

**Comments of the American Chemistry Council
On Docket ID No. OSHA-2010-0034
Request for Information on
Chemical Management and Permissible Exposure Limits (PELs)**

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I. Summary

The American Chemistry Council (ACC) is pleased to provide the following information and comments in response to the Occupational Safety and Health Administration's (OSHA or the Agency) Request for Information (RFI) on Chemical Management and Permissible Exposure Limits (PELs).¹ ACC further appreciates OSHA's decision to provide stakeholders early insight into the Agency's potential approaches to improving the PEL promulgation process. This type of early engagement with knowledgeable stakeholders is an essential component to regulating effectively and efficiently, and ACC is glad to be a constructive participant.

As discussed in detail below, ACC and its members share OSHA's commitment to protecting workers from occupational exposures to hazardous chemicals, as well as OSHA's concern that the statutory constraints have made PEL promulgation cumbersome, time-consuming, and inefficient. Notwithstanding the protracted promulgation process mandated by the Occupational Safety & Health Act ("OSH Act"),² ACC and its members have voluntarily taken steps to identify and manage (or eliminate) occupational exposures to hazardous chemicals. We are proud of our commitment to protecting the health and safety of workers. Indeed, worker health is central to ACC's mission, the subject of one of ACC's most ambitious and successful performance initiatives, and an issue on which ACC has worked constructively with OSHA and other regulatory bodies for years.

In light of this longstanding commitment, ACC offers some suggestions for how OSHA can best work within the confines of the OSH Act and relevant court decisions to most effectively and efficiently protect workers. We caution OSHA, however, against attempting to abbreviate or tailor the PEL promulgation process in ways that would violate the OSH Act or conflict with court precedent. While we recognize the confines of the OSH Act and the weighty process it imposes, OSHA should refrain from attempting to change by regulation or practice what Congress has imposed by statute. Indeed, when OSHA has attempted such changes in the past, the result was years of expended Agency resources with little or no resultant occupational health benefit. Unfortunately, many of the proposed approaches in the RFI mirror those that were previously invalidated.

ACC strongly believes that OSHA can use many of the tools in the RFI to identify and focus its PEL promulgation process on the highest priority chemicals. By a triage of the highest priority chemicals, OSHA can ensure that its efforts will enhance worker protection. It will also ensure that the resulting PEL meets the statutory requirements of the OSH Act as interpreted by the courts.

In the comments that follow, ACC provides its views on the approaches that are consistent with the OSH Act, and ideas on using these approaches to focus on those chemicals that should be the highest priority for the protection of worker health.

¹ 79 Fed. Reg. 61,384 (Oct. 10, 2014).

² 29 U.S.C. § 651 *et seq.*

II. ACC is Committed to Protecting Workers

ACC's commitment to protecting workers from occupational exposures to hazardous substances is demonstrated by its longstanding support of occupational limits and regulatory improvements that protect workers. Even when such increased regulation has been delayed or invalidated by courts, ACC and its members have protected workers by continually developing, promoting, and implementing voluntary safety codes and exposure limits.

1. Support for 1989 PEL Update

Of particular relevance to this RFI is ACC's support for the 1989 "Air Contaminants Rule" that regulated "not a single toxic substance, but 428 different substances."³ OSHA pursued this approach because, at the time, it had only succeeded in issuing 24 PELs after the OSH Act's initial "startup" promulgation of 425 PELs, and because "it would take decades to review currently used chemicals and OSHA would never be able to keep up with so many chemicals which will be newly introduced in the future."⁴

ACC shared, and continues to share, OSHA's concern over the impracticability of updating a large number of PELs with limited resources, and made no objection to OSHA's then transformative view that "to review and regulate many substances in a reasonable period requires some narrowing of the issues, focus of analysis, and reducing the length of discussions in the preamble . . . [and] somewhat less detailed chemical-by-chemical analysis."⁵

The United States Court of Appeals for the Eleventh Circuit (Eleventh Circuit), however, did not support OSHA's approach. The court found that OSHA's approach revealed "a fundamental misperception of the OSH Act and the case law interpreting this."⁶ The court stated that, while the OSH Act gives OSHA the authority to set priorities in establishing PELs,

[i]t does not, however, give OSHA blanket authority to pick and choose what statutory requirements it will follow. The OSH Act mandates that OSHA promulgate the standards that "most adequately" assure that workers will not be exposed to significant risks of material health impairment "to the extent feasible" for the affected industries. Further, section 6(e) and case law require OSHA to adequately explain its determinations. Section 6(b) of the Act does not provide an exception to these requirements for administrative convenience. . . . We have no doubt that the agency acted with the best of intentions. . . . Unfortunately, OSHA's approach to this rulemaking is not consistent with the requirements of the OSH Act.⁷

³ *AFL-CIO v. OSHA*, 965 F.2d 962, 971 (11th Cir. 1992).

⁴ 53 Fed. Reg. 20,960, 20,963 (June 7, 1988).

⁵ 53 Fed. Reg. at 20,963–64.

⁶ *AFL-CIO v. OSHA*, 965 F.2d at 980–81.

⁷ *AFL-CIO v. OSHA*, 965 F.2d at 986–87.

ACC intervened in the Air Contaminants Rule case on behalf of OSHA. Unfortunately, the decision provides an example of the type of well-intended, but ultimately unsuccessful approach that ACC cautions OSHA against revisiting.

2. 2010–2011 PEL Forum

Between 2010 and 2011, OSHA convened an informal dialogue to identify strategies to best protect workers from occupational exposures to hazardous substances while recognizing the limitations placed on OSHA by Congress and the courts. Once again, ACC supported OSHA’s goals and was an active participant in that dialogue. ACC convened multiple meetings with its members and devoted considerable resources to develop and build consensus around several proposed strategies that OSHA could adopt to protect workers more effectively using the Agency’s existing authority under the OSH Act.

To that end, ACC encouraged OSHA to retain PELs as the core element of a comprehensive risk-based approach to controlling occupational exposures to air contaminants, and emphasized that only a risk-based approach can assure that a given contaminant is managed with the appropriate degree of control and that OSHA identify before regulating a “significant risk” of “material” health impairment.

ACC noted that many ACC member companies develop their own occupational exposure limits (OELs)⁸, and these companies are routinely updating their OELs to ensure that their workers are protected. Nonetheless, OSHA’s PEL regulations should be updated so that they can serve as the core of a national, risk-based approach to regulating air contaminant exposures in the workplace.

ACC recommended that OSHA focus on prioritizing those occupational contaminants that pose the greatest risk to the greatest number of workers. Prioritization was, and remains, a key strategy because it recognizes that the PEL promulgation process is time-consuming and it is essential that OSHA put in place a system to ensure that it devotes its resources to the chemicals that pose the greatest risk to worker health. Not only did ACC recommend that OSHA focus on prioritization in the 2010–2011 PEL Forum, ACC provided specific methods by which OSHA could most effectively prioritize such a large and growing number of chemicals in the workplace. In Section IV below, we provide these and other recommendations to ensure that OSHA targets the greatest benefits from the process in which it is required to engage.

ACC also provided OSHA with ideas and strategies for meeting the OSH Act’s stringent analytical requirements as efficiently as possible as required by the OSH Act. ACC suggested that OSHA look to the U.S. Environmental Protection Agency’s (EPA) successful acute exposure guideline levels (AEGL) model to update PELs, and recommended that OSHA outsource as much of the data collection and evaluation process as possible. ACC recommended that OSHA convene an advisory committee, and provided OSHA with specific strategies for using the committee to screen information and information sources, and to share its analytical burdens. ACC also identified credible sources of OELs and recommended that OSHA compile those OELs and make them publically available.

⁸ The term OEL is used for manufacturer-developed limits to distinguish from those developed by independent groups.

ACC also recommended that OSHA explore hazard banding, particularly for those chemicals for which there presently are no PELs. These and other recommendations are explained in greater detail below.

3. ACC Activities to Promote Worker Safety

In addition to its longstanding support for OSHA's efforts to update its PELs, ACC has for decades provided a platform for enhancing the safety of its members' workplaces and products. Indeed, chemical safety is central to ACC's mission and the focus of ACC's research and resources. Foremost among ACC's efforts is its Responsible Care® program. ACC's Responsible Care® program is the chemical industry's world-class environmental, health, safety, and security performance initiative. It has been in place for more than 25 years, is practiced today in more than 60 economies around the world, and is responsible for helping lower the chemical industry's recordable injury and illness rates by 78% since 1990.⁹ To become a member of ACC, a company must commit to the highest standards for protecting health, safety and the environment through participation in the Responsible Care program.

More than 250 companies participate in the Responsible Care program. When ACC member company Chief Executive Officers sign on to Responsible Care, they indicate that they will adhere to the Responsible Care Guiding Principles, which is a set of management practices that direct companies to operate according to excellent industry practices.

The Responsible Care program's Process Safety Code, adopted in 1990 and revised in 2012, sets forth the program's commitment to a culture of process safety throughout chemical facility processing operations, the commitment to set process safety expectations, define accountability for process safety performance, and allocate adequate resources to achieve performance expectations.

In addition to promoting occupational health and safety, the Responsible Care Product Safety Code, also updated in 2012, seeks to drive continuous improvement in chemical product safety.¹⁰ It includes eleven Management Practices that allow chemical manufacturers to evaluate, demonstrate, and continuously improve product safety performance. All ACC Responsible Care® companies must institute the Product Safety Code.

4. Approach to Developing Acceptable Exposure Limits

PELs serve as important guidance for professionals involved in protecting the health and safety of workers exposed to chemicals through the performance of their jobs. Manufacturers often

⁹ AMERICAN CHEMISTRY COUNCIL, RESPONSIBLE CARE®: BY THE NUMBERS (June 2015), *available at* <http://responsiblecare.americanchemistry.com/FactSheet> (last visited Mar. 2, 2015).

