Battery Council International

IN WASHINGTON
c/o Wiley Rein LLP
1776 K Street NW
Washington, D.C. 20006
Tel. 202.719.7000
Fax 202.719.7207

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Ms. Lyn Penniman
Office of Physical Hazards
OSHA
Room N–3718
200 Constitution Avenue N.W.
Washington, DC 20210
penniman.lyn@dol.gov

Re: Docket No. OSHA 2012–0023: Chemical Management and Permissible Exposure Limits (PELs); Request for Information

Dear Ms. Penniman:

The Battery Council International (BCI) is pleased to submit these comments responding to the Occupational Safety and Health Administration's Request for Information on Chemical Management and Permissible Exposure Limits (RFI). 79 Fed. Reg. 61,384 (Oct. 10, 2014).

I. INTRODUCTION

BCI is a non-profit trade association whose members are engaged in the manufacture, distribution, recycling, and retail sale of lead-acid batteries. BCI members account for over 98% of U.S. lead-acid battery production and over 97% of its recycling (*i.e.*, secondary lead smelting) capacity. All lead-acid battery manufacturers and secondary lead smelters are subject to the general industry lead standard and PEL at 29 C.F.R. § 1910.1025.

As an initial matter, BCI is gravely concerned with what OSHA has described as its effort to "short cut" the existing procedures Congress, the courts, and the agency have developed to establish workplace standards. 79 Fed. Reg. at 61,402. The existing rulemaking framework provides a predictable and well-understood process whereby OSHA can transparently develop clear rules that benefit both workers and industry. To "short cut" that framework would ignore OSHA's statutory mandate to balance the desire for stricter standards against the impact on industry, undermine the validity of any future OSHA standard, and likely expose OSHA to legal challenges.

U.S. lead-acid battery manufacturers and secondary lead smelters have established exemplary worker protection programs that far exceed federal requirements. For example, BCI's members voluntarily protect their workers by using a 40 µg/dL medical removal protection level (MRP), while the federal MRP is 60 µg/dL for one test or 50 µg/dL for multiple tests averaged over a prescribed period. The industry has further committed to keeping the blood lead levels of all workers below 30 µg/dL by the end of 2016. BCI was also instrumental in the development of OSHA's e-Tools for battery manufacturing and secondary lead smelting, which are used to train plant workers on effective work practices to avoid harmful lead exposures. With these programs, and without a reduction in OSHA's lead PEL, industry has succeeded in substantially lowering worker blood lead levels.

Over the past several years, BCI has been an active stakeholder in Cal/OSHA's ongoing consideration of potential revisions to California's general industry lead standard, including proposals to change the state's permissible exposure limit (PEL). As a result, our organization has been very involved in analyzing the various methods state and federal agencies have used to establish PELs, the statutes and case law governing those methods, and alternative methods that might properly be used.

With this background, BCI's comments address two key areas:

1) Concerns with OSHA's proposal for increased reliance on modeling of exposures and dose-response outcomes for setting PELs rather than empirical monitoring measurements, including modeling of risks below the currently observed levels; and

2) The need for OSHA to embrace flexible regulatory approaches, such as voluntary industry standards and SECALs, in establishing PELs across work-areas and across industries. The old "one-size-fits-all" approach to PELs and the hierarchy of controls is untenable as industry strives for lower worker exposures.

II. COMMENTS

A. Worker Exposure Models Must be Used with Care, and are Prone to Error

Several of OSHA's questions relate to the increased use of modeling, rather than empirical data, to predict worker exposures and the impact of those exposures on workers' health.[1] While BCI recognizes the utility of modeling, particularly where empirical data is unavailable, OSHA should exercise caution in relying on models designed to meet general population public health evaluation goals, but which have not been designed for or intended for modeling the occupational exposures of adults.

For example, BCI has for the last several years been intimately involved with the California Division of Occupational Safety and Health's (Cal/OSHA) analysis of proposals from

[1] *See, e.g.,* Question IV.A.1 (79 Fed. Reg. at 61,390); Question IV.B.2 (79 Fed. Reg. at 61,399).

the California Department of Public Health (CDPH) for the revision of that state's worker protection standards for lead. CDPH's PEL recommendations, in turn, were based on physiologically based pharmacokinetic (PBPK) modeling conducted by the California Environmental Protection Agency's (Cal/EPA) Office of Environmental Health Hazard Assessment (OEHHA). OEHHA's "Leggett Plus" model was derived from the existing Leggett model for lead exposures; which itself was developed using general population-based epidemiological data, not worker-exposure data.

