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

Re: Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act; Proposed Rule (Jan. 17, 2017); EPA–HQ–OPPT–2016–0636

Dear Sir or Madam:

The Battery Council International provides these comments to EPA on its proposed rule, Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, published January 17, 2017 at 82 Fed. Reg. 4825 (EPA–HQ–OPPT–2016–0636).

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 leads. 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. Overarching Issues

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 prioritization. Each of these comments is applicable to numerous individual sections of the proposed rule, several of which we address subsequently in Section III.

A. EPA should allow high-priority designation of some conditions of use of a chemical and low-priority designation of its other uses.

EPA should comply with 15 U.S.C. § 2605(b)(1)(A) by revising the proposed Prioritization Rule, including but not limited to proposed 40 C.F.R. § 702.1(b), to allow high-priority

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

designation of some conditions of use of a chemical and low-priority designation of others.[2] Failing to do so will not only be inconsistent with the Agency's statutory mandate, but also will overwhelm the resources available to both EPA and the private sector, because many conditions of use that could have been identified as low concern during prioritization will be left for assessment during risk evaluation. Moreover, eliminating low-priority conditions of use from further evaluation as early in the process as possible will increase the resources available to devote to the review of a chemical's high priority uses. Nothing in TSCA requires EPA to wait until the scoping phase to exclude from further evaluation those conditions of use which meet the requirements for low priority designation, and Congress did not intend the Agency to wait that long.[3]

In the Preamble to the proposed rule, EPA states that "[w]hile EPA clearly retains some discretion in determining those conditions of use, as a matter of law, EPA considers that it would be an abuse of that discretion to simply disregard known, intended, or reasonably foreseen uses in its analyses." 82 Fed. Reg. at 4829. This is a constrained and incorrect reading of the statute. Narrowing EPA's attention is precisely what Congress directed when it told EPA to designate as high priority chemicals which "may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure ***under the conditions of use.***" 15 U.S.C. § 2605(b)(1)(B)(i) (emphasis added).

Moving the review of certain conditions of use out of the risk evaluation and up to prioritization will still provide adequate review of all conditions of use. To reinforce the adequacy of such review, BCI recommends below that EPA make the prioritization review more transparent and robust.

A further discussion of this issue, in the context of proposed section 702.1(b) appears in Section III.D, *infra*.

B. EPA should focus prioritization efforts on current and reasonably foreseeable uses of a chemical, not historical but now abandoned or substantially limited conditions of use.

In addition to the requirement that EPA focus on "conditions of use," discussed immediately above, the Lautenberg Act's tight deadlines for Agency action signal that Congress intended EPA to act to focus its evaluation activities as efficiently and tightly as possible. 15 U.S.C. §§ 2605(b)(2) and (b)(4). Only with such focus can those deadlines be met. These considerations also counsel that EPA need only consider in assessments the current and reasonably-foreseeable future conditions of use, and not historical uses which have been completely discontinued, phased out, or substantially limited. EPA's mandate is to consider the

[2] "'Conditions of use' means the circumstances, as determined by the Administrator, 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).
[3] *See, e.g.*, 162 Cong. Rec. S3511, S3516 (daily ed. Jun. 7, 2016) (statement of Sen. David Vitter).

safety of chemical use going forward, and 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 at least implicit recognition of these facts in conducting its assessment of asbestos as part of the initial ten chemical identified for evaluation. Most recently, in a mid-February public meeting, EPA leadership clearly and correctly noted that the Agency does not intend to address historic uses of asbestos.[4] For all 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.

By focusing this way, EPA will be implementing Congressional directive and intention. Avoidance of distraction by evaluation of no longer significant uses is precisely why the statute mandates that the Agency pay attention to "conditions of use." It would be a regrettable waste of Agency resources to focus efforts on such historical uses when those resources could be directed toward current and reasonably foreseeable conditions of use, just as it would for the Agency to ignore the impact of existing regulatory programs (as noted in Section II.C., *infra*).

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

The proposed rule states that EPA has sought to implement the principle that attention should be focused on "those chemical substances with the greatest hazard and exposure potential first, considering available information on the relative hazard and exposure of potential candidates." 82 Fed. Reg. at 4835. This is a correct reading of the statutory text and Congressional intent. 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.

