Occupational Exposure Limits—Do They Have a Future?

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Introduction:

Do we still need traditional Occupational Exposure Limits (OELs) to compare with exposures, perform risk assessments and identify control approaches? Or have traditional OELs run their course of usefulness? Some certainly think so!

On the other hand, if we think that OELs are important to risk assessment and risk management, and recognizing the limited global infrastructures to generate them at the rate needed, do we need to build on what we have and also explore measures and approaches which take our discussions and solutions beyond traditional OELs alone? We have many in this camp as well.

Occupational Exposure Limits (OELs) have been established for airborne workplace chemicals by various regulatory and authoritative organizations now for well over 60 years now. With the changing regulatory arena, shifting centers of manufacturing growth, and move towards a more global view on issues, the time to pause and re-examine their continued value is now.

The authors of this Paper, who represent decades of experience in occupational health in all sectors of the profession, believe that OELs continue to be critical to protecting workers from chemical exposures. We believe that most Industrial Hygienists and other allied risk management professionals strongly support the concept that OELs should be updated, consistent with current scientific knowledge. We also believe that the infrastructure to generate and utilize OELs desperately needs shoring up.

In an effort to suggest a future approach (or several future approaches), we attempted to highlight the historical evolution of OELs, the known OEL setting processes today, their role in industrial (or occupational) hygiene and risk assessment, and today's world community challenges. This Paper presents ideas to revive and reinvent the process. Because the issues and potential remedies are many and complex, we (the authors) do not necessarily support each potential remedy or historical interpretation that follows. In fact, the views and opinions expressed in this

paper are those of the individual authors and may not necessarily represent those of the authors' employers. We do agree, though, that in working together, our profession can lead the way forward.

By way of clarification, if we do decide that there is a need to intensify our efforts on OELs relative to current and future global harmonization, it is important for us to recognize that the term "OEL" refers to two quite distinct exposure limits. The first is widely recognized as a "health-based" OEL (or hOEL) and the second a "regulatory-adjusted" OEL (or rOEL). For health-based OELs, only health-driven risks are considered. The harmonizing global process for health-based OELs will have to define clearly what is to be considered detrimental or adverse, what physiological capacity is to be protected, e.g. functional reserve (transient? or permanent?), and what subpopulations are to be included. The process will have to define the degree of uncertainty permitted in the extrapolation of data from experimental biological systems or from medical surveillance. For the "regulatory adjusted" OELs (or rOEL), consensus from a tri-partite process will have to modify health-based OEL values so that they can include non health based considerations such as economics and technical feasibility in order to serve a regulatory function in the jurisdiction that uses them.

Historical Evolution of OELs:

The evolution of OELs parallels the story of the evolution of EH&S, with roots in Europe.

Few limits for chemical exposures in the occupational environment were developed until 1912 when a list of 20 acute exposure limits were published by Germany's Kobert as "The Smallest Amounts of Noxious Industrial Gases Which Are Toxic and the Amounts Which May Perhaps Be Endured." The U.S. Bureau of Mines published a technical paper in 1921 which included tables of hazardous air concentrations for 33 compounds; the values were derived from the work by Germany's Kobert. Russia published its first MAC list of 30 chemicals in 1930, followed by Germany's list (100 OELs) in 1938.

During the 1940s, U.S. attention was turned to preventing injury and disease in the workplace and an effort undertaken to understand and define "harmful exposures" to substances. World Wars I and II precipitated a crisis in health and safety and the early awareness of risk determination importance. Although early information was being gathered regarding concentrations of substances that caused injury, very little exposure limit information was widely published until the ACGIH published its first list of 148 "Maximum Allowable Concentrations" (MACs) of air contaminants (MACs) in 1946. The MACs became known as "Threshold Limit Values" (TLVs®) in 1950 in the "A.M.A. Archives of Industrial Hygiene and Occupational Medicine." The first Documentation of the Threshold Limit Values was published in 1962 and is now into its seventh edition.

The ACGIH TLV Committee continues to generate exposure limits for chemical substances with the total today approximating 700. For the last 65 years, multiple countries have adopted ACGIH TLVs either without change, or as their basis for national exposure limits. Multiple countries (notable exceptions are India and the U.S) update their regulatory rOELs on a 3 to 5-year frequency.