BCI's experience with OEHHA's modeling efforts has clarified two salient points: (1) agencies with a solely health-based mandate—perhaps understandably—do not consider the feasibility limitations of workplace controls; and (2) dose-response modeling for workers is a delicate process and prone to error.

1. OSHA May Not Rely Solely on Modeling and Recommendations From Public-Health Agencies Due to Differences in Statutory Mandates and Methodologies

In developing the PBPK model, OEHHA and CDPH relied entirely on a body of health-based literature, and did not include any considerations of workplace feasibility. To their credit, both agencies disclosed this failure, but CDPH still urged Cal/OSHA to adopt its recommendations without further evaluation of feasibility. Because Cal/OSHA has a similar statutory mandate as OSHA, this would have been a significant failing on its part. Consequently, the agency is considering feasibility in its deliberations.

Similarly, in any PEL setting rulemaking OSHA must be cognizant of the differences in statutory mandates OSHA and public health agencies and/or bodies. Relying solely on the recommendations of public health agencies without additional analysis of the considerations mandated to OSHA—most importantly, feasibility—would be a violation of OSHA's statutory mandate.

Furthermore, in choosing the target blood lead levels to which OEHHA was to model exposures, CDPH apparently principally relied on a single published article and undertook little, if any, independent analysis. While that article's authors are respected, it is inappropriate for worker-protection agencies such as OSHA to rely so heavily on a limited number of sources. If faced with a similar task, OSHA should review all of the modern science to identify all of the data relevant to its mandate to rely on the "best-available evidence" to support any chosen health outcome target to which a modeling effort would be targeted.[2]

2. Exposure and Uptake Modeling is Prone to Errors

Exposure and uptake modeling is prone to errors based on the inherent intricacies of modeling adult workplace exposure scenarios. The OEHHA modeling effort has a number of

[2] 29 U.S.C. 655(b)(5).

shortcomings that are likely representative of the challenges facing any similar modeling effort for other substances.

For example, OEHHA relied on outdated and foreign particle size monitoring studies and limited the modeled particle sizes to those with a mass median aerodynamic diameter (MMAD) under 15 μm. But, as more recent industry data has revealed, the particles in domestic lead-acid battery manufacturing facilities have an average MMAD that ranges from approximately 21 to 32 μm, and secondary lead smelters' average MMAD ranges from 15 to 25 μm.

The use of inaccurate MMADs was a significant deficiency. First, the under-sized particle size data caused the model to mischaracterize the behavior of particles in air, over-estimating the actual exposure levels. Second, at any given air lead level, larger lead particle sizes present less risk of blood lead uptake. Larger particles are not absorbed as readily by the body, are not deposited as deeply in the respiratory tract, and are cleared from the respiratory tract more rapidly than the smaller particles assumed by OEHHA. This one erroneous MMAD assumption caused the modeling to over-predict the amount of lead available for inhalation and to over-predict the body's uptake from the particulate inhaled. Because it used inaccurate particle size data as a primary input, the OEHHA model could not accurately reflect real-world worker exposures.

OEHHA also made other errors. For example, OEHHA failed to apply the appropriate Multiple-Path Particle Dosimetry (MPPD) inhalability adjustment factor to accommodate particle sizes larger than 8 μm. This appears to have been a simple oversight, because elsewhere in its modeling OEHHA used particle sizes up to 15 μm, but underscores the need for rigorous public review of such modeling. OEHHA also relied on inadequate, older, inhaled particle clearance models, despite recognizing that an improved International Commission on Radiological Protection (ICRP) model is now available.

BCI's analysis of OEHHA's work showed that correcting all of these errors will have a statistically significant impact on the model's predicted relationship between air-lead levels and blood lead levels.

BCI expects that similar attempts to model the impacts of other chemicals on workers will face similar hurdles. OSHA must be careful to rely on the best available science, including data available from industry, and ensure that its modeling efforts are robust and well-reviewed by industry and the public.

B. OSHA Must Embrace Regulatory Flexibility to Best Protect All Workers in All Industries

Another issue facing OSHA is that we now know, as OSHA did not in the mid-1970s, that particulate-in-air levels are not the best predictor of actual worker health outcomes in modern industrial settings. For example, the data collected by BCI's members implementing voluntary worker protection programs demonstrate that in today's well-operated factories, with

proper PPE and worker hygiene practices, there is little correlation between measured air-lead levels and worker blood lead levels. As a result, new approaches are necessary.[3] Instead of continuing to rely on PELs as the primary protection factor for workers, OSHA should focus on measurable health outcomes and provide industry the flexibility to determine the most efficient methods of achieving those health outcomes.

