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Via http://www.regulations.gov/

March 20, 2017

Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Ave, N.W.
Washington, DC 20460–0001

Re: Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act; Proposed Rule (Jan. 19, 2017); EPA–HQ–OPPT–2016–0654

Dear Sir or Madam:

The Battery Council International provides these comments on the proposed rule "Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act," published January 19, 2017 at 82 Fed. Reg. 7562 (EPA–HQ–OPPT–2016–0654).

I. BCI Background

BCI is a non-profit trade association whose members are engaged in the manufacture, distribution, sale, and recycling of lead batteries. BCI members account for over 98% of U.S. lead battery production and 100% of its recycling capacity. Our industry promotes lead battery recycling by collecting and recycling used automotive and other lead batteries, encouraging the enactment of mandatory lead battery recycling laws, and supporting ongoing consumer and industry education efforts.

Today, about 99% of the lead used in batteries (which averages 60% of total unit weight) is recycled and put to work in new batteries. This is a direct result of private sector efforts, without governmental intervention with the complex systems that have been imposed to encourage recycling of so many other consumer products. All other parts of batteries also are recycled: cases (average 10% of total unit weight) and acid (average 30% of total unit weight). This system also avoids collection of large volumes of used batteries outside of regulated secondary smelter sites (which operate under strict permits) and avoids the landfill disposal of lead-acid batteries. This avoids the creation of new "Superfund" sites or even areas of more limited contamination.

About 90% of the lead consumed in the United States currently is used to make lead-acid batteries. Yet the battery manufacturing sector accounts for only 0.81% of nationwide air lead emissions. The recycling *(i.e.,* secondary smelting) sector accounts for only another 0.77%. In contrast, piston aircraft using leaded aviation gas contributed 48.35% of total air lead emissions.

Industry sectors with greater lead emissions than battery manufacturing and recycling include electricity generation, steel mills, ammunition manufacturing, and copper smelting.

The 19,000 lead-exposed workers in the manufacturing and recycling industry have low blood lead levels. Levels of lead-in-blood are the standard measurement of exposure to lead. Four decades ago many industrial workers exposed to lead had blood lead levels well over 60 µg/dL.[1] Today the average blood lead level of workers in the lead battery manufacturing and recycling industries is below 12 µg/dL, which is less than what was the national average for the entire population in the 1970s. And it is 75% below what OSHA requires.

This reflects aggressive industry self-policing. OSHA and state regulations require removing a worker from lead-exposed work if his or her blood lead exceeds 50 µg/dL. For the last two decades, BCI members and others in the lead battery and smelting industries worldwide have committed to having 100% of their workers meet blood lead targets well below that level. Starting in 1998, the industry target was 40 µg/dL, and in 2013 the BCI members committed to bringing all workers below 30 µg/dL by the end of 2016.

Lead batteries also provide an immediate mechanism for reducing greenhouse gas emissions from automobiles. Internal combustion engines (ICEs) will be the predominant power source for vehicles and other equipment for the foreseeable future. The adoption of "stop start" systems that allow engines to stop running when the vehicle is stopped and restart instantly has been shown to reduce greenhouse gas emissions from ICEs by 3-5%. In 2020, most new vehicles sold in the U.S. are expected to employ stop-start systems. Almost all of these vehicles will employ recently-developed lead battery systems to make the stop-start system work, because recent technological advances make lead batteries appropriate for this role and because the batteries are reliable, safe, and affordable.

II. BCI's Overarching Policy Recommendations

This Section II of our comments focuses on cross-cutting issues which impact a number of areas upon which EPA requested comment or which BCI identified as important to risk evaluation. Each of these comments is applicable to a number of individual sections of the proposed rule, several of which we address subsequently in Section III.

A. EPA should focus risk evaluation efforts on current and reasonably foreseeable uses of a chemical, not historical conditions of use.

The Lautenberg Act's relatively short deadlines for action signal that Congress intended EPA to focus its evaluation activities as tightly as possible to conserve resources and to act expediently. 15 U.S.C. §§ 2605(b)(2) and (b)(4). Those deadlines can only be met by focusing on current and reasonably foreseeable conditions of use of a chemical, and not historical conditions of use which have been discontinued or phased-out.

[1] 43 Fed. Reg. 52,972 (Nov. 14, 1978).

