management framework. However, these same professionals admit that only a small number of substances have an OEL and the governmental OEL-setting process is inefficient. Increasingly, professionals have to make risk assessment and risk management decisions without the benefit of OEL-specific guidance from governmental sources.

III. OEL-SETTING PROCESS

In the United States, NIOSH and ACGIH set the majority of recommended OELs and OSHA and MSHA are the only mandatory OEL-setting bodies.

A. *Mechanics of OEL-Setting*

The mechanics of adopting a non-mandatory OEL depends on the procedures internal to the adopting entity. Several national and international OEL-setting organizations, such as the American National Standards Institute (ANSI) and the International Standards Organization (ISO), utilize a process of seeking *consensus* before establishing their recommended OELs. A consensus standards process involves canvassing the opinions, views, and positions of all interested parties and then developing a position that is acceptable to each of the parties. Often, information concerning the economic or technical feasibility of a particular OEL value is taken into consideration—either explicitly or implicitly—during a consensus-building process.

In contrast, NIOSH's RELs and ACGIH's TLVs are not consensus standards. In fact, a TLV represents "health-based values . . . established by [professional] committees that review existing published and peer-reviewed literature in various scientific disciplines (e.g., industrial hygiene, toxicology, occupational medicine, and epidemiology)."¹⁷ No attempt is made to achieve a balance of interests on ACGIH OEL-setting committees,

17. AM. CONFERENCE OF GOVERNMENTAL INDUS. HYGIENISTS, *supra* note 10.

nor is transparency a value in the ACGIH OEL-setting process.

NIOSH sets forth its RELs by using a weight of evidence standard based on health effects and technical feasibility. NIOSH communicates RELs through criteria documents or current intelligence bulletins and makes its recommendations available to OSHA for their consideration in setting PELs. The NIOSH REL-setting process includes formal peer review of the underlying science, involves notification to interested parties of the development of a REL, invites interested parties to submit data for review, and, on occasion, invites public comment.

PELs are developed under section 6 of the OSH Act for non-mining workplaces¹⁸ and under section 101 of the MSH Act for mining establishments.¹⁹ The process of mandatory OEL-setting that OSHA is required to utilize is cumbersome. Like the character of Jacob Marley in Charles Dickens' *A Christmas Carol*,²⁰ section 6, when utilized by OSHA to establish a new PEL, drags along the legal and administrative chains added to the original statutory PEL-adopting process over the nearly thirty-five years since the OSH Act was enacted.

Like Marley's chains, accumulated U.S. Supreme Court and Court of Appeals' opinions,²¹ Executive Order 12,866²² and others, regulatory impact requirements,²³ Paperwork Reduction Act requirements,²⁴ Regulatory Flexibility Act requirements (as amended by the Small Business Regulatory Enforcement Fairness Act),²⁵ executive branch memoranda on plain language, U.S. Administrative Procedures Act requirements,²⁶ and the recent Information Quality Act requirements,²⁷

18. 29 U.S.C. § 655 (2000).

19. 30 U.S.C. § 811(a)(6)(A) (2000) (authorizing Secretary of Labor to promulgate health standards "dealing with toxic materials or harmful physical agents" in order to protect miners from any "material impairment of health or functional capacity. . .").

20. CHARLES DICKENS, *A CHRISTMAS CAROL* 35-40 (Gramercy Publishers 1990) (1843).

21. See, e.g., *Indus. Union Dep't, v. Amer. Petroleum Inst.*, 448 U.S. 607, 662 (1980) (weighing the appropriateness of a standard OSHA established); *Am. Textile Mfrs. Inst. v. Donovan*, 452 U.S. 490 (1981).

22. Exec. Order No. 12,866, 58 Fed. Reg. 51735 (Sept. 30, 1993). Issued in 1993 by President Clinton, Executive Order 12,866 specifies in section 1(b)(7) that "[e]ach agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation."

