ORCHSE Strategies, LLC
2100 M Street NW, Suite 170-357
Washington, DC 20037
+1 202 888 7100
orcstaff@orchse.com
www.orchse.com

October 9, 2015

OSHA Docket Office,
Docket No. OSHA-2012-0023,
U.S. Department of Labor,
Room N-2625,
200 Constitution Avenue, NW
Washington, DC 20210

RE: Chemical Management and Permissible Exposure Limits (PELs); Proposed Rule. Federal Register. Vol. 79, No. 197: Friday, October 10, 2014 - Proposed Rules

Dear Sir/Madam:

ORCHSE Strategies, LLC (ORCHSE) appreciates the opportunity to comment on the Occupational Safety and Health Administration's (OSHA's) October 10th, 2014, Federal register Notice seeking comments and information on its Request for Information on the Management and Permissible Exposure Limits (PELs) Proposed Rule – Federal Register Vol. 79, No. 197.

ORCHSE became an independent enterprise on January 1st, 2014. As the successor to ORC Worldwide and Mercer HSE Networks, ORCHSE has provided a wide array of specialized occupational safety and health services to global businesses for more than 40 years. Currently, more than 120 large (mostly Fortune 500) companies in diverse industries are members of ORCHSE Occupational Safety and Health Networks. The focus of these groups is to promote effective and efficient occupational safety and health programs, policies, and practices, to facilitate constructive communications between businesses and government agencies responsible for establishing national occupational safety and health policy, and to advocate responsible business positions on Agency rulemaking. The activities of ORCHSE's Occupational Safety and Health Networks are based on the premise that providing safe and healthful working conditions is the mutual concern of employers, employees, and government agencies.

It should be noted that member companies of ORCHSE's Occupational Safety and Health Networks have provided substantial information, opinion, and advice to ORCHSE in the development of its comments. ORCHSE selected a variety of questions that were felt to represent the intent of the RFI and submitted the questions as part of an ORCHSE Survey to its members. A significant portion of these comments is a summation of our member's responses, because ORCHSE believes that member company opinion is useful to the Agency. ORCHSE's comments are solely its own and may differ from some of the views and comments of individual member companies.

Background

It is well known that ORCHSE's predecessor organization, ORC Worldwide, had been one of the key contributors to and supporters of the Agency in providing comments and insight on Agency rulemaking and enforcement activity. For example, ORC Worldwide was a key contributor in the development of the original OSHA Process Safety

Management Standard, encouraging the Agency to adopt many of the critical features that were ultimately incorporated into the final standard. ORCHSE continues to believe that constructive input from our organization and its member companies contributes to better and more effective OSHA rulemaking.

ORCHSE appreciates the circumstances under which OSHA has undertaken this pre-rulemaking initiative to examine various aspects of the use of PELs and the issues facing the rulemaking process. Not unlike many standard-setting activities undertaken by the Agency over the years, this Request for Information arose from two significant court rulings that affected the health standard rulemaking processes and procedures—the Benzene decision from the late 1970s and the overturning of the revised PELs in the early 1990s. These two decisions and the actions taken by OSHA in response greatly expanded the cost and time required to complete rulemaking. As a result, OSHA expanded the PEL rulemaking process to include collection of data for determining economic and technological feasibility. The RFI proposes a number of alternatives to obtaining data and information for use in technological and economic feasibility determinations. Additionally, the RFI proposes a number of other questions, which we will address as part of these comments.

ORCHSE General Comments

Current OSHA rulemaking procedures require that the Agency spend a considerable amount of time evaluating and documenting the economic and technological feasibility for any standards under development. OSHA has presented the RFI in a format and fashion that focuses on alternative sources of data and information for use in rulemaking. The PEL RFI is essentially asking if OSHA can rely on existing data and information rather than having to generate supporting data for technological and economic feasibility. In other words, if the data are already accessible and available why should OSHA have to recreate much of the same information? The RFI presents a variety of alternative data sources that OSHA could use rather than generating its own data. Other data sources discussed in the RFI include information from other governmental agencies as well as the peer-reviewed literature, and REACH data from the European Union. While ORCHSE does not believe that any changes to the rulemaking process will take place in the foreseeable future, ORCHSE would support this approach. The use of previously generated data would save costs in the rulemaking process and certainly shorten the time involved. ORCHSE cautions that any data used in rulemaking should be generated by other governmental agencies, such as EPA or NIOSH, or from the peer-reviewed literature.

The PEL RFI also discusses in several places the use of modeling. Modeling can be an effective approach, but it is limited and one should take care in its use. First, the model chosen for application must be validated, specifically for the type of industry or chemical group to which it is being applied. ORCHSE recommends, if modeling is to be used, that the data generated from the modeling approach be compared to actual industrial hygiene sampling for the same chemicals in the same or a comparable industry.