OEL Setting Processes Today:

USA Environment

The United States' occupational exposure level setting activity has generally resided within five frameworks—the **Occupational Safety & Health Administration (OSHA)**, the **National Institute of Occupational Safety & Health (NIOSH)**, the **American Conference of Governmental Industrial Hygienists (ACGIH),** the **American Industrial Hygiene Association (AIHA),** and **state specific regulations.** Additionally, some limited activity has been undertaken by the **Environmental Protection**

Agency (EPA). In the absence of regulatory or well recognized guidance OELs, some companies establish their own OELs for protection of their own workers.

Prior to the late 1960's, there were few federal workplace safety and health standards. Historically, the enactment of safety and health laws was left to the states. Only a few federal laws (such as the **1927 Longshoremen's and Harbor Workers' Compensation Act** and the **1936 Walsh-Healey Public Contracts Act**) directed any attention (as limited as it was) to occupational safety and health. The Walsh-Healey Public Contracts Act incorporated the ACGIH list in 1951, while the Longshoremen's and Harbor Workers' Compensation Act did so in 1960.

Under Section 6 (a) rulemaking within the **Occupational Safety and Health Act (OSHAct) of 1970,** the Secretary of Labor was authorized to adopt (within 2 years) any existing federal standards and national consensus standards as OSHA standards as long as they resulted in improved safety or health. This enabled OSHA to have a strong regulatory base as soon as possible. In 1971 OSHA adopted the safety and health standards derived from the 1969 Walsh-Healy Act revision which included the 1968 ACGIH list of TLVs. With this action, the occupational exposure levels listed by ACGIH became enforceable by law as OSHA's Permissible Exposure Limits (PELs).

After that initial 2-year period, OSHA was required to follow the more onerous 6(b) rulemaking process which provided for more data gathering, individual assessments, public notice and comment, and justification for promulgating standards. OSHA's 6(b) rulemaking process certainly allowed for revisions and upgrades to the standards promulgated under the 6(a) rules. However, it is fair to say that because 6(b) requirements are so onerous and have become even more so with 30+ years of additional case law, increasingly complicated administrative procedures, intense congressional scrutiny, and further societal and court ordered requirements for transparency and risk benefit, the exposure limit setting process has moved along at glacial speed. In fact, OSHA has adopted new or revised PELs for only 16 agents since the 6(a) adoption in 1971. In addition, it has adopted standards for 13 carcinogens that do not include PELs. This is against a backdrop of over 80,000 chemicals in U.S. commerce.

The **National Institute for Occupational Safety and Health (NIOSH)** was established within the Department of Health & Human Services (DHHS) under the provisions of the OSHAct. NIOSH is the principal federal agency engaged in research, education, and training related to occupational safety and health. Under the OSHAct, NIOSH has responsibility for conducting research for new occupational safety and health standards. NIOSH develops criteria for establishing these standards and transmitting the criteria (which include recommended exposure levels) to OSHA. In theory OSHA considers them in the regulatory process, although they have largely been ignored by OSHA. These Recommended Exposure Levels (RELs) are sometimes more restrictive than either ACGIH's or OSHA's OELs. In the late 1970s, NIOSH submitted more than 100 "Criteria Documents" with Recommended Exposure Limits (RELs) to OSHA. Fewer than 10 Criteria Documents have been issued in the last 25 years.

No regulations were issued based on the Criteria Documents, and while they provided useful resources for occupational safety and health professionals, NIOSH opted to redirect its activities away from standards setting reviews. Instead, NIOSH focused on health hazard evaluations of specific worksites in the late 1970s, and in the 1980's, on various industry-wide studies. During the 1988-89 period when OSHA undertook its PEL Project (that was eventually overturned following lawsuits filed by both labor and industry), NIOSH derived RELs for a large number of substances for use in the new OSHA list . With the advent of the National Occupational Research Agenda (NORA) in 1996, NIOSH began focusing on non-REL partnership activities to apply research findings to exposure and risk minimization strategies.