23. Exec. Order No. 12,291, 46 Fed. Reg. 13,193 (Feb. 19, 1981) requires that a regulatory impact analysis be conducted for any rule having major economic consequences on the national economy, individual industries, geographical regions, or levels of government. Similarly, the Regulatory Flexibility Act, 5 U.S.C. §§ 601-612 (2000), requires the OSHA to consider the impact of the regulation on small entities.

24. 44 U.S.C. §§ 3501-3520 (2000).

25. 5 U.S.C. §§ 601-612 (2000).

26. 5 U.S.C. §§ 551-559 (2000).

27. 44 U.S.C. §§ 3516-3520 (2000).

clank and rattle as every PEL rulemaking proceeds through its decade-long developmental cycle. Recently, additional requirements to the OEL-setting process have been developed to ensure peer review of the science underlying each PEL.²⁸

Aside from any discussion of what value these post-1970 section 6 judicial and administrative requirements add to OSHA's ultimate PEL rulemaking product (which is usually a contentious one), there is general agreement that these rulemaking requirements certainly do add *time* to the PEL-setting process and have frustrated the statutory purpose of section 6 of the OSH Act. Frustration over the perceived excessive time delays in setting a particular PEL, or in OSHA's refusal to begin the process of setting a particular PEL, has led some rulemaking petitioners to utilize the U.S. Administrative Procedures Act itself to sue OSHA over its failure to act on a petitioner's request to adopt a particular PEL and to compel OSHA to set a PEL.²⁹ In fact, a PEL for hexavalent chromium is being developed by OSHA now as a result of an order by the U.S. Court of Appeals for the Third Circuit in such a "failure-to-act" lawsuit.³⁰ Even so, a judicially-mandated PEL does not protect it from being challenged after it is promulgated.³¹

B. OEL-Setting Entities

Developed countries have OELs that they establish through their own national entities or that they adopt from another country's OEL-setting entity. Internationally, there are many OEL-setting bodies. As in the United States, some OEL-setting bodies are governmental, some are private sector voluntary consensus standard bodies, and others are specific industry organizations.

The problem with having so many OEL-setting entities throughout the world is that different OEL-setting bodies often establish slightly different exposure limits for an identical toxic agent. Since the scientific and technical methodologies used to set exposure limits may differ from one entity to another, harmonizing the different exposure values is a challenge that has yet to be met internationally. When adopted into law by various national jurisdictions, slight variations in exposure limits can cause enormous confusion and economic inefficiencies among multi-national

28. Final Information Quality Bulletin for Peer Review, 70 Fed. Reg. 2664 (Jan. 14, 2005).

29. OCCUPATIONAL SAFETY AND HEALTH LAW 479-81 (Randy S. Rabinowitz ed., 2nd ed. 2002) (discussing cases filed against OSHA based on unreasonable delay in promulgating standards).

30. See *Pub. Citizen Health Research Group v. Sec'y of Labor*, 314 F.3d 143, 158-59 (3rd Cir. 2002).

31. 29 U.S.C. § 655(f) (2000).

companies who are trying to comply with differing mandatory OELs. Even companies doing business solely in the United States, but in different states, can have difficulties in complying with differing OELs across differing state jurisdictions.³²

The existence of multiple OEL-setting entities may lead to disparities in worker protection from one country to another. These disparities across OEL-setting organizations can be eliminated, but only with strong international collaborations. Harmonizing the scientific methodologies used in developing an OEL, including using the same approaches for interspecies extrapolation, specifying the type of data to be used as the basis of the OEL determination, and making any uncertainties inherent in the OEL calculation transparent, are generally viewed as ways to make the OEL-setting process more uniform from country to country.

Why are there so many OEL-setting bodies throughout the world? The answer may be related to the persistence of the historical *nationalism* paradigm in occupational safety and health that has not yet been supplanted by a *global* paradigm. The phenomenon of an increasingly number of firms doing business in multiple countries is a recent one compared to the history of the OEL-setting bodies. The pressures associated with national economies becoming increasingly integrated may force the nation-based OEL-setting process to become more integrated also.

