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OSHA Docket Office
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U.S. Department of Labor
200 Constitution Avenue, NW
Room N-2625
Washington, D.C. 20210

Subject: OSHA Request for Information: Chemical Management and Permissible Exposure Limits (PELs) [Docket No. OSHA 2012-0023]

To Whom It May Concern:

The American Foundry Society (AFS) is pleased to provide the following comments to the U.S. Department of Labor's (DOL) Occupational Safety and Health Administration (OSHA) in response to the agency's request for information (RFI) on chemical management and permissible exposure limits (PELs) published in the Federal Register on October 10, 2014 at 79 Federal Register 61383-61438.

AFS is the major trade and technical association for the North American metalcasting industry. The association is comprised of more than 7,500 individual members representing over 3,000 metalcasting firms, including foundries, suppliers and customers. Our industry is dominated by small businesses, with over 80 percent of U.S. metalcasters employing fewer than 100 workers. AFS and its member companies are committed to protecting workers and developing and implementing sound government policies that advance health and safety. In fact, worker health is central to AFS' mission and an issue which our association has worked constructively with OSHA.

AFS considers occupational exposure limits to be effective tools in managing exposures and preventing injury and ill health in the workplace. AFS also recognizes that regulatory efforts to update occupational exposure limits have not kept pace with health hazard information developments and that the new chemicals are being introduced at a faster rate than traditional regulatory approaches can keep up with. However, AFS looks at the problem analysis in a different light than that presented in the RFI and would like to propose additional potential actions to address these issues.

General Comments

Statutory Requirements

OSHA finds the statutory requirements burdensome and looks for ways to expedite the process. AFS understands that the regulatory process is rigorous, but believes that the PEL promulgation process provides a valuable opportunity for stakeholders to provide their critical input and data to the agency.

Truncating this process could lead to the violation of the Occupational Safety & Health Act (OSH Act)[1] or conflict with court precedent.

Models may provide value as a screening tool to identify and prioritize chemicals for review. However, models depend on assumptions, require judgement when choosing which model to use, and are no better than the data they rely upon. Using faster and more sophisticated models and tools will not solve the problems created by poor data, inappropriate models and incorrect assumptions.

As noted below, OSHA's recently proposed crystalline silica rulemaking provides a case in point. Failing to perform accurate risk analysis, and thorough and up-to-date technological and economic feasibility reviews invites contention and challenge. Models can provide speed, but cannot supply objectivity or improve accuracy of data.

Alternative Approaches

OSHA's RFI focuses on more rapid screening and non-OEL control approaches such as substitution and control banding. Big data tools and screening processes are useful for marshalling information. However, effective controls depend on an accurate hazard classification, and poor information leads to misplaced priorities. There is a great deal of inaccurate and conflicting hazard classification information in current Safety Data Sheets (SDSs). The most effective service OSHA could provide would be to make accurate information available for users. OSHA's annotated PELs are an example of such an approach.

Under Globally Harmonized System of Classification and Labelling of Chemicals (GHS), employers are required to conduct a hazard assessment, but the information needed to do so is not readily available. Access to a typical Safety Data Sheet (SDS) writing data base with necessary information may cost as much as $200,000, more than most small employers can afford. Leasing the software or using consultants are alternatives, but these options also presents cost barriers. OSHA could make accurate hazard classification information available to small employers at no cost so that the GHS classification information could be improved. Control decisions would be improved as a result.

Another Approach

The OSHA RFI does not address the potential role of voluntary consensus standards in improving workplace health. Many of the OSHA regulations began as voluntary standards which played an active and important role in safety and health improvement before OSHA regulations were enacted. It may be time to promote that process again and for OSHA to play a more active role in voluntary consensus standards development.

Although the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs) process is not a consensus process, other consensus mechanisms such as ASTM International's E34 Occupational Safety and Health Committee already exist. Other organizations such as American Industrial Hygiene Association (AIHA), American Society of Safety Engineers (ASSE), UL, and, National Safety Council (NSC) may be interested in reconstituting committees similar to the ANSI Z37 committee to develop consensus standards if encouraged to do so by OSHA. Employers need Occupational Exposure Limits (OELs) that they can have confidence in. Out dated and non-consensus standards do not provide the credibility and confidence that voluntary consensus standards do. While such standards may be more difficult to

[1] 29 U.S.C. § 651 *et seq.*

enforce than a regulation, they can establish a recognized reference for employer guidance. More importantly, they can promote best practices.

Responses to Specific Questions Raised in the RFI

Question IV A1: OSHA seeks input on the risk assessment process described above. When is a model-based analysis necessary or appropriate to determine significance of risk and to select a new or revised PEL? When should simpler approaches be employed? Are there specific approaches OSHA should consider using when a model-based analysis is not required? To the extent possible, please provide detailed explanation and examples of situations when a model-based risk analysis is or is not necessary to determine significance of risk and to develop a new standard.

It is most important to be accurate and objective. The most effective way to improve the risk assessment process is to make it complete, objective and accurate. To meet its obligation to establish a health risk OSHA must conduct an assessment that meets the following criteria:

- uses objective and reproducible criteria to search and evaluate health risk data and literature;
- applies relevant and objective criteria to select studies for inclusion in meta-analysis review;
- uses best fit methodology for model selection, including threshold models; and,
- evaluates the contribution to disease experience of current exposures that exceed the current general industry PEL.

In the recent health risk assessment for respirable crystalline silica OSHA fell short in several respects. The Preliminary Quantitative Risk Assessment (PQRA) for respirable crystalline silica (RCS) was incomplete because it did not consider all relevant information and did not use the best data available in its analysis. For example, the PQRA analysis included only seven of 30 foundry studies that were referenced in a 2011 position paper entitled Lung Cancer and Foundry Workers, prepared by the Industrial Industries Advisory Council in the UK.[2] Even the seven foundry studies that were used were largely, and arbitrarily, dismissed.

OSHA's RCS PQRA was also deficient with respect to the process used to conduct the review of scientific data. Deficiencies included the following:

- No formal process was described for search criteria or study selection. The search criteria and methods should be transparent and reproducible in any weight of evidence determination.[3] All of the relevant scientific literature should be identified as a first step, prior to an objective selection process. This first step, which is critical to ensure completeness and avoid bias, was missing in the RCS PQRA. The only description of the process appeared on page 8 of the PQRA:

  > *These studies were identified from numerous scientific reviews that have been published previously such as the IARC (1997) and NIOSH (2002) evaluations of scientific literature as well as from literature searches and contact with experts and stakeholders.*

[2] The Industrial Industries Advisory Council Study is available at: http://iiac.independent.gov.uk/pdf/pos_papers/pp29.pdf.

[3] Weed DL. 2005. Weight of evidence: a review of concepts and methods. Risk Anal. 25:1545-1557

Executive Order 12866 requires OSHA to premise a rule upon the best reasonably obtainable scientific data. But this was a haphazard approach that is not reproducible and is subject to bias. Moreover it appears to rely primarily on information that was more than 10 years old.