The American Conference of Governmental Industrial Hygienists (ACGIH) has been the primary body for setting Occupational Exposure Limits in the United States. Its committee for setting limits became a standing committee in 1944, adopting its first list of 148 exposure limits in 1946. The ACGIH exposure limits are considered guidelines intended for use in the practice of industrial hygiene, to be interpreted and applied only by persons in this discipline. They are not developed for use as legal standards, nor are they intended to be fine lines between safe and hazardous concentrations.

Nevertheless, the TLV® process is the largest ongoing process for the revision and setting of chemical exposure limits, is the best recognized internationally, and often provides the starting place for other bodies setting OELs.

In 1984, the **American Industrial Hygiene Association (AIHA)** began the development of Workplace Environmental Exposure Levels (WEELs) to satisfy the need for health-based OELs when there was potential for significant worker exposure to substances that were not sold in large quantities, and thus, not targeted by other OEL setting bodies. The AIHA WEEL-setting process is consistent with those of other NGO OEL-setting bodies (e.g., TLV, MAK, etc.). There are currently about 120 WEELs for agents that otherwise would not have OELs.

Given the lack of updated or new OELs available in the United States to help define risk and authoritatively drive control strategies, health professionals have sought other means to meet the need for health-based OELs in the risk assessment process. Some have embraced the Control Banding approach popular in the United Kingdom, some have based "safe" exposure levels on structurally-equivalent chemical structures for which health-based OELs do exist, some have used OEL values available from other countries, some have employed medical surveillance to calibrate decline in health and performance with exposure improvements, and others have simply focused on good housekeeping and other risk reducing strategies without the ability to know whether the contaminant reduction in exposure is significant.

European Union Environment

Historically, there exists some degree of commonality in the nature of experiences in setting and using health-based OELs across the European Union and its affiliated countries. This is particularly true in the following ways:

- Limits mostly derive from the same limited international data on toxicology and epidemiology, even though the final numeric outcomes differ from one country to another.

- Historically, the ACGIH list of TLV®s was a major influence in the original limits established. For example, Finland's list of OELs was first published in 1960, and like other Nordic countries, heavily influenced by the ACGIH TLV® list. Belgium did not have its own system for establishing OELs and, thus, relied heavily on the ACGIH TLV® list of 1993. Germany's original 1958 MAK list was based mainly on the ACGIH TLV® list. Since 1969, the MAK list has been published separately and independently. And finally, the Netherlands used the ACGIH TLV® list until 1977. Today, it is likely that reliance on the ACGIH TLV® list in the European Union is at a minimum, particularly given that other EU processes have been adopted that more closely integrate the efforts of all EU countries.

- Processes do exist for considerable stakeholder participation. These structures are usually based on tripartite models (government, industry and labor), with the addition of independent expertise. Some stakeholders, such as insurance associations, play a greater role (particularly in Germany).

- There are similarities in the procedures. It is mostly a two-stage process in which the scientific/health based issues are dealt with, usually by "experts," and a second process in which economic and/or technical issues of feasibility are considered. Economic interests and social partners (tripartite) are always represented in the latter stage.

- National systems exist for setting and reviewing OELs, and thus, in most countries, there are roles for the government, industry, unions and others that are legally binding. In the European Union, the European Commission Indicative Occupational Exposure Limits (IOELs) are considered to be legal limits (for airborne chemicals) that are set to protect the health of workers from the ill-health effects of hazardous substances in the workplace. Their legal status derives from the Council Directive 98/24/EC on the protection of health and safety of workers from the risks related to chemical agents

at work (the Chemical Agents Directive or CaD). While countries can choose to set more conservative exposure levels, the IOELs function as a minimum.

- OELs play a limited role in the management of chemical risks in most of Europe. It appears that the limited number of OELs contributes to this, as does the small number of professional Industrial Hygienists. Furthermore, Europe has a more pronounced occupational physician influence which emphasizes treatment and "medically based risk assessments" and focus on acute, rather than longer term, occupational health effects. Much of Europe simply either requires controls (respirators, ventilation, gloves) or, in some cases, bans the substance in question. Air monitoring is rarely performed when compared to U.S. practices. An outstanding question remains though as to whether the controls recommended are effective.