Adopting this approach further implements the principles addressed in the prior two subsections of these comments. Use of chemicals that already are strictly regulated poses far less threat – if any at all – than chemicals that are unregulated. The regulations EPA should 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 during the prioritization process 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 still meet its statutory obligations.

Furthermore, as both an internal management tool and to assist public commenters, EPA should add to its docketed pre-prioritization and prioritization documents a public index of existing laws and regulations issued by EPA, other federal agencies, and key state-based programs that apply

[4] 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.

to current and reasonably foreseeable uses of the substance(s) at issue. It is important that EPA do so during the prioritization process in order for the Agency to accurately assess a chemical's actual risk on a condition of use basis and to avoid wasting resources on addressing issues already controlled through other programs. Defaulting to an assumption that a chemical poses an unregulated risk would dramatically overestimate the real-world risks. EPA cannot lawfully adopt such an approach under its new Lautenberg Act authorities.

In short, EPA should update all phases of the process outlined in the proposed prioritization rule to require evaluation of the existing regulatory landscape of each of the chemicals that it is considering.

D. EPA should exclude conditions of use of chemicals in articles.

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 prioritization evaluations conditions of use of chemicals in articles that result in no or only limited exposures. Including such uses in further review phases makes no sense and would run counter to Congress's direction.[5]

For example, chemicals incorporated into articles such as batteries 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, the principle discussed above that EPA must take into consideration existing regulatory mechanisms will likely demonstrate that virtually no further TSCA attention need be directed to chemicals in those articles.)

E. EPA must make the pre-prioritization process transparent by providing public notice that a chemical is under pre-prioritization consideration and seeking public comment.

EPA has not proposed to provide public notice that a particular chemical is being considered for prioritization during the pre-prioritization process, nor has EPA allowed for any public comment during the pre-prioritization process. These are mistakes.

BCI agrees that EPA should be afforded sufficient time to make fully informed decisions during a "pre-prioritization" period. But EPA also must heed Congress's instruction that the regulatory

[5] 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 if exposure is so low that mitigation would not be necessary or feasible after completion of the risk evaluation.

process be open and transparent.[6] And those principles apply at every stage of the regulatory process.

It thus is imperative for EPA to revise the proposed rule to provide public notice of chemicals under pre-prioritization consideration. Without notice, necessary communication between EPA, industry, and other interested parties will be inhibited and in many cases precluded. Yet input from concerned parties indisputably will be of value to the Agency. In addition to assuring informed regulatory decisions, providing the Agency with as much information as possible as early as possible will prevent unnecessary prioritization and subsequent regulatory efforts.

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.

A. Response to EPA's request for comment "on whether and how EPA should solicit additional input at the pre-prioritization phase." 82 Fed. Reg. at 4831.

EPA should include in the rule mandatory public notice and comment regarding the pre-prioritization candidate selection and screening. Proposed 40 C.F.R. §§ 702.5 and 702.7.

EPA is required by statute to make high or low-priority designations no less than nine months and no longer than a year after a chemical enters the prioritization process. 15 U.S.C. § 2605(b)(1)(C). However, in an apparent effort to afford itself sufficient time to make a fully informed decision, EPA has proposed to incorporate into its Prioritization Rule a pre-prioritization "consideration and screening" process that does not trigger the 9-12-month clock. Proposed 40 C.F.R. §§ 702.5 and 702.7.

BCI is concerned that EPA has not proposed to provide public notice that a particular chemical is being considered for prioritization during the pre-prioritization process. This lack of transparency may inappropriately inhibit needed communication between EPA, industry, and other interested parties. *See* Section II.E., *supra.*

Without notice, there is no formal mechanism for interested parties to know that the Agency is considering a substance. Nor is there any opportunity for others in the public to provide EPA with information that might assist the Agency with its review and decision-making. Yet the Agency clearly will benefit from input from industry and the public as it seeks to identify conditions of use that should be considered high- or low-priority (s*ee* Section II.A., *supra*); conditions of use that may be discontinued or phased out and therefore inappropriate for evaluation (*see* Section II.B., *supra*); conditions of use that are already effectively regulated (*see*

[6] S. Rep. No. 114-67, at 8 (Jun. 18, 2015) (It was the "Committee's intent that EPA's policies, procedures, and guidance should…be transparent to the public.").