MSHA, the Mine Safety and Health Administration was not mentioned under this RFI, yet it regulates many of the same chemicals. Anything OSHA does or any approach OSHA takes should be done in conjunction with and through partnering with MSHA. It is time these two Agencies within the Department of Labor began working more closely together and coordinating their efforts. The PEL issue is a perfect opportunity. In the 1990s, OSHA, MSHA, and NIOSH partnered on a silica exposure reduction issue and all involved felt the partnership had been very effective and accomplished a lot of good.

In looking closely at the OSHA RFI, ORCHSE also sees three other areas in particular that the Agency is seeking comment and information on. These three areas include:

1. The use of OSHA permissible Exposure Limits (PELs) versus the use of the OSHA General Duty Clause (Section 5(a)(1) of the OSH Act).
2. Employer development and use of a chemical management system, especially ideas and recommendations for the small- to medium-sized employers that rely mostly on their hazard communication programs.
3. The feasibility of the use of control and/or hazard banding to manage workplace exposures to hazardous chemicals.

Before discussion of these three areas in the PEL RFI, ORCHSE suggests that the best way to work on these points as well as all the questions asked in the RFI is to seek input from OSHA stakeholders and the regulated community, including employers, employees (unions), professional associations, trade associations, academia, government agencies (NIOSH, EPA) and other interested parties. To obtain this input, ORCHSE recommends that OSHA, through the Secretary of Labor, appoint a short-term (2 years maximum) OSHA Advisory Committee to address workplace exposures to hazardous chemicals. ORCHSE believes that the best path to success is to include input from as many stakeholders as possible so that whatever comes from the OSHA Advisory Committee is regarded as balanced and fair.

OSHA PELs: ORCHSE strongly advises against rule making that would eliminate the existing PELs (not including the expanded health standards) and then, for enforcement purposes, rely on the general duty clause coupled with existing standards such as hazard communication, personal protective equipment, and respiratory protection. Most people in the field of occupational health would acknowledge that the OSHA PELs are old and outdated, and most would agree that many of the existing PELs may not be protective. The fact remains that the majority of small- and medium-sized employers rely on the PELs to determine what is safe and what is unsafe. It is the opinion of ORCHSE that OSHA should not do away with the PELs, but rather works within the framework that many of the current PELs may be inadequate.

OSHA should be encouraging employers to address this problem by stressing the development of, and laying the foundation for, a chemical management system approach. With a chemical management system, individual employers could provide a healthy work environment through managing the chemicals in their workplaces. ORCHSE believes that OSHA took a significant step forward in this process when it published on its web page a comparison of OSHA PELs with the ACGIH TLVs, the NIOSH RELs, and the Cal-OSHA PELs. ORCHSE recommends that OSHA take this several steps further.

OSHA, working with stakeholders, should initiate a campaign outlining the information on the occupational exposure limits (OELs), the benefits of a chemical management program or system, and appropriate use of control and hazard banding, all to educate and encourage employers, employees, trade groups, and professional associations to use the information. Furthermore, Federal OSHA and state OSHA inspectors should distribute this information during inspections and encourage employers to look beyond the PELs. OSHA is also urged to use its free consultation services to recommend that employers put in place the lowest OELs.

OSHA, as part of this educational program should also continually and consistently remind the regulated community that the OSHA PELs were derived in 1968 and many may not be protective. By providing other OELs, OSHA can encourage stakeholders to utilize the lowest exposure levels for comparison of what is, and what is not “safe”. This is also an opportunity to

focus on the benefits of a comprehensive chemical management system. Small- to medium-sized employers should learn that managing chemicals in the workplace is more than simply complying with the hazard communication standard and assuring that workplace exposures are below the existing PELs.

Concerning the use of the General Duty Clause for workplace chemical exposures where there currently is **not** a PEL or where the Agency finds the PEL not to be protective, ORCHSE recommends that OSHA clearly outline and establish the conditions and circumstances where the Agency would apply the General Duty Clause – Section 5(a)(1) of the OSH Act. ORCHSE recommends that Agency enforcement policy be clearly developed to outline the conditions under which OSHA would cite an employer for a chemical exposure under the General Duty Clause where no PEL exists or where the Agency feels that the existing PEL is inadequate. At a minimum ORCHSE would recommend that the following be implemented:

- The Agency must set clear policy and criteria regarding when it proposes to cite employers.
- The conditions and extent of any increased health hazard must be defined clearly before the Agency issues a citation. OSHA could create a table outlining the health effect that the existing OSHA PEL was set to protect against, and compare it to the new health effect OSHA has determined is significant enough to warrant a violation under the General Duty Clause.
- OSHA should not cite employers under the General Duty clause for first-time instances. ORCHSE recommends that the Agency issue a hazard alert letter outlining the exposure level and the health effect, and provide recommendations on what can be done to reduce exposure.
- If a later inspection or a follow-up inspection reveal that the employer has not taken any steps to protect its employees, OSHA, with appropriate documentation, could then issue a General Duty Clause citation.