The European Union continues to play a significant role in standardizing efforts across member countries. These similarities however, do not entirely override national differences apparent in the setting, legal status and use of OELs as well as in their legal context.

In 2005, the Control of Hazardous Substances Hazardous to Health Regulations (COSHH) was passed in the United Kingdom. It heralded a major change in the UK approach to rOELs and the comprehensiveness of application of IH principles to all workplaces. It introduced eight principles, including the following, which apply regardless of whether a substance had an OEL:

- Assess the risks to health from chemicals and decide what controls are needed
- Use those controls and make sure workers use them
- Make sure the controls are working properly
- Inform workers about the risks to health
- Train workers

Furthermore, the COSHH also introduced a new type of limit, Workplace Exposure Limits (WELs) which are not to be exceeded, replacing the Maximum Exposure Limits (MELs) and Occupational Exposure Standards (OESs). And finally, COSHH required assurance that exposure to substances that could cause occupational asthma, cancer, or damage to genes passed down from one generation to the next were reduced as low as reasonably practicable. Since WELs did not exist for a great many substances, the process of Control Banding (and a focus on prescriptive risk control measures as opposed to exposure monitoring and comparison with an existing OEL) became paramount in the UK occupational health system.

Today, Europe's most significant catalyst in setting health-based occupational exposure limits is the European Regulation on Registration Evaluation and Control of Chemicals (REACH). REACH was passed by the European Parliament on 13 December 2006 and entered into force in June 2007. Not least among the changes was the creation of Derived No-Effect Levels (DNELs). This represents a level of exposure above which humans (inclusive of consumers, workers, etc) should not be exposed. Manufacturers and importers are required to calculate DNELs as part of their Chemical Safety Assessment (CSA) for any chemicals used in quantities of 10 tons or more per year. The DNEL is to be published in the manufacturer's Chemical Safety Report and, for hazard communication purposes, in an extended Safety Data Sheet (SDS).

The DNEL is used in the risk characterization part of the CSA as a benchmark to determine adequate control for specified exposure scenarios. Risk to humans can be considered to be adequately controlled if the exposure levels estimated do not exceed the appropriate DNEL. REACH specifies that DNELs shall reflect the likely routes, duration and frequency of exposure. If more than one route of exposure is likely to occur, (oral, dermal or inhalation), then a DNEL must be established for each route of exposure and for the exposure from all routes combined. It may also be necessary to identify different DNELs for each relevant human population (e.g., workers, consumers or humans subject to exposure indirectly via the ambient environment) and possibly for certain vulnerable sub-populations (e.g., children, pregnant women). The DNEL methodology is intended to harmonize the approach to occupational health risk assessment with those used for other types of risk such as environmental exposure. This is important

under REACH, as manufacturers must assess not only human health risks but environmental and physical safety risks as well.

DNELs are generally more conservative than conventional (regulatory) Occupational Exposure Limits (rOELs). The calculation of DNELs follows a rule-based approach in which a series of standardized assessment factors are applied to the toxicological endpoints to allow for uncertainties and inter- /intra - species differences. This can result in a very conservative figure, perhaps two or three orders of magnitude lower than that from the traditional OEL setting process.

DNELs calculated by individual manufacturers and importers are not subject to any requirement for consultation or opportunity for input by interested parties. In contrast, the European process for setting Indicative Occupational Exposure Limit Values (OELs) has been well established, involving experts from member countries on a scientific committee (SCOEL) and providing an opportunity for stakeholders in industry and government to comment on the proposals. These inputs are not included in the REACH process.

Debate is also underway to decide what to do when a DNEL cannot be established. Is it possible to set a Derived Minimum Effect Level (DMEL), based on some concept of acceptable or negligible risk, (such as the "Threshold of Toxicological Concern"), or should such materials automatically be banned because they cannot be adequately controlled? Under REACH, the Derived No Effect Levels (DNELs) must be completed by 2010 for the 'grandfathered' substances registered for commerce and all products must be registered for commerce and use in member states by 2018. It is likely that the European Agency for Chemicals (ECHA) will set up a strategy to look at the validity and coherence of DNELs (even if it is on small samples randomly selected).