Section II.C., *supra*); conditions of use that constitute chemicals in articles (*see* Section II.D., *supra*); and risks that may be posed by substitutes to existing products (*see* Section III.C., *infra*).

Without such outreach, EPA also will fail to comply with its statutory obligation to use the best available science at all regulatory stages. 15 U.S.C. § 2625(h). Thus, EPA must issue public notice and solicit comment regarding the chemicals that are undergoing review for selection and screening during the pre-prioritization process. This will ensure that the Agency is aware of the best and most current science as early as possible in the process and help to prevent unnecessary pre-prioritization efforts.

EPA also should request comment as early as possible about the potential environmental, health, or other benefits the chemical, or products using the chemical, may have (*e.g.*, greenhouse gas reduction potential). Only if EPA considers both the pros and cons of handling and use of a chemical can risks and benefits be properly evaluated in accordance with the Agency's statutory mandate.[7] EPA should also assess the disposal and recycling activities associated with the use of any of the chemical, because doing so is a key part of evaluating the environmental impacts of uses of a chemical and the resulting risk profile(s).

While BCI agrees that EPA should be afforded sufficient time to make fully informed decisions during a "pre-prioritization" period, EPA should heed Congress's instruction that the process be open and transparent. It therefore is imperative for EPA to revise the rule to provide public notice of chemicals under pre-prioritization consideration.

B. 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 4828.

EPA should include in the final rule definitions for the terms identified above, including the parameters to be considered in determining what constitutes "reasonably available information" for use by the Agency during pre-prioritization and prioritization candidate consideration and screening. Without such definitions and parameters, EPA's pre-prioritization rule will not meet its TSCA and Administrative Procedure Act obligations because it will leave open-ended the scope of the "reasonably available information" that the Agency will use during pre-prioritization consideration and screening.[8] The rule (proposed 40 C.F.R. §§ 702.1, 702.5(d), 702.7(c) and (d)) also should expressly reference the statute's related best science and weight of evidence standards. 15 U.S.C. §§ 2625(h) and (i).

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[7] S. Rep. No. 114-67, at 4 (Jun. 18, 2015) (EPA "must consider . . . the benefits of the substance for various uses.").

[8] The Risk Evaluation proposal provides a very limited definition of the term "reasonably available," but it is only temporal in nature and is not applicable to prioritization. "*Reasonably available information* means 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. Further, this definition does nothing to address the quality of information that EPA can use.

The proposed rule states that during initial consideration "EPA will generally consider whether information **available to the Agency** suggests there is hazard and exposure under a condition or conditions of use, and whether a risk evaluation would be needed to determine whether there is an unreasonable risk." Proposed 40 C.F.R. § 702.5(a) (emphasis added). But this limitation to "available" information is only defensible if the Agency also has sought pertinent information from concerned parties outside of EPA. Similarly, the proposed regulations state that during follow-up screening, EPA will "generally use **available information** to screen the candidate chemical substance against . . . criteria and considerations. . . ." Proposed 40 C.F.R. § 702.7(c) (emphasis added). Again, "available" can only be adequate if the Agency has undertaken meaningful outreach. Moreover, only if it has sought information from outside the regulatory agency can EPA comply with the parameters for information sources set forth elsewhere in the proposed regulations: the screening for information "relevant" to the various listed criteria being evaluated by the rule. Proposed 40 C.F.R. § 702.7(d).

The final rule also should make it clear how the Agency will deal with scientific literature data bases that include studies of varied quality. To ensure that only credible information may be used in the prioritization screening process, EPA should add the following or substantially similar language to Section 702.1(g):

> In screening and selecting a potential candidate for prioritization under any provision of 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).

C. Response to EPA's request for comment on whether it "may also consider the relative hazard and exposure of a potential candidate's substitutes". 82 Fed. Reg. at 4835 and proposed 40 C.F.R. § 702.7(b).

The risks associated with replacement of chemicals by potential substitutes (*e.g.*, exposure and health and environmental fate data) should be considered during pre-prioritization and prioritization.