Excluding historical uses from evaluations is supported by the language of the statute which defines "conditions of use" as those uses "under which a chemical substance is intended, known, or reasonably foreseen *to be* manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4) (emphasis added). This definition demonstrates Congress' clear intent to regulate only present and future uses by referencing how a substance is "to be" used, not how it "has been" used. It would waste precious agency resources to include those uses that are no longer being significantly pursued in the Agency's assessments.

EPA has demonstrated its recognition of Congress's direction in its public statements regarding its plans for the assessment of the initial ten chemicals undergoing evaluation. For example, in a mid-February 2017 public meeting, EPA leadership clearly and correctly noted that the Agency does not intend to address historic uses of asbestos.[2] For all of the initial ten substances, EPA has also requested public comment on phased-out uses, presumably to rule out review during the risk evaluation phase of many or all of those uses as well.

That approach will properly implement Congress's directive and intention to avoid expending the Agency's scarce resources on evaluation of historical uses. It would be a regrettable waste of Agency resources to focus efforts on such historical uses when those resources could be directed toward ongoing conditions of use, just as it would for the Agency to ignore the impact of existing regulatory programs (as noted in Section II.B., *infra*).

B. EPA should focus only on conditions of use of a chemical that are not already effectively regulated by EPA or other agencies.

In conducting risk evaluations, EPA must take into account the fact that, for numerous chemicals, most if not all ongoing and foreseeable conditions of use already are subject to extensive, effective regulation that protects workers, consumers, and the environment. The statute envisions this and mandates coordination between federal agencies to avoid regulation duplication or conflicts. 15 U.S.C. § 2608(a). Further discussion of interagency coordination is included in Section III.C., *infra.*

Further, the statute directs EPA to rely on EPA's existing authorities before resorting to regulating a risk posed by a chemical under TSCA:

> "If the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws [administered by EPA], the Administrator shall use such authorities to protect against such risk unless the Administrator determines . . . that it is in the public interest to protect against such risk by actions taken under this chapter." 15 U.S.C. § 2608(b)(1).

[2] EPA's Office of Pollution Prevention and Toxics Public Meeting on Chemical Use Information, February 14, 2017, presentation by Brian Symmes, Acting Director, National Program Chemicals Division.

Congress's directive makes eminent sense. Chemicals that already are strictly regulated pose far fewer potential risks—if any at all—than chemicals that are unregulated. The regulations EPA should, at a minimum, consider in this context include those issued under laws administered, for example, by EPA, OSHA, CPSC, DOT, DOE, as well as state programs such as California's Proposition 65. Only if EPA understands the scope and range of existing regulations that apply to a chemical can the agency accurately assess the chemical's actual risk on a condition of use basis. EPA cannot simply default to an assumption that every chemical poses an unregulated risk and meet its statutory obligations because such an assumption would dramatically overestimate the real-world risks.

Furthermore, as both an internal management tool and to assist public commenters, EPA should include in its public risk evaluation documents a summary of the existing laws and regulations issued by EPA, other federal agencies, and key state-based programs that apply to current and reasonably foreseeable uses of the substance(s) at issue. BCI recommends that this index be developed during prioritization for use during both that process and risk evaluation. It is important that EPA create and allow public review of such a list to ensure that its evaluation of existing regulations, as described above, accurately captures all existing regulatory frameworks.

In short, EPA should update all phases of the process outlined in the risk assessment rule to require evaluation of the existing regulatory landscape of each of the chemicals that it is evaluating, and include a summary of the regulations EPA is reviewing in the documents made available for public feedback.

C. EPA should exclude from risk evaluation conditions of use of chemicals in articles where there is little or no exposure.

The amended TSCA statute grants EPA risk mitigation authority over articles "only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article . . . so that the substance . . . does not present an unreasonable risk." 15 U.S.C. § 2605(c)(2)(E). In the face of this restriction, EPA must exclude from its risk evaluations conditions of use of chemicals in articles that result in no or only limited exposures. Including such uses in the risk evaluation review phases makes no sense and would run counter to Congress's intent.[3]

For example, chemicals incorporated into articles such as a battery do not present any significant exposure risk to consumers. The primary exposure to such chemicals comes during the chemical's manufacture and processing *(i.e.*, incorporation into the battery) or recycling, not during use. Those phases that pose a hazard should be where EPA focuses its prioritization efforts. (And, in the case of batteries and likely many other articles, applying the principle

[3] Congress said that EPA, in deciding how to mitigate risks, should consider "whether restricting an article will actually reduce exposure." 161 Cong. Rec. H4551, H4556 (daily ed. Jun. 23, 2015) (statement of Rep. Shimkus). It is a waste of EPA resources to consider conditions of use in articles during prioritization if exposure is so low that mitigation would not be necessary or feasible after completion of the risk evaluation.

discussed above that EPA must take into consideration existing regulatory mechanisms likely will demonstrate that virtually no further TSCA attention need be directed to chemicals in those articles.)