Chemical Management Programs and Hazard/Control Banding: At a minimum, a chemical management program should include risk assessment and risk reduction protocols coupled with data collection and screening. Most chemical management programs currently in use rely primarily on employers' hazard communication programs. Small- to medium-sized employers rely almost entirely on their hazard communication programs, and to some degree will also use the OSHA free consultation service for advice. More advanced companies will regard their chemical management systems as their hazard communication programs tied together with their respiratory protection programs and their personal protective equipment programs. Larger companies with more resources have added risk assessment systems to their chemical management programs to assess exposures to noise, chemicals, and other hazards – some, as part of this system, additionally develop their own internal OELs.

- ORCHSE recommends that chemical management programs, coupled with control/hazard banding systems, be among the first items for the suggested OSHA Advisory Committee.

OSHA currently has PELs for 450+ chemicals. The TSCA inventory of chemicals in commerce now exceeds 84,000 chemicals. Periodic TSCA chemical data reporting indicates that there are approximately 7,000 chemicals produced at volumes of 25,000 pounds or greater (www.epa.gov/oppt/existing/pubs/principles). EPA's IRIS database has toxicity information on a large proportion of these substances. These figures likely do not include chemical intermediates derived by employers as part of there manufacturing operations. ORCHSE member companies

also tend to have various internal committees to focus on the chemicals they use, intermediates they develop, and their overall assessment process. Most employers do not have these procedures in place. Hence, a chemical management system would help in controlling chemical exposures.

As the nation's champion for occupational health and safety, OSHA must lead the charge in developing a chemical management program. ORCHSE believes a chemical management system is the key to getting at the PEL issue and assuring employee protections. As mentioned previously, the basis for a chemical management program lies in the OSHA hazard communication, exposure control, respiratory protection, and personal protective equipment standards.

The hazard communication standard addresses SDSs, labeling, and training. Most employers, especially small- to medium-sized companies, treat these three areas as separate and independent requirements – they have to have separate programs to label containers, maintain SDSs, and train employees—rather than linked together as an integrated system; many do not see the connection to an overall chemical management system that includes exposure controls, personal protective equipment, and respiratory protection.

With the right approach and much guidance from OSHA, the corner could be turned and employers could learn to tie the individual programs together as part of their overall hazard assessment and chemical management programs.

If the Agency were to provide guidance on how to create an effective chemical management system, employers could learn to use SDSs to assess and evaluate chemicals in use (including assessing exposure levels, the chemicals' interactions with other substances in the workplace, and exposure limit recommendations), and be in a stronger position to assess and control workplace chemical exposures. Observations and points of data collection could then be tied into respiratory protection requirements, personal protective equipment usage, exposure evaluation and control, and whether or not hazard or control banding would be appropriate.

ORCHSE recommends that OSHA, through the suggested OSHA Advisory Committee, work with the Committee to develop a series of chemical management programs or templates that small- and medium-sized employers could use to implement a chemical management system. The templates would be clearly designed to integrate the following:

- Hazard communication
- Personal protective equipment
- Respiratory protection
- Exposure assessments
- Control strategies including engineering controls, work practice/administrative controls, and personal protective equipment
- Where appropriate, hazard or control banding approaches.

ORCHSE recommends that OSHA begin drafting templates of chemical management programs for employers. The templates would help employers assess their work environments and use those assessments to develop controls for employee protection. ORCHSE additionally recommends that employers be encouraged to work with and develop their programs using the templates through partnerships with OSHA or the OSHA free consultation service. The Agency would need to establish policy on enforcement discretion and phase-in periods, and pilot examples as an incentive for employers and/or industry groups to implement these systems.

Additionally, ORCHSE suggests OSHA adopt and support a multi-pronged approach to chemical management. Clearly, not enough PELs or OELs exist to address adequately the number of chemicals in use. Where a PEL and/or an OEL exist, employers should be encouraged to use the lowest OEL and reduce exposure to levels below that OEL (Note: this includes OELs generated independently by companies). In cases where PELs or OELs do exist, control or hazard banding would not be recommended. Where an employer is working with a class of chemicals such as isocyanates, and OELs have been established for some and not for others, control or hazard banding may be appropriate.

ORCHSE encourages OSHA to pilot a variety of different approaches using different levels of chemical management systems. Through working with different groups, OSHA could couple control or hazard banding with focusing on chemicals with existing OELs in different industry sectors. OSHA has always had enforcement flexibility, and through a partnership program, this avenue of employee protection could be explored. ORCHSE further suggests that any approach such as this be paired with OSHA's free consultation services.

These should be developed according to industry sectors, for particular hazards, and for different-sized employers. ORCHSE would strongly encourage the Agency to explore materials in this area already developed by the Health and Safety Executive – COSHH Essentials out of the United Kingdom. Under its approach a variety of control approaches already have been developed for such workplace exposure areas as abrasive blasting, foundries, maintenance work, welding and hot work, and so forth.