- By best "reasonably obtainable" data, we understand Executive Order 12866 to mean that OSHA does not have the authority to select just the studies that it prefers when it is aware of, or through minimal diligence, *reasonably should be* aware of other critical studies. Yet, in the RCS proposal several studies were selected and others were ignored without describing an established methodology to determine which studies merited inclusion and which failed to meet inclusion criteria. Instead, the PQRA contained the statement:

  > *OSHA has included in its review all published studies that the Agency deems relevant to assessing the hazards associated with exposure to respirable crystalline silica*.[4]

  A proper selection methodology should be based on objective criteria for review that can be evaluated by third parties, not merely on the Agency's subjective opinion.

- Study selection for the RCS proposal appeared arbitrary and biased toward a desired result. One of the most glaring examples of arbitrary selection in the PQRA related to studies of the Vermont granite shed workers. Several commenters questioned the reliance on the older, smaller and weaker Attfield and Costello[5] study rather than the newer, stronger and more complete Vacek et al[6] study.[7] The Vacek et al. study had more workers, more lung cancer cases, longer follow-up, better exposure data, and more accurate status determination than the Attfield and Costello study. It is difficult to imagine any objective search and selection criteria which would not favor use of the Vacek et al. study.

- The RCS PQRA failed to adequately consider models that are capable of determining whether a threshold exists and whether such models may fit the data more accurately. The existence of a threshold for health risk is a critical question and should have been properly explored. The linear risk response models chosen in the PQRA were not capable of finding a threshold. Selection of a suitable model must be done with the goal of best fitting the data.

- The RCS PQRA did not adequately consider mechanistic information that could have provided better insight into the existence of a threshold. OSHA's analyses of the occupational data as to respirable crystalline silica exposure failed to adequately consider the weight of evidence for a response threshold, which is supported by results from animal toxicology studies, mechanistic analysis, and epidemiologic studies.

- Due to deficiencies in data search, study selection and model selection the RCS PQRA provided no convincing evidence that any residual disease was due to exposures below the current general industry PEL, rather than to current or past overexposure. The current construction industry PEL permits RCS exposures 250% of the general industry PEL and overexposure to the

[4] PQRA page 8.

[5] Attfield M, Costello J (2004) Quantitative Exposure-Response for Silica Dust and Lung Cancer in Vermont Granite Workers. Am J Ind Med 45:129-138.

[6] Vacek PM, Verma DK, Graham WG, Callas PW, Gibbs GW (2011) Mortality in Vermont Granite Workers and Its Association with Silica Exposure. Occup Environ Med 68:312-8.

[7] See for example comments by Dr. Anthony Cox in OSHA docket document, OSHA-2010-0034-2308.

current general industry PEL is well documented, as is latency of disease. Therefore, current disease could be explained by overexposures to the current general industry PEL.

In summary, the key to improving risk assessment is accuracy, objectivity and reproducibility. Models may provide value as a screening tool to identify and prioritize chemicals for review. However, models are no better than the data they rely upon, as is demonstrated by the way models were used in the RCS PQRA. OSHA would be well advised to pay heed to the often quoted advice of a noted statistician, "Essentially, all models are wrong, but some are useful." [8]

Question IV.A.2: If there is no OSHA PEL for a particular substance used in your facility, does your company/firm develop and/or use internal occupational exposure limits (OELs)? If so, what is the basis and process for establishing the OEL? Do you use an authoritative source, or do you conduct a risk assessment? If so, what sources and risk assessment approaches are applied? What criteria do facilities/firms consider when deciding which authoritative source to use? For example, is rigorous scientific peer review of the OEL an important factor? Is transparency of how the OEL was developed important?

AFS does not develop its own OELs. AFS publishes health and safety guides that summarize health effects associated with various chemical agents and processes common to the foundry industry. Applicable OSHA PELs, NIOSH RELs and ACGIH TLVs are listed for information. Several member companies develop internal limits based on an assessment of available information, including literature reviews, industry experience, and manufacturer recommendations. For example, one foundry process for coremaking uses a tertiary amine catalyst. Triethylamine (TEA) was used initially, but other related compounds have found common application, including dimethylethylamine (DMEA), dimethylisopropylamine (DMIPA), and more dimethylpropylamine (DMPA). The only OSHA PEL for these compounds is for TEA (25 ppm) and is based on irritation. However, manufacturers recommend maintaining exposures below 1 ppm due to eye clouding effects that have been noted since the PEL was established. The German MAK is often used for guidance (1 ppm for TEA, 2 ppm for DMEA and 1 ppm for DMIPA), but there is no value for DMPA.

In addition to accuracy, objectivity and reproducibility in evaluating health effects literature, key factors in developing OEL recommendations are transparency and consensus. The historical process for developing ACGIH TLVs included sufficient involvement of interested parties to provide for transparency and consensus. The resulting TLVs were widely supported. However, AFS finds the current process lacks transparency and consensus which limits the usefulness of current TLVs. A case in point is the TLV for silica which does not appear to be based on a fair and objective analysis of the literature.

With several OSHA PELS out of date and without a working consensus process to develop OELs, it may be time to reconsider the potential role of voluntary consensus standards in improving workplace health. Many of the OSHA regulations began as voluntary standards which played an active and important role in safety and health before OSHA regulations. It may be time for OSHA to promote that process and to play a more active role in voluntary consensus standards

[8] Box, George E. P.; Norman R. Draper (1987). Empirical Model-Building and Response Surfaces, p. 424, Wiley.

development. Although the ACGIH TLV process is not a consensus process, other voluntary consensus mechanisms such as ASTM E34 Occupational Safety and Health Committee already exist. Other organizations (AIHA, ASSE, UL, NSC) may be interested in reconstituting a committee similar to the ANSI Z37 committee to develop voluntary consensus standards.

Voluntary consensus standards often promote safety and health improvements in a best practices approach instead of the lowest common denominator approach required of mandatory standards. In other words, they often pull the bar forward rather than push it from behind. For this reason, they are sometimes capable of advancing safety and health beyond what OSHA can do.

Employers need OELs that they can have confidence in. Out of date PELs and non-consensus TLVs do not provide the credibility and confidence that voluntary consensus standards can. While such standards may not provide the enforceability of a regulation, they can establish a recognized reference for employer guidance.

Question IV.A.3: 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?

AFS supports efficient use of resources to avoid duplication of effort. Many of the agencies listed in the question look at the same body of research. In some cases, another agency's review may include additional research that might not otherwise be part of OSHA's rulemaking, such as information on toxicology mechanism that may provide valuable insight. Of course, the different objectives of these other agency groups need to be understood and taken into consideration in OSHA's evaluation.

Question IV.A.4: OSHA is considering using the Point of Departure (POD) (e.g., BMD, LOAEL, NOAEL), commonly employed by other authoritative organizations for carrying out non-cancer risk assessments as a suitable descriptor of the Low End Toxicity Exposure (LETE) level that represents a significant risk of harm. Is this an appropriate application of the POD by OSHA? Are there other exposure values that OSHA should consider for its LETE?

