March 20, 2017

Docket Control Office (7407M)
Office of Pollution Prevention and Toxics (OPPT)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW Washington, DC 20460-0001

Sent electronically to www.regulations.gov Docket ID# EPA-HQ-OPPT-2016-0636

Re: ACC Comments on EPA's Proposed Procedures for Prioritization of Chemicals for Risk Evaluation under the Toxic Substances Control Act as amended by the Lautenberg Chemical Safety Act

Dear Sir/Madam:

The American Chemistry Council (ACC)[1] appreciates the opportunity to provide written comments to the Office of Chemical Safety and Pollution Prevention to inform the Agency's development of a prioritization process rule under the Toxic Substances Control Act (TSCA), as amended by the Lautenberg Chemical Safety Act (LCSA). ACC is committed to being a constructive stakeholder in the effective implementation of the LCSA and we provide these comments to assist the Agency in its development of a chemical evaluation and management program that is efficient, science-based, and consistent with the legal requirements of the LCSA.

Prioritization is the first step in the LCSA's framework for evaluating active chemicals in commerce and the prioritization process rule must establish a risk-based screening process and criteria to identify high and low priority substances for risk evaluations under the LCSA. If you have any questions, please contact me at: 202-249-6403 or Sarah_Brozena@americanchemistry.com.

Sincerely,

Sarah H. Brozena

Sarah Brozena
Senior Director, Regulatory & Technical Affairs

Cc: Jeffrey Morris, Director, OPPT
Wendy Cleland Hamnett, OCSPP
Ryan Schmit, OCSPP

[1] The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a $797 billion enterprise and a key element of the nation's economy. It is one of the nation's largest exporters, accounting for ten cents out of every dollar in U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.

American Chemistry Council
Comments on EPA's Proposed Procedures for Prioritization of Chemicals for Risk Evaluation under the Toxic Substances Control Act as amended by the Lautenberg Chemical Safety Act

Docket ID# EPA-HQ-OPPT-2016-0636

March 20, 2017

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EXECUTIVE SUMMARY

EPA has suggested four steps in its proposed rule to implement the prioritization requirements of Section 6(b) of the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act:

- "Pre-prioritization" to narrow the pool of potential candidate substances
- Initiation of the prioritization process by identifying candidate substances and soliciting public comment
- Proposed priority designation, including an opportunity for public comment
- Priority designation

The American Chemistry Council (ACC) has three major concerns with EPA's proposed prioritization process rule. Our concerns relate to the proposed pre-prioritization step, the treatment of low priority designations, and EPA's failure to address the LCSA Section 26 science standards in the rule. ACC's comments include specific recommendations to address these concerns.

EPA's proposed prioritization process hinges on the "pre-prioritization" step. EPA does not fully and clearly describe this step, its statutory authority or limitations. Pre-prioritization is not mentioned in TSCA section 6(b) as amended. EPA asserts that the statute leaves it "broad discretion" to choose which chemicals on the TSCA Inventory to put into the prioritization process. However, EPA must exercise its discretion in a reasonable manner and is required to describe the statutory authorities for its exercise of discretion. EPA has not done so here.

EPA intends the pre-prioritization step to inform prioritization decisions and the risk evaluation process, without regard to other relevant provisions of the statute. Because EPA asserts that it may need additional time to gather or develop information for risk evaluations, it has proposed to use the pre-prioritization step to gather information on substances with "insufficient information" for risk evaluation. ACC acknowledges that the statute imposes time constraints on the Agency once the prioritization process is triggered, but we believe that EPA has other tools available to address information needs in both the prioritization and risk evaluation stages in a timely, efficient manner.

For example, in its pre-prioritization step EPA does not address the important relevant testing requirements of Section 4(a)(2)(A) or (B), the statement of need requirements of Section 4(a)(3) or the tiered testing requirements of Section 4(a)(4). As proposed, the pre-prioritization step conflates the prioritization and risk evaluation processes in ways that are confusing to the regulated community. Importantly, the pre-prioritization step appears contrary to congressional intent.

In prioritization, it is very important that all substances be treated consistently, by the same transparent criteria, and that the process is replicable. Other than noting the statutory obligation to designate as high priorities the Work Plan chemicals that meet certain "preference" criteria, the proposed rule does not define the criteria or tools by which EPA will choose Work Plan and other chemicals from the active TSCA Inventory for the pre-prioritization or candidate "pool." EPA did not seek any stakeholder input on this question. EPA has not explained how many chemicals it proposes to include in the pre-prioritization or prioritization pool, or whether and how it will

"batch" chemicals to move them forward into the "initiation of prioritization" step. Although EPA has identified the nine criteria by which it proposes to narrow the pool into a list of candidates for prioritization, EPA does not define the criteria and or discuss the methodology by which these criteria will be applied. EPA proposes no timeframe for the pre-prioritization step, and provides little guidance on the status of chemicals included in pre-prioritization but excluded from prioritization.

EPA's treatment of low priority chemicals raises significant concerns. EPA's proposal to require that low priority designations be based upon "all" conditions of use is a gross misinterpretation of the statute. This flawed interpretation of EPA's authority will cause the Agency to designate most chemicals in commerce as high priorities, and the Agency states as much in the preamble to the proposed rule. Congress did not intend this result. Low priority designations were seen as one mechanism to enhance public confidence in the safety of a chemical substance under its conditions of use, short of a full risk assessment. EPA has continuing authority to revise priority designations at any time based on new information.

EPA has failed to include the LCSA Section 26 science standards in the prioritization process rule itself. EPA continues to assert that, while relevant to prioritization, EPA is not obliged to include these standards in the rule. ACC respectfully but strongly disagrees with EPA's reasoning.

ACC's comments include a series of recommendations to address the shortcomings of the proposed prioritization process rule. Our recommendations describe:

- A transparent process for pooling and batching active chemicals in commerce for prioritization screening.
- A process to gather available information needed to reach a decision.
- A "bridging" step to permit EPA to assess the sufficiency of information for anticipated priority designations of candidate chemicals, which will inform the risk evaluation scoping process (should it be necessary).
- Revisions that recognize EPA's discretion to designate a low priority substance based on one, some or all conditions of use
- Identification of science-based criteria, tools and standards that apply in the prioritization process.

American Chemistry Council
Comments to U.S. Environmental Protection Agency on
Its Proposed Procedures for Prioritization of Chemicals for
Risk Evaluation under the Toxic Substances Control Act

INTRODUCTION

The American Chemistry Council (ACC) is pleased to provide the U.S. Environmental Protection Agency (EPA) these comments on the Agency's proposed procedures for prioritization of chemicals for risk evaluation under the Toxic Substances Control Act (TSCA) as amended by the Lautenberg Chemical Safety Act (LCSA). The LCSA requires EPA to establish, by rule, a risk-based screening process to identify high and low priority substances for risk evaluations under the LCSA.

ACC strongly supported Congress's efforts to update and reform TSCA. One of ACC's principles for modernizing TSCA called on EPA to systematically prioritize chemicals for purposes of risk evaluations. Without a scientifically based prioritization process, EPA would not be able to meet efficiently the other requirements of the LCSA and achieve the objectives of TSCA reform that Congress intended. As discussed in more detail below, EPA's proposed prioritization process falls short.

Congress designed the LCSA to allow chemicals to be systematically prioritized and then to evaluate those substances presenting the greatest potential risk. This design is apparent in every part of the LCSA. It begins with a reclassification of the full catalog of chemistries in U.S. commerce, the TSCA Inventory. The LCSA requires that the TSCA Inventory be sorted, so that chemicals that are currently active in commerce are separated from those no longer manufactured, imported or used; only chemicals that are active in commerce are subject to the prioritization and risk evaluation. This enables EPA to focus resources for its multi-year, time-and-resource intensive risk evaluations on chemicals that are actually in current use. EPA must next undertake a prioritization process, to inform the sequence of chemicals that will undergo risk evaluation. EPA must then undertake a formal scoping process, to define the conditions of use (and potentially exposed sub-populations relevant to the use) that will be included in the scope of the risk evaluation of the chemical.

Prioritization of chemicals for various purposes is not new to the Agency. In 2011, EPA held a Stakeholder Dialogue on Prioritization and established a Discussion Blog for additional input on the topic. In our comments to that discussion blog, ACC identified several general principles for prioritization (Attachment A). We believe these principles are reflected in the LCSA requirements, in particular the LCSA's recognition that prioritization is a risk based screening process that integrates information on both hazard and exposure potential. In 2011, ACC developed a two-step quantitative and qualitative tool to "proof test" our prioritization principles (Attachment B). We presented our principles and our prioritization tool to EPA in 2011, as well as to other industry and NGO stakeholders at the time. In 2012, EPA published its methodology to identify chemicals for its TSCA Work

Plan for Chemical Assessment (TSCA Work Plan) program.

I. ACC's Vision for a TSCA Prioritization Process Consistent with the LCSA

The LCSA requires EPA, by rule, to establish a risk-based screening process to designate chemicals as high or low priorities for risk evaluations. The LCSA includes criteria and considerations by which EPA must make these priority designations. To ensure EPA consistently has risk evaluations underway, the LCSA requires EPA to identify at least one new high priority for every risk evaluation that is completed.[2] EPA's ability to designate additional priorities for evaluation is limited only by the Agency's ability to complete risk evaluations in accordance with the deadlines established by Congress.[3] Thus, Congress requires EPA to carefully choreograph the identification of high priority substances for risk evaluations, in order to ensure that appropriate resources are available to complete the evaluations with the established deadlines. This implies a framework that efficiently coordinates EPA's prioritization process with EPA's risk evaluation process.

ACC's vision for the prioritization process is one that enables EPA to meet all the requirements of the LCSA and congressional intent. Prioritization must be a risk based screening process in which EPA integrates hazard, use and exposure information to designate chemicals or categories of chemicals as either high or low priority for risk evaluations based on the criteria in Section 6. Information used to make prioritization decisions must be reasonably available; new information should be required through Section 4 tools only if EPA makes a determination pursuant to Section 4(a)(2)(B) that new information is necessary for prioritization. Prioritization designations must be based upon the science standards of LCSA Section 26, particularly best available science and weight of the scientific evidence. The basis for prioritization designations must be transparent and EPA's decisions must be communicated objectively and in neutral terms.

ACC's vision of a prioritization process that meets these requirements includes six steps (see discussion below and the flowchart illustrating these steps on the next page and in Attachment C). ACC recommends that EPA clarify the needed timelines, criteria, tools, approaches and processes for these six steps, publish them for comment and include them in the final rule. Alternatively, EPA should propose these clarifications in a supplemental rule prior to the Agency's first application of the prioritization process. ACC's recommended six steps for the prioritization process are as follows:

1. **Pool and Batch:** EPA must "pool" active chemicals in commerce as candidates for designation as high or low priority for risk evaluation, based on transparent criteria/methods/approaches/tools and processes. EPA should then "batch" these candidates for information gathering. As EPA acknowledges in the "re-population" discussion of the preamble to the proposed rule[4], the pace of EPA's completion of risk evaluations factors into the finalization of EPA's prioritization decisions. As a result, ACC expects that the number of candidates per "batch" for information gathering should be relatively small, at least in the early years of LCSA implementation. EPA's development of pools and batches should be subject to

[2] 15 U.S.C.2605(b)(3)(C)
[3] 15 U.S.C. 2605 (b)(2)(C)
[4] 82 Fed.Reg. 4825, 4833 (January 17, 2017).

estimated timeframes.

2. **Information Gathering:** Because Congress intended prioritization decisions to be based on reasonably available information, EPA should take a sequenced approach to information gathering on chemicals that EPA "batches" for prioritization. The sequenced steps should begin with EPA gathering reasonably available information about potential hazards, uses and potential exposure by relying upon sources such as read across/Quantitative Structure Activity Relationship (QSAR) information; Chemical Data Reporting (CDR) reports; EPA's CompTox Dashboard; High Production Volume (HPV) Challenge program; exposure information/models; EPA's Chemical Assessment and Management program (ChAMP); EPA's Voluntary Children's Chemical Evaluation Program (VCCEP); Canada's Chemical Management Program (CMP); OECD's eChemPortal; and robust study summaries developed under the EU's Registration, Evaluation, and Assessment of Chemicals (REACH). If this information is insufficient to designate the priority of a batched chemical, EPA should issue a notice in the Federal Register for voluntary call-ins of the type of information needed for prioritization and request discussions with manufacturers and processors of the chemicals. If voluntary information is still inadequate to prioritize, EPA should consider issuing TSCA Section 8(a) or 8(d) rules to require manufacturers/processors to collect existing information needed to prioritize. Finally, if EPA makes a determination subject to Section 4 requirements that new information is necessary to prioritize (and explaining why), EPA may issue Section 4 rules, orders or consent agreements. EPA should also be held accountable to using that information. The testing/exposure information EPA requires to be developed through Section 4 must be tiered. Finally, throughout the information gathering step, EPA should be asking whether it needs to "iterate" the information gathering process for prioritization, i.e., ask itself whether additional information should be gathered to designate a chemical as a high or low priority and if so to obtain it through the information gathering step process.