One can see such efforts developing on a regional basis. For example, the Nordic Expert Group for Documentation of Occupational Exposure Limits has been collaborating since 1977.³³ The documents generated by the Nordic Expert Group are used by five Scandinavian national regulatory authorities as a common scientific basis for setting national OELs. NIOSH has participated in the Nordic Expert Effort since the early 1980s. The Nordic Expert Group's work over the past twenty-five years suggests that scientific risk assessment can indeed be performed on an international basis.

The Nordic collaborative experience has also set an example for the United Nations to form the International Programme on Chemical Safety (IPCS) among the World Health Organization, the United Nations Environment Programme, and the International Labor Organization.³⁴ The IPCS began the process of development Concise International Chemical Assessment Documents (CICADs), which can provide the basis for true

32. State plans play a significant role in OEL-setting. Of the fifty-six jurisdictions eligible to submit state plans, twenty-six states have done so, and their plans cover forty percent of the nation's workforce. See 29 U.S.C. § 667 (2000) (addressing state plans).

33. Per Lundberg, *The Nordic Expert Group, An Inter-Nordic Project for Assessment of Occupational Risks*, 101 SCI. TOTAL ENV'T. 17, 18-20 (1991).

34. See INT'L PROGRAMME ON CHEM. SAFETY, CHEMICAL SAFETY INFORMATION FROM INTERGOVERNMENTAL ORGANIZATIONS, available at <http://www.inchem.org> (last visited Apr. 19, 2005).

international OEL-setting.³⁵

IV. HOW OFTEN ARE OELS UPDATED?

In the United States, the pace of updating recommended OELs differs from that of updating legally enforceable PELs. The ACGIH amends its List of Threshold Limit Values for Chemical Substances annually, but the process of adopting a new, or revising an existing, threshold limit value can take at least two years. NIOSH updates its RELs periodically depending on resource availability. Internationally, some OELs, whether recommended or mandatory, are also periodically reviewed and amended. Even the international bodies doing the best job of updating their OELs have hundreds of exposure limit values that are based on old ACGIH TLVs.

On the mandatory OEL front in the United States, most PELs are scientifically dated. In 1971, using the newly minted OSH Act, OSHA adopted most of the 1968 ACGIH's TLVs that were being enforced by the United States Department of Labor under the Walsh-Healy Act³⁶ as PELs. OSHA did so only when a consensus OEL, such as those established by the ANSI, was not available. Since the toxicological information on which the 1968 TLVs were based was largely generated in the mid-1960s, most of OSHA's currently enforceable TLVs are thirty-five to forty years old. Furthermore, many of the 1968 TLVs had not been rigorously scientifically reviewed since the late 1940s.

In 1989, OSHA decided to update its original 1971 list of chemical PELs in a single rulemaking—asserted by OSHA to be a *generic* approach—by establishing new PELs for 428 chemicals.³⁷ In 1992, the U.S. Court of Appeals for the Eleventh Circuit vacated OSHA's PEL update.³⁸ Significantly, though, the Court did not condemn a generic approach to PEL-setting, but stated:

By contrast, the new Air Contaminants Standard is an amalgamation of 428 unrelated substance exposure limits. There is little in common to this group of diverse substances except the fact that OSHA considers them toxic and in need of regulation. In fact, this rulemaking is the antithesis of a "generic" rulemaking: it is a set of 428 specific and individual substance exposure limits.³⁹

35. See INT'L PROGRAMME ON CHEM. SAFETY, CONCISE INTERNATIONAL CHEMICAL ASSESSMENT DOCUMENTS (CICADS), available at <http://www.inchem.org/pages/cicads.html> (last visited Apr. 19, 2005).

36. Walsh-Healey Public Contracts Act, 41 U.S.C. §§ 35–45 (2000).

37. 54 Fed. Reg. 2332 (1989).

38. AFL-CIO v. OSHA, 965 F.2d 962, 987 (11th Cir. 1992).

39. *Id.* at 972.