The current PEL standards, most based on frameworks developed in the 1970s, incorporate a "hierarchy of controls" that places primary reliance on large-scale engineering controls to reduce air-lead levels. The PEL is the principle measure of the adequacy of those engineering controls. But this hierarchy approach no longer makes sense and must be reconsidered. Troublingly, it subordinates all other methods of preventing worker exposure, even if more effective in a particular situation. Indeed, most PEL regulations instruct employers to make significant efforts to achieve the PELs through engineering controls—and fail—before requiring them to even consider other protections that may be more effective.

Especially in light of advances in hygiene practices, education, and personal protection technology, revising PEL standards by simply ratcheting down the air levels to extremely low numbers fails workers by discouraging the use of other methods, despite their known effectiveness. And by not relying on the most efficient methods, the PEL-only approach unnecessarily increases manufacturers' capital cost obligations and jeopardizes workers' jobs. A considerable amount of scientific research and improvements in worker safety systems, policies, and practices have accumulated since the 1970s. These systems, policies, and practices, when used in combination with controlled air lead levels, provide a much more logical focus for regulatory revision than does the primary reliance on a PEL.

1. Changes in the Industry and Worker Protection Equipment and Practices Obviate the Existing Regulatory Regime

When it evaluated the lead-acid battery industry during the development of the lead standard in the 1970s, the OSHA's economic impact analysis estimated that there were approximately 200 battery manufacturing facilities nationwide, many of which were not meeting the then-effective PEL of 100 $\mu g/m^3$. Furthermore, OSHA determined that the respiratory personal protective equipment (PPE) available in that era was ineffective at protecting workers due, in part, to discomfort and the resulting likely non-compliance. In that situation, federal and state regulators chose to use easily-measured air-lead limits as the primary, most easily enforceable, method of addressing worker exposure. However, different considerations apply today.

First, industry itself has changed. Nationwide, there are now only approximately fifty lead battery manufacturing facilities. They are well-maintained and technologically-advanced and outperform the requirements of the current federal and state regimes for worker blood lead levels. All have well-established, rigorous worker exposure prevention programs and a

[3] Question IV.C.7 (79 Fed. Reg. at 61,4105).

demonstrated record of success. Today, the average blood lead level of battery industry employees in lead-exposed positions is below 15 µg/dL, and BCI members have voluntarily committed to keeping the blood lead levels of all workers below 30 µg/dL by the end of 2016.

Second, modern respiratory PPE is vastly superior to the PPE evaluated when the federal standard was adopted in the 1970s. Modern respirators provide workers an individualized fit and are far more efficient than those available in the 1970s. When properly worn and cared for, PPE can protect workers above the lead-in-air levels present in any currently operating facility. Furthermore, workers today better understand the need to protect their own health, and BCI members' experience is that worker compliance with respiratory protection and hygiene practices is excellent.

Indeed, many employers in the lead-acid battery and secondary smelting industries today have made compliance with respiratory protection instructions a job requirement. BCI members make respirators readily available even to those employees whose air exposures would not otherwise require respirators but who wish to take extra precautions (and many choose to do so). And, because employees are better educated on the risks of exposure, they are ready and willing to wear respirators as instructed.

Third, employers' worker protection policies and programs have dramatically improved since the 1970s. BCI members have worked for many years to develop better worker hygiene practices and equipment well beyond those required by existing regulations. And BCI members have worked with OSHA to develop comprehensive "etool" occupational safety and health training programs for battery manufacturers[4] and lead smelters.[5]

Today, BCI members have full-time professional worker health staffs, require workers exposed over the current PEL to shower after their shifts and encourage others to do so as well, provide their workers with specialized soaps and shampoos that are specially designed to aid the removal of lead, provide company laundry services for work clothes, and provide considerable additional employee support. Workers also are trained and educated on the problems posed by smoking, hand-to-mouth contamination, take-home lead, and other hygiene issues. For any individual worker as to whom blood lead testing reveals potential hygiene issues, those employees receive one-on-one instruction and counseling to ensure they are using the best techniques.