OELs Are Critical to Industrial Hygiene and Risk Assessment:

Essentially every definition of risk assessment (RA) lists the activity of RA as the integration of toxic potential and potency with the exposure to that potential. Industrial hygienists measure or otherwise estimate exposure in the scenarios of interest. Thus, exposure is only half of the story and, as a professional group, industrial hygienists almost invariably rely on the health-based OEL to put that estimated exposure into context relative to its potential to elicit an untoward health effect in the exposed individual. When an industrial hygienist compares measured or estimated exposure (EXP) with the exposure limit (could be an rOEL / OEL), he or she almost invariably does so with the classic hazard index ratio of EXP/OEL. For industrial hygienists, the health-based OEL embodies the toxicity (or hazard) half of the equation. In this prevailing scheme, the industrial hygienist views a low health-based OEL as signifying a graded indicator of high hazard and a high OEL as a relatively low quantitative measure of toxic potential for the controlling adverse health effect. Thus, if the exposure limits (EL, TLV, OEL, etc.) are reasonably well established and well explained, this time-honored approach should allow exposure experts, stakeholders, and others not expert in toxicology to put the estimated exposures into context.

Indeed, if it is assumed that the agent's health effect or toxicology represents half the knowledge needed to do a risk assessment (with exposure representing the other half), then essentially all of the information for the toxicology of the compound can be considered to reside within this limit.

It should be reasonably obvious that exposure assessors measure or otherwise estimate human exposure, and this exposure has no contextual meaning without a valid toxicological benchmark (an exposure limit) with which to compare it. The health-based OEL is the single point of exposure chosen by a group of experts that embodies the concept of an acceptable level of toxic response. Given the singular and central importance of their role to the practice of risk assessment and industrial hygiene, a close examination and evaluation of the substance and meaning of the health-based OELs is warranted. Their continued development and use is critical.

Having said that, not everyone places a high value on OELs. In some countries, OELs exist but are rarely employed except by a few large companies. Other countries have OELs and no Industrial

Hygienists to gauge conformance to them. And yet, other countries apply risk assessment schemes and control measures without knowing if they really work. Control Banding is often employed when bridging the gap between quantitative exposure and hazard data and no scientific data. It appears to offer a somewhat loose approach in using OELs within the occupational setting. There is a need, however, to validate the Hazard Control Banding approach.

Today's World Community Challenges:

The world community's challenges relative to risk assessment and OELs include the following:

1. ***The number of chemicals entering commerce today far outstrips the ability of global OEL-developing organizations to keep pace.*** Globally, there are now Occupational Exposure Limits for only 3,000 different chemicals (with over 100,000 bought and sold in the world market place). Many of these OELs are more than 10 years old.

2. ***OELs are not true thresholds of toxic effect***. They are, however, a threshold of less than absolute protection and are intended to allow an "acceptable risk." The acceptability of the risk should ultimately be determined by the cultural body politic of the society and thus could be different for different groups.

   For example, setting of Short Term Exposure Limits (STELs) should be a function of the evidence for short term effects that may occur at concentrations that can exist in the workplace. The kinetics of the short term effect is the key parameter, and effects that occur related to toxicant half times or say two hours or less are more likely to warrant a short term limit. However, while for a chemical there may be some evidence for acute toxicity at possible concentrations, it may be insufficient to set a limit, and information about kinetics may be absent. Thus, another approach is to examine the ratio of the long term limit to a conservative short term limit. The ratio is an indicator of how likely the short term value may be reached if a workplace is well controlled to the long term value. Such a calculation is not used to set a short term limit but rather to give a margin of certainty that the long term value will adequately control both the acute and chronic effects of the chemical. If the ratio indicates that short term concentrations are likely to reach *possibly* dangerous levels even in workplaces well controlled at the long term limit, the best the OEL author can do is warn the user. However there is no standard approach for this relatively frequent situation. One author may choose to force a short term limit based on what another believes to be inadequate data.

   The U.S. limits (TLVs) are based on toxicological considerations, but statistical considerations about the occupational exposure distributions play an important role when, as is often the case, toxicological data are inadequate. The EU approach is based on toxicological considerations. These short term values have gained more importance over the years since the exposure patterns at the workplace are less and less "continuous," with exposure peaks being more the norm.