Use of a Point of Departure (POD) approach to determine a Low End Toxicity Exposure (LETE) has potential meaning and value for OSHA's risk assessment process. As long as the process is accurate, objective and reproducible, and is used in support of, not in place of reasonable judgments, AFS supports such use.

Question IV.A.5: Several methodologies have been utilized to adjust critical study exposures to a worker equivalent under representative occupational exposure conditions including standard ventilation rates, allometric scaling, and toxicokinetic modeling. What are reasonable and acceptable methods to determine worker equivalent exposure concentrations, especially from studies in animals or other experimental systems?

Adjusting exposures is a complex undertaking and one which depends on numerous biological, physical, environmental and process-related factors. It is not possible to specify any individual

modeling or adjustment method that can be used for all situations. Rather, AFS simply points out that the choice and application of whatever methodology is used should be accurate, objective and reproducible. Such criteria are necessary for appropriate judgments about methodology and inference.

Question IV.A.6: OSHA is considering a Margin of Exposure approach that compares the LETE with the Lowest Technologically Feasible Exposure (LTFE) as a decision tool for low dose extrapolation. Is this a reasonable means of determining if further low dose extrapolation methods are needed to meet agency significant risk findings? What other approaches should be considered?

AFS agrees with the concept that the LTFE may be a useful decision tool that could make it unnecessary to do extensive extrapolation in some cases. However, caution is advised lest the regulatory process evolve simply into a feasibility proceeding without adequate discussion of health risk. This Margin of Exposure (MOE) approach only seems applicable where there is general agreement on the MOE, LETE and LFTE, something that would only be possible with accurate, objective and reproducible methods and conclusions.

Question IV.A.7: Can the uncertainty factor methodology for extrapolating below the observed range for non-cancer effects be successfully adapted by OSHA to streamline its risk assessment process for the purpose of setting updated PELs? Why or why not? Are there advantages and disadvantages to applying extrapolation factor distributions rather than single uncertainty factor values? Please explain your reasoning.

Uncertainty must be dealt with in any proceeding that lacks complete information, and almost all health risk assessments are based on information that contains data gaps. The selection of sample populations to study, extrapolation of animal to human toxicity response, characterization of exposure, and many other aspects of risk assessment create uncertainty about estimates of effect. The key issue is not whether uncertainty factors are useful or necessary, but whether the uncertainty factors are reasonable. As pointed out in the RFI with regard to the 1989 rulemaking:

> The Eleventh Circuit ruled that OSHA had failed to show how uncertainty factors addressed the extent of risk posed by individual substances and that similarly, OSHA failed to explain the method it used to derive the safety factors.[9]

Uncertainty must be dealt with in a carefully articulated process using methods that are reasonable and repeatable. The problem is not the use of uncertainty factors per se, but rather the lack of openness and articulation. Another issue related to uncertainty is how uncertainty or safety factors associated with multiple variables are combined or multiplied. The risk assessment community has developed various methods for handling multiple uncertainty factors and these should be used and explained as appropriate.

Models are often used to deal with uncertainty. The best approach when using models is to use multiple models to determine a best fit of the data, rather than predetermining a single model or

[9] Federal Register Vol. 79 p. 61394

selecting a model based on outcome. For example, using a linear model for a substance that has a threshold exposure level for human risk may lead to an inappropriate OEL.

OSHA's approach to uncertainty should be clear, objective and carefully articulated. Uncertainty must be dealt with, but assumptions, data selection, models and safety factors must be reasonable and repeatable.

Question IV.A.8: Are 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? Why or why not? Are there other suitable approaches?

Judgments based on similar structure, mode of action, mechanism, or metabolism to predict similar endpoints are useful for screening and may be useful for risk assessments, but are only appropriate when no data is available or when available data supports the prediction. Such methods should not be used in place of chemical specific data when such data is available. For example, calcium and beryllium are both bivalent metals but have very different toxicology profiles. Structural analogies may be useful but only when no other data exists.

Question IV.A.9: How should OSHA utilize the new molecular-based toxicity data, high throughput and computer-based computational approaches being generated on many workplace chemicals and the updated NRC risk-based decision making framework to inform future Agency risk assessments?

Molecular-based toxicity data and computational approaches are exciting and useful developments, but their limitations must be recognized along with their promise. These may be excellent screening tools and may be capable of bringing vast amounts of information together to improve the risk assessment process. However, some judgment is still needed in applying the results from these tools. For example, the toxic endpoint (workplace, environment, or consumer) must be considered for relevance to the workplace. In some cases the toxicity endpoint may focus on one specific effect that is not relevant to workplace exposures while failing to focus on another effect that is relevant. The main advantages of these approaches are to incorporate large information sources in the risk assessment and to provide helpful mechanistic insights. However, they do not take the place of exposure related occupational risk assessment

Question IV.B.1: 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?

Before answering the question at hand, it is necessary to address assumptions that underlie the series of questions about technological feasibility. AFS believes that OSHA's exposure assessments are based on a flawed assumption that the geometric mean is an appropriate test to demonstrate the ability of most operations in an industry to meet a standard. The geometric mean cannot be used to satisfy a "most operations, most of the time" test in a situation where noncompliance is an integral part of normal process variation.

The variation in exposures associated with an operation must be considered. This point is readily made with a pair of six sided dice. The geometric mean of a distribution of dice pair throws is likely

to be 7. However, that does not indicate that a not-to-be-exceeded standard of 8 or 9 or 10 is possible. Indeed, a typical operation would find such a standard to be impossible to meet.

Variability of RCS exposures in a foundry environment is even more likely than is apparent from the dice analogy. AFS submitted an analysis to the RCS record that used National Institute for Occupational Safety and Health (NIOSH) methodology to demonstrate how much of the exposure distribution for several foundry jobs was due to the process itself and how much was due to other causes.[10] The study data demonstrated that 84% of the exposures are integral to the process itself.

The analysis showed that, even if one assumes that the geometric mean for most of the foundry jobs is below the 50 µg/m^3 proposed PEL, the 84% confidence limit for the exposure distribution exceeded the 100 µg/m^3 **current** PEL. Predictable dice rolls of 10, 11, or 12 are part of the normal dice roll process, and would preclude a finding that the typical dice thrower can meet a not-to-exceed standard of 9. The data submitted by AFS demonstrate that for jobs where sufficient data is available to permit an assessment of statistical variation, those jobs currently do not even meet the **current** 100 µg/m^3 PEL, much less the 50 µg/m^3 proposed PEL.

Thus, the geometric mean does not provide evidence of the ability of the typical employer to meet the PEL unless the variation of exposures is understood and characterized. Regardless of how OSHA obtains information on industry profiles, the feasibility determination must consider variability of the data. The geometric mean does not by itself indicate feasibility.

Question IV.B.2: 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.

Modeling can provide useful information, but results must be interpreted with caution. Real world exposures are affected by many factors that cannot be easily modelled particularly for manufacturers, such as process upsets, equipment breakdowns, and material handling equipment movement.