EPA says in the rule preamble that it has sought to codify in the rule a general objective to "select those chemical substances with the greatest hazard and exposure potential first, considering available information on the relative hazard and exposure of potential candidates." 82 Fed. Reg. at 4835.[9] EPA further says that it "may also consider the relative hazard and exposure of a potential candidate's substitutes," and seeks comment on whether that is appropriate. EPA also includes this same language in the proposal at § 702.7(b). *Id.*

[9] However, EPA is not required to select candidates or initiate prioritization pursuant to 40 C.F.R. § 702.9 in any ranked or hierarchical order. *Id*.

EPA should review the risks of substitutes as early in the chemical assessment process as possible, during pre-prioritization. This will allow EPA to determine the best candidates for high-priority designation.

The fact that the statute precludes EPA from considering costs or other "non-risk" factors during prioritization and risk evaluation in determining whether a chemical substance may present an unreasonable risk of injury to health or the environment[10] does not mean that EPA is prohibited from considering "risk" factors during prioritization evaluation.

This does not mean that EPA must speculate about alternatives, however. The agency still must have a solid basis for its decision-making. To be lawful, practical and conserve resources, EPA should only consider those substitutes that will be available during the risk evaluation/risk mitigation phase for the chemical under review.

D. Comments regarding Proposed § 702.1(b).

EPA should revise Proposed 40 C.F.R. § 702.1(b) to allow, as to a particular chemical, high-priority designation of some conditions of use and low-priority designation of others. *See* Section II.A., *supra*.

If the Agency fails to make this change, both it and others will be overwhelmed by having to complete risk evaluations on conditions of use that could have been, during prioritization, identified to be of low concern. This, in turn, will diminish the quality of review of the chemical's significant uses and delay the review of other chemicals.

This approach is completely consistent with the statutory scheme. EPA's assertion in the preamble to the prioritization rule "that it would be an abuse of that discretion to simply disregard known, intended, or reasonably foreseen uses in its analyses" is simply incorrect. 82 Fed. Reg. at 4829. The statute requires EPA to designate chemicals as high-priority those which "present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure ***under the conditions of use."*** 15 U.S.C. § 2605(b)(1)(B)(i) (emphasis added). This language clearly demonstrates not only that EPA has discretion to give different weights to risks arising under different conditions of use, but also that Congress has instructed the Agency not to designate as high priorities those conditions of use which do not present an unreasonable risk.[11]

EPA recognizes the rationality of this approach in the proposed Risk Evaluation Rule. Proposed 40 C.F.R. § 702.39(a)(6) states that "EPA may conduct a risk evaluation on a chemical substance in phases to allow the Agency to proceed with risk management on particular conditions of use. For example, EPA may determine that a chemical substance presents an unreasonable risk of injury to health or the environment under one or more conditions of use, and address such unreasonable risk through rulemaking under TSCA section 6(a), while other conditions of use

[10] 15 U.S.C. §2605(b)(4).
[11] Moreover, EPA can revisit a low-priority designation should facts merit such action. 15 U.S.C. § 2605(b)(3)(B).

remain under evaluation." 82 Fed. Reg. 7562, 7578 (Jan. 19, 2017). But the proposed prioritization rule would undermine a phased approach by requiring the Agency to continue to evaluate all possible conditions of use as part of risk evaluation, including those that the agency may have already determined are of low risk, at least until the scoping document is finalized.

For all the reasons just discussed, EPA should not designate as high-priority conditions of use which have been discontinued or substantially phased out, or conditions of use already sufficiently regulated by law or regulations issued by EPA or other federal or state agencies. The entire focus of the TSCA scheme is prospective, otherwise unregulated risk. *See* Sections II.B and II.C., *supra.*

In light of the stringent timelines imposed by the statute, the scheme embodied in TSCA clearly is not one through which Congress intended for every imaginable use of a chemical to be exhaustively assessed as part of the agency's designation process. Instead, EPA must consider a more pragmatic approach. The solution is for EPA to use its statutory authority to focus early in the prioritization process on important limiting factors, such as use phase outs, exempted article uses, highly regulated uses, or low exposure uses. This approach would allow EPA to identify chemicals and conditions of use that pose a greater concern than others, and thus enable EPA to more effectively meet its statutory obligations to prioritize within a limited period of time those chemicals which present unreasonable risks "under the conditions of use."

E. Comments regarding Proposed § 702.1(c).

The language of proposed 40 C.F.R. § 702.1(c) that emphasizes EPA's authority to regulate chemical categories where appropriate is reasonable and consistent with the Agency's statutory mandate.