D. EPA should amend the rule to consider the risks and characteristics of substitutes, but only those substitutes that will be available during the risk evaluation/risk mitigation phase for the chemical under review.

EPA is required to "conduct risk evaluations . . . to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." 15 U.S.C. § 2605(b)(4)(A). It does not, however, prohibit EPA from considering "risk" factors during evaluation, including risks of substitutes. Nor does it preclude a broad reading of factors pertinent to injury to the environment, including the absence of mechanisms for recycling and other elements of sustainability.

To inform its risk assessment, EPA should also amend the rule to consider the risks of both the chemical under review and its potential substitutes. As a relevant Committee report states, "[i]n applying the unreasonable risk standard, EPA must consider . . . the availability of substitutes for such uses."[4]

Reviewing the risks of substitutes, including the substitute's hazards and life cycle, will allow EPA to compare chemicals and their possible substitutes to establish relative risk. Making a finding of "unreasonable" risk inherently requires, among other things, reference to the relative risks and characteristics of substitutes in order to determine whether whatever degree of risk may be presented is more or less than that of substitutes. Moreover, to comply with the statutory scheme and be practical and conserve resources, EPA should only consider those substitutes that will be available during the risk mitigation phase for the chemical under review and the mechanisms that will be available at that time to address all risk-presenting aspects of their lifecycles.

E. Before imposing new testing requirements in connection with a risk evaluation, EPA must work with industry, where possible, to evaluate REACH dossiers for existing studies that could be used instead.

For purposes of conducting prioritization or a risk evaluation, EPA cannot require the generation of new data by rule, order or consent agreement unless there is "insufficient information and experience," and testing is necessary to determine the effects of the substance on health or the environment. 15 U.S.C. § 2603(a)(1)(A). As the Senate Environment and Public Works Committee recognized, EPA should "systematically search for and identify relevant information

[4] S. Rep. No. 114-67, at 3-4 (Jun. 18, 2015).

that is available to inform safety assessments and determinations, both to minimize the potential for duplicative testing and unnecessary animal testing."[5]

One key resource that will likely be sufficient for many of EPA's needs is the extensive body of data that has already been produced for many chemicals under the REACH program in Europe at great cost to industry. Much of that data will be directly applicable to EPA's evaluation, and its availability will obviate the need to require industry to develop new data. Therefore, before imposing new testing requirements in connection with a risk evaluation, EPA must work with industry, where possible, to evaluate REACH dossiers, existing studies, and data.

Moreover, EPA should be explicit in the text of the final rule that this will be done. Only by doing so can the Agency properly implement its statutory obligations.

F. EPA should not default to the precautionary principle in the absence of data.

EPA should not use the absence of data or an incomplete analysis to form the basis of an "unreasonable risk" determination, *i.e.*, it should not use the so-called "precautionary principle." Nothing in the statute directs EPA to assume a risk to health or the environment absent evidence of that risk. To the contrary, the statute directs EPA to "integrate and assess *available* information on hazards and exposures for the conditions of use." 15 U.S.C. § 2605(c)(4)(F)(i). This is confirmed in the legislative history, which confirms that TSCA is intended to "ensure that EPA uses the best available science [and] bases scientific decisions on the weight of the scientific evidence."[6] The statute thus precludes EPA from making assumptions about the meaning of *unavailable* information.

This issue may become particularly important if EPA identifies a "gap" in the data, or is unable to identify concrete scientific data to fill that gap within the statutorily-mandated period. In these cases, EPA must base its conclusions on the data actually available, and not default assumptions. Where there is a lack of data, EPA should engage with industry and the public to obtain appropriate information, including existing internationally accepted data, models, and products such as those generated in the European Union under REACH. *See* Section II.E., *supra.*

III. Specific Comments

In addition to the overarching policy recommendations set forth above, BCI provides the following specific responses to several specific questions posed by EPA in the preamble to the proposed rule or that arise from specific proposed provisions.