No further action has been taken by OSHA to update the now thirty-five year old PELs, save for a failed short-lived effort in 1995 to update twenty PELs.⁴⁰ OSHA has succeeded in updating at least one PEL since 1989—the PEL for methylene chloride.⁴¹ As a result of the slow pace of PEL-setting, up-to-date recommended OELs outnumber up-to-date enforceable PELs by several orders of magnitude. Furthermore, occupational safety and health professionals find it difficult to represent OSHA's current PELs as the gold standard for risk assessment and risk management purposes. Worker advocates point to the lack of health protection that out-of-date PELs represent for workers. Since risk management is still a part of any occupational safety and health professional's job, these professionals are increasingly utilizing OELs derived from non-OSHA sources as a standard of professional practice. Occupational health professionals often advise their clients that adherence to thirty-five year old PELs may not protect the company from legal liability for relying on out-of-date PELs.⁴² The government's slow pace of adopting or revising PELs, RELs, and other OELs has led some to ask if we are indeed living in a post-OEL world. Save for the occasional agency-initiated, or the even rarer, judicially-mandated, PEL rulemaking, the statutory promise of section 6 of the 1970 OSH Act seems dimmer and dimmer every year.

V. ARE OCCUPATIONAL EXPOSURE LIMITS EFFECTIVE?

Many occupational safety and health professionals have credited OELs with forcing protective changes in workplace exposure measurement and exposure control that would not have happened but for their existence. The effectiveness of a system of assessing the risks of toxic agent exposure, and controlling exposure to those risks, is largely dependent on scientifically up-to-date OELs, including enforceable ones like PELs. The small number of substances for which an OEL has been developed suggests that a risk management model dependent on up-to-date OELs cannot function optimally.

40. Dennis J. Paustenbach, *OSHA's Program for Updating the Permissible Exposure Limits (PELs): Can Risk Assessment Help "Move the Ball Forward?"* 5 RISK IN PERSP. 1, 3-5 (1997).

41. 29 C.F.R. § 1910.1052 (2004).

42. John F. Meagher, *The Future of Occupational Exposure Limits*, OCCUPATIONAL HAZARDS, July 23, 2002, at 49, available at <http://www.occupationalhazards.com/issues/32> (last visited Apr. 19, 2005).

A. *Small and Medium-Sized Employers*

Even when a current OEL exists for a particular toxic agent, small to medium-sized employers (SMEs) have less resources and expertise to implement an exposure assessment and control plan that is fully responsive to the control measures necessitated by the OEL.⁴³ This is because SMEs face several barriers in assessing and managing toxic agent risks in the workplace. These barriers are largely due to a lack of technical expertise in understanding complex government occupational health standards; a lack of financial access to safety technology; the narrowness of a small employer's operating financial margin; a lack of time to devote to controlling occupational injury and illness; transaction costs of doing business; a distinct aversion or obliviousness to governmental regulations; and the SMEs' desire to bypass the present complex risk assessment approach for occupational health risks and have a simple risk control matrix to implement. Much concern exists currently about how effective an OEL-dependent risk management model is for the large number of SMEs.

B. *Low Probability of Enforcement*

If a firm has only a low probability of being inspected by government to determine its compliance with an OEL (especially SMEs), even a scientifically up-to-date OEL can have little effect in protecting work health. For instance, the NIOSH World Report indicates that between 1993 and 1999 about thirty-one percent of OSHA enforcement samples for respirable quartz exceeded the PEL.⁴⁴ These samples came largely from large firms with both more technical risk assessment capability and a higher probability of being inspected. Even so, nearly one-third failed to meet the OEL requirement. Any consideration of the effectiveness of OELs leads to a larger inquiry about the effectiveness of the risk management model of which they are the cornerstone.

C. *Out-of-Date PELs*

Few professionals in occupational safety and health would argue that out-of-date PELs should not be updated. In 1998 (and again in 2002), the AIHA stated in its White Paper on PELs "[i]t is a disservice to worker

43. R.M. Russell, et al., *An Introduction to a UK Scheme to Help Small Firms Control Health Risks from Chemicals*, 42 ANNALS OF OCCUPATIONAL HYGIENE 367, 367–76 (1998).