OEL Calculations: Where chemical-specific data are available, ORCHSE encourages OSHA to support employers in calculating OELs, rather than relying on the control- or hazard-banding approach. Chemical-specific data are available on a large number of substances from a variety of sources, notably EPA's IRIS database, which is on line and has toxicity data on a vast number of substances that EPA has evaluated. Companies can calculate OELs for substances using this type of data and references available in the literature (ECETOC Technical Report No. 101, Guidance for Setting Occupational Exposure Limits: Emphasis on Data-Poor Substances. 2006 - European Centre for Ecotoxicity and Toxicity of Chemicals, Brussels.) Where this is not feasible, as with small- to medium-sized employers, a control- or hazard-banding approach can be encouraged.

Control and Hazard Banding: The purpose of hazard banding (classifying a compound based on its inherent toxicological properties) is to enable safe handling of compounds for which minimal data are available (and for companies that don't have the resources to establish OELs). These control and hazard bands would need to be a part of a mature chemical management program because the control and hazard bands must be linked to controls, but the controls must be selected based on a risk assessment by EHS professionals. These programs should include hazard categorization (hazard banding), followed by exposure assessment and ultimately risk assessment (determining the appropriate handling of the compound). The risk assessment is dependent on numerous factors, including volume of compound handled, frequency handled, physical form of compound, task being performed, etc. To be effective this process must be linked to a mature chemical handling/management program (Naumann, B.D. et al. 1996. Performance-based exposure control limits for pharmaceutical active ingredients. AIHA Journal 57: 33-42).

ORCHSE does not encourage OSHA to launch directly into a control- or hazard-banding approach. With control and hazard banding, one size does not fit all. In ORCHSE's opinion,

control and hazard banding first should be developed on a case-by-case basis for different industry sectors. For example, control or hazard banding in the pharmaceutical industry would not be the same as that recommended for a foundry or machine shop. Again, where an OEL exists, or where one can be developed, employers should be encouraged to compare their workplace exposure levels with those OELs. Where an employer works with chemicals for which OELs do not exist, or there is a mixture of chemicals with OELs and those without OELs, a combination of using existing OELs, calculation of new OELs, and a control or hazard-banding approach could be appropriate.

For employers involved in the manufacture of new products and chemicals, ORCHSE additionally recommends that OSHA encourage the development of product stewardship programs addressing the life cycles of their products. For example:

- Establish product stewardship programs for new materials where the product or material would be accompanied by recommendations for the safe use of the product along with recommendations for regulatory compliance. This information would accompany new products in conjunction with the SDS sheet. These companies should also be encouraged to partner with the Agency in this process.
- As part of the partnership, employers should examine their products for lifecycle impacts and establish a category level that could be used to drive improvements under their design, procurement, manufacturing, marketing, use by an employer, and removal at the end of a life cycle. The hazard category and appropriate control recommendations (non-existent, slight, moderate, and severe) should accompany the material along with the SDS through each stage of the life cycle.
  For example, manufacturing refractive ceramic fiber gaskets may create an inhalation hazard without proper controls in place. Installation of a formed product, however, likely presents a minimal employee exposure hazard. At the end of the lifecycle, when the gasket is brittle, it once again may create a dust inhalation hazard to the employees who remove the gasket. Recommendations for use of respiratory protection and ventilation during the gasket removal phase should be available. This hazard information, as part of the manufacturer life cycle considerations should accompany the material along with the SDS during its use.
- With new products, companies should be encouraged to organize product teams to collaborate with sustainability experts to implement recommended improvements, and to ensure that marketed environmental claims are reviewed and approved in accordance with applicable guidelines.

Summary of Member Comments

1. **OSHA is considering greater reliance on peer-reviewed toxicological evaluations by other Federal agencies, such as NIOSH, EPA, ATSDR, NIEHS and NTP for hazard identification and dose-response analysis in the observed range. What advantages and disadvantages would result from this approach and could it be used in support of the PEL update process?**

   Advantages:
   - Provides for available resource to accomplish the workload in a timely manner;
   - Takes advantage of technical capabilities of those organizations;
   - Uses already available, peer-reviewed toxicological information - especially useful if data is lacking;
   - Many agencies referenced in the RFI already have well-defined scientific and peer-review protocols;

- Effective and consistent use of peer-reviewed data;
- Assures that the correct population is targeted;
- OSHA would have to make sure it is using data as it relates to workers or extrapolates to workers from whole population evaluations (ORC does not endorse this approach.)
- This would allow for OELs to be based on current science and not on compromise, law suits, and so forth and would also be a consistent approach across chemicals;
- This would set forth exposure data that is more meaningful and based on the newest available dose-response information. This data would also be reviewed by multiple agencies ensuring acceptance; and
- In this approach feasibility is factored into any exposure limit set. As OSHA itself states on p. 61391, some other agencies are not required to consider feasibility when developing limits; OSHA factors in the intent of the analysis by the other agencies. Some agencies focus on more susceptible populations or exposure length (e.g. 40 hr. workweek vs. 24/7 exposures); and OSHA would review the quality of studies included in other agency evaluations.