   Furthermore, with a growing emphasis placed on the environment, the past 10 years have also seen the development of environmental community exposure guidelines for airborne contaminants. These levels are generally developed using models that differ from those used for occupational settings, with the recommended exposure levels being generally more restrictive than those ascribed to workplaces. This makes sense in that community exposures are generally "round the clock" exposures (as opposed to an occupational workplace setting) and include more sensitive populations (the very young, the very old, and chemically sensitive individuals). However, there remain inconsistencies in the "science" used to set the two types of exposure limits.

   And finally, many organizations are now obliged to address the full life cycle (supplier-manufacturer-customer-disposer) of occupational, environmental and product exposures for the

development of appropriate exposure levels and risk management measures recommended on Material Safety Data Sheets and other documents. This adds to the complexity of risk determinations which need to be framed.

3. ***The REACH regulations will change the playing field with regard to*** the quality and availability of hazard assessment input data:

   - The reliability of a study which becomes part of the OEL toxicological data set needs to be understood and evaluated using a verified scoring system (i.e., Klemisch scoring) to rate the validity of a study for use as a pivotal endpoint in setting an OEL. There is precedence for this in the U.S. in that the Office of Management & Budget (OMB) requires this for some EPA work and the EU REACH and Biocidal Products Directive (BPD) protocols require Klemisch scoring.

   - It is difficult to capture all pertinent data for setting OELs because most company data has not been made public. The result is often incomplete data sets, resulting in final endpoints which are not accurate. Efforts to encourage companies to share their scientific data should be considered beyond the REACH submissions which may remain proprietary or business confidential. However, all endpoints selected as a point of departure for the derivation of a DNEL must be published on the internet by ECHA for the public access.

   - There is a requirement in the REACH legislation that requires ECHA to publish a database on the internet of the DNELs that are officially accepted for various substances.

4. ***With regard to resources and expertise needed to establish OELs*:**

   - There is not an adequate investment by governments in the developed countries to establish and revise OELs or to maintain the organizational structure to do so. Not all generated data is published and/or peer-reviewed. Non-published data is perceived as less credible, is not widely available to interested parties, and may be excluded from consideration.

   - In the absence of governmental support, development of exposure levels is now placing an ever increasing burden on already overworked volunteers (at least in the case of AIHA WEELS, ACGIH TLVs, SCOEL and German MAKs) to review scientific literature, which is sometimes voluminous and other times scarce. In some cases, these groups work under the threat of law suits that cause much greater attention to process than to science.

   - After health-based OELs are set by organizations such as ACGIH, volunteers are under increasing stress from various types of challenges that require many additional hours be spent responding to those challenges. Often, the time spent post OEL setting is greater than the time to define the OEL.

   - While many countries today require that employers provide a “safe workplace” (thus suggesting the need for risk assessments and OELs for use as comparators), most employers do not have the infrastructure to provide an adequate risk assessment and often rely on the information provided in a supplier’s Material Safety Data Sheet (MSDS).

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5. ***With regard to the possibility of scientific bias as a result of working for a particular sector, whether it be government, industry, academia or labor:***

   There is a critical need to avoid the appearance of bias through the proper ‘balance’ of expertise and affiliations on committees (EU, industry, tripartite, ACGIH, others) which develop OELs. A template exists within the EPA’s tripartite Acute Exposure Guideline Levels Committee, whereby there is a rigorous review by all voting members of the group, followed by a second independent National Academy of Science review to add further consistency and credibility. This has proven

to be a very laborious and slow process, but an excellent example of collaboration by all interested parties, including global participation by Russia and EU states.

6. ***As regards process consistencies in determining OELs:***

   There are a variety of processes used to set OELs. Generally, they involve the review of toxicity data to determine critical studies, health effects, and toxicity endpoints. Safety and uncertainty factors are then applied to the critical data to derive an OEL value. There is considerable judgment involved in both the selection of critical studies, health effects, and endpoints and in the application of appropriate safety and uncertainty factors. Even when considering the same toxicity data, variability in individual or institutional criteria for selection and application of those aspects can lead to large differences in final OEL value recommendations.