44. NAT'L INST. FOR OCCUPATIONAL SAFETY AND HEALTH, WORK-RELATED LUNG DISEASE SURVEILLANCE REPORT, tbl. 3-20 (2003), available at <http://www.cdc.gov/niosh/docs/2003-111/pdfs/2003-111d.pdf>.

health that the majority of OSHA PELs are based on recommendations that were made almost 30 years ago.”⁴⁵

Yet, as the last thirty-five years has proven, setting OELs as mandatory PELs, or even as recommended RELs, WEELs or TLVs, is a time- and resource-intensive process. When examining the current substance-by-substance quantitative risk assessment (QRA) approach,⁴⁶ given the current number of possibly toxic chemicals in commercial use which lack an OEL, it is not hard to conclude that the current OEL-setting process is less than fully effective in protecting workers from exposure to toxic chemicals in the workplace.⁴⁷ And the situation does not look like it will get much better anytime soon.

Compared with the number of chemicals in commercial use, relatively few substances have OELs, let alone PELs.⁴⁸ For instance, the Organisation of Economic Co-operation and Development (OECD) List of high production volume chemicals—chemicals produced at levels greater than 1000 tons per year in at least one of the thirty member countries—contains 4843 chemicals.⁴⁹ Only a small percentage of these chemicals have OELs established for them.⁵⁰

When compared to the number of chemicals for which a recommended or mandatory OEL exists, the task of OEL-setting seems daunting under our existing QRA, OEL-development paradigm.⁵¹ Indeed, the level of new OEL/PEL throughput needed to meet the challenge of out-of-date OELs/PELs for existing chemicals, and new chemicals in need of an OEL/PEL, appears to exceed the capacity of our existing scientific and regulatory systems based on past performance.

Many in the safety and health community, together with those in the

45. AM. INDUS. HYGIENE ASS'N, AIHA'S WHITE PAPER ON PERMISSIBLE EXPOSURE LIMITS (PELS), *available at* <http://www.aiha.org/GovernmentAffairs-PR/html/GAWPpermexpo.htm> [hereinafter AIHA'S WHITE PAPER].

46. Quantitative risk assessment (QRA) “is a process of extrapolating from the range of direct observation to a lower and potentially safer range, for which there are few or no data.” P.A. Schulte et al., *Risk Assessment and Regulation of Carcinogens in the Workplace*, 2 CLINICS OCCUPATIONAL & ENVTL. MED. 727 (2002).

47. Ellen K. Silbergeld, *Risk Assessment: The Perspective and Experience of U.S. Environmentalists*, 101 ENVTL. HEALTH PERSP. 102, 100–04 (1993) *available at* <http://ehp.niehs.nih.gov/members/1993/101-2/silbergeld-full.html> (last visited Apr. 19, 2005).

48. Paul Hewett, *Interpretation and Use of Occupational Exposure Limits for Chronic Disease Agents* 11 OCCUPATIONAL MED.: STATE OF THE ART REVIEWS 561, 576 (1996).

49. ORG. FOR ECON. CO-OPERATION AND DEV., THE 2004 OECD LIST OF HIGH PRODUCTION VOLUME CHEMICALS, *available at* <http://www.oecd.org/dataoecd/55/38/33883530.pdf>.

50. *Id.*

51. Leslie Stayner, et al., *Risk Assessment at the Crossroads of the 21st Century: Opportunities and Challenges for Research*, 8 HUMAN AND ECOLOGICAL RISK ASSESSMENT 1195, 1196–1202 (2002).

employer and labor communities, are now examining ways to jump-start a PEL update process. Others are examining new strategies for how to set OELs. And, some are even considering new paradigms for controlling risk in the complete absence of traditional OELs.