3. **Sufficient Information to Designate:** If EPA concludes it has sufficient information to designate the priority of a substance it can move that substance to the "Initiation of prioritization" step. If EPA concludes it has sufficient information to designate a substance as a high priority chemical, it should conduct a "pre-screening" review to identify potential data/information needs for scoping the risk evaluation (a bridging step between prioritization and scoping). If information on the chemical is deemed sufficient for scoping, the high priority chemical can then be put into the queue for "initiation" of the prioritization process at the appropriate time. If information is determined not sufficient for scoping, EPA should begin to collect/develop necessary information to scope the risk evaluation. This information screening "bridge" step should help EPA meet the 6-month statutory deadline for scoping a risk evaluation. However, this step would not replace either scoping itself or the anticipated need for EPA to collect other information during scoping. Further, it is not anticipated that this

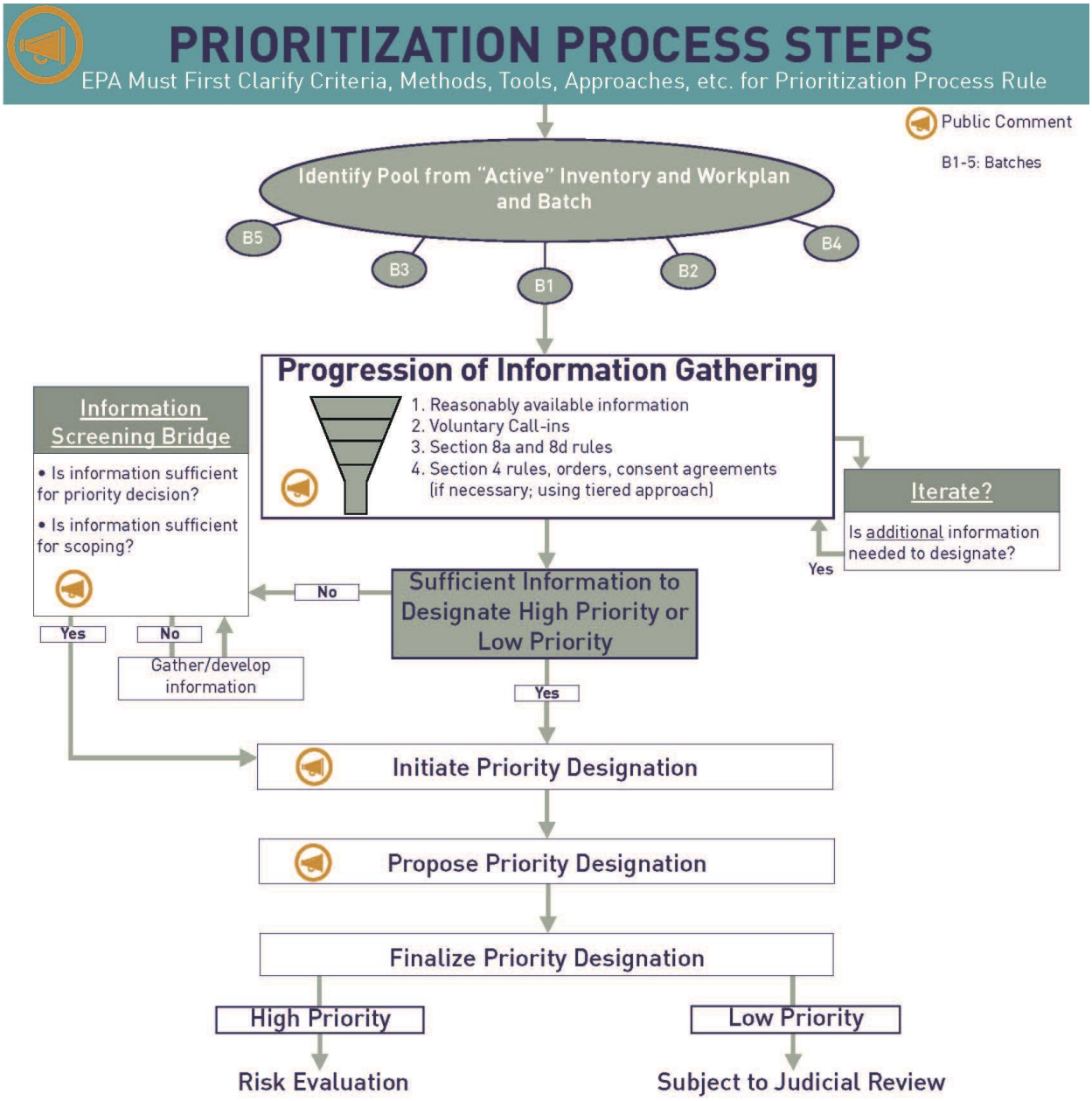
step will develop all the information it will need for risk evaluation. EPA will not necessarily know what information it may need for risk evaluation until it actually conducts it.

4. **Initiate the Priority Designation:** EPA must announce a candidate for prioritization and request "relevant information" about that chemical and provide 90 days for persons to submit that information to EPA. The LCSA deadlines for priority setting (no less than 9 months; no more than 12 months) begin at this step. EPA will "pace" its priority designations to be ready when risk evaluations are near completion and ready to be replaced with a new priority.

5. **Propose Priority Designation:** EPA must propose a designation of a chemical as a high or low priority, including the basis for its proposal, and provide a 90 day public comment period.

6. **Finalize the Designation of High Priority or Low Priority Chemical:** EPA must finalize its designation of the chemical as either a high or low priority within the statutory deadlines (no less than 9 months; no more than 12 months). Low priority chemical designations are final agency action, subject to judicial review. EPA must communicate final designations of high priority chemicals very carefully to prevent the creation of "red-lists" of chemicals and other mis-interpretations by states or the marketplace.

   To help EPA understand ACC's vision of the prioritization process, we have attempted to capture a simplified version of it in the flowchart below. (See comments' text for more details.)


PRIORITIZATION PROCESS STEPS
EPA Must First Clarify Criteria, Methods, Tools, Approaches, etc. for Prioritization Process Rule
Public Comment
B1-5: Batches
Identify Pool from "Active" Inventory and Workplan and Batch
B5
B3
B1
B2
B4
Progression of Information Gathering
1. Reasonably available information
2. Voluntary Call-ins
3. Section 8a and 8d rules
4. Section 4 rules, orders, consent agreements (if necessary; using tiered approach)
Iterate?
Is additional information needed to designate?
Yes
Information Screening Bridge
• Is information sufficient for priority decision?
• Is information sufficient for scoping?
No
Sufficient Information to Designate High Priority or Low Priority
Yes
No
Gather/develop information
Yes
Initiate Priority Designation
Propose Priority Designation
Finalize Priority Designation
High Priority
Low Priority
Risk Evaluation
Subject to Judicial Review

II. Overview of LCSA Prioritization Process Requirements

Sections 6(b)(1) and (2) of the LCSA address EPA's prioritization of chemical substances for risk evaluations. Section 6(b)(1) directs EPA to establish – by rule – a "risk based screening process," including criteria for designating substances as high or low priority for risk evaluations. The language at Section 6(b)(1)(A) specifies what EPA must "consider" in this process and it lays out criteria by which substances will be designated as high priority or low priority. These include "consideration of the hazard and exposure potential of a chemical substance or a category of chemical substances (including consideration of persistence and bioaccumulation, potentially exposed or susceptible subpopulations and storage near significant sources of drinking water), the conditions of use or significant changes in the conditions of use of the chemical substance, and the volume or significant changes in the volume of the chemical substance manufactured or processed."

Section 6(b)(1) prescribes: a timeframe (between 9-12 months) within which final prioritization designations must be made once EPA initiates the process; a requirement that EPA request interested persons submit "relevant information"; a time period (90 days from initiation of the prioritization process) for persons to submit information to EPA; a requirement that EPA propose its priority designation "along with an identification of the information, analysis, and basis" used to make the designation; and a 90 day public comment period on the proposed designation. There is also an opportunity to extend the deadline for submitting information to EPA if that information is required under Section 4, subject to certain limitations.

Section 6(b)(2)(A) makes clear that the prioritization process rule does not apply to EPA's identification of the first 10 high priority substances. Section 6(b)(2)(D), requires EPA to give "preference" to TSCA Work Plan chemicals that meet specific persistence and bioaccumulation criteria, are known human carcinogens and have high acute and chronic toxicity.

EPA's proposed prioritization process rule establishes four steps or phases in prioritization: 1) "pre- prioritization" during which EPA would narrow a pool of potential candidates for high or low priority designation, loosely based on application of nine criteria EPA used to identify the 90 Work Plan chemicals, and subject them to information gathering; 2) "initiation" of the prioritization process in which EPA would announce candidates as high or low priority and provide a 90 day public comment period; 3) EPA's "proposed" designation of chemicals as high or low priority (with EPA's basis) with another 90 day public comment period; and 4) EPA's "finalization" of the priority designations.

Three of EPA's proposed process steps for prioritization (initiation, proposal and finalization) are largely recitations of the statute. The first step, pre-prioritization, in contrast, represents EPA's attempt to create a pragmatic solution to the statute's tight timeframes that do not allow much time to collect or develop information needed for prioritization. However, EPA's proposed pre-prioritization step is opaque, leaving many questions unanswered about how it would work and whether it is in fact authorized by the LCSA.

III. EPA Should Clarify Pre-Prioritization Step in Final Rule or Alternatively in Supplemental Rule

EPA asserts that "TSCA does not limit how EPA must ultimately select a candidate chemical substance to put into the prioritization process"[5] and that it has "broad discretion"[6] to choose what chemicals to put into the prioritization process. Therefore, EPA proposes to select candidates from the TSCA Inventory based on both the policy objectives in preamble section III A (identifying high priorities with greatest hazard and exposure potential first; designating low priorities to "conserve resources for the chemical substances with the greatest potential risks"[7] and giving the public notice of substances for which potential risks are low or non-existent) and the pre-prioritization considerations in preamble section III F (the preferences for Work Plan Chemical designations, the high and low priority criteria in the LCSA Section 6(b), and the nine Work Plan criteria).[8]

This is as much detail as EPA has provided to explain the criteria that will underpin EPA's selection of candidates to go into the "pools" of candidates in the pre-prioritization step in the first instance. The regulated community needs more detail and clarity around this step since EPA suggests it will narrow its focus on chemical substances from the entire TSCA Inventory using these criteria.[9] The general public needs more detail to have confidence that EPA is using a transparent, credible prioritization process. Greater specificity is required regarding how EPA will select chemicals that go into the candidate "pools," how often EPA expects to identify new "pools" of candidates; how many chemicals will be in each "pool"; whether all candidate chemicals in a candidate pool move to initiation and if so, whether there are any timelines for EPA to move chemicals from the pool to the initiation step, etc. This information is important so the regulated community can plan to gather available information about the candidates and potentially budget to develop new information that may be needed for prioritization. Whether through this rulemaking or in a supplemental rulemaking, EPA should provide opportunity for public comment on the criteria and methods by which it will identify the pools of candidates for possible prioritization.

It is also essential that EPA provide greater clarity about the pre-prioritization step to ensure it is consistent with the LCSA requirements and congressional intent for a prioritization process screening rule. Pre-prioritization is not even mentioned in the LCSA. EPA describes pre-prioritization as the first step in the prioritization process, but later implies that it is in fact outside of the prioritization process for designating chemicals as high or low priority for risk evaluations.[10] EPA asks for public comment on whether and how EPA should solicit additional input at this pre-prioritization stage, but that is difficult to respond to in detail since it is not clear exactly how this pre-prioritization stage will function. There is no discussion of key steps in the pre-prioritization process other than EPA's discussion of narrowing the candidates through criteria, and gathering or developing information about these candidates.