7. ***As regards the consistent decrease in OELs over time:***

   It can be readily shown that many more OELs have decreased with time than have increased. The reasonable explanation for this fact is that some toxic effects associated with the substances of interest were not known or not yet proven with sufficient scientific evidence at the time the OEL was set. Over time, the generation of better scientific knowledge of these adverse effects has lead to systematically lowered OELs. Given that perhaps the largest portion of scientific uncertainty resides in a basic lack of information, this heretofore historic trend could be interpreted as a failure to handle the uncertainty stemming for an admitted lack of basic knowledge. Given modern advances in toxicology, it is hoped and anticipated that information about the potential adverse effects associated with chemical exposure will be anticipated and predicted more often and with better accuracy. This, in turn, will allow for a reasonable consideration of scientifically uncertain, but possible, adverse outcomes and appropriately gauged OELs that account for them. Such an approach would imply an acceptance of the "precautionary principle" for the occupational environment. If this is done properly, one should see as many OELs increasing with time as those which are decreasing.

Future Direction?:

We believe that Industrial Hygienists and allied professionals consider Occupational Exposure Limits (OELs) to be one of the most effective tools for performing risk assessments upon which risk management strategies for worker protection can be based.

We may never have OELs for all chemical hazards; however, it is critical that we accelerate the establishment of credible and respected OELs to provide a basis for protecting workers. It could be argued that the first step in approaching this large task is to come to some agreement on a unitary scientific approach in assessing “hazard” and applying hazard assessments to OEL setting. This would allow more groups to become involved in a credible way. There are many roadblocks to this seemingly obvious solution. These include legal and regulatory issues, economic issues, political and cultural issues and other factors outside of the usual scientific arguments on health effects. These difficulties have resulted in an absence of any significant development of OELs in the United States and, seemingly, the rest of the world. Those that have been developed outside of the regulatory system as guidance have been subject to significant litigation. At our present rate of progress, it is extremely unlikely that significant numbers of new OELs will to be developed. Litigation could further reduce, restrict or eliminate the efforts of organizations like ACGIH to generate new OELs. There are many in our profession who consider this an unacceptable future. There are other potential approaches to this problem. So, how can we revive the OEL-setting process in a way that provides benefits to all parties involved?

Europe has launched REACH which requires the development of DNELs. However, these will not be consensus recommendations, but rather values determined by the manufacturer or supplier of the material. These manufacturers and suppliers have a very broad range of technical resources and knowledge. As one might guess, small manufacturers will not have the resources to do exhaustive

studies. The level of scientific review of the DNELs once submitted is unclear at this time. Additionally, it remains to be seen how effective this system will be in protecting workers.

Control Banding is another approach some would suggest might take the place of OELs. Some would argue that Control Banding does incorporate the concept of OELs since they are defined in hazard bands or ranges of target exposure rather than single values. They certainly move the user towards a decision of "how much is too much." The big advantage is that, if well executed and guided by professionals who appreciate the science of toxicology, hazard bands can be set for materials that may not have enough toxicity and hazard data available to set a formal single point OEL. Nevertheless, Control Banding still ultimately requires some form of OEL to be adequately applied. Furthermore, the specificity and sensitivity of Control Banding has only been minimally validated, and the preliminary results have not been impressive.

There are governments around the world that are still establishing OELs. These values are not generally applied outside of the host country and may include many more considerations than just health effects in their derivation. Additionally, actual measurements for ambient air levels of the OEL substances are rarely performed except in a few countries. This suggests that the traditional use of OELs is not widely practiced worldwide.

In closing, we believe that Occupational Exposure Limits (OELs) are absolutely critical. We hope that this Paper will encourage our broad audience of stakeholders to discuss the critical issues, continue the dialogue and, as a call to action, help determine what the future for OELs should be. In working together, our profession can lead a way forward!

The authors and contributors welcome your thoughts and input. The challenges and opportunities described impact us all. We believe they are significant enough that action needs to be taken sooner rather than later. Please send us your comments and thoughts on this issue and the options available to approach this challenge. Your input will help us determine how to move forward.