VI. IS THERE A BETTER WAY?

A number of alternatives have been proposed in the United States to solve various aspects of the OEL timeliness and utility problems. Among these proposals are those that merely tinker with the OEL-development process; those that suggest generic approaches to PEL-setting; others that propose making legislative changes to the OSH Act to simplify the OEL adoption process; those that involve U.S. participation in a globally harmonized system of classification and labeling of chemicals; and those that suggest shifting the emphasis from resource-intensive QRA to qualitative risk assessment and simple control methods through “control banding.”

A. *OSHA Improvements*

Various suggestions have focused on how OSHA can prioritize chemicals with outdated PELs for update consideration. These proposals emphasize that the process has to be totally transparent, scientifically-driven, with stakeholder input at every step of the way. In 2000, the National Advisory Committee on Occupational Safety and Health (NACOSH) prepared a report on OSHA’s standards development process and made several recommendations that NACOSH believed would improve the existing PEL-development process.⁵² Specifically, the NACOSH recommended that OSHA make more effective use of standards advisory committees and negotiated rulemaking committees, and partner more effectively with consensus standards-setting organizations and professional associations.⁵³

Others have suggested that OSHA should charter an occupational exposure limit committee under the Federal Advisory Committee Act (FACA),⁵⁴ similar to the National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances formed in 1995 by the United

52. THE NATIONAL ADVISORY COMMITTEE ON OCCUPATIONAL SAFETY AND HEALTH (NACOSH), OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, REPORT AND RECOMMENDATIONS RELATED TO OSHA’S STANDARDS DEVELOPMENT PROCESS (2000), available at <http://www.osha.gov/dop/nacosh/nreport.html>.

53. *Id.*

54. 5 U.S.C. app. §§ 1–16 (2000).

States Environmental Protection Agency.⁵⁵ The new PEL Advisory Committee would recommend to OSHA candidate PELs for updating through a transparent, public committee process. Presumably, OSHA would then promptly update the suggested PELs.

B. Statutory Changes

The OSH Act itself has been suggested as in need of reform when it comes to simplifying the standards development process. Proponents of a statutory approach have noted that, while prioritizing which chemicals should be updated is useful, the current standards adoption process in section 6—as amended by subsequent events—is the real rate-limiting step in updating PELs. The types of statutory changes suggested range from allowing OSHA some permanent dispensation from the various administrative requirements for PEL updating to allowing OSHA permission for a one time update of PELs as the statute originally permitted in 1970. Going one step further, the AIHA has suggested establishing legislatively a “not arbitrary or capricious” criterion rather than a “substantial evidence on the record” legal standard of review (as was set forth in the benzene decision in 1980)⁵⁶ and applying it to judicial review of challenged PELs.⁵⁷

Others have suggested giving OSHA limited legislative authority to update the PELs generically as broad chemical classes. On July 16, 2002, the House of Representatives’ Subcommittee on Workforce Protections held its third hearing to build consensus among various stakeholders about how PELs can be updated.⁵⁸ No additional agency or congressional activity, though, has as yet occurred following the 2002 hearing.

C. Broader Approaches

Meanwhile, broader alternative approaches to the current substance-by-substance OEL-setting process are developing internationally. The impetus for these approaches is the realization that the traditional risk assessment and risk management approaches that are used in developed countries may not translate well to developing countries or even to small-to medium-sized employers in developed countries. As discussed above,

55. Meagher, *supra* note 42, at 51.

56. *Indus. Union Dep’t v. Amer. Petroleum Inst.*, 448 U.S. 607, 672 (1980).

57. AIHA’S WHITE PAPER, *supra* note 45.

58. Jim Nash, *Congress Eyes Law to Update PELs*, OCCUPATIONAL HAZARDS, Sept. 2002 at 12; *see also* Press Release, Committee on Education and the Workforce, Subcommittee Hears Testimony on Updating OSHA Exposure Limits (July 16, 2002), available at <http://www.edworkforce.house.gov/press/press107/oshapels71502.htm> (announcing hearing).

the traditional approaches are not thought effective since only larger firms have the technical resources to assess risk quantitatively, the list of potentially harmful agents needing an OEL is very large, and governmental enforcement of protective OELs is limited. No country has more than a few hundred OELs, while workers are potentially exposed to thousands of potentially harmful agents.