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[5] 82 Fed. Reg. at 4831.
[6] Id. at 4830.
[7] Id. at 4829.
[8] Id. at 4830.
[9] EPA must correct this statement in the final rule because Congress intended EPA to identify substances from those classified as active in commerce during the Inventory Reset, not from the whole TSCA Inventory.
[10] 82 Fed. Reg. at 4831.

EPA must accurately communicate the purpose of the resulting list of "narrowed" candidates to prevent mis-interpretation of the significance of the listing. As EPA has made clear, prioritization is not a risk evaluation. Therefore, ACC suggests that EPA develop a neutral name to describe such a list of candidates for potential prioritization. One suggestion is to call it "Candidate Chemicals for Potential Information Gathering"

RECOMMENDATION: ***For all the reasons discussed above, ACC strongly urges EPA to publish a notice on these needed clarifications to the prioritization process, amending its original proposal and seek public comment on these before finalizing this rule. In the alternative, EPA should propose and finalize a supplemental rule containing detailed clarifications, definitions, criteria, methods, etc. before its first application of the prioritization process.***

A. EPA Should Update Its TSCA Work Plan Criteria Before Using Them in Pre-Prioritization of Non-Work Plan Chemicals and Should Begin Planning to Integrate 21st Century Tools

Although EPA distinguishes the TSCA Work Plan chemicals program from the LCSA's requirements, EPA has proposed using nine of the criteria it used in its 2012 TSCA Work Plan methodology (to identify Work Plan chemicals) as "considerations" it will use in pre-prioritization to initially narrow the pool of potential candidate chemicals that move into prioritization. EPA's proposal to use these qualitative list-based criteria for this purpose is not appropriate, since some of them do not fulfill the best available science standard required by Section 26 of the LCSA. For example, the persistence and bioaccumulation criteria that EPA used in its Work Plan methodology are out of date.[11] [12] [13]Another example is the criteria on detection in human and/or ecological biomonitoring programs. ACC recognizes the utility of biomonitoring data to understand potential for exposure, but mere detection in biomonitoring samples does not indicate that a risk is present; rather the information only suggests it must be considered in conjunction with hazard data to establish the relative priority of a substance for further assessment. Indeed, as future analytical capabilities continue to expand and detection limits are driven increasingly lower, using biomonitoring data in a meaningful way will be even more important to an efficient, thoughtful process that effectively directs resources to assessing chemicals of greatest priority.

Biomonitoring data is not only an important tool to verify exposures occurring among humans, it also can serve as a robust and irrefutable exposure metric that can be used quantitatively to calculate risks using Biomonitoring Equivalents[14] For example, Health Canada has utilized Biomonitoring Equivalents (BEs) as a tool for prioritization as part of their Chemicals Management Plan (CMP)[15] Likewise, Aylward et al. (2013)[16] have analyzed US based biomonitoring data from NHANES in the context of US EPA risk assessment (cancer and non-cancer) values using the

[11] SETAC Pellston Workshop on Science-Based Guidance and Framework for the Evaluation and Identification of PBTs and POPs.

[12] The Origin and Evolution of Assessment Criteria for Persistent, Bioaccumulative and Toxic (PBT) chemicals and Persistent Organic Pollutants (POPs), M. Matthies et al., Environ.Sci.: Processes Impacts, 2016, DOI 10.1039/C6EM00311G.

[13] Comparing Laboratory and Field Measured Bioaccumulation Endpoints, Burkhard et al, IEAM, Vol 8, Number 1, 2011.

[14] Becker RA, Hays SM, Robinson S, Aylward LL., 2012. Development of screening tools for the interpretation of chemical biomonitoring data. J Toxicol.; Article ID: 941082. doi: 10.1155/2012/941082.

[15] St-Amand, A., K. Werry, L.L. Aylward, S.M. Hays, A. Nong. 2014. Screening of population level biomonitoring data from the Canadian Health Measures Survey in a risk-based context. Toxicol. Letters. 231(2):126-34.

[16] Aylward LL, Kirman CR, Schoeny R, Portier CJ, Hays SM. 2013. Evaluation of biomonitoring data from the CDC National Exposure Report in a risk assessment context: perspectives across chemicals. Environ Health Perspect. 121(3):287-94.

corresponding BEs. Since data from NHANES is largely considered indicative of general population exposures, this approach can be a useful tool to determine whether general population exposures exceed EPA's reference concentrations (RfCs), reference doses (RfDs), or unit cancer risks. Although biomonitoring results can be an important component of prioritization, when BEs are available for substances under consideration by the Agency, they should be used to place biomonitoring concentrations into a health risk context. Such use is consistent with the LCSA mandate for EPA to employ best available science in a risk-based framework for priority setting under TSCA.

EPA should establish a criteria-based approach to narrowing the pools of candidate chemicals for prioritization that is representative of the current state of knowledge with the opportunity to update this approach to reflect new science developments. Nowhere in EPA's proposal does it reference any of the 21st Century hazard and exposure based tools that EPA might use to identify either the pools for the prioritization process or to narrow the candidates in the prioritization pool. Tools developed by EPA's Office of Research and Development – such as ToxCast, ExpoCast, SHEDs-HT,etc. – hold particular promise in the near term for prioritization screening activities. Further, EPA should make certain that the databases underpinning some of its qualitative criteria are current, e.g. the Household Products Database as a source of information about presence of chemicals in consumer products. Finally, EPA should consider and review the details of risk assessment developed for other regulatory regions, such as Canada and the EU as source for designating high and low priority chemicals.

RECOMMENDATION: EPA should update and fine-tune its current TSCA Work Plan criteria (e.g. persistence and bioaccumulation; biomonitoring) and databases before implementing its prioritization process. In addition, EPA should consider the applying 21st Century tools and begin the planning needed for OCSPP to integrate these into the prioritization process when they are ready to be used for these purposes. EPA should also consider the risk assessments developed for other regulatory regions such as Canada and the EU as sources for designating high and low priority chemicals.

B. EPA's Proposed Use of the Pre-Prioritization Step to Gather Information for Risk Evaluations Needs to Be Better Supported and Articulated

One of the most surprising elements of EPA's proposed prioritization process rule was the discussion of its plans to use a pre-prioritization step to gather information for risk evaluations on substances with "insufficient information" for risk evaluation.[17] EPA has authority under Section 8 of TSCA to gather existing information about chemicals and under Section 4 to develop new information when needed for risk evaluations. EPA's plan to address risk evaluation information needs, even before a chemical is prioritized, raises several significant concerns, however. First, the proposal has the potential to create "fishing expeditions" for data. Second, it is an unrealistic expectation for EPA to think it could know at the pre- prioritization stage what information it might need to begin gathering/requiring for risk evaluation – well before it has even designated the chemical as a high priority. Finally, EPA has failed to discuss the limitations in Section 4 on EPA's authority to require industry to develop new information for risk evaluations (e.g. EPA must issue statements of need). ACC's concerns are exacerbated by the fact that EPA's discussion of this proposed activity during the pre-prioritization step is vague.

[17] "For chemicals with insufficient information to conduct a risk evaluation, EPA generally expects to pursue a significant amount of data gathering before initiating prioritization." 82 Fed. Reg. at 4828.

ACC is well aware that information about potential hazards and potential uses and exposures of a chemical is critical to sound decision-making by EPA – for both prioritization and risk evaluation decisions. ACC is also well aware of the aggressive timeframes within which both prioritization and risk evaluations must be conducted. ACC strongly believes that both prioritization and risk evaluation processes are more efficient if they use iterative and tiered processes and that these processes help ensure science-based decision-making. ACC recommends therefore that EPA clearly distinguish in the prioritization process rule those elements that are specific to gathering of reasonably available information and those elements relating to the development of existing or new information through TSCA Sections 8 and 4.

For example, information gathering about candidate chemicals for high and low priority designations should be clearly sequential and iterative. EPA should first gather reasonably available information about potential hazards, uses and potential exposures of a candidate chemical and integrate that information. Sources of such information could include: QSAR and read-across information; information from the Chemical Data Reporting (CDR) and from EPA's Dashboard; information from the TSCA Work Plan Chemicals program as well as from other EPA efforts to develop and assess chemicals such as EPA's High Production Volume (HPV) Challenge Program, its Voluntary Children's Chemical Evaluation Program (VCCEP) and its Chemical Assessment and Management Program (ChAMP); exposure scenario information –both actual or estimated from exposure models; information from Canada's Chemical Management Program (CMP) and from the European Chemical Agency's (ECHA) robust study summaries developed for REACH; and REACH use scenarios (though EPA must be cognizant of potential differences in EU and U.S. use scenarios and address these through U.S.-centric use mapping).

As EPA is gathering reasonably available information, it could also request voluntary submission of information about a candidate chemical's potential hazards, uses and exposure from manufacturers, processors, distributors and users of candidate chemicals. It should invite discussions with manufacturers, processors, distributors and downstream users of a candidate chemical.

If EPA concludes after it has implemented those initial information gathering steps that it still needs more information to prioritize, it should then turn to its Section 8(a) and 8(d) rule authority to seek additional existing information. Only if after using its Section 8 authority EPA determines that new information is necessary to prioritize should EPA then consider using its Section 4 test rule/order or consent agreement authorities to develop that information. Section 4 imposes limitations on when EPA can develop new information for prioritization. Congress generally expected EPA to base prioritization decisions on reasonably available information. EPA should acknowledge these limitations in the final rule – both in the preamble and the rule itself.

Once EPA can make a preliminary determination that it has sufficient, integrated hazard, use and exposure information to designate a candidate chemical as a low or high priority, EPA should use a "bridging" step for chemicals being considered as high priority candidates before prioritization is actually initiated. At this "bridging" step, the Agency could consider whether it has sufficient information to "scope" a risk evaluation of the chemical. In this step, EPA might conduct a screening review of the candidate chemical to ascertain what additional hazard, use and exposure information might be needed to scope a risk evaluation of a high priority candidate. If information is identified as needed, and could be gathered/developed at this stage, the Agency could seek to obtain it. EPA's expectation that it can obtain all the information it needs to conduct a risk evaluation at the "pre-prioritization" stage, however, is unrealistic. EPA will have to consider other approaches to efficiently meet the risk evaluation process's statutory deadlines.

To address preliminary "insufficient" information findings, an additional "iterative" step might also be useful. Such a step might allow the Agency time to pursue different avenues for information before automatically defaulting to a high priority designation based on a finding of "insufficient" information to designate a candidate as a low priority. EPA's preamble discussion of the sufficiency or insufficiency of information to designate high or low priorities for risk evaluations is conclusory at best.[18] EPA provides little indication how it will decide whether the available information it has or can gather is sufficient or not; and what it will take to be considered "sufficient." EPA must provide greater clarity here, as well as for purposes of EPA's determination of the need for new information and its use of Section 4 in priority setting. ACC's comments on the proposed risk evaluation rule provide a definition of "sufficiency of information" that might be adaptable to the prioritization context.[19] ACC urges EPA to better explain the application of this concept more fully in the prioritization process rule.

Finally, the Section 4 "statement of needs" requirement must be met if EPA concludes it can't prioritize without the development of new information. Overall, information gathering and information development at any stage in the prioritization process should use tiered and iterative processes for greater efficiencies, for meeting animal welfare requirements, and for meeting statutory deadlines. Integration of hazard, use and exposure information in a risk-based screen is also essential to prioritization which Congress intended would be a risk-based screening process, not a risk evaluation.

RECOMMENDATION: ***EPA should use tiered, iterative approaches to information gathering/development in the prioritization process rule. EPA should also carefully delineate the requirements imposed on EPA to make determinations of need for new information in prioritization and statements of need for risk evaluations, as required by Section 4 of TSCA. EPA must also integrate hazard, use and exposure information in its prioritization risk based screening process.***

C. The Importance of Transparency in Prioritization Cannot Be Over-Emphasized

As discussed above, there are many questions that the Agency must answer in its final rule concerning the specific steps of the prioritization process. Many of these steps also raise transparency issues. One of the most fundamental transparency issues that the Agency needs to address in the prioritization process is adequate notice to manufacturers and processors at critical points in the process.