Disadvantage:

- Those organizations likely have different missions than OSHA, so there is concern that high reliance on their output may result in PELs that are not actually feasible to achieve by the regulated community;
- OSHA must ensure other agencies' approaches are reviewed scientifically to ensure the quality of data;
- A protocol should be established to ensure that toxicological evaluations used were reviewed by more than one reviewer;
- The disadvantages to using ATSDR, EPA and other studies are that they target whole populations and not those "at-risk". Additional standard deviations from whole population values should be considered for more "at risk" employees; and
- The potential failure to include the cost associated with PEL compliance if so adopted. However, including this information would be advantageous.

2. Are quantitative structure-activity relationships - QSAR, read-across, and trend analysis - acceptable methods for developing risk assessments for a category of chemicals with similar structural alerts (chemical groupings known to be associated with a particular type of toxic effect, e.g., mutagenicity) or other toxicologically relevant physiochemical attributes?

These are good screening tools for further analysis but not sufficient in and of themselves – more authoritative studies would still be needed. The structure-activity relationship approach is a good tool when data are lacking but, more importantly, one should consider whether the skill, education, background, and/or funding are available to apply it in all industrial settings.

Additionally, one would need to have some assurance that the limitations of SAR are understood, and one would really have to obtain sufficient information for an adequate risk assessment. And, individual resource considerations are not enough to appropriately test every chemical.

3. Why or why not? Are there other suitable approaches?

Literature searches, and understanding exposure routes of entry and associated factors are important to consider.

In general QSAR, read-across, and trend analysis are good screening tools for chemical toxicity, but are not sufficient in and of themselves – one still needs more authoritative studies. It appears that these methods show promise and would help with efficiency in the PEL setting process by allowing OSHA to cover a larger range of chemicals without additional effort. These approaches should be considered for use with chemicals when other data are not available. In an effort to use current data their use also should be paired with ongoing literature searches for new studies of similar chemicals or of a specific chemical. Control banding would be another consideration.

Will the mutagenic effects for each chemical be ranked as part of this approach? There can be too much variation in the magnitude and type of effect of individual substances for conclusive grouping.

4. **OSHA described how it obtains information necessary to conduct its industry profiles. Are there additional or better sources of information on the industries where exposures are likely, the numbers of workers and current exposure levels that OSHA could use?**

   General comments under this question included setting up groups to discuss other sources of Information, work though the Journal of Occupational and Environmental and Hygiene, work through professional associations such as AIHA, ACGIH, and ASSE, and with AIHA-certified laboratories.

5. **In cases where there is no exposure information available, to what degree should OSHA rely on modeling results to develop exposure profiles and feasible control strategies? Please explain why or why not.**

   The use of modeling where other data are not available can be appropriate as long as the limitations are understood. The use of modeling is a proactive approach to develop exposure profiles when such data are lacking. OSHA could use modeling results; however, the best results might come from focus groups organized through NIOSH.

   Modeling can be used as a tool in the overall evaluation process, but should not be relied on too heavily. The quality of the model would have a major impact on the outcome of the evaluation.

   One could use the Control Banding approaches like Stoffenmanager used in EU but this also needs to be validated with real data. As described on pages 61398-99 of the RFI, the process for obtaining data to model is very labor-intensive, as it requires extensive time in the actual workplace to obtain work area measurements, it seems to provide no additional benefit – for example, the same or less time could be spent taking actual industrial hygiene measurements as opposed to deriving data for modeling.

   Modeling results should not be used for developing exposure profiles. However, if OSHA does use modeling to predict exposures, such models must be validated. The best validation method would be to compare against actual industrial hygiene measurements from different types of workplaces. Reviewing exposure data from chemicals of similar toxicological/physical properties (i.e. control banding) could be useful. Used appropriately within a variety of industries, modeling could prove effective; with the appropriate controls and reviews in place, OSHA could consider using modeling results to develop exposure profiles and feasible control strategies.

6. What partnerships should OSHA seek to obtain information required to most efficiently construct models of work environments?

The most important partnership in any endeavor offered under this RFI would be with NIOSH and MSHA. The Agency also should consider forming partnerships with AIHA, ACGIH, ASSE, Universities, the Toxicology Excellence for Risk Assessment Center at the University of Cincinnati [TERA] - Occupational Alliance for Risk Science [OARS] (the WEEL-Generating Group), private industry, professional and trade organizations, International Organizations, and WHO – to name a few. Including more stakeholders in partnerships and sharing data and information broadly will lead to a better and more accepted process.