Is there a better risk assessment and risk management paradigm to deal with this situation than the one we have been using for decades? Three developments are worth noting under the topic of newer paradigms.

First, a globally harmonized system (GHS) for the classification and labeling of chemicals is developing under the auspices of the United Nations.⁵⁹ The GHS has the potential to bring together risk assessment and risk management in a globally consistent strategy for chemicals, and may provide a context for the use of newer exposure control tools without the need for technically-intensive risk assessment.

Second, one of those newer risk management approaches is *control banding*. Control banding is an approach to protecting worker health that focuses more resources on exposure controls than on quantitatively assessing risk by means of an OEL. Control banding obviates expensive and technically difficult exposure assessment altogether. Rather, control banding is a more qualitative approach to risk assessment.

Control banding groups hazards into hazard “control bands” based on (1) their common hazardous properties (as derived from manufacturers’ information through so-called “R” or risk phrases); (2) the task being performed by workers; and (3) the quantity of chemical being used. The control bands are based on the traditional principles of industrial hygiene: substitution, administrative controls, engineering controls and containment. In chemical control banding, a chemical is assigned to a “band” for control measures, based on its hazard classification. Based on a control banding approach, controls for chemicals that have never had an OEL can be developed and implemented without the need for setting an OEL. Originally developed by the pharmaceutical industry as a way of managing the risk associated with rapidly developing new drug entities, and utilized by the Health and Safety Executive in Great Britain for risk management for SMEs,⁶⁰ interest in the United States is growing in this new approach.⁶¹

59. U.S. ENVTL. PROT. AGENCY, GLOBALLY HARMONIZED SYSTEM (GHS) FOR CLASSIFICATION AND LABELLING OF CHEMICALS, *available at* <http://www.epa.gov/oppead1/international/globalharmon.htm> (last visited Apr. 19, 2005) (explaining the U.N.’s effort to establish a GHS).

60. *See* Control of Substances Hazardous to Health (COSHH) Essentials, *Easy Steps to Control Health Risks from Chemicals*, at <http://www.coshh-essentials.org.uk/Home.asp?Staging=False> (last visited Apr. 19, 2005) (demonstrating risk analysis).

61. The Second International Conference on Control Banding was held in Cincinnati, Ohio on March 1-3, 2004 (conference papers available at <http://www.acgih.org/>)

Third, the European Union (EU) is considering a new system based on a White Paper on a future chemicals policy.⁶² The White Paper attempts to reverse the traditional risk assessment paradigm where the government is required to show adverse risks from use of a particular chemical before regulating to one in which the manufacturer is required to show the absence or the acceptability of risks associated with the chemical before the chemical is allowed to be marketed. The EU has approved, but has not as yet adopted, the new approach to governmental risk regulation, which is called REACH (registration, evaluation and authorization of chemicals).⁶³

VII. CONCLUSION

Many in the workplace safety and health world would agree that OELs have served an important role in ensuring worker protection from toxic agent risks. However, the statutory and administrative methods for development and adoption of OELs may not be as effective as they were first envisioned when the OSH Act was adopted in 1970. The inefficient OEL-setting process in the United States, coupled with the changes occasioned by a more globally integrated U.S. economy, suggests that it may be time to review our current methods for assessing and managing risk in the occupational setting.

events/ControlBand/).

62. EUROPEAN COMM'N, WHITE PAPER ON THE STRATEGY FOR A FUTURE CHEMICALS POLICY (2001), available at <http://europa.eu.int/comm/environment/chemicals/whitepaper.htm>.

63. C.D. Money, *European Experiences in the Development of Approaches for the Successful Control of Workplace Health Risks*, 47 ANNALS OF OCCUPATIONAL HYGIENE 533, 534-40 (2003), available at <http://annhyg.oupjournals.org/cgi/content/full/47/7/533>.