While it may be obvious that EPA would provide notice and request for comment/input once a chemical is in a "pool" or narrowed to be included in a "batch" to be prioritized, the Agency should also provide earlier notice about what groups of active chemicals in commerce from which it plans to identify potential candidates for prioritization. The Agency should also explain the methodology it will use to narrow and refine the pool of candidates. With each pool of candidates, the Agency should explain how it applied its methodology to narrow that pool and how it plans to "batch" them for efficient prioritization screening. The Agency should be clear about the number of chemicals it will address in each "batch" and how much time it will provide to gather information about a chemical in a batch.

[18] Id. at 4830 and 4831.

[19] Sufficiency of information means that, taking into account the importance of the determination, the Agency has appropriately relied on the best available science, considering the weight of the scientific evidence to make a reasoned and transparent fit-for-purpose determination.

Transparency in the prioritization process is critical to enable the regulated community to understand the Agency's methodologies, criteria and processes and to better plan how they should prepare in advance. In addition, transparency is critical to instill public trust and confidence in the determinations ultimately made by EPA. Much of the pre-prioritization process is opaque as proposed. Without more transparency, the rule establishing the prioritization process risks being unduly vague and EPA's actions under it both arbitrary and capricious.

RECOMMENDATION: ***Greater transparency is a central tenet of the LCSA. EPA must provide as much early notice as possible in the prioritization process, including about the methodology, criteria and processes it will use to select a "pool" of candidates for potential prioritization, to narrow and "batch" these pools, and its anticipated timing for announcing pools and narrowing batches, and about requiring information to be gathered, etc.***

IV. EPA's Interpretation of Its Authority to Designate Low Priority Substances Is Short-Sighted, Contrary to Congressional Intent, Inconsistent with Best Available Science and Must Be Revised

A. EPA's Interpretation of Conditions of Use in the Prioritization Context Is a Strained Reading of the Statute and Contrary to Congressional Intent and Policy Objectives.

Under the LCSA, EPA must designate chemicals as high or low priority for risk evaluations. The key criteria by which EPA must determine whether a chemical is a high or low priority, however, are its hazard potential and exposure potential **under its conditions of use** and significant changes in the conditions of use. EPA's proposed prioritization process rule allows high priority chemicals to be designated as such based on a single condition of use, but requires all low priority designations to be based on "**all** conditions of use." This requirement for low priority designations is not mandated by the LCSA and was not intended by Congress. EPA concludes that the standard for a low priority chemical "effectively requires EPA to determine that under no conditions of use does the chemical meet the high priority substance standard."[20] This proposed standard for designating low priority chemicals is such a high hurdle even EPA admits "it will be more difficult to support such designations."[21]

EPA bases its reasoning for its proposed approach to low priority designations on a cramped reading of the LCSA Sections 6(b)(1)(B)(i) and (ii) provisions on identification of high priority and low-priority substances and on its broad interpretation of the term "conditions of use" throughout its proposed implementation of the LCSA to mean "all" conditions of use. ACC discusses this same EPA interpretation of "conditions of use" in depth in ACC's comments on EPA's proposed risk evaluation process rule.[22]

In the preamble to the proposed prioritization process rule, EPA first emphasizes that Section 6(b)(1)(B)(ii)'s provision for designating a substance as a low priority must have "information sufficient" to establish that a substance does not meet the (B)(i) standard for designating a chemical as a high priority chemical. EPA discusses its rationale for concluding it can designate high priority

[20] 82 Fed. Reg. at 4830.
[21] Id.
[22] American Chemistry Council Comments on the Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act (RIN 2070-AK20).

chemicals under "a single condition of use, provided the hazard and exposure potential associated with that single use support such a designation."[23] But EPA then creates a "converse" construct of the high priority designation standard to support its position on low priority designations. EPA concludes that since it can designate a chemical as a high priority because of the Section 6(b)(1)(B)(i) language, "***a*** potential hazard and ***a*** potential route of exposure under ***the*** conditions of use,"[24] that low priorities can be so designated only if they don't meet this high priority standard under ***all*** conditions of use. This argument in the "converse" coupled with EPA's interpretation of "the" conditions of use to mean "all" conditions of use is strained and counter to Congressional intent.

A better interpretation is that a chemical could be designated low priority if it **does not** meet the "may present an unreasonable risk" high priority standard for "a" potential hazard or "a" potential route of exposure ***under a, some, or all conditions of use.*** EPA has flexibility here that it needs to apply, given the 6(b)(1) requirement for EPA to designate chemicals as low priority and the important policy objectives for low priority designations.[25] EPA's strained reading of the phrase "conditions of use" in designating low priority chemicals is wholly at odds with congressional intent to help the Agency focus its risk evaluation resources on high priority chemicals and conditions of use that raise the greatest potential for risk. [26] Further, EPA's reference to its Safer Chemicals Ingredients List (SCIL)[27] as a starting point for identifying low priority chemicals is disingenuous since the SCIL list does not represent all conditions of use of those chemicals.

A chemical under certain conditions of use may warrant a risk evaluation while that same chemical under other conditions of use may not warrant a risk evaluation at all. EPA should not have to scope a risk evaluation or conduct risk evaluations on most chemicals under all conditions of use before it can conclude that a certain use is not likely to present an unreasonable risk. EPA should be able to set aside chemicals for certain conditions of use through low priority designations where EPA concludes that the chemical does not meet the "may" present standard for those conditions of use. Designating low priorities for risk evaluations based on less than "all" conditions of use will help EPA meet its deadlines for scoping risk evaluations, will conserve resources, and will enable EPA to focus its risk evaluation efforts on chemicals that meet the high priority criteria under certain conditions of use. EPA has authority to determine that certain conditions of use of a chemical are likely to have low potential for risk and can be designated as "low priority" for risk evaluation. EPA should use this authority to help it focus its risk evaluations on chemicals designated as high priority under certain conditions of use.

B. EPA's Abuse of Discretion Argument

EPA provides as its rationale for addressing all conditions of use in the low priority designation process that EPA "considers that it would be an abuse of that discretion to simply disregard known,

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[23] 82 Fed. Reg.at 4830.

[24] 15 U.S.C. 2605(b)(1)(B)(i) (emphasis added).

[25] 82 Fed. Reg. at 4829, Section IIIA notes "conserving resources" and giving "the public notice of chemical substances for which potential risks are likely low or nonexistent," as important policy objectives.

[26] See Senate Congressional Record, June 7, 2016, at page 3519, in which Senator Vitter states: "The language of the compromise makes clear that EPA has to make a determination on all conditions of use considered in the scope but the Agency is given the discretion to determine the conditions of use that the Agency will address in its evaluation of the priority chemical. This assures that the Agency's focus on priority chemicals is on conditions of use that raise the greatest potential for risk. This also assures that the Agency can effectively assess and control priority chemicals and meet the new law's deadlines. Without this discretion to focus chemical risk assessments on certain conditions of use, the Agency's job would be more difficult." https://www.congress.gov/crec/2016/06/07/CREC-2016-06-07-pt1-PgS3511.pdf

[27] 82 Fed. Reg. at 4830.

intended or reasonably foreseen uses in its analyses."[28] This rationale is specious. In addition to the points raised in ACC's comments on EPA's proposed risk evaluation process rule concerning "reasonably foreseen" uses, Congress anticipated that the prioritization process would be an iterative process, not a "one and done" process as EPA wishes to construct (except when it does not, as in its discussion of revisions to priority designations).

EPA has the authority to designate chemicals as low or high priority based on reasonably available information. The Agency can rely on new information where necessary, and should seek "sufficient" information, but EPA does not need "perfect" or "complete" information on "all" known, intended or reasonably foreseen conditions of use at the prioritization stage. EPA can return to a chemical later in time and designate it as a high priority for a condition of use not addressed in the original priority designation. EPA has the authority to focus its priority designations and its risk evaluations on certain conditions of use.

Rather than an abuse of discretion, it would be a proper exercise of EPA's discretion -- given the many conditions of use of some chemicals, the aggressive deadlines which Congress established in the LCSA, and the limitations on EPA resources – for EPA to focus on even a single condition of use when designating the priority of a chemical for a risk evaluation. In fact, it might be an abuse of discretion if EPA insists on assessing "all" conditions of use and that decision jeopardizes the intended purpose of the LCSA to focus the Agency's risk evaluation efforts on a chemical's risks under its conditions of use in order to produce timely, high quality risk based decisions on chemicals. In its proposed rule's treatment of low priority designations, EPA has chosen an interpretation that violates other sections of the LCSA such as the statutory deadlines for the prioritization process as a whole.

C. EPA's Default to High Priority Designations Is Flawed Due to EPA's All Conditions of Use Interpretation.

If the Agency concludes it has insufficient information to designate a chemical as a low priority, EPA proposes that the chemical automatically default to a high priority designation.[29] While there is a sound policy basis for this principle – to create incentives for the timely development of hazard, use and exposure information for prioritization purposes – the application of this policy will undermine the ability of the Agency to make low priority designations. Further, the fact that EPA would make this default determination at the proposed "pre-prioritization" step implies that EPA will seldom initiate low priority designations during the official prioritization process, as Congress envisioned. EPA's ability to focus its risk evaluation resources will be seriously challenged.

To avoid this result, EPA should amend its inflexible "all" conditions of use requirement and consider creative solutions to improve the Agency's ability to make low priority designations, consistent with the statute. Here are some suggestions for EPA's consideration:

- Add an iterative step to allow another opportunity for development of sufficient information to support low priority designations.
- Develop criteria to allow for low priority designations under certain conditions of use, e.g., uses of low concern polymers; conditions of use of a chemical already regulated under other statutes, e.g., disposal under RCRA; etc.

[28] Id. at 4829.
[29] 82 Fed. Reg. at 4827.

- Make revision of high priority designations to low priority more efficient. Low priority designations can be triggered for potential revision to high priority designation (within the confines of the prioritization process) purely on the basis of new information. But high priority designations can only be revised to be a low priority after going through a complete risk evaluation. In light of the value of low priority designations to conserving EPA's resources, EPA should consider whether there are faster, more efficient ways in which EPA could revise a high priority designation to low priority, e.g. after the information screening "bridge" step before scoping the risk evaluation, discussed above.

D. Congress Authorized Ongoing Designations of Low Priority Chemicals

In the preamble to the proposed rule, EPA discusses the LCSA's requirement that it continue to designate high priority substances. The Agency then asserts that there is no "comparable requirement to continue designating additional Low-Priority Substances" after three and one half years from enactment.[30] This conclusion is flawed.

A better reading of LCSA Section 6(b)(2)(C) is that ongoing designations are expected of both high and low priority substances. The section does not distinguish between high and low priorities but instead says, "The Administrator shall continue to designate ***priority substances*** …" Even under the EPA's apparent reading of this provision, nothing in the LCSA prevents EPA from continuing to designate low priorities, and it is manifestly in EPA's best interests to do so. Congressional intent for continuing designations of low priorities is also clear.[31]

While EPA contends that "the statute does not require EPA to designate more than twenty Low-Priority Substances," it also admits that "doing so ensures that chemicals substances with clearly low hazard and exposure potential are taken out of consideration for further assessment, thereby conserving resources for the chemical substances with the greatest potential risks. There is also value in identifying Low- Priority Substances as part of this process, as it gives the public notice of chemical substances for which potential risks are likely low or nonexistent, and industry some insight into which chemical substances are likely not be regulated under TSCA."[32] The more low priority designations EPA can make, the better focused will be EPA's risk evaluations of high priority chemicals. EPA should specifically acknowledge its continuing designations of both high and low priority substances in the rule itself.

E. Best Available Risk-Based Scientific Procedures Enable EPA to Designate Low Priority Chemicals

Risk-based prioritization approaches, using fit-for-purpose science-based procedures to integrate toxicity information with exposure information have been employed successfully by Canada to prioritize the 23,000 substances on the Canadian Domestic Substances List (similar to U.S. TSCA Inventory). Of these 23,000 substances, Canada determined that less than 20% required further assessment, resulting in setting aside approximately 19,000 as low priority. If EPA used similar best available scientific risk-based procedures to prioritize chemicals, the Agency should be

[30] 82 Fed. Reg. at 4827.