¹⁰ *Responsible Care® Product Safety Code*, AMERICAN CHEMISTRY COUNCIL, <http://responsiblecare.americanchemistry.com/Responsible-Care-Program-Elements/Product-Safety-Code> (last visited Feb. 23, 2015).

choose to adopt more stringent exposure limits where no PEL exists or where the PEL is higher than the limit recommended by ACGIH[®] or another organization.¹¹ There are also circumstances where a substance to be used in the workplace has not yet been reviewed by OSHA or other organizations and no occupational limit exists. This can be particularly important for ACC members as they introduce new substances into the marketplace and work to ensure that they are used safely.

In addition to the PEL, ACC members include on their safety data sheets (SDSs) other relevant occupational limits that have been established through a robust review process – particularly if those limits are lower than the PEL. If no PEL exists, or if the PEL is higher than the other limits listed, ACC members generally recommend that the lowest of the relevant limits be followed.

In cases where no occupational limits have been established, ACC members often seek to nominate the substance for review by ACGIH or OARS for the development of a recommended exposure limit. Since this process can take a year or more, our members also may use standard toxicological and industrial hygiene practices to develop an OEL for the protection of workers in the meantime.

III. The OSH Act, Court Decisions Interpreting the OSH Act, and Other Statutory Obligations Require PELs to be Promulgated Through a Rigorous and Detailed Analytical Process

The inability of OSHA's PEL promulgation process to keep pace with the introduction of new chemicals or new data for currently regulated chemicals in the workplace is well known and well documented. As a consequence, the sources of delay in OSHA's standard setting process have been closely examined as well.

In 2012, the U.S. Government Accountability Office (GAO) published a report that quantified the length of time it took OSHA to promulgate major health and safety standards.¹² GAO analyzed 58 major health and safety standards issued between 1981 and 2010,¹³ and found that, on average, OSHA took approximately 93 months (7 years, 9 months) to develop and issue new health and safety standards.¹⁴ The report found that OSHA required less time to promulgate health standards, which are understood to require more analytical rigor than safety standards (6 years, 4 months versus 8 years, 6 months).¹⁵

GAO concluded that the pace of OSHA rulemaking was significantly constrained by the OSH Act and the substantial body of jurisprudence on the OSH Act's procedural and analytical

¹¹ A comparison of occupational limits suggests that two-thirds of the substances for which a TLV[®] exists either have a higher (less-protective) PEL or no PEL.

¹² See GAO REPORT, *supra*.

¹³ GAO REPORT, *supra*, at 7.

¹⁴ GAO REPORT, *supra*, at 8.

¹⁵ GAO REPORT, *supra*, at 9.

requirements.¹⁶ Indeed, of the six streamlining recommendations contained in the report, GAO acknowledged that three required Congressional action to amend the OSH Act.¹⁷

ACC has focused its recommendations on actions that are within OSHA's existing authority and that focus the agency on the highest priority exposures. Recommending actions that are currently within OSHA's authority, however, requires an understanding of the types of actions identified by courts as beyond OSHA's authority. In offering these recommendations, ACC was guided by the following limitations and analytical requirements mandated by the OSH Act and courts interpreting the OSH Act:¹⁸

- Substantial Evidence - Section 6(f) of the OSH Act provides that “the determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole.” Significantly, this standard requires “more rigorous scrutiny” of, or a “harder look” at, OSHA's action than the more deferential “arbitrary and capricious” standard of review under the Administrative Procedure Act (APA).¹⁹
- Significance of Risk - Section 6(b)(5) of the OSH Act instructs OSHA, in dealing with toxic materials or harmful physical agents, to set a standard that most adequately ensures, to the extent feasible on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard for the period of his working life.²⁰ Each element of this requirement has been litigated and dissected in court decisions. In the so-called *Benzene* case,²¹ the Supreme Court stated that OSHA, “before issuing any standard, [must] determine that it is reasonably necessary and appropriate to remedy a significant risk of material health impairment.”²² To meet this threshold inquiry, the Eleventh Circuit held that OSHA must determine: (1) what health impairment is “material,” and (2) what constitutes a “significant risk” of such impairment.”²³

¹⁶ GAO REPORT, *supra*, at 26–29.

¹⁷ GAO REPORT, *supra*, at 34–36.

¹⁸ Attached hereto as Appendix A is a detailed discussion tracing the outline of OSHA's authority under the OSH Act and those sources of promulgation delay that are beyond OSHA's authority to fix. ACC provides it to effectuate our genuine interest in seeing OSHA resources devoted to those remedies that are actually able to improve workplace health and safety because they can survive legal challenges.

¹⁹ See *Color Pigments Manufacturers Association, Inc. v. OSHA*, 16 F.3d 1157, 1160 (11th Cir. 1994); *Asbestos Information Assn. v. OSHA*, 727 F.2d 415, 421 (5th Cir. 1984); *AFL-CIO v. Marshall*, 617 F.2d 636, 649 (D.C. Cir. 1979).

²⁰ 29 U.S.C. § 655(b).

²¹ *IUD, AFL-CIO v. API*, 448 U.S. 607.

²² *IUD, AFL-CIO v. API*, 448 U.S. at 639.

²³ *AFL-CIO v. OSHA*, 965 F.2d at 973.

- Technological Feasibility – The “feasibility” requirement in Section 6(b)(5) of the OSH Act has been interpreted to require an assessment of both technological and economic feasibility.²⁴ To demonstrate technological feasibility, courts have held that “OSHA must prove a reasonable possibility that a typical firm will be able to develop and install engineering and work practice controls that can meet the PEL in most of its operations”²⁵ While courts have not required OSHA to prove technological feasibility with certainty, they have required its record “to show modern technology has at least conceived some industrial strategies or devices which are likely to be capable of meeting the PEL and which the industries are generally capable of adopting.”²⁶ Critically, courts have held that OSHA cannot conduct the technological feasibility analysis on a broad or generalized basis - “feasibility is to be tested industry-by-industry,” and OSHA must “examine the technological feasibility of each industry individually.”²⁷
- Economic Feasibility - Section 6(b)(5) of the OSH Act requires OSHA to conduct “a reasonable assessment of the likely range of costs of its standard, and the likely effects of those costs on the industry.”²⁸ The Agency need not establish economic feasibility in a particular way, but it must be thorough in explaining the best available evidence on which it relies.²⁹ OSHA’s estimations of costs in a given industry are factual determinations that must be supported by substantial evidence.³⁰ Similar to OSHA’s technological feasibility analysis, court holdings clearly demonstrate that economic feasibility determinations must be made on an industry-specific basis unless OSHA can prove that grouping is appropriate and will not conceal particularities of individual industries.³¹

IV. OSHA Should Prioritize the PEL Revision Process to Address the Most Significant Potential Risks to Workers

OSHA should develop a robust prioritization program that ensures that its limited resources are used as efficiently as possible to protect as many workers as possible as effectively as possible.

²⁴ E.g., *ATMI v. Donovan*, 452 U.S. at 514; *United Steelworkers of America v. Marshall*, 647 F.2d 1189, 1251 (11th Cir. 1980).

²⁵ *Public Citizen Health Research Group v. Department of Labor*, 557 F.3d 165 (3rd Cir. 2009) (quoting *United Steelworkers*, 647 F.2d at 1272).

²⁶ *United Steelworkers*, 647 F.2d at 1266.

²⁷ *United Steelworkers*, 647 F.2d at 1301.

²⁸ *United Steelworkers*, 647 F.2d at 1266.

²⁹ *United Steelworkers*, 647 F.2d at 1267.

³⁰ See *Texas Independent Ginners Assn. v. Marshall*, 630 F.2d 398, 411 (5th Cir. 1980).

³¹ *AFL-CIO v. OSHA*, 965 F.2d at 982.

1. Tiered Approach

The RFI suggests reliance on a tiered approach (the Tiered Approach) to the risk assessment that includes three stages: (1) an analysis of the chemical's dose-response relationship in the observed range that derives a Low-End Toxicity Exposure (LETE); (2) a Margin of Exposure (MOE) determination based on the relationship between the LETE and the Lowest Technologically Feasible Exposure (LTFE); and, (3) if necessary, an extrapolation of the dose-response relationship to assess risk at doses below those in the observed range (Point of Departure (POD)).³²

OSHA suggests, and ACC agrees, that this third step is only necessary when it is technologically feasible to control exposures to a substance at levels below the point where adverse responses have been observed. Stated differently, there is little reason for OSHA to expend time and resources to quantify risk at levels below that which can feasibly be controlled because the standard will be set at the lowest point feasible.

That said, because OSHA suggests using the Tiered Approach within the "significance of risk" analysis, it will nonetheless likely require substantial and extensive analysis. To avoid the time-consuming extrapolation of risk below the POD, OSHA would likely be required to take on a potentially more exhaustive analysis of the LTFE. The case law is clear that technological feasibility analyses must meet the same strict "substantial evidence" standard as risk analyses. For technological feasibility, however, OSHA must analyze the feasibility of controls on an industry-by-industry basis.

Accordingly, ACC does not believe that the Tiered Approach can be used to streamline the OSH Act's required risk analysis. We agree, however, that the Tiered Approach could more effectively be applied as a screening tool because it generates information that is relevant and useful for effective prioritization.

A Tiered Approach could identify chemicals for which there have been observed adverse impacts. Focusing on chemicals where adverse impacts have been observed (as opposed to modeled) would help OSHA identify chemicals that may be more hazardous and that may require the less rigorous risk analysis. Often, challenges to OSHA's risk analyses are based on the extrapolation of hazards at low doses from observed impacts at higher doses. By focusing on chemicals for which observed impacts have been identified and measured, OSHA need not spend resources developing and defending dose-response models.

The second step of a Tiered Approach compares a chemical's observed impacts with an estimation of the level at which the chemical can be feasibly controlled. If this second step identifies observed impacts, which are the most easily assessed, at levels above the level to which control technologies can feasibly reduce exposure, OSHA should prioritize that chemical.

Chemicals can be ranked more precisely by measuring the delta between the LETE and LTFE. The greater the difference between the lowest observed impact and the lowest level of feasible control (large MOE), the higher OSHA should prioritize the PEL for that chemical. While a

³² 79 Fed. Reg. at 61,391.