[5] S. Rep. No. 114-67, at 9.
[6] 162 Cong. Rec. S3511, S3522 (daily ed. Jun. 7, 2016) (statement of Sen. David Vitter).

A. Response to EPA's request for comment "regarding the pros and cons of codifying these or other definitions and/or approaches" [*e.g.*, definitions of "reasonably available information," "best available science" and "weight-of-the evidence."] 82 Fed. Reg. at 7572.

EPA should include in the rule qualitative parameters implementing the law's requirement that EPA use the best science to better define what types of data constitute the "reasonably available information" the Agency can use during risk evaluation.

The proposed rule defines "reasonably available information" only temporally by limiting such information to "existing information that EPA possesses or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation." Proposed 40 C.F.R. § 702.33. Improperly, however, the definition makes no reference to the statute's related best science and weight of evidence standards. 15 U.S.C. §§ 2625(h) and (i). This leaves the scope of available information impermissibly open-ended. This must be corrected.

In the preamble, EPA states that it believes it "is not obliged" to include in its regulations language implementing Congress's mandate to use the best available science when making risk evaluation, and therefore EPA is exercising its "complete discretion" to leave those requirements out of the rule. 82 Fed. Reg. at 7565. This is incorrect. The use of the best science is one of the most important elements of a valid and statutorily-compliant risk evaluation. EPA must commit itself to only using the best science by incorporating these requirements directly into the rule.

An appropriate way to assure that only the best science may be used during the risk evaluation process would be to add language to the proposed rule under a new section 702.39(b)(6) as follows:

> In conducting risk evaluations under this rule, EPA shall, to the extent that it makes a decision based on science, use reasonably available scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available scientific standards and weight of scientific evidence, consistent with the terms of 15 U.S.C. § 2625(h) and (i).

B. Response to EPA's request for comment regarding whether EPA "should . . . require[ ] that a list of appropriate guidance documents be included on a case-by-case basis as part of the scoping document that undergoes public review and comment?" 82 Fed. Reg. at 7573.

Yes. To promote the consistent use of the best science, EPA should require that a list of appropriate guidance documents be included on a case-by-case basis as part of the scoping document that undergoes public review and comment.

In conducting risk evaluations, EPA proposes to use "[e]xisting EPA guidance, where available and relevant . . . . In addition, other scientifically relevant methods or guidance may be used in a risk evaluation." Proposed 40 C.F.R. § 702.39(a)(2). The only specific guidance document referenced in the statute is the Metals Framework, which EPA has codified into the rule as required by statute. 15 U.S.C. § 2605(b)(2)(E).

The rule should codify, however, a process for the public to comment on the most appropriate other guidance to be used during risk assessment. BCI agrees that EPA should do this by requiring that a list of appropriate guidance documents be included as part of the scoping document that undergoes public review and comment.

EPA additionally "asks if the current guidance documents are sufficient and whether there are additional guidance documents that should be relevant but may not be on the lists available on EPA's Web site (*https://www.epa.gov/risk/risk-assessment-guidelines*)." 82 Fed. Reg. at 7573. EPA should also incorporate relevant guidance documents available from foreign jurisdictions, including the Organisation for Economic Co-operation and Development (OECD) guidance on evaluation of environmental risks of metal compounds.[7]

C. Response to EPA's request for comment whether "codifying . . . [interagency collaboration] … is necessary?" 82 Fed. Reg. at 7573.

Yes. EPA should codify the process and procedures that will govern EPA's mandatory interagency collaboration on risk evaluations and other statutorily-required actions. *See* Section II.B., *supra.*

The preamble to the proposed rule states that EPA is committed to ensuring there is interagency engagement and dialogue, but that the Agency it is not proposing to codify any particular process out of concern that doing so might lead to an overly bureaucratic process. 82 Fed. Reg. at 7567-68. EPA's concern is misplaced. It is the proposed approach that is inconsistent with the statute. Because the statute mandates interagency collaboration but does not provide the procedural details, EPA is obliged to be more specific about procedures.