[31] Senate Committee on Environment and Public Works Report 114-67 to accompany S. 697, at pages 11-12. https://www.congress.gov/114/crpt/srpt67/CRPT-114srpt67.pdf

[32] 82 Fed.Reg. at 4829.

able to differentiate low priority from high priority substances efficiently and effectively. As noted above, differentiating and designating Low-Priority Substances—chemicals with clearly low hazard and exposure potential—enables the Agency to communicate to the public and the commercial sector those chemical substances for which potential risks are likely low or nonexistent. The scientific methods and procedures are available, or will soon be available in the case of 21st Century Tools, for EPA to conduct risk based prioritization, and the Agency should make use of these best available scientific tools for prioritization.

RECOMMENDATION: ***For all the reasons discussed above, EPA should revise its proposed rule to make clear that the Agency has broad and flexible authority to designate chemicals as low priorities for risk evaluations based on a, some or all conditions of use.***

V. Scientific Standards Must Be Referenced in the Prioritization Process Rule

A. Prioritization Decisions Must Be Based on Section 26 Standards for Best Available Science, Weight of the Scientific Evidence, and Transparency

Pursuant to Section 26 of the LCSA, EPA must ensure that its high and low priority designations under Section 6(b) are based on the best available science and the weight of the scientific evidence and that it make the basis of its decisions available to the public. Because these are prioritization decisions, however, it is ACC's expectation that EPA's application of these standards would be "fit for the purpose" of prioritization as opposed to risk evaluation. For example, greater uncertainty and more conservatism in the "best available science" information that is used for prioritization purposes may be anticipated. Prioritization decisions might be made on the basis of estimated information from an exposure model while a risk evaluation decision might require actual exposure information in some cases.

ACC urges EPA to reference the Section 26 science standards in the prioritization process rule in order to hold itself accountable to meet these standards within its Section 6 decisions designating high and low priority substances for risk evaluations. The Sections 26 (h), (i) and (j) provisions are legally mandated requirements of the LCSA and are equally applicable to the prioritization process and risk evaluation "rule" requirements. Including references to these sections in the rule itself would aid understanding and application of these requirements by EPA, the regulated community and stakeholders. This in turn would better ensure consistency in EPA's prioritization decisions over time, and ultimately enhance the credibility of these decisions. Importantly, because EPA's low priority designations are subject to judicial review, clarity on the application of EPA's science standards is necessary.

If Congress had intended the scientific standards of "best available science" or "weight of the scientific evidence" to be incorporated into guidance alone, it would have included them only in Section 26(l) on "policies, procedures and guidance." In addition to including these standards in the prioritization rule, EPA can certainly also describe some of the details of its prioritization methodology and decision making process in later-developed guidance.

Inclusion in the rule of specific references to Sections 26(h), (i) and (j) requirements about the scientific information, methods, models, characterization of uncertainty of information to prioritize, and use of weight of the scientific evidence to make decisions, puts the regulated community on notice about the quality of the information needed for EPA to support sound prioritization decisions. If EPA only includes references to these standards in guidance, it implies that EPA could ignore

these requirements if it chooses to do so. This is not the case.

B. EPA Should Address Other LCSA Science-Based Requirements in the Rule (Such As Tiered Testing and Animal Welfare Requirements). EPA Should Also Include a "Reserved" Placeholder in the Prioritization Rule for Incorporation of 21st Century Methods for Prioritization.

Section 4(a)(4) of the LCSA requires EPA to use tiered testing and assessment approaches when EPA needs to develop new information under this section. EPA should include this requirement in its prioritization process rule at the appropriate steps.

Similarly, Section 4(h) requires the Agency to promote the development and incorporation of new scientifically valid test methods that are alternatives to testing of vertebrate animals. These types of methods may be of particular early importance to EPA during the prioritization process and therefore should be referenced in the rule. The Senate Environment and Public Works Committee's Report clearly articulated the importance of the animal welfare provisions in its report on the Senate approved legislation, S. 697, that preceded the development of the House and Senate compromise in the LCSA:

"[The Act] includes extensive provisions by which EPA is to minimize the use of animals in testing under TSCA. EPA is to consider integrated testing strategies, greater efficiencies in testing through category approaches and formation of consortia, tiered testing and assessment strategies, and alternative testing methods, among others. Importantly, EPA is to develop a strategic plan to promote the development and implementation of reliable test methods to reduce, refine, or replace the use of laboratory animals.[33]

Finally, EPA's Office of Research and Development has been working on 21st Century methods (high throughput hazard and exposure tools like ToxCast and ExpoCast) that scientists believe will be of great value to EPA's prioritization efforts under the LCSA in the near future. EPA should include a "reserved" section in the prioritization process rule to allow the Agency the opportunity to include references to these tools.

VI. Responses to EPA's Questions

A. Animal welfare requirements and scientific standards

EPA requests comment on pros and cons of codifying Section 4 animal welfare requirements and Section 26 scientific standards and definitions in the prioritization procedural rule. ***Response:*** These are legal requirements of the LCSA and so should be incorporated into the rule rather than solely in non-binding guidance. Putting these into guidance alone suggests that EPA views these requirements as not being mandatory, which is not correct. ACC sees no downside to codifying these requirements into the rule. EPA's rationales for not doing so – these requirements are applicable without inclusion in a rule; EPA is not directed to implement these requirements by rule; and these requirements can be addressed in guidance – miss the point. The upsides are many:

- Codifying them in the rule will provide the regulated community, the

[33] Senate Committee on Environment and Public Works Report 114-67 to accompany S. 697, at page 10. See also Congressional Record S3520 (June 7, 2016) (Statement of Senator Inhofe on section 4 during the Senate debate on LCSA). https://www.congress.gov/crec/2016/06/07/CREC-2016-06-07-pt1-PgS3511.pdf

broader stakeholder community and EPA itself greater certainty about what EPA must rely upon in making prioritization designations

- Codifying these requirements in the rule will assure consistency in EPA's prioritization decisions
- All of the above will enhance the credibility of EPA's prioritization decisions.

B. EPA requests comments on its proposed process for prioritization overall.

Response: First, EPA relies heavily upon the "pre-prioritization" step in the process rule, but provides very little detail about how it would function. As recommended above, EPA must clarify this step and should publish a notice with more details and seek public comments on it before finalizing this rule. Alternatively, EPA should propose and finalize a supplemental rule to provide the necessary level of detail before EPA's first application of the prioritization process.

Second, EPA's process for prioritization overall seems resigned to codifying a "slow road" to prioritization by a) ignoring the value of low priority designations; and b) lining up high priority chemicals to wait for what EPA envisions as a slow risk evaluation throughput. EPA's prioritization process, in other words, lacks vision for the potential future throughput of the program. The role of 21st century tools will help the Agency both prioritize chemicals and evaluate the risks of high priority chemicals, consistent with Congress's intent that the Agency make timely decisions.

C. Public input at pre-prioritization step

EPA requests comment on whether and how EPA should solicit additional input at the pre-prioritization phase." ***Response:*** It is not only appropriate, but well advised for EPA to solicit public input at each stage of the prioritization process. From a "data quality" perspective it is important for the public to have the opportunity to comment on the data/information that EPA believes is relevant to prioritization of chemicals for risk evaluation. As discussed in our comments above, ACC believes EPA must take a sequenced, step-wise approach to gathering available information and/or developing new information in the pre- prioritization stage. It makes sense for EPA to first gather reasonably available information, then solicit public input to identify additional data/information from stakeholders, on a voluntary basis. Then EPA should use reporting tools under Section 8 for additional existing information if needed. Only after using these approaches should the Agency consider ordering the development of new information for prioritization purposes, subject to the requirements of LCSA Section 4.

D. Consideration of substitutes in pre-prioritization

EPA asks "whether and how information on the availability of chemical substitutes should be taken into account during this phase [pre-prioritization] of the prioritization process". ***Response:*** Substitutes are not relevant to and should not be considered in the prioritization process. Both the LCSA and EPA's proposed prioritization process rule (at 702.11(b)) make clear that EPA cannot consider "non-risk factors" as part of prioritization. The availability of "substitutes" is a "non-risk factor." Alternatives can certainly be taken into account in the risk management stage, after the risk evaluation, but do not have a role in the prioritization process.

VII. Additional Specific Comments

A. Category of Chemical Substances

LCSA Section 6(b)(1)(A) specifically authorizes EPA to prioritize a category of chemical substances in its prioritization process and EPA's proposed rule at Section 702.1(c) makes clear that nothing in the prioritization procedures should be interpreted as a limitation on EPA's existing TSCA Section 26(c) authority for EPA to take actions on categories of chemicals. The term "category of chemical substances" was already defined in TSCA Section 26(c).

Therefore, it will underpin any prioritization of categories that EPA might undertake.[34] EPA's proposed prioritization process rule does not otherwise address the category issue, but ACC urges EPA to take note that in the prioritization (and risk evaluation) contexts, chemicals in a category may not all have the same hazards, applications or conditions of use, so there will be questions about how EPA would address the hazard and use profiles in the prioritization context. It will be critical for EPA to ensure that any category approach taken is science based. Further, it is very important that EPA be transparent when it contemplates category approaches to prioritization so that stakeholders can fully understand all the factors leading to EPA's consideration of a category of chemicals for prioritizing for risk evaluations.

B. Inactive chemicals and new chemicals

EPA makes clear in the preamble that "all chemical substances listed on the TSCA Inventory are subject to prioritization"[35] and that it has authority to prioritize both new chemicals and inactive chemicals for risk evaluations under Section 6.[36] The Agency also notes, however, that EPA does not expect new chemicals to be high priority candidates because EPA will be making risk determinations about new chemicals under Section 5.

The Agency also notes that the Inventory Reset rulemaking will distinguish active from inactive chemicals in commerce, which will "inform EPA's exposure judgments during the prioritization process."[37] ACC interprets EPA's discussion to suggest that prioritization of inactive chemicals is anticipated to occur only in exceptional cases. Inactive chemicals, under the Inventory Reset definition, will not have been in commerce for the past 10 years, so prioritization of these will likely be reserved for "legacy" chemical issues, e.g., those whose disposal conditions may at some later point in time suggest the need for an updated TSCA risk evaluation to derive a risk management clean-up standard.

It is ACC's view, however, that the broader directive to EPA in the LCSA is to focus its prioritization process on the designation of high and low priority chemicals that are active in commerce; and that the scope of the risk evaluation should focus on chemicals under those conditions of use that present the greatest or lowest potential for both toxicity and exposure.

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[34] TSCA 26(c) (15 U.S.C 2625(c)) defines "category of chemical substances" as a "group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this chapter, except that such term does not mean a group of chemical substances which are grouped together solely on the basis of their being new chemical substances."

[35] 82 Fed.Reg. at 4830.

[36] Id.

[37] 82 Fed. Reg. at 4830.

C. Waivers

EPA has proposed that all comments that could be raised on issues in a proposed low priority designation be presented during the comment period, and that any issues not raised then be considered to have been waived. Waived issues could not form the basis of an objection or challenge in any subsequent administrative or judicial proceeding on the designation of the substance as a low priority substance (which is subject to judicial review). EPA points to the statutory deadlines in the prioritization process as the policy justification for this proposal.[38]

ACC urges EPA to remove this waiver requirement from the prioritization rule. First, it is inconsistent with Congress's intent that the prioritization process be iterative and science-based. Low priority designations should be able to be modified – expanded or contracted – based on new information that is brought to the Agency's attention after the designation. This new information might not have been known during the public comment period on the low priority designation. It would be bad public policy to consider new information waived because that could discourage stakeholders from gathering or developing relevant information about a chemical. Second, participation in the notice and comment rulemaking process of prioritization is governed by statute – through the Administrative Procedures Act (APA) and the judicial review provisions of Section 19 of TSCA. There are no issue exhaustion provisions in TSCA. EPA cannot by regulation, impose an issue exhaustion requirement that trumps the statutory rights and obligations of stakeholders under the APA and TSCA Section 19.[39]

D. Definitions

As an addendum to ACC's recommendations for EPA to reference the Section 26 science standards in the prioritization process rule, ACC offers the following definitions for EPA's consideration:

- **Best available science** means information that has been evaluated based on its strengths, limitations and relevance and the Agency is relying on the highest quality information. In evaluating best available science the Agency will also consider the peer review of the science, whether the study was conducted in accordance with sound and objective practices, and if the data were collected by accepted methods or best available methods. To ensure transparency regarding best available science the Agency will describe and document any assumptions and methods used, and address variability, uncertainty, the degree of independent verification and peer review.
- **Weight of the evidence** means a systematic review method that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.