These efforts have been profoundly successful. By the end of 2014, less than two-tenths of one percent (0.2%) of battery manufacturing and secondary smelter employees nationwide had blood lead levels above 35 µg/dL. None were over 40 µg/dL. And, as noted above, the national average blood lead level of the industry's employees is below 15 µg/dL. OSHA should recognize industry's successes in improving the measurable health outcomes through means other than engineering controls, and embrace an increased use of approaches such as

[4] Available at www.osha.gov/SLTC/etools/battery_manufacturing/index.html.
[5] Available at www.osha.gov/SLTC/etools/leadsmelter/index.html.

individualized work practices, respiratory protection, and good hygiene *in conjunction with* controlling particulate levels with engineering controls to best protect worker health. The absolute primacy of engineering controls in the hierarchy of controls simply is no longer the most effective means of protecting workers.

2. OSHA Should Evaluate New Regimes to Match the New Reality

If OSHA chooses to reevaluate existing standards, or to develop new standards, it will have an opportunity to adopt a new regime that is better crafted to protect worker health in the modern industrial environment. The dramatic, voluntary improvements adopted by many industries mean that OSHA will be addressing much reduced exposure levels—often well below the current regulatory mandates—and evaluation of much more subtle health effects. Relying solely on stringently-controlled levels of particulates-in-air is not now the best mechanism for controlling worker exposures (if it ever was).

Instead of simply reusing the forty-year-old "one-size-fits-all" approach of ever tightening (and extraordinarily expensive) facility-wide engineering controls, OSHA should embrace the most effective available protective measures—namely controlling particulate in air levels to a reasonable level in conjunction with individualized work practices, respiratory protection, and good hygiene. OSHA has recognized this reality in the RFI and in a limited number of prior rulemakings.

One potential regulatory approach that merits OSHA's continued attention was embraced by OSHA as part of the cadmium standard. It is the creation of "separate engineering control air limits" (SECALs) for certain processes or work areas (29 C.F.R. 1910.1027(f)(1)(ii)). This approach has also been adopted, in varying forms, in other PEL regulations. The cadmium standard establishes a single PEL, but it also includes a number of SECALs for specific industry sectors. In SECAL areas a higher particulate level is acceptable, so long as certain additional worker protection measures are implemented.

OSHA explained the SECAL framework this way when the standard was promulgated: "Employers in a particular industry covered by the SECAL will be obligated to achieve the SECAL by engineering and work practice controls to the extent feasible and to protect employees from exposures above the PEL by any mix of compliance methods, including . . . work practice controls and respirators."[6] That is, OSHA recognized the economic and technical infeasibility of facility-wide reliance upon engineering controls to meet the PEL, and provided for alternate frameworks.

The industry sectors granted SECALs were approved by OSHA based on "evidence on current exposures and [because] the effectiveness of additional controls indicated that the PEL of 5 µg/m3 is not feasible with engineering controls . . . ."[7] The SECALs were set at the levels OSHA determined were "the lowest feasible level that could be achieved by engineering and

[6] Preamble to Final Cadmium Standard, 57 Fed. Reg. 42,102, 42,336 (Sept. 14, 1992).
[7] *Id*. at 42,212.

work practice controls" in those areas.[8] OSHA determined that a "two-tier [SECAL] structure . . . is simultaneously more protective of workers' health and feasible."[9]

OSHA should continue to embrace the SECAL approach when it evaluates changes to existing PELs or new PELs. A SECAL framework works well in industries, like the lead-acid battery manufacturing industry, where different sub-sectors, facilities, and work areas face very different exposure scenarios and economic concerns than other general industry entities. OSHA should recognize the different situations of these industries, and also recognize the exemplary worker protection regimes the battery manufacturing, secondary lead smelting industries, and certain other industries have adopted.

Many industries have a long and proven record of using a combination of comprehensive worker health protection practices in these areas (engineering control and work practices plus PPE, hygiene, and education) to achieve worker blood lead levels far below those currently required by OSHA. That track record of success provides a substantial basis to give OSHA confidence that workers in those industries would continue to be more than adequately protected by a SECAL approach by requiring that those successful additional techniques be implemented.

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If you have questions about this submittal, please contact David Weinberg, BCI's legal counsel, at 202-719-7102 or dweinberg@wileyrein.com.

Respectfully submitted,

Randy Reyer
BCI Industrial Health Committee Chairman

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[8] *Id*. at 42,336.
[9] *Id*. at 42,343.