For example, TSCA requires EPA to coordinate its actions under the law with the Secretary of Health and Human Services and "the heads of any other appropriate Federal executive department or agency, any relevant independent regulatory agency, and any other appropriate instrumentality of the Federal Government for the purpose of achieving the maximum enforcement of this [Act] . . . *while imposing the least burdens of duplicative requirements* . . . and for other purposes." 15 U.S.C. § 2608(d) (emphasis added). EPA also is not to exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety and health. *Id.* at § 2608(c). EPA's regulations should explain how EPA intends to implement these mandates. The most appropriate way is for EPA to defer attention to occupational health

[7] OECD Guidance On The Incorporation Of Bioavailability Concepts For Assessing The Chemical Ecological Risk And/Or Environmental Threshold Values Of Metals And Inorganic Metal Compounds, ENV/JM/MONO(2016)66 (Dec. 19, 2016).

protections where OSHA has adopted a specific standard addressing the chemical substance(s) at issue.

More generally, this statutory mandate does not require that extraordinary detail be provided in the rule. Instead, the processes to be followed and principles to be applied should be sufficiently defined that both governmental staff and outsiders know what is to be expected. Issues to be addressed should include how EPA will determine if consultation is necessary (if, for example, a pertinent OSHA standard exists, EPA may be able to defer to it without further communication with that agency), when and how to inform appropriate agencies of the chemicals under evaluation, and when during risk evaluation the agency will engage with other agencies.

D. Response to EPA's request for comment "on whether and how the proposed rule could provide additional transparency, public accountability, opportunities for public participation[?]" 82 Fed. Reg. at 7565.

The proposed 30-day comment period on the scoping document (proposed 40 C.F.R. § 702.39(c)(6)(ii)) is woefully inadequate. The comment period for the scoping document probably will be the single most important public comment period throughout the TSCA evaluation process, because it will define the breadth of the risk evaluation and thus also the breadth of potential chemical use restrictions. 30 days will not allow industry or others in the public adequate time to thoughtfully evaluate EPA's draft or to provide meaningful feedback. At least 90 days must be allowed for the comment period to be meaningful. Thus, instead of the proposed approach, EPA should publish the draft scoping document much earlier in the process. EPA will have had considerable time in the pre-prioritization and prioritization phases to develop a draft scope. If release for comment were to occur no later than the final prioritization designation for a chemical, at least a 90-day period can be accommodated. EPA will still have adequate time to review and properly respond to those comments prior to publishing the final scoping document.

EPA also should eliminate the proposed waiver language from the final rule. EPA's proposed rule states that, with regard to the draft risk-evaluation scoping document, "[a]ny issues not raised [during the comment period] will be considered to have been waived, and may not form the basis for an objection or challenge in any subsequent administrative or judicial proceeding." Proposed 40 C.F.R. § 702.39(c)(6)(iii). This is at best overbroad, because it implies that even issues unrelated to those specifically referenced in the scoping document might be waived for a future challenge. That would be wholly unjustifiable. But an even more fundamental problem exists: EPA has provided no factual support for its approach of precluding from input those who only belatedly become aware of the Agency's activities as to a particular chemical or who first have an interest in that chemical after the comment period has elapsed.

The proposed 30-day comment period on the draft risk evaluation (proposed 40 C.F.R. § 702.45(a)) also is inadequate. A draft risk assessment is a highly complex, high-impact document that includes a risk determination which could directly drive risk mitigation measures. This is too important a document to release with only a 30-day comment period. Moreover,

EPA's proposal is inconsistent with a fair reading of TSCA. While the statute requires that this comment period be "no less than 30 days," that is not a mandate for EPA to provide only 30 days. 15 U.S.C. § 2605(b)(4)(G). To the contrary, Congress's choice to use the phrase "no less than" implicitly suggests that a longer comment period is likely appropriate in most circumstances.

The only constraint on the length of this comment period is the requirement that EPA issue a final risk assessment within three years, with a possible extension of six months. That certainly allows for more than a 30-day opportunity. Industry and other interested parties must be provided at least 120 days to review the document and provide meaningful feedback and comments.

E. Comments regarding Proposed § 702.39(a)(7).

Proposed 40 C.F.R. § 702.39(a)(7) requires the use of the Metals Framework in assessing such materials. This is required by the statute (15 U.S.C. § 2605(b)(2)(E)) and sound policy.