Models are useful for calculating mean exposures under idealized conditions, but as noted above, characterizing variability is also critical to exposure assessment.[11] The mean exposure is not sufficient by itself to determine feasibility. Modeling requires certain assumptions and generalizations that may not provide variability information.

To provide useful interpretations, any use of modeling must clearly explain all assumptions and parameters and must be reproducible.

Question IV.B.3: What partnerships should OSHA seek to obtain information required to most efficiently construct models of work environments? More specifically, how should OSHA select facility layouts to model that are representative of typical work environments in a particular industry? Note that the considerations should include variables such as work area dimensions, production volumes and ventilation rates in order to develop models for both large and small scale operations.

For the foundry industry, it is very difficult to generalize about work environments. No two foundries are alike. Foundries vary in facility size from less than 1000 square feet to over several million, in number of employees from fewer than 5 to over 1000, in production rate from less than

[10] OSHA-2010-0034-2379 Appendix 4 Critique of the Interpretation of Foundry Silica Sampling Results Used by OSHA as Support of Feasibility of Foundries Meeting a Reduced Silica Exposure Limit.

[11] OSHA-2010-0034-2379 Appendix 4 Critique of the Interpretation of Foundry Silica Sampling Results Used by OSHA as Support of Feasibility of Foundries Meeting a Reduced Silica Exposure Limit.

one casting per week to tens of thousands per day, and in size of casting from a few ounces to over 100 tons.

In addition, there are significant differences in melting process (cupola, crucible, induction, electric arc, reverberatory furnace, etc.), mold binder chemistry (green sand, air set, gas hardened, shell, lost foam, etc.) molding method (jolt, squeeze, slinger, vacuum, flaskless, etc), core chemistry (multiple hot, cold and warm box systems), gating and risering practices, and cleaning and finishing methods. In the Preliminary Economic Analysis (PEA) for foundries in OSHA's silica proposal, it recognizes differences in alloy types, but from an exposure and control standpoint -- there are many other more significant differences between foundries.

Modeling has been done for the foundry industry to develop air emissions factors for specific resin and binder systems associated with the casting process. It is important to note that this modeling could not be done simply with computer calculations, but instead involved the construction of a 60,000 square foot experimental foundry under the Casting Emission Reduction Program (CERP). Emissions factors were generated under carefully defined conditions to provide useable data linked to specific resins. A modeling team provided resources for foundries to make reasonable predictions to their own processes.

As demonstrated by Casting Emission Reduction Program (CERP), modeling for the foundry industry is a major undertaking, one that requires real world data, precise definition of numerous process variables, and careful application of results. A description of CERP can be found at: http://www.afsinc.org/files/1409-320%20cerp%20accomplishments%20public.pdf.[12] Based on the CERP experience discussed above, accurate modeling for foundry exposure data may require considerable cost, time and simulation efforts.

The exposures associated with different resin systems, molding materials, scrap sources and process variables in the foundry process cannot be predicted accurately from a model. The chemistry of a system may be known and it may be possible, for example, to predict that formaldehyde may be produced when a certain resin system is used to produce cores. However, the amount of formaldehyde that will be released will depend on numerous variables, some of which change daily or hourly. Examples of variables include sand purity, temperature, humidity, part geometry, and part handling requirements, such as secondary finishing or assembly of complex cores. Experimentation and simulation can provide useful emission factor data based on a limited set of conditions. Even then, those factors must be applied to each foundry according to its own production and process situations. There is no such thing as a typical layout or work environment for the foundry industry.

Question IV.B.4: Should OSHA use only models that have been validated? If so, what criteria for model validation should be employed?

It would be difficult to use in any meaningful way results from models that have not been validated. Validation should provide an indication that results are predictive of real world situations, both for accuracy and variability under specific defined and controlled circumstances. Extrapolation and inferences would only then be possible for real world situations, and even then would require careful professional evaluation and judgment.

Question IV.B.5: What exposure models are you aware of that can be useful for predicting workplace exposures and help OSHA create exposure profiles and in what circumstances?

[12] The facility is currently managed by Technikon, LLC. http://www.technikonllc.com/about.php

Various models have been described for exposure prediction,[13] but none can predict workplace exposures in foundries except in extreme cases of very high or very low exposure levels. These models may be useful for screening or go/no go decisions, but are not useful for predicting foundry workplace exposures. As demonstrated by CERP, a large number of process, equipment and environmental variables must be defined and controlled to accurately interpret experimental data in order for that data to be used in modeling. Even then the modeling results must be applied to each foundry's specific operations and cannot be generally applied across the industry.

Question IV.B.6: Should OSHA consider CFD models primarily for indoor operations, outdoor operations, or both? What limitations exist with these two different types of models?

Given the broad diversity of foundry operations, these methods are only applicable to a single specific foundry. Generalizing results across a range of foundries usually requires too many assumptions to render results meaningful. Only for very high or very low exposure might the results be useful for decision making.

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

AFS recognizes that relevant information may exist in various regulatory databases and supports its use by OSHA if interpreted appropriately. However, OSHA has no suggestions for how to overcome constraints to obtain the data.

Question IV.B.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?

While the logic of this approach is appealing, the practical application may be troublesome because of a misinterpretation of what it means to "prove feasibility." For example, in the RCS rulemaking OSHA's PEA used 22 case histories to argue that reducing exposure levels to the proposed PEL could be achieved. The 22 case histories involved lengthy compliance processes and numerous trial and error attempts to reduce silica levels. Far from the simplistic, one-size-fits-all and magic-bullet solutions that were referenced in the PEA's conclusory assertion of feasibility, the cases actually described multi-year, multi-step, and often unsuccessful attempts to meet even the current PEL for silica.

Typical of the lengthy compliance process is the following discussion which appears on page IV-155 of the PEA under the heading "Additional Controls for Abrasive Blasting Operators":

> *A series of air sampling results demonstrates the value of identifying, enclosing, and ventilating all substantial sources of exposure associated with abrasive blasting operations. OSHA visited a gray and ductile iron foundry where the abrasive blasting operator exposures were due to a combination of dust sources. The foundry made incremental modifications and eventually reduced operator silica results by 75 to 85 percent, to levels less than 50 µg/m^3. Initially, in 1994, two workers sorted castings from a conveyer arriving from the shakeout area and loaded and unloaded an automated shot blasting machine (presumably a batch process). The ventilation was poor ("0 CFM") in the sorting area, and*

[13] See for example http://acmg.seas.harvard.edu/people/faculty/djj/book/bookchap3.html

results of 178 µg/m^3 and 184 µg/m^3 were obtained for these two operators (OSHA SEP Inspection Report 101548626). The facility replaced the shot blasting machine and associated ventilation, as well as covered and ventilated a section of the conveyer coming from the shakeout. During a second evaluation it was evident that these changes had not reduced the silica exposure levels (195 µg/m^3 and 246 µg/m^3).