FOLLOWING AS SEPARATE ATTACHMENT

Glossary:

Acronym or Term	Definition
ACGIH TLVs®	American Conference of Governmental Hygienists Threshold Limit Values®
AIHA WEELS	American Industrial Hygiene Association Workplace Environmental Exposure Levels
BPD	European Community Classification system, the Biocidal Products Directive 98/8/EC (BPD) concerning the placing of biocidal products on the market
CAS #s	CAS registry number, unique numerical identifiers for chemical substances. **CAS registry numbers** are unique numerical identifiers for chemical compounds, polymers, biological sequences, mixtures and alloys. They are also referred to as **CAS numbers**, **CAS RNs** or **CAS #s**.
DMEL (worker)	Derived Minimum Effect Level (DMEL), based on some concept of acceptable or negligible risk, (such as the "Threshold of Toxicological Concern")
DNEL (worker)	Derived No Effect Levels – The Derived No-Effect Level (DNEL) is defined in Annex 1 of REACH as the level of exposure above which humans should not be exposed. – Manufacturers and importers are required to calculate DNELs as part of their Chemical Safety Assessment (CSA) for any chemicals used in quantities of 10 tons or more per year. – The DNEL is to be published in the manufacturer's Chemical Safety Report and, for hazard communication, in an extended Safety Data Sheet. – This process for setting worker DNELs and DMELs primarily uses a structured algorithm utilizing NOELs and NOAELs or LOAELs and default "margins of safety." – Worker DNELs (or DMELs) are reported as an allowable daily dose: • Inhalation: ppm • Dermal and Oral : "mg/kg/day"
EU	European Union
German MAKs	Maximale Arbeitsplatzkonzentration" (maximum workplace concentration now renamed to workplace limit value) set by the German MAK-Kommission, which are similar to the NIOSH RELs in the USA. They are used then to establish TRGS 900 OEVs (equivalent to OSHA PELs).
GLP	Good Laboratory Practice (GLP) embodies a set of principles that provides a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived. These studies are undertaken to generate data by which the hazards and risks to users, consumers and third parties, including the environment, can be assessed for pharmaceuticals, agrochemicals, cosmetics, food and feed additives and contaminants, novel foods and biocides. GLP helps assure regulatory authorities that the data submitted are a true reflection of the results obtained during the study and can therefore be relied upon when making risk/safety assessments.

IUCLID 5	**IUCLID** (**International Uniform Chemical Information Database**) is a software application that can be used by anyone (especially chemical industry companies and government authorities) to capture, store, maintain and exchange data on intrinsic and hazard properties of chemical substances. IUCLID is maintained under the responsibility of the Toxicology and Chemical Substances (TCS), commonly known as European Chemicals Bureau (ECB) within the Institute for Health and Consumer Protection (IHCP) of the Joint Research Centre (JRC) of the European Commission, and is distributed free of charge. Version 5 (IUCLID5) was made available on 13 June 2007. IUCLID5 is the key tool for chemical industry to fulfil data submission obligations under REACH, a European Union law covering the production and use of chemical substances.
MACs	Maximum Allowable Concentrations originally set by the American Conference of Governmental Industrial Hygienists TLV® Committee. They were the original TLV and were similar to Ceiling values currently set.
OELs	Occupational Exposure Limits. Term commonly used globally.
OELs	In the law of the European Union, **indicative limit values**, more exactly **indicative occupational exposure limit values** (IOELVs), are human exposure limits to hazardous substances specified by the Council of the European Union based on expert research and advice. They are not binding on member states but must be taken into consideration in setting national occupational exposure limits. Some member states have pre-existing national limits lower than the IOELV and are not required to revise these upwards. In practice, most member states adopt the IOELV but there are some variances upwards and downwards.
OEVs	Occupational Exposure Values. Term commonly used by ACGIH.
OMB	Office of Management and Budget, a group that oversees the activities of federal agencies in the United States
PELs	Permissible Exposure Limits set by OSHA
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) is a European Union regulation that came into force on 1st June 2007 and replaces a number of European Directives and Regulations with a single system. When REACH is fully in force, it will require all companies manufacturing or importing chemical substances into the European Union in quantities of one ton or more per year to register these substances with a new European Chemicals Agency in Helsinki, Finland. Because REACH applies to some substances that are contained in objects ('articles' in REACH terminology), any company importing goods into Europe could be affected.