7. How can exposure information in REACH be incorporated into OSHA's technological feasibility analysis?

The response from ORCHSE members was mixed on this question. Some commented that use of REACH data is not appropriate; others that it is acceptable and appropriate; still others that REACH data could be used on a case-by-case basis. For example, exposure information from REACH could be included in technological feasibility analyses in the same way as other data from current sources such as EPA and NIOSH. Care should be taken to ensure that the data reflect similar operations to those in the U.S. The DNELs can be looked at well, but these are task-focused so they may not be comparable.

8. To what extent and in what circumstances should OSHA argue that feasibility for a regulatory alternative can be established by proving the feasibility of reducing the highest exposures to the level proposed by that regulatory alternative?

Responses here were mixed as well, some reporting that the approach is defensible if OSHA incorporates some discussion of cost vs. benefit, but that it may be too limited in scope and not comprehensive for rulemaking.

Others considered the approach to be problematic, in that it assumes that the same controls can be used in both high-exposure and lower-exposure situations. This may not in fact be true. Controls at a chemical manufacturing facility with high exposures to a pure chemical may not be feasible once the chemical is combined in a mixture and sold to a facility that did not manufacture it. A simple high-low comparison assumes a one-size-fits-all set of controls that is not likely. Some of this variability may be controlled if OSHA appropriately distinguishes between industries, but it would still be necessary to demonstrate that control is comparable between the highest and lower levels of exposure within an industry. To move forward with such an approach the Agency would need to show to what extent occupational diseases and symptoms would be reduced.

9. To what extent and in what circumstances can OSHA argue that feasibility for a regulatory alternative can be established by the enforcement of a lower PEL (e.g., the 1989 PEL) by an individual state or states?

The argument can be made when toxicological data substantiate a lower PEL. Adoption of a lower exposure limit by an individual state should never be regarded as evidence of feasibility for OSHA. The state may have followed a different exposure limit setting process or have different feasibility criteria. The data and information can be used as part of the whole data set, but not solely as the basis for a determination. Feasibility would have to be

determined through comparing industries and operations in many states.

For example, a state with a large number of semiconductor manufacturers, such as California, would have a different profile when compared with a state with a high number of auto manufacturers, such as Michigan. The mere fact that a state has a lower PEL on its books is insufficient in the absence of other feasibility factors. The actual experience of the state in its enforcement efforts, and the experience of the regulated community, should be given greater weight. OSHA is national in scope—industries and companies transcend state borders—therefore this approach may not demonstrate feasibility across large corporations.

10. Should OSHA consider greater use of process-oriented regulations, such as regulations on abrasive blasting, welding, or degreasing, as an approach to health standards?

Responses from ORCHSE members were both "yes" and "no. However, OSHA should at least open a dialogue on this concept. There are still a number of questions about which processes would be priorities for such rule making. There are already a number of effective process-oriented regulations already in place (e.g. the OSHA Laboratory Standard, welding, the Process Safety Management Standard, etc.) OSHA should consider moving forward with this concept on a case-by-case basis with input from stakeholders. Additionally, process-oriented regulations can be considered where a sweeping regulation would likely hit too many roadblocks. The most hazardous environments/processes should be considered for the initial regulatory approach. This could then be expanded. Lastly, if process-oriented regulations can be shown to be feasible and able to lower general exposures below specific PELs or OELs, they should be incorporated by federal standard

11. Should such an approach be combined with a control banding approach?

ORCHSE members both agreed and disagreed with the control-banding approach. Overall, the responses indicated that it was a useful where no OELs existed. Several responses stressed that OSHA should evaluate the success of the UK COSHH Essentials as justification. Others reported that the approach would be appropriate if done by chemical family and for some tasks, such as welding, that could be banded based on consideration for similar tasks and exposure pathways.

OSHA should consider the possibility of non-mandatory advisory information on control banding alternatives to strict PEL compliance.

12. Should OSHA consider issuing substance-specific standards in segments, as the analysis of a particular process or industry is completed rather than waiting until every process and industry using a substance has been thoroughly analyzed?

This would be a place where control banding could be applied (along with supporting hazard or chemical management plans). However, this could be tricky as new process/industry information could require significant revisions or exclusions from a previously published substance-specific standard. Alternatively, waiting for all process/industry information could result in overexposures. A balance should be sought.

In contrast, other members commented that OSHA should not pursue substance-specific industry-segmented regulation. This has the potential to be even more confusing and unwieldy than the current regulatory process. While it might speed up the regulatory process for some, in the long run it could create inconsistent coverage and more regulatory

red tape.

13. Should OSHA consider and encourage substitution and elimination of substances that cause significant risk in workplaces even if such substitution or elimination will eliminate or alter the competitive structure of the industry or industries that produce the hazardous substance?

Substitution and/or elimination are the hierarchy of controls preferred methods of control for an occupational exposure. That being said, OSHA should not require substitution or elimination. Rather, OSHA could provide non-mandatory information that would enable companies to consider such changes. OSHA should explore coordinating with other agencies on substitution/elimination efforts (EPA, NIOSH, MSHA). A mandatory substitution/elimination program has the potential to cause problems for industries that are required to use particular chemicals in order to meet other regulatory requirements.