Several months later the workers continued to perform similar work, but were now placing castings sorted from the conveyer into skip buckets used to load the blasting machine. During this third evaluation, results of 47 µg/m^3 and 107 µg/m^3 were obtained for the two abrasive blasting operators, whose primary source of exposure was now reportedly dust from the shakeout conveyer and skip buckets. The foundry next added an enclosure over the skip buckets and further covered a sand conveyer next to the shot blasting machine. The shakeout conveyer, however, was noted to be a continuing source of exposure during a fourth evaluation, at which time results of 72 µg/m^3 and 80 µg/m^3 were reported for the abrasive blasting operators.

Finally, 21 months after the initial evaluation, the facility added an enclosure and LEV to the exit from the shakeout, and also added LEV to the skip bucket enclosure. These controls, combined with previous modifications (new blasting machine with LEV, enclosed and exhausted sand and shakeout conveyers) were associated with results of 34 µg/m^3 and 47 µg/m^3 for the abrasive blasting operators who continued to sort castings (25 percent of the shift) and operate the shot blasting machine [OSHA Special Emphasis Program (SEP) Inspection Report 101548626].

The case file for the OSHA SEP Inspection Report 101548626 contains a letter from the OSHA Area Director referring to the same samples cited by the PEA and concluding:

> It is reasonable to expect that on any particular day an overexposure to respirable silica could occur.[14]

Conversely, the PEA uses the two isolated samples to erroneously infer technological feasibility of the proposed PEL for abrasive blasting operators, across the entire range of foundry industry operations. The OSHA Area Director in charge of enforcement correctly points out that the data used by the PEA do not demonstrate compliance with even the current PEL.

Of additional concern in this case is that the PEA distills the benefits obtained from several years of concerted effort and application of multiple control techniques down to two overly simple steps: "(1) automating and enclosing abrasive blasting operations using properly ventilated equipment and (2) following manufacturer's recommendations for abrasive blasting machine use and maintenance." Many of the case studies involve years of work to find the right solution for a particular foundry and it is not proper to assume that the particular measures that eventually and uniquely worked in one foundry will automatically achieve the same effectiveness in other completely different situations.

As this example demonstrates, the problem is not with the concept of using control of high exposures to demonstrate feasibility. Rather it is with the assumptions that exposures are controlled when they are not, and the assumption that certain selective efforts taken out of

[14] Exhibit 1 attached to AFS post hearing comments - OSHA SEP inspection report 101548626 contained in document OSHA-2010-0034-0128.

context were solely responsible for control. The misinterpretation of feasibility information is a much more fundamental problem than posed by this question.

Question IV.B.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 (See Appendix B)] by an individual state or states?

A lower PEL in one state does not necessarily indicate feasibility. The industrial make up varies from state to state, so certain affected industries may not be represented in every state, and may not have been part of the process that adopted a lower PEL there. Moreover, it may be that some affected industries have closed or moved from one state to another because of an inability to operate within the regulatory climate. It is also possible that enforcement approaches are different from those permitted by OSHA rule (for example, allowing use of respiratory protection to achieve compliance with a lower PEL).

Question IV.B.10: What are the appropriate criteria that OSHA should use to assess whether control strategies implemented in a process from one industry are applicable to a process from another industry (e.g., similarity of chemicals, type, extent and duration of exposures, similar uses)?

Controls for certain generic processes (e.g. welding) may apply across several industries, but many industries have unique situations that must be considered. For example, welding in confined spaces or on hazardous substrates may require different controls from welding on a seat frame. For the foundry industry, wet methods for dust control may be appropriate for some industries, but may be inappropriate for situations involving molten metal.

Vendors are a key resource to help assess applications and impacts. However, care must be used to understand that one vendor does not represent the entire industry. For example, in the PEA for the recent OSHA RCS proposal, OSHA specified a vastly inadequate 15 gallon vacuum for foundries based on a vendor recommendation (likely taken out of context). Foundries use hundreds of tons of sand and a much larger (and ten or more times more expensive) 2 cubic yard unit is more appropriate. Similarly, in the same PEA OSHA based its economic feasibility assessment for abrasive blasting on a glove box unit based on vendor input (again likely out of context) Some individual castings are larger than the abrasive blasting cabinet specified. A typical shot or tumble blast machine appropriate for foundries is much larger and may be 50 times more expensive. The point is that vendors can provide useful information, but the context is important when applying the information from one industry to another. It is also important to find a vendor that services the industry affected.

It must also be remembered that vendors have an interest in promoting their own product, and may even make unrealistic claims for performance. Vendor information needs to be vetted by users.

Question IV.B.11: Regardless of the industries involved, are there criteria that OSHA should use to show that control strategies implemented in a process from one operation are applicable to a process from another operation? Please explain.

Successful control strategies from one operation are no guarantee of control or applicability in another. Not only is control performance not guaranteed across industries, it is often not even achieved in identical operations. Numerous unique process and environmental characteristics can impact the likelihood that a control that is successful in one situation will be successful in another. For example, a ventilation design that works successfully in one industry may fail in a foundry environment due to heat, thermal currents, particle velocity and an abrasive environment. Experimentation and adaptation are required to test and verify designs that work. Two specific examples are provided by the OSHA RCS proposal. Vacuuming was proposed for clean up, but resin coated sand that sticks to surfaces requires greater force to move than a vacuum can provide. Wet methods were suggested, but these create a hazard in the presence of molten metal.

Question IV.B.12: How should OSHA take into consideration the size of a business or facility when determining technological feasibility?

There are many important differences between business operations, including size and scale. A case in point may be large highly automated foundries which focus on production of a very few part numbers and represent only a small number of foundries, although they represent a larger portion of total tonnage of metal melted in the industry. Such highly automated foundries are not set-up for production changes that would permit producing small runs or specialized castings. Indeed, many operators of such foundries outsource production of smaller runs of castings to other specialized foundries and focus instead on the large volume castings suited for continuous production.

There is a large difference in feasibility of controls between a large production foundry and a small job shop foundry. Generalizations are limited, as some job shop foundries can also be large, producing unique hundred ton plus castings one at a time. Nevertheless, staying with the comparison of large and small foundries, the impact of the differences is illustrated by the range of costs in EPA estimates of ventilation controls.[15] For example, for a pulse-jet cleaned fabric filter baghouse, EPA estimated capital costs of $6 to $26 per CFM and operation and maintenance costs of $5 to $24 per CFM depending on various foundry sizes and processes. With respect to ventilation costs for the pulse-jet fabric baghouse, large operations with ventilation requirements of up to 2,000,000 CFM may incur annualized costs closer to the $6 per CFM low end of the range, while smaller operations may incur annualized costs more than 6 times greater, closer to the $39 per CFM high end of the range. It would not be appropriate to infer feasibility of controls between operations with such widely differing cost structures and vastly different processes.

Question IV.C.1: Should OSHA consider greater use of process oriented regulations, such as regulations on abrasive blasting, welding, or degreasing, as an approach to health standards? Should such an approach be combined with a control banding approach?

Process oriented regulations can be efficient, and the examples in the question seem to be suitable candidates. One advantage of this approach is that certain processes involve a limited number of equipment suppliers, thus helping to focus some aspects of the feasibility discussions. A process

[15] See http://www.epa.gov/ttncatc1/products.html. http://www.epa.gov/ttn/catc/dir1/ff-pulse.pdf

oriented approach may also allow some grouping of substances, such as paint solvents, for example.