Tiered Approach is not the sole means by which OSHA should prioritize, it is a useful tool for identifying those occupational health hazards that have the most straightforward risk analyses and that technology will likely be able to address.

2. Use of Existing Resources

Effective prioritization also requires an understanding of the prevalence of potentially hazardous chemicals in the workplace. OSHA can look to a few existing information sources to generate an understanding of worker exposure potential sufficient for building a framework to analyze and rank relative risks, even if that information alone did not meet the OSH Act's high evidentiary standard for actually promulgating a PEL.

a. *EPA's Chemical Data Reporting (CDR) Data*

The information that EPA has collected as part of its Chemical Data Reporting (CDR) Rule could be used to support the prioritization of chemicals for PEL development. Under the CDR EPA collects information on chemicals manufactured or imported at a single site at 25,000 pounds or greater that is included on the Toxic Substances Control Act (TSCA) Chemical Substance Inventory. Currently 7,674 chemicals on the public Inventory meet the threshold for the program.³³ The data involved includes screening-level exposure-related information on manufacturing and import, industrial processing and use, and consumer and commercial use.³⁴ EPA makes CDR information publicly available to the extent possible.³⁵ ACC concurs with OSHA's conclusion that OSHA can use this information to better understand how workers are exposed to chemicals, and the industries and occupations where exposures to chemicals might occur.³⁶

b. *OSHA and NIOSH Data*

NIOSH and OSHA's own data also provide a wealth of information relevant to PEL prioritization. NIOSH and OSHA jointly conducted preliminary research on health risks associated with exposure and extent of occupational exposure in the 1980s in preparation to issue their 1989 PEL revision. While some of this data may be outdated, it still may prove valuable in an assessment of knowledge on occupational exposures, and which substances should be updated first.

OSHA compiles information from its enforcement and On-Site Consultation programs that help to identify substance uses and exposures. OSHA compliance officers often take industrial hygiene samples when monitoring worker exposures to chemical hazards. Many of these samples are submitted to the Salt Lake Technical Center (SLTC) for analysis, and the results, including data on personal, area, and bulk samples for various airborne contaminants, are maintained on

³³ 79 Fed. Reg. at 61,386.

³⁴ 79 Fed. Reg. 61,407-08.

³⁵ 79 Fed. Reg. at 61,386.

³⁶ 79 Fed. Reg. at 61,407.

OSHA's web site. OSHA should be sure to source science and information from all sections of its operations to contribute toward the prioritization of PELs.

NIOSH maintains an active risk assessment program that recently evaluated many chemicals that OSHA may want to consider within a PEL update.³⁷ OSHA could obtain this risk assessment data for its own analysis as this data may point to the chemicals with significant worker exposure and/or risk.

As part of its Health Hazard Evaluation Program, NIOSH also conducts site visits, reviews exposure records, and may conduct its own sampling. This information is summarized in a report to the employer and maintained in NIOSH's chemical exposure health database. Although the OSHA and NIOSH databases may be limited in scope, they can help to identify substances or applications that may require priority consideration for PEL revision. This information could also be used to determine what chemicals frequently result in workplace exposures, and whether these exposures are significant.

The RFI suggests that OSHA is considering increasing its reliance on toxicological evaluations from other federal agencies for hazard identification and, as part of a potential Tiered Approach, to identify chemicals for which there are adverse impacts in the observed range.³⁸ OSHA should already be considering such data, and the OSH Act's evidentiary standards arguably require this. To the extent the phrase "increasing its reliance" suggests an intent to adopt these toxicological evaluations by proxy or to accept them without applying its own independent and rigorous analysis, such an approach would clearly conflict with well-settled case law.³⁹

While ACC recognizes that information from other agencies can be useful to OSHA, we do not believe that information from other agencies is universally appropriate and that OSHA can substitute it for a rulemaking or establish a rigid framework for relying on it more. Different agencies collect and generate data pursuant to different statutory mandates for different purposes and with different procedures for verification and review. Accordingly, information from different agencies may reflect the need for more or less protective standards, and may employ analytical approaches that are more or less rigorous than OSHA's. Moreover, the information generated at these agencies, and the processes under which the information is generated, are subject to change.

OSHA should develop criteria for evaluating and using other agencies' information. A criteria-based approach would preserve OSHA's ability to leverage and utilize relevant information from other agencies, but make the product of that utilization more reliable and transparent by applying a process to screen the information.

Although NIOSH's information could be valuable in PEL prioritization and risk assessment, OSHA cannot and should not replace its own analysis with that of NIOSH. OSHA must

³⁷ 79 Fed. Reg. 61,392.

³⁸ 79 Fed. Reg. at 61,392 (Q. IV.A.3).

³⁹ See, e.g., *ATMI v. Donovan*, 452 U.S. 490; *Public Citizen Health Research Group*, 557 F.3d 165; *AFL-CIO v. OSHA*, 965 F.2d 962.

consider and interpret all data presented to it from all sources; it may not simply adopt the analysis and conclusions of other organizations.

c. *Other Established Limits*

Consideration of a wide variety of data is essential to establishing a legally defensible standard. Indeed, the RFI notes several agencies and information sources already consulted by OSHA. Another potentially helpful tool for prioritizing substances is a comparison of existing PELs with the exposure limits established by NIOSH, ACGIH, OARS, and others to evaluate those substances that may be in the greatest need of a PEL revision or the establishment of a new PEL. By comparing its own limits to those established by other authoritative groups, OSHA can quickly evaluate which PELs have new data available that may be useful for a further evaluation. OSHA can also evaluate which existing PELs are not consistent with more recent evaluations. The magnitude of the discrepancy between a PEL and another limit for a particular substance may also help to define OSHA's priorities. Substances for which an exposure limit has been established by one of these authoritative groups, but for which no corresponding PEL exists, also may warrant priority consideration by OSHA.

d. *Data Submitted to ECHA for REACH Compliance*

The RFI suggests that OSHA is considering reliance on data from the European Chemicals Agency's (ECHA) Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) to inform its technological feasibility analyses.⁴⁰ The RFI further identifies some impediments to accessing REACH data, such as confidentiality and restrictions on the dissemination of information.⁴¹ ACC agrees that there may be limitations on REACH data-sharing, but to the extent information can be obtained, we encourage OSHA to consider it. Although the uses of a substance in Europe may not always mirror those in the United States, the REACH information may provide important insights into where and how a substance may be used.

While consideration of data from other sources and government bodies is legally defensible and in fact, required under the OSH Act, inflexible reliance or adoption of other entities' findings is not permitted by the OSH Act or court interpretations thereof. As noted in *United Steelworkers*, "the one who decides must hear."⁴²

3. Hazard Banding

OSHA may be able to use a hazard banding approach to rank the hazards associated with various chemicals. Under a hazard banding approach, chemicals are characterized by common attributes (*e.g.*, similar function, physiochemical structure, constituents, or known toxicological impact), so that hazards known about one chemical or more chemicals in the group can be used to infer hazard and hazard thresholds in other chemicals within the group for which there are little or no

⁴⁰ 79 Fed. Reg. at 61,400.

⁴¹ 79 Fed. Reg. at 61,400.

⁴² 647 F. 2d at 1217.

known data.⁴³ Hazard banding allows substances to be placed into a discrete category that represents the severity of the hazards they present, as determined by an expert evaluation of the dose-response relationships derived from toxicological data. When this information is cross-referenced against information regarding levels of exposure, OSHA can determine which chemicals have high hazard and exposure levels and should thus be prioritized for a PEL rulemaking.

There are several well-established hazard banding schemes, including the United Kingdom's Control of Substances Hazardous to Health (COSHH) regulation table.⁴⁴ Members of the AIHA WEEL Committee have also developed a WEEL-Banding Matrix.⁴⁵ Hazard banding would have the benefit of providing a process for risk assessments and encouraging voluntary adoption of controls for chemicals that do not have PELs, and as a resource for data on substances should OSHA later move to develop a PEL for a substance classified in the hazard banding scheme.

ACC suggests that when developing a hazard banding system, OSHA consult with NIOSH's working group of hazard-banding experts, who are currently working to integrate the WEEL Banding Matrix and the COSHH bands with the Global Harmonized System Health Phases Hazard Banding Matrix. OSHA could build upon the work done by other schemes to develop its own hazard banding system, which could be less analytically rigorous than the PEL promulgation process. OSHA may elect to engage an advisory committee to do this work; however, the Agency must be careful to not let any hazard banding system evolve into a control banding system.

Further, OSHA's suggestion that a hazard banding approach could be used to assess the significance of risk under the OSH Act discounts the fact that various iterations of this approach have been invalidated by the courts. In the *Benzene* challenge, the Supreme Court invalidated a similar process wherein OSHA based its risk analysis on "rigid and categorical assumptions about the health dangers of benzene, rather than specific evidence of its likely harm at the current and new PEL's [sic]."⁴⁶ In the *Air Contaminants* case, the Eleventh Circuit invalidated an approach under which 428 chemicals were grouped according to primary health effects, and while the significance of risk was supported by "various studies of that substance and the health effects found at various levels of exposure to that substance," OSHA provided no explicit quantification or explanation of the risk from those substances.⁴⁷ The court held that "OSHA is

⁴³ 79 Fed. Reg. at 61,394.

⁴⁴ See U.K. HEALTH & SAFETY EXECUTIVE, THE TECHNICAL BASIS FOR COSHH ESSENTIALS: EASY STEPS TO CONTROL CHEMICALS, available at <http://www.coshh-essentials.org.uk/assets/live/CETB.pdf> (last visited Mar. 2, 2015).

⁴⁵ See Susan Ripple, The Dow Chemical Company, Setting Global Environmental Health & Safety Standards at 34 (Dec. 10, 2008), available at https://www.cihconline.com/conf08_presentations/Completed%20Presentations/26.1%20Susan%20Ripple%20-%20Dow%20Setting%20Global%20Standards.pdf.

⁴⁶ *United Steelworkers*, 647 F.2d at 1246 (citing *IUD, AFL-CIO v. API*, 448 U.S. at 613).