For example, in several cases, EPA requires the use of methylene chloride (an OSHA regulated carcinogen) for analytical methods. These include EPA Method 8082a for Polychlorinated Biphenyls (PCBs) by Gas Chromatography, USEPA Test Method 23 (40CFR60, Appendix A), and Proposed Test Method 202 (40CFR63, Appendix M, aka OTM-028). The latter two methods are used for stack tests and other emissions sampling procedures.

While substitution is a preferred control, one must consider the availability of data regarding the substitute. Often, fewer data are available on the toxicity of substitutes and they are considered safer when they actually may not be.

Some members said that OSHA should consider encouraging substitution and/or elimination of high-risk substances, even at the risk of creating a competitive disadvantage. Other members commented that it is fine for OSHA to encourage substitution, but it should never be mandated by regulation. OSHA may not have the capability to fully evaluate feasible alternatives that meet all business needs. Substitution is a very complicated process and the needs vary widely by industry and individual company. Instead, OSHA should strive to find a way to encourage win/win situations. Continuing to reasonably push substitution and elimination while minimizing alteration of the competitive structure of industry would be the best of all worlds.

14. Are there other approaches OSHA could use that would provide for more timely and less resource-intensive economic feasibility analyses?

This is a difficult area as many employers are not willing to give away or provide their cost information. QSAR, trend analysis and read-across should be considered when exploring timelier and less resource intensive economic feasibility analyses.

15. In determining the level of industry detail at which OSHA should conduct an economic feasibility analysis for a comprehensive PELs update, what considerations should OSHA take into account?

We received a variety of comments on this question, including:

- Demonstrating an increase in disease or harm along with timing Industry economic health;
- Most common industrial applications and engineering control cost data; the relative financial stability of the company using the product. If they bankrupt an entire

segment, unemployment will lead to other impacts on their former workers' health;
- Large corporations have the resources to get below existing PELS and indeed probably use TLVs already, however, small companies need tax breaks and technical help from OSHA;
- Tie economics in with medical/health costs. If a comprehensive PEL list will not be possible then go with grouping by process, chemical type, or consider other reasonable groupings;
- Need to balance viability of global and national competition - key also resides in enforcement to create a level playing field. It's not so much the lack of regulation; stringent rules without strong enforcement doesn't manage risk very well. There needs to be stronger consequence and penalties, more along the lines of EPA. We don't necessarily need a regulatory remedy - we might need a legislative remedy. Our legislature doesn't seem to put this as a very high priority.

16. What factors should OSHA consider in determining whether a chemical should be part of an overall PELs update or subject to substance-specific rulemaking?

A variety of comments were received including:
- Demonstrated evidence of increased disease or harm.
- SAR, relationship of physiologic effects.
- Prioritization process based on toxicological properties. Another approach would be to define a substance specific standard for a group a similar materials (example: toxic metals, Cd, Cr6, Pb) and then add materials to the toxic metal grouping instead of a separate standard (example: add Be to the group instead of another nearly identical substance specific standard).
- Pace of innovation and use of substance in question scope of use toxicity
- Additional factors should be physicochemical (particle size, morphology, etc.) and other properties (states, etc.).
- Degree of hazard should be one of the primary factors. Significant hazards should be considered for the more intensive substance-specific rulemaking.
- Need to look at body of science and weight of evidence for health effects for specific compound and the beneficial effects of lower exposure standard.
- Toxicity, potential for exposure, hazard ratio, volume of chemical in commerce, number of industries with exposure potential, potential for exposure to the public...
- Look at OSHA logs to see if any incidents are related to specific chemical exposures. Incorporate overall PEL update from existing lists- ACGIH TLVs, REACH substances, etc.

17. Should OSHA consider some application groups for a given chemical as subject to a PELs update rulemaking if some other application groups present feasibility issues that make them inadvisable candidates for a PELs rulemaking?

Few comments were received on this question. The comments received varied from “yes”, or “no”, to “could support”.

17. How could OSHA use the information generated under HazCom 2012 to pursue means of managing and controlling chemical exposures in an approach other than substance-by-substance regulation?

Most commenters did not understand what OSHA was asking under this question. A few comments included:

- Too broad and general - can't translate into demonstrating significant risk.
- OSHA could develop non-mandatory guidelines on how to use the classification information created under HazCom 2012 to develop qualitative risk assessments, exposure banding or control banding. Another option would be to develop a database tool similar to the United Kingdom's COSHH Essentials software that would allow for input of these classifications into a system that guides the user to control-banding options.
- Use Control Banding for chemicals that have certain risk phrases-use as criteria for health hazard scoring. Use also for Nano materials. OSHA should take a look at the UK'S COSHH Essentials.