It is not clear how control banding would be used to reduce regulatory analysis efforts unless it permitted a tiered approach to controls. For example, abrasive blasting in a glove box may require fewer controls and regulatory requirements than blasting in an occupied blasting room.

Question IV.C.2: 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 approach has promise, especially where exposures to a particular substance occur mainly in one industry. However, there are two potential problems with this approach that need to be considered.

One is that the analysis for different industries may lead to different feasibility conclusions, and as a consequence, different standards. Some employers with operations that straddle multiple industries may be confused about which standard to apply. For example, foundries may operate independently, as captive foundries in another industry, or may perform machining or painting as adjunct operations to the foundry. If a standard were to apply differently to these operations it could be confusing.

Secondly, there could be a due process issue if the total cost impacts to an industry were assessed in parts on a process by process basis, rather than all at once. Some industries may not be able to respond as effectively to regulatory proposals on a segment by segment basis or process by process basis.

Question IV.C.3: 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?

Please refer to the answer to question IV.B.9 above.

Question IV.C.4: Should OSHA consider providing ranges of costs for industries in situations where even the upper range of the costs would obviously not provide a threat to the existence of competitive structure of an industry?

Ranges are an acceptable approach to analysis, but as the answer to question IV.C.9 below demonstrates, the need for accuracy is an overriding concern. The errors and omissions associated with the OSHA PEA for RCS led to a cost estimate for the foundry industry so far below the actual costs that the use of ranges would have been irrelevant.

Question IV.C.5: What peer-reviewed economics literature should OSHA consult when determining whether the competitive structure of an industry would be altered? Are there any instances where an OSHA standard did threaten the existence or competitive structure of an industry? What were they and what is the evidence that an OSHA standard was the origin of the difficulties?

AFS does not have a response the first part of the question. As for the rest, over the past few decades many companies, including many foundries have closed for a variety of reasons. Regulatory costs were a factor in many of the business decisions, but it is not possible to determine how much or in how many closings OSHA regulations were a factor.

Question IV.C.6: 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 is often an effective control option for employers to use voluntarily, but should not be mandated by regulation. Often, an industry's use of substitution is based on broad feasibility considerations, including effects on cost, product quality and customer acceptance. Regulatory requirements may already provide strong incentives for substitution where that option is practical. Mandated substitution could have the effect of a product ban, and that may be beyond the scope of OSHA's authority. The technical capability and resources needed to assess the numerous product performance implications of substitution would likely add to OSHA's resource and time burden rather than reduce it.

Question IV.C.7: Are there other approaches OSHA could use that would provide for more timely and less resource-intensive economic feasibility analyses?

The most timely and least resource-intensive feasibility analysis strategy is to do a better job at the outset. As the answer to question IV.C.9 below shows, OSHA's analysis for the RCS proposal was flawed in numerous major respects and produced a cost estimate that was so far from the actual cost that great additional effort is required to develop a valid feasibility evaluation.

Question IV.C.8: 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? What level of detail do you think is sufficient to justify the presumption of feasibility for such a standard? Please explain.

If materials or processes are used differently in different industries the current approach is most efficient. The impact on competition and trade will need to be assessed within specific industries.

Question IV.C.9: Are the methodologies suggested above appropriate to establish economic feasibility for a comprehensive PELs update? Why or why not? What other cost effective methods are available for OSHA to establish economic feasibility for such a rulemaking?

The methodologies suggested above may have advantages in certain circumstances, but it is more important to correct errors in the methodologies currently used. The OSHA PEA for RCS contains numerous examples of errors and omissions which need to be corrected to achieve an accurate estimation of costs associated with any proposed rule. In the RCS rulemaking URS and Environomics conducted an analysis which partially corrected OSHA's errors and omissions and determined that the foundry industry annual incremental cost for compliance would be $2.2

billion, in contrast to the $44 million estimate in the PEA.[16] The following errors and omissions account for much of the 50 fold discrepancy in estimates:

1. **Marginal Cost Error** - The PEA methodology assumed the same cost to reduce exposures to below a PEL of 50 μg/m^3 as to below a PEL of 100 μg/m^3. That is contrary to economic theory. It also ignores the normal practice of implementing less costly controls first, followed by more expensive controls if the first attempts are not successful
2. **Discounted Cost Error** - The PEA discounted about two thirds of the cost of foundry compliance on the theory that employers need to meet the current standard and that cost should not be counted. This wrongly assumed the same cost to achieve the lower level, assumed no costs for those below 50 μg/m^3, and was based on outdated and enforcement-biased exposure numbers.
3. **Under 50 Error** - The PEA did not calculate any cost for workers exposed to concentrations below 50 μg/m^3 even though employers may need to install controls for people exposed above 15 or 20 μg/m^3 because of exposure variability.
4. **First-time Success Error** - The PEA assumed that there is one set of controls for an operation, that those controls are obvious, and that they will be completely successful. This is not the way it works in practice. Even the cases referenced in the PEA bore out the fact that multiple attempts are necessary and often unsuccessful at first.[17]
5. **Per-Worker Discount** -The PEA divided control costs by the number of workers assumed exposed, typically four. However, the number of workers per job is often less than four. And in some cases, particularly small employers, workers may do multiple jobs. The per-worker methodology omits costs for automated operations.
6. **Missing Controls** - The PEA based its technological feasibility assertion on controls which it omitted from its economic feasibility analysis. For example, for abrasive blasters the PEA described a "new blasting machine with LEV, enclosed and exhausted sand conveyors, an enclosure and LEV to the shakeout exit, and LEV to the skip bucket enclosure", all of which were omitted from the economic analysis.
7. **Uncosted Controls** - The PEA listed 46 control options for foundry job categories, but provided cost estimates for only 24 of these. The 46 control options did not include the many controls omitted from the analysis such as the ones referenced in point 6 above. Costs associated with some of the uncosted controls, such as automation, enclosure, and substitution of non-silica sand, could have exceeded the PEA estimate for all controls for the entire industry.
8. **Erroneous Unit Costs** - Many of the cost assumptions in the PEA were not credible. For example the PEA assumed a 15 gallon HEPA vacuum for cleanup in an operation processing tons of sand per hour. The PEA assumed abrasive blasting costs based on a glove box operation which is grossly undersized. Most foundries which use equipment costing 50-100 times more than assumed.[18] Many other erroneous costs and assumptions were discussed in the AFS review.[19]
9. **Missing Operations** - Several common foundry processes were omitted from the PEA. These included cut off saws, powder burning, gas torch cutting, and arc air operations.

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[16] See "Critique of OSHA's Cost Models for the Proposed Crystalline Silica Standard and Explanation of the Modifications to Those Cost Models Made by URS Corporation" and comments by Stuart Sessions of Environomics, submitted to docket on behalf of the American Chemistry Council's Silica Panel.

[17] The AFS review of cases can be found in the docket as Appendix 2 to document number OSHA-2010-0034-2379.