[38] Id. at 4833.

[39] See ACC Comments on EPA's Proposed Rule: Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act (RIN 2070-AK20) for additional discussion of the waiver/lock down/issue exhaustion issue.

E. Repopulation of High Priority Substances

EPA's preamble discussion of the "repopulation" of high priority substances[40] presents a reasonable approach by which the Agency could meet the LCSA obligation to finalize the designation of one new high priority substance upon completion of a risk evaluation for another substance. The one-for-one approach makes sense as this program gets underway.

ACC suggests, however, that EPA consider a placeholder in its rule to anticipate changes in the rate at which EPA might be able to conduct risk evaluations over time (based on use of 21st Century tools and methods) and hence potentially change the rate at which EPA may need to designate high priorities for risk evaluation.

VIII. Summary of ACC's Recommendations:

Throughout these comments, ACC has included many specific recommendations for EPA to consider as it develops its final prioritization process rule to address ACC's concerns about the proposed rule. These recommendations urge EPA to direct its authority on what it is mandated to do under the LCSA – designate high priority and low priority chemicals for risk evaluations in accordance with both the criteria in LCSA Section 6 and the LCSA Section 26 science based standards. To help the regulated community provide EPA the information the Agency will need to prioritize chemicals for risk evaluations, EPA must clarify the prioritization process as a whole and develop an efficient and focused prioritization process rule that meets the LCSA mandate and Congressional intent.

ACC strongly urges EPA to amend its proposal to include these suggested recommendations and seek public comment before finalizing the prioritization process rule. Alternatively, EPA should propose a supplemental rule providing more detail and clarifications on the prioritization process steps involved and finalize it prior to the Agency's first application of the prioritization process . To help foster the submission of information needed to prioritize chemicals for risk evaluations, EPA must ultimately develop an efficient and focused prioritization process rule that clearly lays out the major steps for meeting its mandate.

[40] 82 Fed. Reg. at 4833.

ACC's General Principles on Prioritization

(Developed for EPA Dialogue 7-2011)

- EPA should **systematically prioritize** chemicals for purposes of safe use determinations.
- As a general matter, prioritization should be based on **existing hazard and exposure data and information (including models, read across, QSAR, etc.)** and **industry should be responsible** for providing EPA with this data and information.
- Chemicals **lacking adequate hazard and exposure** information should be considered **a higher priority** (until relevant information is provided that suggests otherwise).
- Industry should be provided an **opportunity to provide EPA additional data/information.** (Timing is an issue, however. And the format in which the information is provided to EPA must be useable/digestible by EPA, e.g. robust summaries.)
- **Hazard, use and exposure based criteria should be integrated** to form the basis for EPA's prioritization decisions. Prioritization should not be based on either hazard-only or exposure- only information.
- The prioritization process and science based criteria that EPA uses to prioritize chemicals must be **transparent.**
- Prioritization should be a **dynamic, iterative process**. Re-examination of priorities should occur as new information becomes available and as new chemicals are approved for manufacturing.
- For prioritization to be successful, it must include three critical elements: **reliable and up-to- date chemical data and information; evaluation criteria that consider both hazard and exposure information together; and established cutoffs to make priority decisions.**
- **EPA's communication about priority chemicals must be clear about what the list is and what it is not, to avoid unintended consequences of product de-selection** purely on the basis of listing.
- **Transparency; consistent, scientific criteria; intersection of both hazard and exposure information; dynamic process** so new information can be incorporated as it is made available and so if priorities are initially "wrong" they can be corrected.

Attachment B

ACC Prioritization Screening Approach

I. Introduction

This document provides background on ACC's approach to chemical prioritization screening. The approach is based on the following general principles:

- The purpose of this approach is to identify substances as priority to receive more detailed evaluation and assessment which, when conducted, could possibly lead to risk management measures.
- Apply a science- and risk-based approach, considering both the degree of hazard and extent of exposure potential in setting priorities.
- Include criteria applicable to the range of chemicals being screened. Apply this principle through a two-step process rather than just those information elements available only for subsets of chemicals.
- Leverage available data and existing hazard classification frameworks already in use across industry and agreed by regulators.
- Incorporate relevant science advances where there is broad acceptance in the scientific community, e.g. improvements in how persistence and bioaccumulation considerations are addressed.
- Allow for the incorporation of significant new information to ensure prioritization decisions remain current.
- Adopt a simple, transparent screening method.
- Include opportunity for public review and comment to ensure the best available data and information is used in prioritization decisions.
- Allow professional judgment to be applied where appropriate, e.g. in hazard classification and second-tier ranking.

II. Applying Initial Screening Step in ACC's Prioritization Approach

The first step in applying ACC's prioritization approach is to apply criteria on human health and environmental toxicity potential to chemical substances.

A. Hazard Potential

The U.N. Globally Harmonized System of Classification and Labeling (GHS) was developed and internationally agreed to by many governments to provide criteria and a consistent approach for hazard classification of chemicals. It can also provide a recognized and generally accepted method for sorting chemicals in a prioritization process. The GHS framework has been used by international bodies, such as the OECD and WHO, and was endorsed by EPA's National Pollution Prevention and Toxics Advisory Committee (NPPTAC) to support prioritization.

The GHS system applies to both human health and ecological endpoints. It includes criteria for both human and ecological health. For human health, criteria are available for both acute and chronic classifications, as well as CMR categorization. For ecological

endpoints, criteria are similarly available for both acute and chronic classification. The use of one common system allows for appropriate assessment of all substances. GHS classification information is readily available for all substances, as U.S. manufacturers have developed GHS classifications for their products to meet international requirements.

ACC's support of the GHS criteria for purposes of this prioritization tool is not a categorical endorsement of the GHS criteria for any other purpose. ACC has been an active participant in the development of GHS and supports the system in principle. The GHS has not been broadly implemented to date in the U.S., although the Occupational Safety and Health Administration (OSHA) has indicated an intent to publish a regulation applying GHS in the workplace. ACC's December 29, 2009, comments on OSHA's proposed rule to modify the existing Hazard Communication Standard (HCS) to reflect the GHS urged that implementation of the GHS adhere to certain principles (e.g., continued application of the "Building Block Approach" of the Purple Book). ACC made specific recommendations concerning details of the Hazard Classification definitions, cut-off values, among others. ACC stands behind those comments. In ACC's view, the use of GHS criteria in a screening-level prioritization of chemicals can materially assist in determining which chemicals receive additional evaluation by the Environmental Protection Agency, but does not necessarily preclude the use of other appropriate, applicable criteria developed under other systems.

To classify a chemical in a hazard based priority ranking where there is not direct data on the chemical, EPA can employ the full range of approaches, such as QSAR, SAR, read- across and other modeling tools in which EPA has confidence based on molecular structure. In those situations where there still remains insufficient information on either environmental or human health hazards, the chemical would be classified as "high" for its environmental or health ranking.

1. ***Environmental Ranking***

Table 1 provides a summary of how GHS criteria could be logically used for chemical management prioritization.

Table 1. Environmental Safety - Hazard Ranking

GHS Classification - Environmental	**Ranking**	**Environmental Rank Score**
Acute I or Chronic I or Insufficient Information to Classify	High	4
Acute II or Chronic II	Medium High	3
Acute III or Chronic III/IV or none	Medium	2
Not classified	Low	1

2. ***Human Health Ranking***

Table 2. Human Health - Hazard Ranking

GHS Classification - Human Health	Ranking	Health Rank Score
GHS CMR Cat 1a, 1b; OR Repeat Dose </= 10 mg/kg/day (oral); </= 20 mg/kg/day (dermal); </= 50 ppm/6hr/day (gas inhalation); </= 0.2 mg/l/6h/day (vapour inhalation); </= 0.02 mg/l/6h/day (dust mist fume inhal). OR insufficient information to classify	High	4
GHS CMR Cat 2; OR Repeat Dose 10 - 100 mg/kg/day (oral); 20 - 200 mg/kg/day (dermal); 50 - 250 ppm/6hr/day (gas inhalation); 0.2 - 1.0 mg/l/6h/day (vapour inhalation); 0.02 - 0.2 mg/l/6h/day (dust mist fume inhal).	Medium High	3
Not carcinogen/mutagen/repro/develop;OR Repeat Dose 100 - 1000 mg/kg/day (oral); 200 - 2000 mg/kg/day (dermal); 250 - 1000 ppm/6hr/day (gas inhalation); 1.0 - 5.0 mg/l/6h/day (vapour inhalation); 0.2 - 1.0 mg/l/6h/day (dust mist fume inhal).	Medium	2
Not carcinogen/mutagen/repro/develop; OR Repeat Dose >1000 mg/kg/day (oral); > 2000 mg/kg/day (dermal); > 1000 ppm/6hr/day (gas inhalation); >5.0 mg/l/6h/day (vapour inhalation); > 1.0 mg/l/6h/day (dust mist fume inhal).	Low	1

It is important to note that specific concerns about children's health (specifically potential hazards and adverse effects on the nervous system) and those caused by endocrine disruption mechanisms are addressed in this prioritization process:

- The GHS CMR "R" classification includes specific evaluation of effects on development in utero and upon growth, maturation and reproduction. ("R" stands for reproductive toxicity and includes adverse effects on sexual function and fertility, as well as developmental toxicity in offspring).
- Endocrine activity is not a distinct toxicological hazard per se, but rather a measure of a compound's ability to interact with components of the endocrine system. The prioritization process evaluates data and information on relevant apical tests, including tests for reproduction and developmental toxicity (potential endocrine pathways). Thus, even if specific

screening for potential endocrine activity has not yet been conducted on certain compounds, hazard identification based on observable outcomes from apical toxicity tests (e.g., outcomes such as pathologic states indicative of disease conditions) covers all modes of action, including endocrine pathways.

- The toxicity information evaluated (CMR and repeat dose toxicity) is directly relevant to evaluating potential hazards to all individuals, including children. Such data typically includes: 1) identification and definition of possible hazards upon all major organ systems from both acute and repeated exposures, including the nervous system; 2) detection of potential hazards arising from in utero exposures, including possible effects on the nervous system; 3) evaluation of potential of a substance to affect reproduction; and 4) evaluation of the potential of a substance to damage DNA.

Integration of Hazard Elements:

Each of the environmental and human health classifications is assigned a numeric value based upon its ranking, with 1 being the lowest value and 4 the highest. The greatest ranking (highest hazard potential score) of either Environmental or Human Health is used in a substance-specific priority ranking. The numeric value does not imply relative weighting, but rather a numerical order of priority.

B. Exposure Potential Ranking

The screening method allows for an initial indication of the extent of exposure potential by considering:

1. The chemical's uses and use pattern(s).
2. Production volume as a first pass indicator of relative emission/release potential since magnitude and route (i.e. air, water, soil) of emissions is not available for all substances.
3. Persistence and bioaccumulation characteristics of the substance.

Together the 3 elements are used to rank exposure potential.

1. Use Patterns

The proposed approach applies the most current 2006 TSCA Inventory Update Reporting rule (IUR, now called the Chemical Data Reporting rule (CDR) data. To keep the initial prioritization simple and transparent, the approach "bins" different use patterns to align with general exposure potential – intermediates, industrial use, commercial use and consumer use. These patterns are the same as those reported in the IUR and are consistent with REACH exposure categories (intermediates, worker, professional, consumer). Chemicals with consumer product use are likely to have widespread potential for general population exposures and are given high priority ranking within the approach. For the initial prioritization approach, child specific products are captured under general consumer products and all consumer products are weighted equally (see additional discussion below under Second Tier Considerations). Intermediates will have low general population exposures, since these substances are consumed, by definition, within the workplace. Therefore, they are given the lowest priority ranking within the approach. In the context of the proposed approach, the intermediates category includes both intermediates and non-isolated intermediates. A chemical used in multiple use patterns is

assigned the priority of the highest use, e.g., a chemical in both industrial and commercial uses would be assigned the commercial Medium-High rank.