⁴⁷ *AFL-CIO v. OSHA*, 965 F.2d at 975.

not entitled to take short-cuts with statutory requirements simply because it chose to combine multiple substances in a single rulemaking.”⁴⁸

For a hazard banding approach to be used as part of a “significance of risk” analysis under the OSH Act, it would have to result in individualized and quantified chemical-specific risk assessments based on substantial evidence, and adequate explanation of the assumptions applied to extrapolate risks from one chemical to another (and the basis for those assumptions). As such, there is no *per se* prohibition on using hazard banding for the “significance of risk” analysis, but the OSH Act’s requirements for individualized quantification of risk may undercut the prospect that this approach will save OSHA time and resources. ACC’s recommendation, therefore, remains that hazard banding is a useful tool for prioritizing chemicals within OSHA’s standard-setting process.

4. Uncertainty Factors

When, in assessing standards under the Tiered Approach, the MOE requires OSHA to extrapolate a low dose-response model below the range of observed adverse impacts, OSHA should not abandon its probabilistic approach to rely on uncertainty factors. OSHA’s prior attempt to rely on uncertainty factors was invalidated by the Eleventh Circuit in the *Air Contaminants* case.⁴⁹

OSHA, through the application of substantial evidence, is required to evaluate the significance of risk of material impairment at current exposures to plot the point at which the significant risk of material impairment can be eliminated. The product of an uncertainty factor approach is far different, largely because it was developed to answer a different question—namely, whether a specific dose can be considered safe.

We do not contend that OSHA is prohibited from examining uncertainty factors as part of its risk analysis approach. We do believe, however, that singularly relying on an uncertainty factor approach in the face of a legal decision invalidating the exact same approach lacks scientific justification and will likely result in the fruitless expenditure of resources.

V. Potential Approaches to Assessing Feasibility

Assessing feasibility is an important part of developing a PEL, and seeing as this is the area in which OSHA has struggled the most in a number of recent health standard promulgations, ACC provides these suggestions to simplify and improve this process. A full and statutorily sufficient feasibility analysis includes examinations of the economic ability of an industry to bear the introduction of control measures and the current state of technology in reducing exposures from work processes. These analyses must be made on an industry-specific basis sufficient to meet the OSH Act’s requirements. ACC suggests OSHA consider the following points:

⁴⁸ *AFL-CIO v. OSHA*, 965 F.2d at 975.

⁴⁹ *AFL-CIO v. OSHA*, 965 F.2d 962.

1. Use of Process-Specific Standards

ACC believes that there is potential merit in devoting agency resources to the promulgation of process-specific standards. Emission-generating processes, while themselves numerous, are likely far less numerous than chemicals and potentially more amenable to a prioritization scheme that could target those processes that could benefit the greatest number of workers.

Process-specific standards would likely take as much, if not more, time and resources to promulgate than PELs because they are somewhat novel and because, by design, they would address multiple hazards. Still, in some strategically selected circumstances, devoting more time to a process-specific standard could result in the greatest potential occupational health benefit.

Importantly, while process-specific standards could create potential occupational health benefits, they should be promulgated in lieu of, rather than in addition to, PELs. Regulation of a single workplace—in fact, even a single worker—through both chemical-specific and process-specific standards would pose significant compliance issues that could actually undermine a single standard and drain enforcement resources. Imposing both standards in a single work environment would result in a multi-PEL workplace where mandated exposure levels could change depending on the task being undertaken by the worker, the product run, or whether maintenance was being conducted.

In the hexavalent chromium rule, OSHA successfully defended its decision to adopt a uniform PEL because of the infeasibility of enforcing different PELs for the same chemical in the same workplace. “OSHA explained that multiple PELs would create an ‘enormous evidentiary burden,’ and associated implementation delays, in order for the Agency to define the precise situations under which employers would be required to meet a lower PEL.”⁵⁰ OSHA noted that multiple PELs would cause problems for compliance and enforcement because workplaces and employees would be subject to multiple categories of exposure, and it would be difficult to distinguish exposures from different sources.⁵¹ The court noted that this was a legislative policy decision that it would uphold as long as the administrative record reasonably supported it.⁵²

ACC believes that process-specific standards that are promulgated with the recognition that they must be complementary to, and not duplicative of or in conflict with, the PEL system can be an important and efficient tool for OSHA. In addition to avoiding duplication, OSHA should also avoid promulgating process-specific standards that equate to control banding.

Mandated control banding could have adverse health effects. Because specific controls (or types of controls) would be required for the wide range of exposures that would fall within one of the small number of hazard bands, control banding would be certain to produce examples of control requirements that were excessive or inappropriate. It would also produce cases where “under-control” occurred. A recent NIOSH review of the literature on control banding and efforts to validate the approach cited concerns about its effectiveness and potential to produce “potentially

⁵⁰ *Public Citizen Health Research Group*, 557 F.3d at 183–84.

⁵¹ *Public Citizen Health Research Group*, 557 F.3d at 184.

⁵² *Public Citizen Health Research Group*, 557 F.3d at 183.

inappropriate workplace confidence” in the system.⁵³ NIOSH concluded that “[a]dditional development, evaluation, and discussion are required before widespread implementation of control banding in the United States can be recommended.”⁵⁴

A control banding approach could be marginally less objectionable if OSHA provided employers sufficient flexibility to develop and implement programs tailored to their own workplaces.

2. Use of Modeling to Assess Exposures

ACC agrees that modeling is a valuable tool for assessing exposures, but modeling should be based on industry-specific information so that it accurately reflects the use in the industry and complies with the requirements of the OSH Act. Computational fluid dynamics (CFD) models, for instance, are not appropriate for assessing workplace exposures, and, therefore, the feasibility of controls.

As an initial matter, these models do not obviate the need for exposure data as the data are necessary to develop and calibrate the model. Even when sufficient exposure data are available, modeling workplace exposures using CFD requires users to input key details to define the “geometry” of the workplace and to identify with precision the orientation and spatial distribution of emission sources, controls, and workers. It also requires the user to identify those factors influencing the fluid dynamics of hazardous emissions in the workplace including temperature, ventilation, the emission-generating process or substrate, and walls and equipment that may impede or alter airflow.

These highly site-specific model inputs make CFD models a poor choice for characterizing exposures in even a single workplace because an individual workplace will frequently have significant variability with respect to equipment configurations, product runs, location of employees, and even weather changes and related ventilation changes. Even though, as OSHA points out, the science underlying CFD models has made great advances, the fact that the CFD models are more sophisticated does not obviate the need to run them on site-specific data.

Far from providing a means of broadly assessing technical feasibility across an industry, CFD models would be challenged to assess exposures in a single workplace. Even if CFD models could credibly model exposures in a single workplace, there is no “typical workplace” in the chemical industry—or likely any industry for that matter—from which OSHA could model a “typical exposure scenario” and therefore, feasibility. This “generic” view of a standard workplace conflicts with the OSH Act, numerous court decisions, and OSHA’s own approach to enforcement.

⁵³ DEPARTMENT OF HEALTH AND HUMAN SERVICES NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH, QUALITATIVE RISK CHARACTERIZATION AND MANAGEMENT OF OCCUPATIONAL HAZARDS: CONTROL BANDING 40 (Aug. 2009), available at <http://www.cdc.gov/niosh/docs/2009-152/pdfs/2009-152.pdf> (last visited Mar. 2, 2015).

⁵⁴ QUALITATIVE RISK CHARACTERIZATION AND MANAGEMENT OF OCCUPATIONAL HAZARDS, *supra*, at vii.

3. Presuming Technological Feasibility in One Industry Based on Findings in a Different Industry

The RFI also discusses a potential approach to streamlining the technological feasibility analysis by assessing feasibility only for those industries identified by OSHA as having the highest exposures and most complex control issues and, if OSHA then determines that a standard is technologically feasible for those industries, assuming it is technologically feasible for any industry with lower exposures or more simple control options.⁵⁵ While such an approach may make sense in theory, it is undermined by real world practicalities that impede the simple extrapolation of control feasibility and compliance data from one industry to another.

Emissions and control scenarios are rarely amenable to ranking from highest to lowest or hardest to easiest. An examination of various industries' aggregate emissions levels could overlook key details on whether, for instance, the emissions are static or intermittent, contain different particle sizes, densities, or risks, or are emitted from one or multiple sources. An examination of generic control efficacy would be unlikely to provide OSHA with any insight into whether such controls can be used for the manufacture of certain products, whether such controls are physically capable of attachment to the industry's specific equipment, whether the control would interfere with other control equipment or guarding, or whether the employee to be protected is in a fixed position or works in varying locations. Indeed, in the hexavalent chromium rule, OSHA recognized that pigment, catalyst, and dye producers could not use certain ventilation systems that were feasible for controlling larger emissions of welding fumes because the systems disrupted the application of coatings that required small particle sizes.⁵⁶ Even within the welding "process," OSHA's hexavalent chemical rule recognized that emissions, exposures, and controls would vary based on type of welding, type and size of welding substrate, working environment, and the position of the welder.⁵⁷

The OSH Act does not allow standards to be developed based on "a general presumption of feasibility for an industry."⁵⁸ More specifically, the approach discussed in the RFI is, in all material respects, the same as OSHA's approach to "other industries" in setting the lead standard. In the lead standard, OSHA conducted more extensive analysis for ten of seventeen industries and, for the remaining seven industries, presumed technological feasibility based on their presumed lower emissions and their need for only "very simple engineering controls."⁵⁹ The court rejected this approach because "the undisputed principle that feasibility is to be tested industry-by-industry demands that OSHA examine the technological feasibility of each industry individually."⁶⁰ To be sure, the court did not prohibit OSHA from using relevant control and

⁵⁵ 79 Fed. Reg. at 61,401.

⁵⁶ See *Public Citizen Health Research Group*, 557 F.3d at 181.

⁵⁷ See *Public Citizen Health Research Group*, 557 F.3d at 180.

⁵⁸ *AFL-CIO v. OSHA*, 965 F.2d at 981 (citing *United Steelworkers*, 647 F.2d at 1266; *ASARCO, Inc. v. OSHA*, 746 F.2d 483, 496 (9th Cir. 1984)).