As EPA states, TSCA provides EPA with authority to take action on categories of chemical substances. 15 U.S.C. § 2625(c). "Category of Chemical Substances" is defined at 15 U.S.C. § 2625(c)(2)(A). It thus is fully appropriate to include in the Prioritization Rule the proposed clear statement that nothing in the rule shall be construed as a limitation on EPA's authority to take action with respect to categories of chemical substances, and where appropriate, EPA can prioritize and evaluate categories of chemical substances. For example, a particular metal and its compounds are often reviewed together because of similar toxicological and environmental fate profiles. Recognizing this and proceeding on a category basis will conserve resources of both EPA and industry during prioritization.

F. Comments regarding Proposed § 702.1(e).

EPA should delete the language in Proposed 40 C.F.R. § 702.1(e) that could be interpreted to grant EPA the discretion to ignore the Metals Framework during prioritization.

The statute clearly requires the Metals Framework to be used for both prioritization and risk evaluation. 15 U.S.C. § 2605(b)(2)(E). However, the language EPA has proposed in the prioritization rule can be read to transform that requirement into an optional element: "In

identifying priorities for chemical substances that are metals or metal compounds, EPA will**,** ***as appropriate*****,** refer to relevant considerations from 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." Proposed 40 C.F.R. § 702.1(e) (emphasis added). EPA also says in the preamble to the proposed rule that "[d]uring the prioritization process, EPA will not be conducting chemical risk assessments; and, consequently, much of this guidance will not be directly relevant." 82 Fed. Reg. at 4827.

These statements, whether in the rule or preamble, are inconsistent with the statutory language and Congress's intent[12] and undermine the scientific importance of the Metals Framework to the prioritization process. EPA does not have discretion to decide not to use the Metals Framework.

To address this issue, BCI concurs with the North American Metals Coalition (NAMC) and National Mining Association (NMA) that the following revision to the proposed rule should be made:

> *Metals or metal compounds.* In identifying priorities and screening criteria for chemical substances that are metals or metal compounds, EPA will~~, as appropriate, refer to relevant considerations from the~~ use, among other sources, 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.[13]

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."

Furthermore, we agree with the NAMC and NMA's joint comment that provisions at 40 C.F.R. § 702.5 must be modified to ensure metals are properly screened.[14] EPA should recognize in the text of 40 C.F.R. § 702.5(c)(1) that metals and metal compounds should be evaluated for persistence, bioaccumulation, and toxicity only as outlined in the Framework document. Likewise, any screening evaluation conducted during pre-prioritization of metals used in children's products (40 C.F.R. § 705(c)(2)) and in consumer products (40 C.F.R. § 705(c)(3)) should properly reference the bioavailability of the metal in those products.

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[12] *See* S. Rep. No. 114-67, at 18 ("For PBT Work Plan chemicals and in assessing subsequent high priority chemicals, the Committee believes that EPA's Framework for Metals Risk Assessment (EPA 120/R–07/001) (Mar. 2007) should be consulted for metals and metal compounds.").
[13] 82 Fed. Reg. at 4834-35 (proposed 40 C.F.R. § 702.1(e)).
[14] *Id.* at 4835 (proposed 40 C.F.R. § 702.5).

G. Comments regarding Proposed § 702.7(f).

During prioritization screening, EPA should add to proposed 40 C.F.R. § 702.7(f) a prohibition on EPA exercising its data development authority as to uses of chemicals that are excluded from coverage by the statute, such as uses in articles and replacement parts.

As discussed in Section II.D, *supra*, and below, the statute severely limits EPA's risk mitigation authority over articles and replacement parts. The 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). Similarly, the statute requires EPA to exempt from TSCA regulation replacement parts for complex durable goods and complex consumer goods that are designed prior to the date of the applicable risk mitigation rule. *Id.* § 2605(c)(2)(D).

In light of these explicit and significant restrictions on EPA's authority, these restrictions should be recognized during the prioritization process. Even without the above-quoted statutory limitations it would make no sense to prioritize exempt uses or applications or to require the development of data to support such prioritization. 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 the manufacturing and processing phases should be where EPA focuses prioritization evaluation efforts for articles.

To comply with these statutory directives, EPA should exclude articles and replacement parts from the prioritization process, and do so 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.

* * *

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