As EPA accurately describes the Framework on the Agency's website, it "is a science-based document that addresses the special attributes and behaviors of metals and metal compounds to be considered when assessing their human health and ecological risks. The document describes basic principles to be considered in assessing risks posed by metals and is intended to foster consistency in how these principles are applied across the Agency's programs and regions when conducting these assessments."[8]

EPA's commitment that it "will use" the Framework is appropriate and is the only way to ensure that it adheres to the statute. However, we also recommend the following changes to proposed 40 C.F.R. § 702.39(a)(7):

> In evaluating chemical substances that are metals or metal compounds, EPA will use, <u>among other sources,</u> the Framework for Metals Assessment of the Office of the Science Advisor, Risk Assessment Forum, dated March 2007, or a successor document that addresses metals risk assessment and is peer reviewed by the Science Advisory Board.

Among the other sources that BCI anticipates EPA will use in metal prioritization is the Organization for Economic Cooperation and Development (OECD) December 2016 document, "Guidance on the Incorporation of Bioavailability Concepts for Assessing the Chemical Ecological Risk and/or Environmental Threshold Values of Metals and Inorganic Metal Compounds." *See* Section III.B., *supra.*

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[8] EPA, Framework for Metals Risk Assessment, available at https://www.epa.gov/risk/framework-metals-risk assessment.

F. Comments regarding Proposed § 702.39(c)(4).

Proposed 40 C.F.R. § 702.39(c)(4) would require the risk evaluation "scope" document to include a Conceptual Model that describes actual or predicted relationships between the chemical substance and human and environmental receptors. Among other things, EPA has proposed that the Conceptual Model consider the life-cycle of the chemical substance, including manufacture, processing, distribution in commerce, storage, use, and disposal.

This approach embodies sound policy. It is critical to the conduct of a fair and accurate risk evaluation that the Agency consider the entire life-cycle of a chemical. For example, a chemical that is safely recycled and never disposed of is almost certain to have a much smaller environmental footprint than a similar chemical that is not recycled. These considerations must weigh into EPA's unreasonable risk determination considerations. Likewise, if a chemical is only used in articles or is already highly regulated, this also must be taken into consideration. *See* Sections II.B and C., *supra.*

G. Comments regarding 15 U.S.C. §§ 2605(c)(2)(D) and (E).

EPA has failed to address in the proposed rule key limiting provisions in the statute which prohibit EPA from regulating replacement parts and articles. Appropriate provisions doing so should be incorporated in the final rule.

The first omission relates to the provision that authorizes EPA to place limitations on chemical substances in articles "only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article . . . so that the substance . . . does not present an unreasonable risk." 15 U.S.C. § 2605(c)(2)(E). The second relates to the provision that exempts from regulation replacement parts for complex durable goods and complex consumer goods, designed prior to rule promulgation, unless the replacement part contributes significantly to the risk(s) identified in the risk evaluation. 15 U.S.C. § 2605(c)(2)(D). It expressly "requires EPA to be careful in addressing replacement parts." 161 Cong. Rec. H4551, H4556 (daily ed. Jun. 23, 2015) (statement of Rep. Shimkus).

To properly implement these Congressional mandates, these restrictions must be recognized during the risk evaluation process. Even without the statutory provisions, it would make no sense to subject exempt conditions of use to risk evaluation. For example, in the case of a chemical incorporated into an article, it is usually the case that the primary potential for exposure will be during chemical manufacturing and processing, not use. Thus, even if EPA had discretion to ignore Congressional direction (which it does not), rational policy would require that EPA evaluate only the manufacturing and processing phases of articles.

Moreover, EPA should revise proposed section 702.39(a)(6) to exclude articles and replacement parts from the risk evaluation process as early as possible. This means, for example, EPA should exclude manufacturers involved in such conditions of use from information production and

collection activities pertinent solely to chemicals as they are incorporated into such products. *See* Sections II.C., *supra.*

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BCI appreciates the opportunity to provide these comments to the Agency. If you have any questions or require further information, please contact BCI's legal counsel David B. Weinberg of Wiley Rein LLP at 202-719-7102 or dweinberg@wileyrein.com.

Sincerely,

/s/ Timothy Lafond

Timothy J. Lafond, P.E.
Chair
BCI Environmental Committee