⁵⁹ See *United Steelworkers*, 647 F.2d at 1301.

⁶⁰ *United Steelworkers*, 647 F.2d at 1301.

exposure data from other industries,⁶¹ but it did hold OSHA to the requirement to examine each industry and explain its feasibility determinations for each industry.

4. Demonstrating Feasibility Based on the Existence of Industries in States with Stricter PELs

The RFI suggests that, in lieu of the method for assessing economic feasibility that it developed in response to adverse court decisions, OSHA could infer economic feasibility by placing a “major emphasis” on:

evidence that a significant portion of an industry is already meeting a standard. Such evidence is an obvious indication that a standard is both technologically and economically feasible for that industry. After all, the actual fact that a majority of employers of all sizes is meeting a standard, while remaining viable, should be more convincing than a set of cost estimates in an economic analysis in predicting that employers in a given industry could meet a standard.⁶²

ACC believes that the RFI has appropriately identified an important data source for assessment of economic feasibility, and while we do not know what OSHA intends with the phrase “major emphasis,” we caution OSHA against adopting as its feasibility analysis a single data point among a large amount of available and potentially relevant data. OSHA is correct that courts will still find standards to be economically feasible even if more marginal companies go out of business or so long as the standards do not cause “massive dislocation” in or “imperil the existence of” industry,⁶³ but OSHA incorrectly suggests that this interpretation somehow mitigates against the need to conduct an industry-specific inquiry. Indeed, the court held that the OSH Act allows OSHA to promulgate standards with adverse economic consequences, but that the assessment of those consequences must always be industry-by-industry. OSHA’s belief that, “[i]n the real world, industries are rarely eliminated or have their competitive structure radically altered”⁶⁴ because of compliance costs, is unlikely to change the fact that courts are inclined to invalidate any standard that is not based on an industry-by-industry analysis and supported by substantial evidence.

Further, the RFI suggests that OSHA may use as evidence of feasibility the fact that industries in states with approved programs and stricter PELs are economically viable.⁶⁵ Again, ACC supports consideration of this information as an important data point, but does not believe that demonstration of compliance with a stricter state PEL equates to a determination of economic feasibility.

OSHA must make its determination based on substantial evidence. Compliance with a state PEL is relevant, but OSHA still must analyze and explain why compliance in a single state would

⁶¹ In fact, that practice is common, if not universally used, in OSHA standard-setting.

⁶² 79 Fed. Reg. at 61,403.

⁶³ 79 Fed. Reg. at 61,403, citing *United Steelworkers*, 647 F. 2d. at 1265.

⁶⁴ 79 Fed. Reg. at 61,403.

⁶⁵ 79 Fed. Reg. at 61,403.

reflect feasibility in other states. OSHA would also be required, with some precision, to specify the industry to which this evidence could be extrapolated. OSHA must recognize, as it has in the past that economic feasibility cannot be accurately assessed at an aggregate industry level.

Further, OSHA should recognize that the continued presence of an industry in a state with a stricter PEL may not provide evidence of economic feasibility at all. The inquiry must examine the economic impact on those state industries at the time the PEL was lowered. Consider, for example, a state PEL that led to the insolvency or relocation of 75 out of 100 businesses in a particular industry sector. The approach in the RFI suggests that the presence of 25 businesses in the state proves the economic feasibility of the proposed standard for industry. There is no reading of the OSH Act or case law, however, under which a rule that displaces 75% of companies in an industry sector is economically feasible for that sector.

VI. OSHA Should Provide a Transparent Approach to This Rulemaking with Ample Opportunity to Comment

1. Creation of an Advisory Group to Assist in PEL Prioritization and Development

ACC advocates for the creation of an advisory group, or multiple advisory groups, to assist in PEL prioritization and development. This would be in line with OSHA's mandate under the OSH Act, and OSHA already makes use of one advisory committee in its work. GAO has recognized that "[f]ederal advisory committees are sometimes established to address controversial issues about which the government believes it is necessary to solicit the advice of individuals with the relevant background and/or expertise from outside the government."⁶⁶ The potential success of an advisory committee system can be seen in the example provided by EPA's National Advisory Committee for the Development of Acute Exposure Guideline Levels for Hazardous Substances (AEGL Committee).

The OSH Act provides that "[w]henver the Secretary . . . determines that a rule should be promulgated in order to serve the objectives of this Act, the Secretary may request the recommendations of an advisory committee appointed under section 7 of this Act."⁶⁷ The Secretary is to provide the advisory committee with his own proposals, the factual information developed, and other data from research, demonstrations, and experiments.⁶⁸ The advisory committee will submit its recommendations 90 days after it is appointed or within the time period prescribed by the Secretary, which cannot exceed 270 days.⁶⁹ OSHA already maintains a standing National Advisory Committee on Safety and Health (NACOSH), which advises the Secretaries of Labor and Health and Human Services on occupational safety and health programs and policies.⁷⁰ NACOSH has a total of 12 representatives from labor, the occupational health

⁶⁶ U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-04-328, FEDERAL ADVISORY COMMITTEES: ADDITIONAL GUIDANCE COULD HELP AGENCIES BETTER ENSURE INDEPENDENCE AND BALANCE (Apr. 2004), at 15.

⁶⁷ 29 U.S.C. § 655(b)(1).

⁶⁸ 29 U.S.C. § 655(b) (1).

⁶⁹ 29 U.S.C. § 655(b) (1).

⁷⁰ *National Advisory Committee on Occupational Safety and Health*, U.S. DEPARTMENT OF LABOR, <https://www.osha.gov/dop/nacosh/nacosh.html> (last visited Feb. 26, 2014).

professions, the occupational safety professions, and the public.⁷¹ Section 7 of the OSH Act prescribes more specifics regarding the composition and operation of NACOSH and other OSHA advisory committees.⁷²

OSHA could use an advisory committee or committees to more efficiently move through data collection and evaluation. The committee could use an evidence-based review system to conduct uniform systematic evaluations of the relevance and reliability of chemical research and testing investigations, and then to integrate this information in an overall assessment of the weight of the scientific evidence. The committee could request existing information and data, weigh the resulting data, and then propose scientifically justifiable OELs. The committee could also review any existing OELs, such as TLVs or WEELs, and the data underlying them to ensure that all suggestions and data for standards face the same review process. ACC proposes that the committee not address economic and technical feasibility, recognizing that the committee-recommended OELs would not officially be PELs. Even if OSHA elects not to use a committee to conduct this in-depth data review and OEL development, a committee could still be helpful to OSHA in collecting data and information on substances or suggesting how chemicals should be prioritized, for example.

An expert peer review of an advisory council's findings and OEL suggestions would be highly valuable, and likely is required for PEL rulemakings by the Office of Management and Budget's Final Information Quality Bulletin for Peer Review.⁷³

The experience of EPA's AEGL Committee shows the potential value of a committee approach to updating PELs. The AEGL Committee was formed in 1986 to develop and recommend Acute Exposure Guideline Levels (AEGLs) for hazardous chemicals for use in chemical emergency programs.⁷⁴ The AEGL Committee generated final or interim AEGLs for 273 chemicals in less than 15 years⁷⁵ at a cost of approximately \$50,000 per chemical.⁷⁶ The AEGL Committee used voting majorities instead of consensus decision-making, thus allowing it to operate more quickly, and because EPA empaneled it, it met the "fairly balanced" requirement of the Federal Advisory Committee Act.⁷⁷ Having completed its work, the AEGL Committee folded in 2011.⁷⁸ Though it is arguably easier to establish values for acute exposure hazards than for chronic health hazards, this is likely to be only a difference of degree, and the AEGL Committee remains an admirable example for OSHA to follow in establishing an advisory committee.

⁷¹ *National Advisory Committee on Occupational Safety and Health, supra.*

⁷² 29 U.S.C. § 656.

⁷³ Final Information Quality Bulletin for Peer Review, 70 Fed. Reg. at 2,664 (Jan. 14, 2005).

⁷⁴ *Acute Exposure Guideline Levels (AEGLs): History of the AEGL Program*, U.S. ENVIRONMENTAL PROTECTION AGENCY, <http://www.epa.gov/opptintr/aegl/pubs/history.htm> (last visited Feb. 26, 2014).

⁷⁵ *Acute Exposure Guideline Levels, supra.*

⁷⁶ Paul S. Tobin, Acute Exposure Guideline Levels Designated Federal Officer, U.S. Environmental Protection Agency Office of Pollution Prevention and Toxics, Presentation to American Industrial Hygiene Association Board of Directors (Jan. 2009).

⁷⁷ 5 U.S.C. app. § 5(b) (2).

⁷⁸ *Acute Exposure Guideline Levels, supra.*

2. Use of Additional RFIs to Collect Input and Provide Opportunity for Comment

ACC understands that the present RFI is itself a screening exercise, suggesting a substantial number of potential avenues that OSHA could take in updating PELs and regulating occupational exposures to chemicals. The comments and information OSHA receives in response to this present RFI will allow it to narrow down the potential options it has in moving forward with improving health standards.

RFIs and the public comment and information collected from them will help OSHA develop PELs that are more protective of worker safety, more thoroughly and accurately representative of technological feasibility in a variety of industries, and that more completely consider economic costs for affected industries. OSHA's determinations are highly reliant upon collection of scientific data on health effects of substances at varying exposure levels; employers' ability to install and integrate control technologies into their work processes; and the costs and other economic effects that employers and industries would incur as a result of the new standard. Additional RFIs and comment opportunities would allow the general public, affected employers and companies, industry representatives like ACC, and others to help OSHA determine how best it can effectively leverage the knowledge of the regulated community to efficiently develop and promulgate PELs.

As OSHA moves forward, it will presumably refine the options identified in the RFI and will be increasingly able to more specifically describe and define the options it intends to pursue. Similarly, interested parties and the public will be able to provide OSHA with more detailed and relevant feedback. For this reason, OSHA should repeatedly offer stakeholders the opportunity to comment throughout the rulemaking process.