18. How could such an approach satisfy legal requirements to reduce significant risk of material impairment and for technological and economic feasibility?

The basic comment received was that ORCHSE members were not sure this was feasible or that it would actually work.

19. How can OSHA use the concepts of health hazard and control banding most effectively in developing health standards?

- OSHA should not mandate control or hazard banding approaches, but should support their non-mandatory use.
- We could not support the use of hazard or control banding across the broad scope of general industry - it may be something that could be applied on an industry-by-industry approach. A slow phased in approach would be the most important with OSHA providing a lot of support, information, assistance, and enforcement discretion during the process.
- By recognizing them in a standard and partnering with organization(s) to promote these principles (e.g. training).
- Control and hazard banding would mitigate some of the adversarial positions taken thereby leading to a cooperative approach which is always more efficient.
- Tie in the costs in terms worker health to push the health hazard/control banding. Also a healthy/happy worker will perform better. Control banding will also exhaust fewer resources by utilizing existing information where practicable.
- Use a rule for overall Control and hazard banding- the methodology is required but there is some flexibility in application.

20. OSHA requests comment on whether and how task-based exposure control approaches might be effectively used as a regulatory strategy for health standards.

As with the banding processes, OSHA should not consider:

- Regulations based on task-based exposure control. However, OSHA should consider providing non-mandatory guidance on the use of such controls. A web toolkit on how to apply these processes would be very useful.
- Similar to prior answer provided - define acceptable engineering controls through exposure studies and then require through health standards (example: the ACGIH Ventilation Manual).
- Paramount with any heath standard should be worker exposure and adverse health effects. Task based exposure would be more based on the "delivery" of the pollutant into the breathing zone, on the workers skin, etc. Actual concentration limits based on worker health do and will guide those responsible for the health of the worker. We

would still like to encourage, as Low As is Reasonably Achievable (ALARA) wherever possible.

- These approaches are fine for reducing exposure, but shouldn't be used solely in place of PELs. They also must be appropriate and reasonable approaches that don't put undue burden on industry with little value added.
- Make industry and academic/government labs tie together their injury/illness incidents with control banding for chemicals, as a first tier of what is required. Then can go by health risk scores like carcinogens, respiratory sensitizers etc. as also what is required. Then can work down to include irritants etc. with lower health risks.

In Summary

ORCHSE supports OSHA in the use of existing data and information sources to establish technological and economic feasibility. This approach would save time and money in the regulatory process. ORCHSE urges the Agency to use only data and information developed by other governmental Agencies or that is available in the peer-reviewed literature.

Concerning the use of outdated OSHA PELs; ORCHSE supports expanding use of the OEL tables OSHA has already developed, whereby employers would be encouraged to control their workplace exposures to the lowest OEL.

With respect to Agency use of the General Duty Clause to cite an employer in the absence of an existing PEL or where the current PEL is inadequate, ORCHSE recommends that on first instance, the Agency place the employer on notice through the use of a hazard alert letter. At a minimum the letter should define the health effects, provide information on the exposure level, and provide several control or abatement recommendations.

The Agency should establish a short-term (2 years) Advisory Committee to work with OSHA and provide recommendations on use of the General Duty Clause, establishment of chemical management programs or systems, and the use of control and hazard banding.

ORCHSE recommends that OSHA coordinate and work closely with NIOSH and MSHA in any endeavor regarding the PEL or chemical management system/program areas.

ORCHSE recommends that the Agency and its partners develop multiple templates for implementing and using chemical management programs. The different templates would accommodate use by different-sized employers and would address the needs of both employers with just a few chemicals and those that may have thousands of chemicals on site. All template programs should carefully tie the use of the hazard communication program/standard with the respiratory protection and personal protective equipment standards/programs. These programs should then be coupled with risk assessment and exposure evaluation and control processes. Concerning control or hazard banding, ORCHSE believes OSHA should explore these approaches. Where OELs exist, ORCHSE recommends that they be used as part of the assessment and hazard control aspects of employers' chemical management systems. Where OELs do not exist, or cannot be calculated, control banding and hazard banding approaches should be explored. ORCHSE encourages the Agency to consider using the United Kingdom's COSHH Essentials programs and control/hazard banding approaches in getting started. These already have been developed, and many employers within the United States already are using these existing strategies.

With any new approach, the Agency must provide enforcement flexibility to the regulated

community. OSHA should explore partnerships, cooperative program efforts, and work with VPPPA and/or SHARP participants. To encourage employers to adopt chemical management programs, the Agency must assure employers that, as long as workers are protected, it will not issue citations to participating companies.

ORCHSE applauds OSHA on its efforts to continue a broad-based dialog on the PELs issue and affirms its commitment to working together toward finding workable solutions.

Thank you for the opportunity to comment.

Sincerely,

Richard Fairfax
Senior Consulting Advisor

Dee Woodhull
Partner

Scott Madar
Partner

Steve Newell
Partner