[18] PEA page V-A-69.

[19] The AFS review of cost estimates can be found in the docket as Appendix 3 to document number OSHA-2010-0034-2379.

10. **Impact of EPA Requirements** – The PEA failed to address some of the highest costs triggered by the OSHA proposal, those that are associated with meeting EPA requirements.
11. **ISO/CEN Change** – Although relatively minor compared to the impact of the other errors, the PEA failed to consider the impact of a lowered effective standard due to the proposed sample strategy change.

As these many methodology errors demonstrate, there is a lot of work to do in fixing current methodology before looking for other changes and improvements.

Question IV.C.10: What factors should OSHA consider in determining whether a chemical should be part of an overall PELs update or subject to substance-specific rulemaking? 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?

The impact of regulation should determine whether analysis is appropriate for individual industries or for groups. Certain processes with multiple exposures, such as spray painting, for example may allow multiple PELs to be addressed.

Question V.A.1. How might publicly available information on the properties and toxicity of HPV chemicals be utilized by employers to identify chemical hazards and protect workers from these hazards? OSHA is also interested to hear from commenters who may currently make use of these data in their worker protection programs.

Many employers, particularly small ones do not have easy access to reliable information. In some cases the problem is too much information and not enough clarity or confidence in the correct information. Effective controls depend on an accurate hazard classification, and poor information leads to misplaced priorities. It would be very helpful to get good information into the hands of users. OSHA's annotated PELs are an example of such an approach, but even that information is not the same for the three non-OSHA OELs.

Under GHS employers are required to conduct a hazard assessment, but the information needed to do so is not readily available. In many cases, such information has been collected and made available in SDS writing data bases. However, access to a typical SDS writing data base with necessary information may cost as much as $200,000, more than many small employers can afford. Leasing the software or using consultants are alternatives, but these options also presents cost barriers. OSHA could make accurate hazard classification information available to small employers so that the GHS classification information could be improved. Control decisions would be improved as a result.

There is another approach to making credible information available to employers that they can use with confidence. Many of the OSHA regulations began as voluntary standards which played an active and important role in safety and health improvement before OSHA. Voluntary standards continue to play an important role in certain areas of health and safety. For example, NFPA standards are widely recognized and respected and many industries work to maintain conformance. Several ANSI standards (e.g. ANSI B11 series) continue to define appropriate practice.

It may be time to promote that process again for exposure limits and for OSHA to play a more active role in voluntary consensus standards development. Although the ACGIH TLV process is not a consensus process, other consensus mechanisms such as ASTM E34 Occupational Safety and Health Committee already exist. Other organizations (AIHA, ASSE, UL, NSC) may be interested in reconstituting committees similar to the ANSI Z37 committee to develop consensus standards if encouraged to do so by OSHA. Employers need OELs that they can have confidence in. Out of date and inconsistent non-consensus standards do not provide the credibility and confidence that voluntary consensus standards do. While such standards may be more difficult to enforce than a regulation, they can establish a recognized reference for employer guidance. More importantly, they can promote best practices.

Question V.A.2. How might the information on the properties and toxicity of chemicals generated by CompTox, ToxCast, and/or Tox21 be utilized by employers to identify chemical hazards and protect workers from these hazards? OSHA is also interested to hear from commenters who may currently make use of these data in their worker protection programs.

High-throughput methods are gaining interest and attraction, but are not yet ready to replace more traditional methods. Data from these methods may be useful, but are usually limited to a narrow range of effects, such as endocrine disruption. They are useful for screening, particularly in certain industries, such as pharmaceutical, but have not yet had much application in the foundry industry.

Question V.A.3: Are QSAR, read-across, and trend analysis useful and acceptable methods for developing hazard information utilizing multiple data sets for a specific group of chemicals?

These are useful screening methods in the absence of more traditional hazard assessment tools. However, their value depends upon how accurate are the assumptions that form the basis of the grouping or relationship. These techniques do not have wide application in the foundry industry, but one example is the evaluation of dimethylethylamine (DMEA) exposure based on its structural similarity to triethylamine (TEA).

Question V.A.4: Are there other acceptable methods that can be used to develop hazard information for multiple chemicals within a group?

The wide range of potentially relevant physical and chemical properties requires a case by case evaluation. For example, vapor pressure may be a significant factor in one case, and chemical structure in another.

Question V.A.5: What are the advantages and disadvantages of each method?

AFS elects not to respond to this question at this time.

Question V.A.6: OSHA is interested in the experiences of companies that have had to prepare chemical dossiers and submit registration information to the European Chemicals Agency (ECHA) ECHA. In particular, how might the approaches be used to support occupational exposure assessments and development of use-specific risk management in the United States?

AFS elects not to respond to this question at this time.

Question V.A.7: To what extent is information developed under REACH used by U.S. businesses to promote product stewardship and ensure safe use of substances and mixtures by product users?

Businesses may use information developed under REACH as another resource. Companies who export to the EU may be required to gather more extensive information, or to reformulate products or develop substitute materials.

Question V.A.8: Should OSHA pursue efforts to obtain data from ECHA that companies are required to provide under REACH?

If such information can be made available AFS encourages OSHA to use it. However, it should be noted that the correct interpretation of data is more important than the quantity of it.

Question V.B.1: To what extent do you currently consider elimination and substitution for controlling exposures to chemical hazards?

Substitution and elimination are standard control approaches and common considerations in the foundry industry, as in many other industries. These are at the top of the hierarchy of controls. However, careful analysis, including testing and experimentation is necessary to make sure that performance, quality and safety are not compromised. Care is required to avoid substituting an unknown, unstudied, new, and more toxic chemical for an older well studied one.

Question V.B.2: What approaches would most effectively encourage businesses to consider substitution and adopt safer substitutes?

Substitution should add value to the process. Safety is already an incentive and the marketplace does an efficient job of encouraging substitution where it makes sense. For example, many foundry core-making operations have substituted cold-box processes for hot-box processes that generate formaldehyde. However, there are situations where substitution is not possible. Some hot-box operations cannot be replaced for quality or performance reasons. Intricate designs and the need for precise finishes may require a resin with formaldehyde. Similarly, some foundries have been able to use non-silica sand in certain operations, but many other foundries who have looked into it have found that for a variety of reasons (e.g. shrinkage, compatibility with binder systems, etc.) it could not work in their operation. Substitution cannot simply be about one factor.

Question V.B.3: What options would be least burdensome to industry, especially small businesses? What options would be most burdensome?

Hazard information is useful for aiding substitution decisions, but a major consideration is the particular application. Two chemicals may be similar and may be acceptably substituted for one application but not for another. For example, two chemicals may perform similarly when used as paint solvents, but when used in core resins may have different gassing rates leading one to cause defects and the other to behave acceptably.

Foundries, including small ones frequently look for and experiment with process improvements, often with the help of material suppliers. For example, suppliers have been leading changes in core making chemistry, such as the replacement of TEA with other less flammable tertiary amines discussed in the answer to question IV.A.2 above.