VII. OSHA's Attempt to Use the General Duty Clause to Enforce Exposure Levels Lower than Existing PELs is Impermissible

The OSH Act imposes on employers a "general duty" to provide each employee a workplace that is free from "recognized hazards" that are likely to cause death or serious physical harm to his employees.⁷⁹ Recent initiatives by OSHA and questions posed in its RFI seem to indicate that OSHA intends to increasingly use the general duty clause to enforce stricter exposure limits lower than those promulgated by rule.

In 2013, OSHA unveiled its "Chemical Safety Toolkit,"⁸⁰ which annotated existing PELs to reference stricter occupational exposure limits developed by entities such as the California

⁷⁹ 29 U.S.C. § 654(a) (2). The U.S. Government Accountability Office ("GAO") noted in its report that OSHA can cite employers for failing to adequately protect workers from a specific workplace hazard even if it has not set a standard on that hazard. GAO described a 2008 enforcement case against Walmart in which OSHA used the general duty clause to issue a citation for a worker death. OSHA explained to GAO that OSHA must have evidence that the hazard is "recognized" in the industry and that the employer failed to take reasonable protective measures. *See* U.S. GOV'T ACCOUNTABILITY OFFICE, *supra*, at 23–24.

⁸⁰ News Release, U.S. Department of Labor, OSHA Releases New Resources to Better Protect Workers from Hazardous Chemicals (Oct. 24, 2013), *available* at https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=NEWS_RELEASES&p_id=24990.

Division of Occupational Safety & Health, the National Institute for Occupational Safety and Health, and the American Conference of Governmental Industrial Hygienists.⁸¹ In OSHA's view, the Chemical Safety Toolkit puts employers on notice that their employees may face exposure hazards even if the employer is complying with all published PELs. Within months, OSHA brought an enforcement action against a company in full compliance with existing PELs, but which had employees exposed above the Chemical Safety Toolkit's annotated limits.⁸² Even more recently, OSHA published an enforcement directive on the Hazard Communication Standard⁸³ outlining for its inspectors how to identify general duty clause violations through information provided in the SDS. As explained by OSHA, an SDS likely provides three of the four elements necessary to substantiate a general duty clause enforcement action: (1) identification of the hazard, (2) the likelihood that exposure could result in death or serious bodily injury; (3) employers' recognition of the hazard/severity; and (4) controls/work practices to protect employees from the hazard.⁸⁴ The feasibility of controls and work practices, however, would still need to be demonstrated for the specific workplace. Nonetheless, OSHA's directive to its inspectors is clear—compliance with published PELs does not make employers “in compliance.” Additionally, in this RFI OSHA asks, “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?”⁸⁵

While ACC strongly supports transparency, the sharing of information, and the publicizing of the latest materials on exposure hazards, OSHA cannot use the general duty clause to enforce different, stricter exposure limits because doing so violates the OSH Act.

OSHA's regulations under the OSH Act state that “[i]f a particular standard is specifically applicable to a condition, practice, means, method, operation, or process, it shall prevail over any different general standard which might otherwise be applicable to the same condition, practice, means, method, operation, or process.”⁸⁶ OSHA's regulation similarly provides that “[a]n employer who is in compliance with any standard in this part shall be deemed to be in compliance with the requirement of section 5(a)(1) of the Act, but only to the extent of the condition, practice, means, method, operation, or process covered by the standard.”⁸⁷ As such, OSHA's own regulations reveal that the general duty clause is to be used in lieu of more specific

⁸¹ *See generally id.*

⁸² *See, e.g.,* OSHA Regional News Release, U.S. Department of Labor Office of Public Affairs Region 5, Fiberglass Inc. Agrees to Limit Employee Exposure to Styrene, Accept General Duty Clause Citation Issued by OSHA at Like Mills, Wis., Fiberglass Plant (July 31, 2014), *available at* https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=NEWS_RELEASES&p_id=26466.

⁸³ U.S. DEPARTMENT OF LABOR, OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, CPL 02-02-079, INSPECTION PROCEDURES FOR THE HAZARD COMMUNICATION STANDARD (HCS 2012) (July 9, 2015), *available at* https://www.osha.gov/OshDoc/Directive_pdf/CPL_02-02-079.pdf.

⁸⁴ *See id.* at 86–88.

⁸⁵ 79 Fed. Reg. at 61,406.

⁸⁶ 29 C.F.R. § 1910.5(c)(1).

⁸⁷ 29 C.F.R. § 1910.5(f).

standards – not to create compliance obligations different and more stringent than the directly applicable standard.

PELs are promulgated by regulation. Therefore, using the general duty clause to enforce voluntary occupational exposure limits far different than those in PELs, creates a new obligation without observance of the rulemaking processes mandated by the OSH Act. Moreover, use of exposure limits set by other entities creates considerable uncertainty and makes it harder for both employees and employers to understand the applicable limits – particularly when these cross-referenced limits are changed through standard-setting processes outside of agency rulemaking. And even if it were permissible for OSHA to overlook its regulatory obligations in lieu of outside standards, the fact that exposures in a workplace exceed a stricter outside standard would not amount to a violation of the general duty clause. OSHA would still need to make case-specific determinations on the significance of the risk posed by any exceedance and the feasibility of controlling exposures to stricter limits. As such, to the extent OSHA views the general duty clause as a means by which it can avoid the OSH Act's rigorous PEL promulgation requirements, that goal would be undermined by the OSH Act's requirements to make the same type of industry-specific risk and feasibility analyses that are required in promulgated PELs.

VIII. Conclusion

As previously stated, ACC and its members share OSHA's commitment to protecting workers from occupational exposures to hazardous chemicals, as well as OSHA's concern that the statutory constraints have made PEL promulgation cumbersome, time-consuming, and inefficient. ACC strongly believes that OSHA can use many of the tools in the RFI to identify and focus its PEL promulgation process on the highest priority chemicals. By a triage of the highest priority chemicals, OSHA can ensure that its efforts will enhance worker protection. It will also ensure that the resulting PEL meets the statutory requirements of the OSH Act as interpreted by the courts.

APPENDIX A

OSH Act Section 6(b) and Court Interpretations Thereof

As explained by the court in *Industrial Union Department, AFL-CIO v. Hodgson*, OSHA decision-making is based on “the exercise of delegated power to make within certain limits decisions that Congress normally makes itself, and by processes, as the courts have long recognized and accepted, peculiar to itself.”⁸⁸ Indeed, through the OSH Act, Congress delegated the federal government an unprecedented amount of authority to protect the health and safety of American workers. Within this delegation of authority, however, Congress imposed “certain limits” in the form of analytical and procedural requirements for the promulgation of health and safety standards

Section 6(b) of the OSH Act outlines in detail the manner by which OSHA may promulgate, modify, or revoke any occupational safety or health standard.⁸⁹ Three major analytical requirements include consideration of: the significance of risk, technological feasibility, and economic feasibility.

Section 6(f) of the OSH Act provides that “the determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole.” In interpreting that requirement, the Supreme Court has held that substantial evidence is “such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.”⁹⁰

Significantly, this standard requires “more rigorous scrutiny” of, or a “harder look” at, OSHA’s action than the more deferential “arbitrary and capricious” standard of review under the Administrative Procedure Act (“APA”).⁹¹ The more rigorous substantial evidence review requires the court, unlike a more deferential arbitrary and capricious standard, to review countervailing evidence unresponsive of OSHA’s decision.⁹² It requires OSHA, on the other hand, to demonstrate that this evidentiary burden has been met. As noted by the Supreme Court, “[o]rdinarily, it is the proponent of the rule or order who has the burden of proof in administrative proceedings” and Congress intended OSHA to “bear the normal burden of establishing a need for a proposed standard.”⁹³

⁸⁸ *Industrial Union Department, AFL-CIO v. Hodgson*, 499 F.2d 467, 475 (D.C. Cir. 1974).

⁸⁹ 29 U.S.C. § 655(b).

⁹⁰ *American Textile Manufacturers Institute, Inc. v. Donovan*, 452 U.S. 490, 522 (1981) (quoting *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 477 (1951)).

⁹¹ See *Color Pigments Manufacturers Association, Inc. v. OSHA*, 16 F.3d 1157, 1160 (11th Cir. 1994); *Asbestos Information Assn. v. OSHA*, 727 F.2d 415, 421 (5th Cir. 1984); *AFL-CIO v. Marshall*, 617 F.2d 636, 649 (D.C. Cir. 1979).

⁹² *AFL-CIO v. Marshall*, 617 F.2d at 649 n.44 (citing *Universal Camera*, 340 U.S. at 481–82).

⁹³ *Industrial Union Department, AFL-CIO v. American Petroleum Institute*, 448 U.S. 607, 653 (1980).

Analogous regulatory agencies, like EPA, do not have to meet this same evidentiary standard to promulgate and defend their rules. As GAO found, the very realistic expectation that OSHA standards will be challenged in court and the prospect of defending the action under such a strict standard:

requires staff to perform more extensive research and analysis to support a new standard. For example, OSHA officials explained that the substantial evidence standard requires that OSHA staff conduct a large volume of detailed research in order to understand all industrial process that involve the hazard being regulated and to ensure that a given hazard would be feasible for each process.⁹⁴

Indeed, GAO noted in its report that the OSHA staff and experts it consulted believed that the PEL process could be expedited significantly if the OSH Act's substantial evidence standard were replaced by the APA's more deferential "arbitrary and capricious" standard.⁹⁵ Implicit within this recommendation and explicit within GAO's report, however, is that only Congress can change the evidentiary standard to which it required OSHA standards be held.

I. Significance of Risk

In addition to holding OSHA standards to a rigorous evidentiary standard, Section 6(b)(5) of the OSH Act instructs OSHA, in dealing with toxic materials or harmful physical agents, to set a standard that most adequately ensures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard for the period of his working life.⁹⁶ Each element of this requirement has been litigated and dissected in court decisions. Of relevance to this analysis are those cases explaining "significant risk."