Table 3. Use Patterns - Exposure Ranking

Use Pattern	Ranking	Use Pattern Score
Consumer	High	4
Commercial	Medium-High	3
Industrial	Medium	2
Intermediates	Low	1

The IUR Definitions of these terms are (40 CFR 710.3, 710.43):

- "consumer use" means the use of a chemical substance or a mixture containing a chemical substance (including as part of article) when sold to or made available to consumers for their use.
- "commercial use" means the use of a chemical substance or a mixture containing a chemical substance (including as part of an article) in a commercial enterprise providing saleable goods or services.
- "industrial use" means use at a site at which one or more chemical substances or mixtures are manufactured (including imported).
- "intermediate" means any chemical substance:
    - which is intentionally removed from the equipment in which it is manufactured, and
    - which either is consumed in whole or in part in chemical reaction(s) used for the intentional manufacture of other chemical substance(s) or mixture(s), or is intentionally present for the purpose of altering the rate of such chemical reaction(s)
- "non-isolated intermediate" means any intermediate that is not intentionally removed from the equipment in which is it manufactured, including the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, and any equipment through which the substance passes during a continuous flow process, but not including tanks or other vessels in which the substance is stored after its manufacture.

2. Production Volume

Recognizing that detailed exposure information will not be available for all substances to be screened, the proposed approach uses production volume as an indicator of exposure, which is widely used in many prioritization schemes. As production volume is just a rough surrogate of emissions, ACC suggests only very broad categories, covering about two orders of magnitude each. It may be useful to consider how additional exposure estimates may be applied in the second tier assessment.

Table 4. Production Volume as Emission Surrogate - Exposure Ranking

Production Volume as Emission Surrogate	Ranking	Volume Score
>= 100,000,000 lbs national aggregate	High	4
1,000,000 lbs to < 100,000,000 lbs national aggregate	Medium – High	3

>= 25,000 lbs to < 1,000,000 lbs national aggregate	Medium	2
< 25,000 lbs (below IUR site reporting limit)	Low	1

3. Persistence and Bioaccumulation

Persistence and bioaccumulation are viewed as indicators of exposure, and therefore are considered under the exposure axis of the approach. A persistent substance that is emitted to the environment at the same rate as a non-persistent substance with similar partitioning properties will result in higher exposure to humans and the environment. In fact, multimedia modeling clearly indicates that environmental persistence in the compartment to which a substance partitions is a good indicator of human exposure potential (MacLeod & McKone et al. 2004). Similarly, substances that are not subject to biotransformation by higher organisms will exhibit a high bioaccumulation potential that results in higher exposures via the food chain (Arnot et al. 2010). Therefore, it is recommended to apply the proposed persistence and bioaccumulation criteria in assessment of exposure potential as described below.

The persistent and bioaccumulative (P&B) criteria of the proposed approach are targeted toward organic chemicals. Separate assessment criteria are likely needed for P&B evaluation for inorganics/metals, as in the approach taken by Canada's Chemical Management Program (CMP).

For assessing persistence, based upon recent expert consensus (Boethling et al., 2009) it is recommended to distinguish persistent from non-persistent chemicals using the following criteria:

- Volatile chemicals can be defined using a vapor pressure cut-off (i.e., > 1000 Pa)
    - For volatile chemicals, persistent versus non-persistent chemicals are differentiated using a half-life cut-off in air (e.g., a substance is not persistent if air half life is < 2 days).
    - For non-volatile chemicals, non-persistent substances can be defined as substances that are deemed:
        - readily or inherently biodegradable using standard biodegradation tests (OECD 301, 302, 306 test guidelines) or SAR or read across from measured data on a related substance,
        - show an equivalent degree of degradation (i.e. >20% in 28 days) via an abiotic degradation mechanism such as photolysis (OECD 316) or hydrolysis (OECD 111),
        - evaluation of simulation data from transformation in soil, marine water/sediment, brackish water/sediment, surface water/sediment, oceanic water die away (e.g. OECD 308/309) have half lives below 180 days, OR
        - if data are lacking, evaluation via BIOWIN model (EPIWEB 4)
    - Non-volatile substances that are not biodegradable or subject to abiotic losses based on the above criteria would be considered persistent.

For assessing bioaccumulation, the key question for screening is the potential for biomagnification based on recent expert consensus (Gobas et al. 2009). To determine if a substance has the potential to biomagnify the following metrics have been agreed:

- Trophic Magnification Factor (TMF)>1, fish Biomagnification Factor (BMF)>1, fish Bioaccumulation Factor (BAF)/Bioconcentration Factor (BCF) > 5000. These metrics can be

derived using lab or field measurements (where available) or recently improved computational models that are included in EPA's EPIWEB model that can be freely downloaded at www.epa.gov/oppt/exposure/pubs/episuite.htm.

This approach allows all organics to be addressed and is a scientifically updated version of the approach used in Canada's CMP.

Based on the above recommendations, substances can be grouped with regard to persistence and bioaccumulation as follows:

Table 5. Persistence and Bioaccumulation - Exposure Ranking

Persistence and Bioaccumulation	**P&B Ranking**	**P&B Score**
Persistent and Bioaccumulative	High	5
Persistent and Not Bioaccumulative OR Not Persistent and Bioaccumulative	Medium	3
Not Persistent and Not Bioaccumulative	Low	1

Integration of Exposure Elements:

As demonstrated in the tables, each factor (use pattern, P&B, and production volume) would be assigned a numeric score based upon its ranking. All 3 factors are added to arrive at an overall value. These values are then separated into categories from low to high exposure potential. A proposed "banding" approach is illustrated in Table 6.

Table 6. Integration of Exposure Rankings

Combined Score – All 3 elements	**Exposure Rank**	**Exposure Ranking Score**
11 – 13	High	5
9 – 10	Medium High	4
7 – 8	Medium	3
5 – 6	Medium Low	2
3 – 4	Low	1

Overall Priority Grouping:

In the overall approach, both hazard and exposure elements are considered when placing a substance in a risk-based prioritization ranking. The overall prioritization score for priority grouping and risk evaluation is based on the combined consideration of the hazard and exposure rankings. Priority Groups 7, 8, and 9 are deemed High Priority; Priority Groups 4, 5, and 6 are Medium Priority; and Priority Groups 2 and 3 are Low Priority.

Review and Comment:

It is important that screening be done in an open and transparent way and that the best available information be used. When screening for thousands of chemicals, EPA may not have access to all available information. The process should provide an opportunity for review and comment on initial rankings and an opportunity to submit additional relevant data and information to update proposed rankings with improved information.

III. Second Tier Considerations:

After the initial screening, some substances within individual priority groupings may require further rank ordering, particularly where a large number of chemicals are in the same priority group. Listed below are the types of information that will be useful to consider in this Second Tier rank ordering:

Biomonitoring/Environmental Monitoring Data:

Mere detection of chemicals in humans or the environment, i.e.,"found in biomonitoring (CDC), found in water (NCOD), and found in air", while providing an indication of exposure, does not provide a useful criterion for exposure potential because almost any industrial or commercial chemical could be detected at trace levels, given increasingly sensitive analytical methods. Therefore, detection alone primarily reflects only the fact that a specific chemical was included in a measurement program. This criterion will also tend to bias the prioritization of chemicals for which well-established analytical methods are available. Consequently, this criterion is not used in the initial prioritization scheme. However, within a particular priority grouping, reliable monitoring information should be considered for Second Tier rank ordering within a quantitative process that assesses if the data is above a level of concern (i.e., places it in a risk context).

Use in Children's Products:

Protection of childrens' health is a top priority and, in the initial ranking, child-specific products are captured under general consumer products and all consumer products are weighted equally. The specific IUR reporting of information on chemical use in products intended for children would be considered further within a particular priority grouping for Second Tier rank ordering, noting the following points:

- the IUR definition is based upon use in a child specific product rather than child specific exposure potential[1] (see below). Without knowing a specific product type, it is difficult to understand if

[1] IUR definition (Federal Register Volume 75, Number 156, Friday August 30, 2010, p. 49686): Intended for use by children means the chemical substance or mixture is used in or on a product that is specifically intended for use by children age 14 or younger. A chemical substance or mixture is intended for use by children when the submitter answers "yes" to at least on of the following questions for the product into which the submitter's chemical substance or mixture is incorporated:

(1) Is the product commonly recognized (i.e., by a reasonable person) as being intended for children age 14 or younger?

(2) Does the manufacturer of the product state through product labeling or other written materials that the product is intended for or will be used by children age 14 or younger?

(3) Is the advertising, promotion, or marketing of the product aimed at children age 14 or younger?

potential child exposure is greater than for a non-child specific product. For example, how does child exposure to a general use cleaner compare to exposure from use in a child's raincoat. In the VCCEP assessments, there are examples for inhalation exposures where estimates of passive child exposure during adult product use exceeded conservative estimates of child exposure during active use of a child-specific product (such as a hobby product) – differences were related to the amount of product used and substance concentration within the product (MEK VCCEP Submission).

- the IUR definition targets children age 14 and younger. Younger children may be exposed to a variety of non-child specific products that are in general household use. Older children may be exposed to a variety of additional products.
- the IUR information request is targeted to manufacturers, which may not have direct knowledge of all uses, particularly the presence in products for specific subpopulations, such as children. Therefore, it is not clear that the information requested for the IUR information would be consistently available across all substances being screened. Ideally, this information should be requested from formulators of child-specific products.

Therefore, for the initial prioritization approach, which represents a broad, unrefined categorization, child specific products are captured under general consumer products and all consumer products are weighted equally. The IUR information on child specific use would be utilized within a particular priority grouping for Second Tier rank ordering. If the IUR information is utilized, it is important that the limitations above be considered in its application.

Emissions Data:

Production volume, which is readily available for substances, is used in this proposed approach, but only serves as a surrogate for environmental emissions. For further prioritization, data or estimates of environmental emissions can be used to refine prioritization. Estimates of environmental emissions will be available for some substances (e.g., TRI data). When TRI data are utilized it should be recognized that it addresses only emissions that result from industrial and not wide dispersive uses. In other cases, emissions estimates can be developed as a percentage of production volume based upon consideration of use categories. Within a particular priority grouping, available emissions information can be considered for Second Tier rank ordering, with the understanding that emissions information is not an indicator of actual exposure.

Similarly, non-isolated system intermediates, by definition, would have de minimis exposure potential. Therefore, this IUR information could be considered within a particular priority grouping for Second Tier rank ordering.

International Risk Management Actions:

An initial screening approach for chemical prioritization should be based upon consistent application of specific hazard and exposure science elements that define risk potential.

The hazard and exposure elements should be applicable across all substances being evaluated. For initial screening, existence of international risk management action plans should not be a factor that determines priority grouping. Risk management plans may be based upon many factors, including political drivers. It is unclear how factors, their relative weighting, and the rigor of the evaluation may vary across agencies and substances. For initial screening

purposes, the same science-based criteria should be used to rank all substances. Consideration of existing international risk management plans could be utilized to check the functioning of the approach and could be considered within a particular priority grouping for Second Tier rank ordering with the possible effect of moving a chemical up in a grouping if actions are being taken internationally.

IV. Summary

ACC's prioritization approach is an example of a risk-based screening prioritization process that implements the general principles outlined at the outset of this document. It is based upon widely available information that can be utilized to understand the relative priority of chemicals for further evaluation from a risk perspective, i.e., integrating both hazard and exposure elements. Implementation of the screening framework will be most effective when utilizing the best available information. When conducting screening for thousands of chemicals, EPA may not have access to all available information. An open and iterative process that includes an opportunity for review and comment on initial rankings, together with the information that led to the result, and an opportunity to update the ranking with improved information will create a transparent and scientifically sound process.

V. References

Arnot, J.A., D. Mackay, T. F. Parkerton, R. T. Zaleski, C. S. Warren (2010), Multimedia modeling of human exposure to chemical substances: The roles of food web biomagnification and biotransformation, Environmental Toxicology and Chemistry 29(1):45–55.

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MacLeod, M., T. E. McKone (2004). Multimedia persistence as an indicator of potential for population-level intake of environmental contaminants, Environmental Toxicology and Chemistry 23(10):2465–2472.