The marketplace dynamic encourages substitution of new and better materials if viable. In the foundry industry, many new melting, pouring, and core making processes have been developed and are in common use. The diversity of methods in use today is the result of different processes and materials being suitable for different applications, alloys, strength and finish requirements, end use environments, etc. This diversity is not due to the delayed adoption of one single new and superior technique.

Question V.B.4: What information and support do businesses need to identify and transition to safer alternatives? What are the most effective means to provide this information and support?

Recognizing that businesses need to determine if alternatives can work in their process, it would be helpful to have credible information on safety of alternatives. Regulators cannot presume to understand all the relevant process and product engineering variables that affect a substitution decision. For example, there are thousands of specific metal alloys with varying elemental contents for specific applications. No regulator can simply decide that one ingredient can replace another across the entire range of applications. However, providing clear and accurate information on the relative health hazards of different chemicals would be a useful service.

The supply chain is an important link in the evolution of process materials and must be involved in any transition to new alternatives. For example, foundry resin suppliers are key participants in any changes to core-making chemistry. Resin suppliers played an important role in the CERP research discussed earlier.

Question V.B.5: How could OSHA leverage existing data resources to provide necessary substitution information to businesses?

Many of the data resources mentioned in the RFI contain useful information, but it needs to be distilled and summarized to be clear and useful. Assumptions should be listed to help users understand and voluntarily apply the guidance as appropriate. Where possible, guidance should be industry specific. This may require participation by users and suppliers. Examples of users and suppliers collaborating on chemical selection advice can be found in two ASTM standards on metalworking fluids.[20]

Question V.B.6: What tools or methods could be used by OSHA and/or employers to conduct comparative hazard assessments? What criteria should be considered when comparing chemical hazards?

Each tool or list contains certain value assumptions which may not be universally applicable. Priorities based on fire safety, greenhouse gas reduction, aquatic toxicity, bioaccumulation, indoor air, or various other properties may not apply to occupational exposures in the same way.

[20] ASTM E 2169 Standard practice for selecting antimicrobial pesticides for use in water-miscible metalworking fluids; ASTM E 1497 Standard practice for selection and safe use of water-miscible and straight oil metal removal fluids.

Different routes of occupational exposure may also affect choice of substitute in different applications. It is unlikely that any universally applicable list is possible, but sufficient explanatory information could permit useful guidance.

Question V.B.7: What tools or methods could be used by OSHA and/or employers to evaluate and compare the performance and cost attributes of alternatives? What criteria should be considered when evaluating performance and cost?

Research and experimentation are required to evaluate and compare performance of alternatives. In some cases suppliers can play an important role in the process. In the foundry industry with so many process variables to consider, most chemical changes require considerable experimental effort to implement. A change that causes defective castings is not considered suitable.

Substitution is a complex undertaking that requires research and testing. For example, eliminating lead from brass is not as simple as changing the alloy mix. When zinc is used in place of lead for brass water valves and pumps it may dissolve out of the alloy when exposed to chlorinated or high mineral content drinking water, causing catastrophic failure. When non-silica sand is used to replace silica several factors must be considered. For example, some alloys and core chemistries are incompatible with substitutes. Moreover, the casting shrinkage and temperature profiles are different and patterns must be reengineered because dimensions change. For a foundry with 10,000 patterns, some of which are only used once a decade, it is not feasible to redesign all of the molding and core patterns. Patterns are very expensive to produce and changes are not only expensive but require approval by the customer.

The criteria to be considered are often too complex to be determined without extensive study. The low-lead water valve example was one that many people learned the hard way. Another lesson learned the hard way was that seals and valves designed for one catalyst may not perform well for an alternative catalyst. Because there are so many potential unintended adverse consequences associated with alternatives, no mandated substitution is possible that can account for all usage situations, and no single set of criteria can be specified that can account for all of the potential consequences.

Question V.B.8: 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?

An accurate hazard classification is critical to information generation under HazCom 2012. Unfortunately, many suppliers seem to lack access to accurate information and apply pictograms and warnings to products based on ingredients present in small concentrations as if they were present in concentrated form. Before the HazCom 2012 information can realize its full potential, it must be accurate. In some cases access to the classification data may be a problem. This may be an issue that OSHA could focus on.

Question V.B.9: How could such an approach satisfy legal requirements to reduce significant risk of material impairment and for technological and economic feasibility?

Before this approach could be used the risk and hazard classification information must be accurate and process information must be understood. Both of those criteria are challenging. For example, accurate hazard classification information is difficult for mixtures. And OSHA is unlikely to have the technical capability to specify controls that would be appropriate across industries. For example, as the PEA for the recent RCS proposal shows, OSHA specified a vastly inadequate 15 gallon vacuum instead of a 2 cubic yard unit, and an inappropriate glove box for abrasive blasting instead of a shot or tumble blast machine. If OSHA misunderstands the process characteristics associated with an industry it is specifically analyzing, it is unlikely to be capable of accurately specifying controls across several industries at once.

Providing useful recommendations, especially with input from affected industries could be a valuable service, but mandatory approaches would be unlikely to satisfy legal requirements.

Question V.B.10.: Please describe your experience in using health hazard and/or control banding to address exposures to chemicals in the workplace.

AFS elects not to respond to this question at this time.

Question V.B.11.: Are additional studies available that have examined the effectiveness of health hazard and control banding strategies in protecting workers?

AFS is not aware of these.

Question V.B.12.: How can OSHA most effectively use the concepts of health hazard and control banding in developing health standards?

OSHA could provide useful resources in the form of hazard classification information and control information for businesses to use as appropriate.

V.B.13.: How might OSHA use voluntary guidance approaches to assist businesses (particularly small businesses) with implementing the principles of hazard banding in their chemical safety plans? Could the GHS chemical classifications be the starting point for a useful voluntary hazard banding scheme? What types of information, tools, or other resources could OSHA provide that would be most effective to assist businesses, unions, and other safety and health stakeholders with operationalizing hazard banding principles in the workplace?

Voluntary approaches would be the most useful way to assist businesses. Voluntary approaches can incorporate best practice recommendations which are often more protective than mandatory standards. Mandatory standards often represent the lowest common denominator rather than best practice.

Improving the accuracy of GHS information would also be a valuable approach.

Encouraging the development of voluntary consensus standards could also move the bar higher as various stakeholders work to improve practices.

Question V.B.14.: Should OSHA consider greater use of specification standards or guidance as an approach to developing health standards? If so, for what kinds of operations are specification approaches best suited?

> This approach may be especially suitable to specific industries or processes where there is relatively little variation from one operation to another.

Question V.B.15: OSHA requests comment on whether and how task-based exposure control approaches might be effectively used as a regulatory strategy for health standards.

> Task-based approaches could be applied for operations with significant commonality. As a voluntary recommendation, it could have wide applicability. As a regulatory strategy it would only be suitable to specific industries or processes where there is relatively little variation from one operation to another.

Thank you for the opportunity to provide comments on OSHA's RFI concerning Chemical Management and PELs.

Sincerely,

Jerry Call
CEO
American Foundry Society