The first major case to interpret this requirement is the so-called *Benzene* case,⁹⁷ in which the American Petroleum Institute challenged OSHA's standard for benzene. The court stated that OSHA, "before issuing any standard, [must] determine that it is reasonably necessary and appropriate to remedy a significant risk of material health impairment."⁹⁸ The Supreme Court described this as a "threshold finding."⁹⁹

To understand this relatively ambiguous phrase, the Supreme Court extracted the meaning from the statement and intent of its drafters. In reviewing the legislative history, the Supreme Court found that Senator Dominick noted that the original wording of Section 6(b)(5) required a standard that ensured that "no employee will suffer any impairment," and that this would be a

⁹⁴ GAO REPORT, *supra*, at 18.

⁹⁵ GAO REPORT, *supra*, at 30.

⁹⁶ 29 U.S.C. § 655(b).

⁹⁷ *IUD, AFL-CIO v. API*, 448 U.S. 607.

⁹⁸ *IUD, AFL-CIO v. API*, 448 U.S. at 639.

⁹⁹ *IUD, AFL-CIO v. API*, 448 U.S. at 640.

near-impossible edict to meet.¹⁰⁰ He then offered an amendment, which was accepted, that changed the term “any impairment” to “material impairment.”

Based on the documentation explaining the intent of this change in wording, the Court determined that “significant risk” involves a finding that, in the absence of changes in practices mandated by a potential standard, that workplaces would be “unsafe” in that workers would be threatened with a significant risk of harm.¹⁰¹ The Court, however, cautioned that a “significant risk” finding is not a “mathematical straitjacket;” OSHA is to be given leeway in developing findings based on scientific knowledge, and that policy considerations may also be at issue.¹⁰² It also gave an example with regard to finding significant risk that OSHA has since adopted as its threshold for assessing the significance of risk:

Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant and take appropriate steps to decrease or eliminate it.¹⁰³

According to OSHA officials consulted by GAO for its report, “this decision essentially established a standard of medical and scientific certainty that has resulted in OSHA staff having to spend an inordinate amount of effort gathering data to support the need for a standard.”¹⁰⁴

Subsequent to the Supreme Court’s holding in the *Benzene* case, the Eleventh Circuit in the *Air Contaminants* case outlined the actions OSHA must take in assessing the significance of risk.¹⁰⁵ In making this essential threshold inquiry, the court held that OSHA must determine: (1) what health impairments are “material,” and (2) what constitutes a “significant risk” of such impairment.”¹⁰⁶ OSHA will therefore bear the burden of “proving by substantial evidence that such a risk exists and that the proposed standard is necessary.”¹⁰⁷ OSHA must provide at least an estimate of the actual risk associated with a particular toxic substance, and explain in an understandable way why the risk is significant.¹⁰⁸ OSHA could satisfy this requirement, as it had

¹⁰⁰ See *IUD, AFL-CIO v. API*, 448 U.S. at 647 (emphasis added).

¹⁰¹ *IUD, AFL-CIO v. API*, 448 U.S. at 642.

¹⁰² *IUD, AFL-CIO v. API*, 448 U.S. at 655.

¹⁰³ *IUD, AFL-CIO v. API*, 448 U.S. at 655.

¹⁰⁴ GAO REPORT, *supra*, at 19.

¹⁰⁵ *AFL-CIO v. OSHA*, 965 F.2d 962.

¹⁰⁶ *AFL-CIO v. OSHA*, 965 F.2d at 973.

¹⁰⁷ *AFL-CIO v. OSHA*, 965 F.2d at 973.

¹⁰⁸ *AFL-CIO v. OSHA*, 965 F.2d at 973.

in the past, by estimating either the number of workers likely to suffer the effects of exposure, or the percentage of risk to any particular worker.¹⁰⁹

At issue in the *Air Contaminants* action was OSHA's decision to not quantify or explain the risk of each individual substance, deciding instead to summarize studies on the substance and health effects of various levels of exposure, and to provide a summary statement that the new PEL would reduce the significant risk of material health effects shown to be caused by that substance. As we explained in our comments, ACC shared OSHA's profound interest in making the PEL system as protective as possible and supported OSHA's necessity-based omnibus approach. The Eleventh Circuit, however, found this approach insufficient and that OSHA had failed to establish for each individual substance that existing exposure levels in the workplace presented a significant risk of material health impairment, or that the new standards eliminated or substantially lessened the risk. The court's opinion made it clear that the significance of risk finding must be made specifically and in detail for each substance that OSHA proposes to regulate.

II. Feasibility

While the OSH Act's rigorous standard for judicial review and unique prerequisite that OSHA evaluate the significance of risk before promulgating a standard surely contribute to the lengthy standard-setting process, the OSH Act's requirement that OSHA assess feasibility confounds OSHA's efforts at expediency because it requires both significant analytical rigor and an industry-by-industry approach.

Section 6(b)(5) of the OSH Act commands OSHA to set a standard that "most adequately assures, to the extent feasible," that workers will be protected from significant risk of material impairment. As many courts have noted, the phrase "to the extent feasible" is by no means a model of legislative clarity.¹¹⁰ Owing to its ambiguity, contested interpretations of this phrase have been litigated extensively and from this body of case law emerged an understanding of OSHA's requirement to demonstrate the feasibility of its health standards.

To understand what is required as part of the feasibility inquiry, the courts again looked to the legislative history of the OSH Act. Courts found as significant the fact that early versions of the bill that ultimately became the OSH Act did not contain the phrase "to the extent feasible." The debate surrounding the inclusion of the phrase, therefore, provides reasonably clear insight into the intent behind adding the phrase.

When Senator Javits offered his amendment to add the feasibility consideration in the Senate Committee on Labor and Public Welfare, he explained:

As a result of this amendment the secretary, in setting standards, is expressly required to consider feasibility of proposed standards. This is an improvement over the Daniels bill, which might be interpreted to require *absolute* health and

¹⁰⁹ *AFL-CIO v. OSHA*, 965 F.2d at 973.

¹¹⁰ *E.g.*, *ATMI v. Donovan*, 452 U.S. at 514; *United Steelworkers of America v. Marshall*, 647 F.2d 1189, 1251 (11th Cir. 1980).

safety in all cases, regardless of feasibility, and the Administration bill, which contains no criteria at all.¹¹¹

The discussion of feasibility continued through the Senate floor debate, where Senator Dominick continued to express concern that the potential language of the bill (with the Javits amendment) would still be viewed as requiring absolute safety. Senator Dominick offered, and the Senate approved, the language on feasibility that is found in the OSH Act today. As Senator Dominick explained:

What we are trying to do in the bill . . . was to say that when we are dealing with toxic agents or physical agents, we ought to take such steps as are feasible and practical to provide an atmosphere within which a person's health or safety would not be affected. Unfortunately, we had language providing that anyone would be assured that no one would have a hazard . . .¹¹²

This draft of the OSH Act, requiring a feasibility analysis, ultimately prevailed over other Congressional draft versions that did not require a feasibility consideration or that did not provide criteria for OSHA standards.¹¹³ Therefore, by prescription of statute, OSHA must take into consideration feasibility concerns when establishing standards. OSHA interpreted “feasible” to mean “technologically achievable at a cost that would not impair the viability of the industries subject to the regulation.”¹¹⁴

Having looked to the legislative history to determine that the use of the phrase “to the extent feasible” was indeed purposeful, the Supreme Court looked to the plain meaning of the word “feasible” to understand what analysis OSHA is required to undertake. The Supreme Court relied on Webster's Dictionary to define “feasibility” as “capable of being done, executed, or affected.”¹¹⁵ OSHA's inquiry into the capability of meeting a standard, the Supreme Court reasoned, must include an analysis of both technological and economic feasibility.¹¹⁶ “[A]ny standard that was not economically or technologically feasible would *a fortiori* not be reasonably necessary or appropriate under the Act.”¹¹⁷

These two feasibility analyses, discussed below, were further developed in a number of court decisions that followed. Importantly, as with the significance of risk, “the burden is on OSHA to show by substantial evidence that the standard is feasible.”¹¹⁸

¹¹¹ S. REP. NO. 91-1282, at 58 (1970), LEG. HIST. 197 (emphasis added).

¹¹² 116 CONG. REC. 37,622 (1970), LEG. HIST. 502.

¹¹³ *IUD, AFL-CIO v. Hodgson*, 499 F.2d at 477 (internal citations omitted).

¹¹⁴ *IUD, AFL-CIO v. API*, 448 U.S. at 639.

¹¹⁵ *ATMI v. Donovan*, 452 U.S. at 508–09.

¹¹⁶ *ATMI v. Donovan*, 452 U.S. at 513 n.31.

¹¹⁷ *ATMI v. Donovan*, 452 U.S. at 513 n.31 (internal quotations omitted).

¹¹⁸ *AFL-CIO v. OSHA*, 965 F.2d at 980 (citing *United Steelworkers*, 647 F.2d at 1264–67).

1. Technological Feasibility

To demonstrate technological feasibility and meet the substantial evidence standard, courts have held that “OSHA must prove a reasonable possibility that a typical firm will be able to develop and install engineering and work practice controls that can meet the PEL in most of its operations”¹¹⁹ While courts have not required OSHA to prove technological feasibility with certainty, they have required its record “to show modern technology has at least conceived some industrial strategies or devices which are likely to be capable of meeting the PEL and which the industries are generally capable of adopting.”¹²⁰

Critically, courts have held that OSHA cannot conduct the technological feasibility analysis on a broad or generalized basis. The court in *United Steelworkers* explicitly held that “feasibility is to be tested industry-by-industry,” and that OSHA must “examine the technological feasibility of each industry individually.”¹²¹

This requirement that technological feasibility be assessed on an industry-by-industry basis was central to the Eleventh Circuit’s review of OSHA’s 1989 effort to update numerous PELs in the Air Contaminants rule. OSHA had discussed technological feasibility by industry sector using classification groupings, and gave a general discussion of how generic engineering controls could be used in a given sector. The court, however, found that OSHA did not establish technological feasibility because there still needs to be “a specific industry-by-industry determination that a ‘typical firm will be able to develop and install engineering and work practice controls that can meet the PEL in most of its operations.’”¹²² While ACC supported OSHA’s challenged approach, this decision made clear that, even though OSHA may seek to establish technological feasibility findings for a group of industries, it must still conduct sufficient industry-by-industry determinations to be able to explain why a set of findings can adequately represent the industries in the group.