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Proposed Prioritization Approach

DRAFT May 6, 2011

Exposure Elements				
Use Pattern	intermediate	industrial - not intermediate	commercial	consumer
Use Score	1	2	3	4
Persistence / Bioaccumulation (PB)	not P, not B		P & not B OR B & not P	P&B
PB Score	1		3	5
Tonnage	<25,000 lbs (below IUR site reporting limit)	25,000 - <1MM lbs IUR aggregate	1MM- <100MM lbs IUR aggregate	≥ 100MM lbs IUR aggregate
Tonnage Score	1	2	3	4
SUM (Use + PB + Tonnage Scores)	range 3 -13			

PRIORITY GROUPING = Hazard + Exposure Rankings				Exposure Ranking = Based on Sum (Use + PB + Tonnage Scores)				
				3-4	5-6	7-8	9-10	11-13
				low	med-low	medium	med-high	high
Hazard Ranking = Higher Score from Environmental and Human Health Hazards				1	2	3	4	5
		Environmental Hazard	Human Health Hazard					
1	low	not classified	Not carcinogen/mutagen/repro/develop; OR Repeat Dose >1000 mg/kg/day (oral); > 2000 mg/kg/day (dermal); > 1000 ppm/6hr/day (gas inhalation); >5.0 mg/l/6h/day (vapour inhalation); > 1.0 mg/l/6h/day (dust mist fume inhal).	2	3	4	5	6
2	medium	Acute III OR Chronic III/IV ; [not acutely toxic and no chronic data]	Not carcinogen/mutagen/repro/develop;OR Repeat Dose 100 - 1000 mg/kg/day (oral); 200 - 2000 mg/kg/day (dermal); 250 - 1000 ppm/6hr/day (gas inhalation); 1.0 - 5.0 mg/l/6h/day (vapour inhalation); 0.2 - 1.0 mg/l/6h/day (dust mist fume inhal).	3	4	5	6	7
3	med-high	Acute II or Chronic II	GHS CMR Cat 2; OR GHS Repeat Dose Cat 2: Repeat Dose 10 - 100 mg/kg/day (oral); 20 - 200 mg/kg/day (dermal); 50 - 250 ppm/6hr/day (gas inhalation); 0.2 - 1.0 mg/l/6h/day (vapour inhalation); 0.02 - 0.2 mg/l/6h/day (dust mist fume inhal).	4	5	6	7	8
4	high	Acute I OR Chronic I OR insufficient information to classify	GHS CMR Cat 1a, 1b; OR GHS Repeat Dose Cat 1: Repeat Dose </= 10 mg/kg/day (oral); </= 20 mg/kg/day (dermal); </= 50 ppm/6hr/day (gas inhalation); </= 0.2 mg/l/6h/day (vapour inhalation); </= 0.02 mg/l/6h/day (dust mist fume inhal). OR insufficient information to classify	5	6	7	8	9

Hazard and Exposure Criteria for Prioritization Approach

HAZARD

Environment and Human Health Classifications based upon GHS

Environmental:

From GHS classification guidance document:

Table 4.1.2: Classification scheme for substances hazardous to the aquatic environment

Classification categories			
Acute hazard (*Note 1*)	**Long-term hazard** (*Note 2*)		
	Adequate chronic toxicity data available		**Adequate chronic toxicity data not available** (*Note 1*)
	Non-rapidly degradable substances (*Note 3*)	**Rapidly degradable substances** (*Note 3*)	
Category: Acute 1 $L(E)C_{50} \leq 1.00$	**Category: Chronic 1** NOEC or $EC_x \leq 0.1$	**Category: Chronic 1** NOEC or $EC_x \leq 0.01$	**Category: Chronic 1** $L(E)C_{50} \leq 1.00$ and lack of rapid degradability and/or BCF $\geq$ 500 or, if absent log $K_{ow} \geq 4$
Category: Acute 2 $1.00 < L(E)C_{50} \leq 10.0$	**Category: Chronic 2** $0.1 <$ NOEC or $EC_x \leq 1$	**Category: Chronic 2** $0.01 <$ NOEC or $EC_x \leq 0.1$	**Category: Chronic 2** $1.00 < L(E)C_{50} \leq 10.0$ and lack of rapid degradability and/or BCF $\geq$ 500 or, if absent log $K_{ow} \geq 4$
Category: Acute 3 $10.0 < L(E)C_{50} \leq 100$		**Category: Chronic 3** $0.1 <$ NOEC or $EC_x \leq 1$	**Category: Chronic 3** $10.0 < L(E)C_{50} \leq 100$ and lack of rapid degradability and/or BCF $\geq$ 500 or, if absent log $K_{ow} \geq 4$
	Category: Chronic 4 (*Note 4*) Example: (*Note 5*) No acute toxicity and lack of rapid degradability and BCF $\geq$ 500 or, if absent log Kow $\geq$ 4, unless NOECs > 1 mg/l		

Human Health:

As above, based upon GHS

EXPOSURE

Use Elements - based upon IUR

Intermediate consumed during industrial processing
industrial (not intermediate) - used in an industrial setting
commercial occupational use in nonindustrial setting
consumer general population residential use

Persistence:

Volatile substance (VP > 1000 Pa): Not Persistent if air half life < 2 days
Nonvolatile (VP < 1000 Pa): Not Persistent if:
a) ready biodegradability (OECD 301)
b) inherent biodegradability (OECD 301, 302, 306)
c) read across from measured data on a related substance.
d) equivalent degree of degradation (i.e. >20% in 28 days) via an abiotic degradation mechanism such as photolysis (OECD 316) or hydrolysis (OECD 111)

OR, a substance is Not Persistent if:
e) evaluation of simulation data from transformation in soil, marine water/sediment, brackish water/sediment, surface water/sediment, oceanic water die away (e.g., OECD 308/309) have half lives below 180 days.

OR, if data are lacking:
f) evaluation via BIOWIN model (EPIWEB 4)

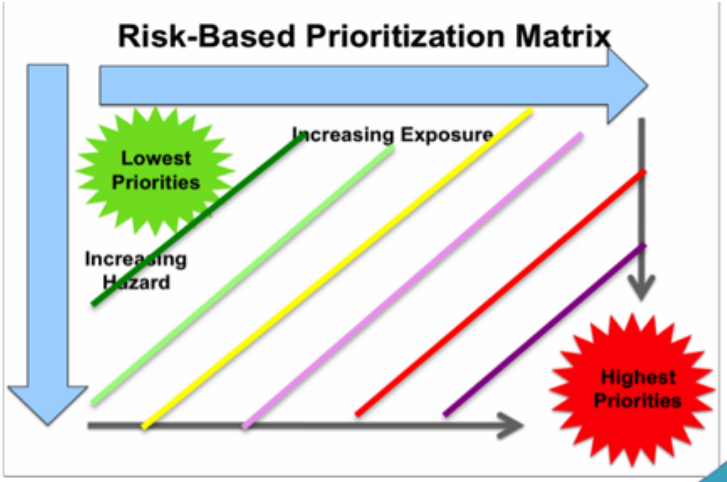
Bioaccumulation:

A substance is not bioaccumulative if:
a) measured TMF < 1 (field study)
b) measured fish BMF < 1 (lab study)
c) measured fish BCF < 5000 (lab study)
d) predicted BCF < 5000 using the BCFBAF model included in EPIWIN 4 The above order reflects the preference for use in decision-making

NOTE -- P&B CRITERIA ARE FOR ORGANICS

Tonnage - based upon IUR reporting ranges

< 25,000 lbs (below IUR site reporting limit)
25,000 - <1 MM lbs national aggregate
1MM - <100 MM lbs national aggregate
≥100 MM lbs national aggregate

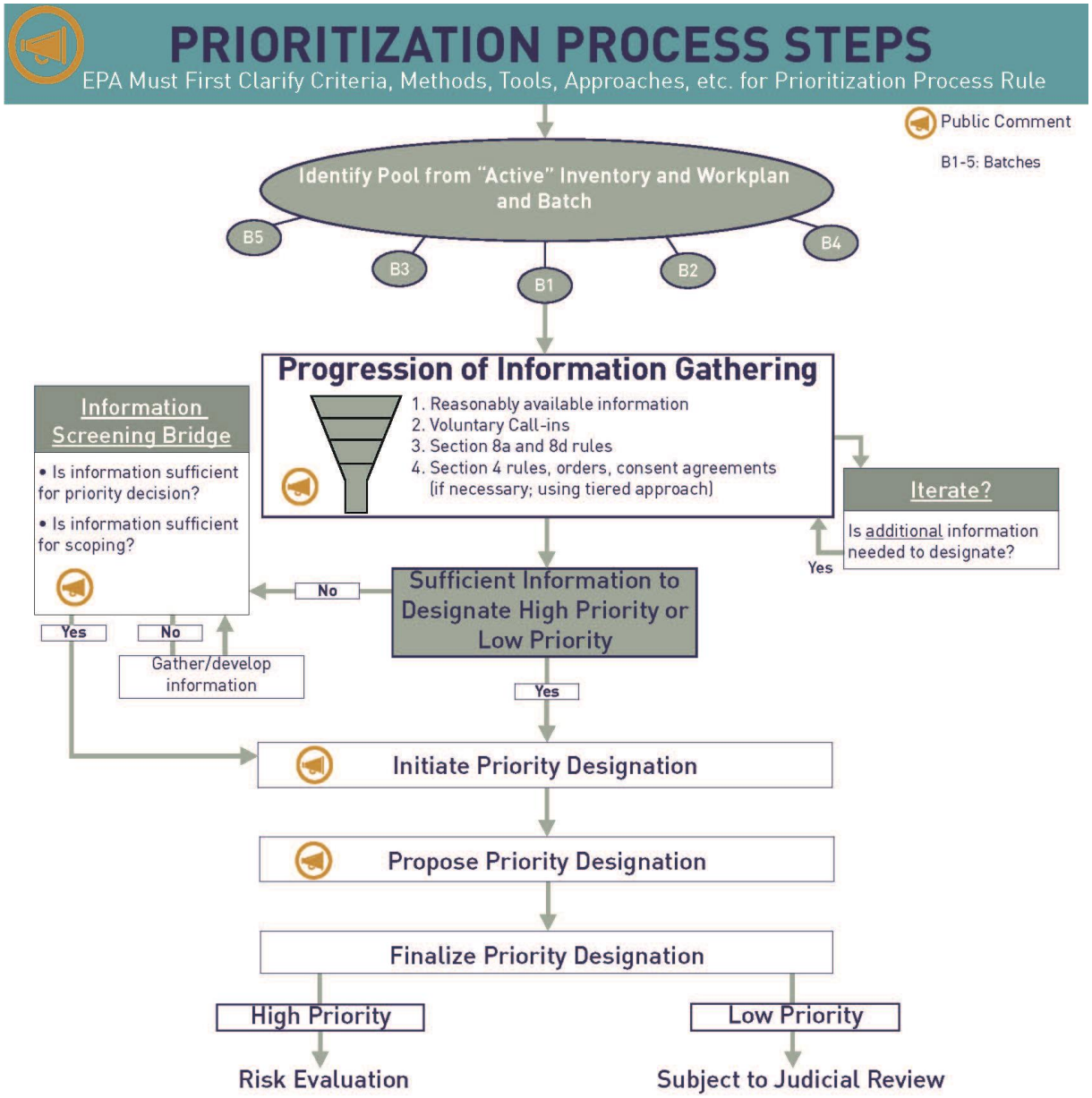


Two-Step Prioritization Process

Second Tier

Rank Ordering within Priority Groups

- Biomonitoring / Environmental Monitoring
- Use in Children's Products
- Emissions (e.g. TRI)
- International Risk Management Actions


PRIORITIZATION PROCESS STEPS
EPA Must First Clarify Criteria, Methods, Tools, Approaches, etc. for Prioritization Process Rule
Public Comment
B1-5: Batches
Identify Pool from "Active" Inventory and Workplan and Batch
B5
B3
B1
B2
B4
Progression of Information Gathering
1. Reasonably available information
2. Voluntary Call-ins
3. Section 8a and 8d rules
4. Section 4 rules, orders, consent agreements (if necessary; using tiered approach)
Iterate?
Is additional information needed to designate?
Yes
Information Screening Bridge
• Is information sufficient for priority decision?
• Is information sufficient for scoping?
No
Sufficient Information to Designate High Priority or Low Priority
Yes
No
Gather/develop information
Yes
Initiate Priority Designation
Propose Priority Designation
Finalize Priority Designation
High Priority
Low Priority
Risk Evaluation
Subject to Judicial Review