The impact of this holding (and others like it) was made clear by GAO in its review of OSHA’s challenges in expeditiously developing health and safety standards.¹²³ That report noted that:

For the technological feasibility analysis, the staff identifies the controls required by the standard and determines if each of them is technologically feasible for employers to implement. Agency officials told us this is an enormous undertaking because, for example, sometimes there are no sources of the applications of various chemicals or technologies. According to OSHA officials, this also requires visits to multiple worksites¹²⁴

¹¹⁹ *Public Citizen Health Research Group v. Department of Labor*, 557 F.3d 165 (3rd Cir. 2009) (quoting *United Steelworkers*, 647 F.2d at 1272).

¹²⁰ *United Steelworkers*, 647 F.2d at 1266.

¹²¹ *United Steelworkers*, 647 F.2d at 1301.

¹²² *AFL-CIO v. OSHA*, 965 F.2d at 981.

¹²³ See GAO REPORT, *supra*, at 14.

¹²⁴ GAO REPORT, *supra*, at 14.

While GAO recommended that OSHA could improve its strategies for assessing feasibility, it recognized that the most effective options for streamlining the process would require Congressional action.

2. Economic Feasibility

The court in the *Industrial Union Department, AFL-CIO v. Hodgson* case provides an insightful context for the economic feasibility analysis. The court explained that Congress chose to include the feasibility assessment in their final version of the OSH Act because Congress did not intend to put employers out of business by requiring unavailable protective devices or by making financial viability generally impossible.¹²⁵ The court did note, however, that “[s]tandards may be economically feasible even though, from the standpoint of employers, they are financially burdensome and affect profit margins adversely.”¹²⁶

These broad guiderails between allowing OSHA to promulgate economically burdensome standards and the prohibition against imperiling the existence of the industry have been refined in a number of subsequent court decisions. The court in *United Steelworkers* assessed existing case law to summarize that “the practical question is whether the standard threatens the competitive stability of an industry . . . or whether any intra-industry or inter-industry discrimination in the standard might wreck such stability or lead to undue concentration.”¹²⁷ The D.C. Circuit similarly held that, while OSHA can promulgate standards that “portend disaster for some marginal firms,” it cannot promulgate standards under which compliance is “likely to disable the industry from competing with substitute products, or markedly to increase concentration within the industry.”¹²⁸ Similarly, the compliance costs in relation to the revenues of the industry cannot be so high as to “force a material segment of the industry out of business.”¹²⁹

Proving economic feasibility requires OSHA to conduct “a reasonable assessment of the likely range of costs of its standard, and the likely effects of those costs on the industry.”¹³⁰ OSHA is allowed to use consultants and other external information in developing these costs, and can produce its own estimate of costs and their effect on the industry.¹³¹ The Agency need not establish economic feasibility in a particular way, but it should be thorough in explaining the best available evidence on which it relies.¹³² Further, while OSHA is not required to prove economic

¹²⁵ *IUD, AFL-CIO v. Hodgson*, 499 F.2d at 477–478.

¹²⁶ *IUD, AFL-CIO v. Hodgson*, 499 F.2d at 478.

¹²⁷ *United Steelworkers*, 647 F.2d at 1265.

¹²⁸ *National Cottonseed Products Ass’n v. Brock*, 825 F.2d 482, 487 (D.C. Cir. 1987).

¹²⁹ *National Cottonseed Products Ass’n*, 825 F.2d at 487.

¹³⁰ *United Steelworkers*, 647 F.2d at 1266.

¹³¹ *United Steelworkers*, 647 F.2d at 1266.

¹³² *United Steelworkers*, 647 F.2d at 1267.

feasibility with certainty,¹³³ as with technological feasibility, OSHA's estimations of costs in a given industry are factual determinations which must be supported by substantial evidence.¹³⁴

Similar to OSHA's technological feasibility analysis, court holdings clearly demonstrate that economic feasibility determinations must be made on an industry-specific basis. For instance, the Eleventh Circuit in *AFL-CIO v. OSHA* found that OSHA was not allowed to assess economic feasibility for industry sectors without explaining why such broad groupings were appropriate.¹³⁵ Economic feasibility must be evaluated on an industry-by-industry basis unless OSHA can prove that grouping is appropriate and will not result in concealing particularities of individual industries.¹³⁶

As with technological feasibility, GAO identified the practical impact on OSHA's standard setting of the requirement to assess economic feasibility on an industry-by-industry basis.¹³⁷

When OSHA performs an economic feasibility analysis, it concludes that a standard is economically feasible if the affected industry or industries will maintain long-term profitability and competitiveness. . . . To do this, staff and contractors, by analyzing information they collect when visiting worksites, must assess the extent to which employers in the affected industries can afford to implement the required controls. In addition to the site visits, OSHA staff sometimes conducts industry-wide surveys to determine baseline practices and collect other relevant information needed for the technological and economic feasibility analyses. According to OSHA officials, the process of developing a survey and having it approved by OMB takes a minimum of 1 year.¹³⁸

The OSH Act's mandated economic feasibility analysis—cumbersome and slow as it may be—is now just one stage of a multi-stage economic feasibility analysis that pulls in even more analytical requirements from executive actions and statutes Congress developed subsequent to the OSH Act.

II. Other Congressional Action and Statutes Create Delays in PEL Promulgation

As referenced above, subsequent Congressional and executive action and statutes introduced following development of the OSH Act create delays in PEL promulgation. GAO describes the sequence of these inquiries as follows:

In addition to the feasibility analyses, OSHA staff generally must also conduct economic analyses. First, OSHA must assess the costs and benefits of significant

¹³³ *United Steelworker*, 647 F.2d at 1266.

¹³⁴ *See Texas Independent Ginners Ass'n v. Marshall*, 630 F.2d 398, 411 (5th Cir. 1980).

¹³⁵ *AFL-CIO v. OSHA*, 965 F.2d at 982.

¹³⁶ *AFL-CIO v. OSHA*, 965 F.2d at 982.

¹³⁷ *See* GAO REPORT, *supra*, at 14.

¹³⁸ GAO REPORT, *supra*, at 15.

standards as required by Executive Order 12866. Second, under the Small Business Regulatory Enforcement Fairness Act of 1996, if OSHA determines that a potential standard would have a significant economic impact on a substantial number of small entities, such as a business, it is one of three federal agencies that must initiate a panel process that seeks and considers input from representatives of the affected small businesses. The small business panel takes several months of work that many other federal agencies do not have to complete in order to issue regulations. Agency officials told us they want to consult with small businesses, but that the provisions laid out in the requirement make it too formal a process and are duplicative of the public hearings they hold after publishing the proposed rule. Finally, according to OMB guidelines, if a potential standard is projected to have an economic impact of more than \$500 million, OSHA must initiate a peer review of the underlying scientific analyses.¹³⁹

While the OSH Act already requires a deep and particularized analysis of economic feasibility, Congress and the Executive Branch have imposed a number of additional requirements on the OSHA standard setting process, including:

The Paperwork Reduction Act of 1980 requires agencies to publish for public comment and submit to the Office of Information and Regulatory Affairs any proposed collection of information associated with a proposed rule. Agencies must certify that the collection of information is necessary for the proper performance of agency functions, is not unnecessarily duplicative, and reduces burden on respondents to the extent practicable and appropriate. Information collections must inform respondents why the information is being collected and how the information will be used. The Office of Information and Regulatory Affairs must approve the information collection.¹⁴⁰

The Regulatory Flexibility Act of 1980 requires agencies to conduct a regulatory flexibility analysis that describes the reasons for and objectives of the rule, a description and estimate of the impact of the proposed rule on small businesses and entities, and a description of potential alternatives that would minimize that impact. Agencies then must publish the analysis for public comment alongside the proposed rule. Alternately, agencies can certify that the proposed rule would not have “a significant economic impact upon a substantial number of small entities.” When a final rule is issued, the agency must publish a final regulatory flexibility analysis or certification; they must address the comments received and why alternatives were rejected.¹⁴¹ Executive Order 12866, issued in 1993 and updated by Executive Order 13563 in 2011, requires agencies to submit “significant” regulatory actions to the Office of Information and Regulatory Affairs before publishing them in the Federal Register. This submission must include the text of the regulatory action as well as the agency’s assessment of its potential costs and benefits. If the significant factor is economic impact, the agency must submit a cost-benefit analysis of the proposed rule and potential alternatives.¹⁴²

¹³⁹ GAO REPORT, *supra*, at 15 (internal citations omitted).

¹⁴⁰ GAO REPORT, *supra*, Appendix II at 44.

¹⁴¹ GAO REPORT, *supra*, Appendix II at 44.

¹⁴² GAO REPORT, *supra*, Appendix II at 44.

The Small Business Regulatory Enforcement Fairness Act of 1996 requires OSHA, EPA, and the Bureau of Consumer Financial Protection to work with the Small Business Administration if a proposed rule is expected to have a significant impact on a substantial number of small businesses and entities. OSHA and the Small Business Administration must form panels with representatives of affected small businesses, take recommendations from them, and publish them alongside the proposed rule.¹⁴³

The Congressional Review Act of 1996 requires agencies to submit rules to Congress and GAO before they can take effect. GAO must report to Congress on agencies' compliance with procedural requirements in proposing the rule. Congress can enact a joint resolution of disapproval within a certain time period after a rule is submitted which prevents the rule from taking effect in its present form. Congress has previously used this joint resolution power to stonewall OSHA standard-setting regulations.¹⁴⁴

The Information Quality Act of 2000 tasked the Office of Management and Budget with issuing guidelines that require agencies to conduct a peer review of certain scientific information.¹⁴⁵ During the PEL development process, OSHA must seek peer review of its risk assessment findings.

¹⁴³ GAO REPORT, *supra*, Appendix II at 44.

¹⁴⁴ GAO REPORT, *supra*, Appendix II at 45.

¹⁴⁵ GAO REPORT, *supra*, Appendix II at 45.