March 20, 2017

Jeffery Morris, Ph.D., Director
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001
(*via* *www.regulations.gov*)

Re: Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act (TSCA); **Docket No. EPA-HQ-OPPT-2016-0636**

Dear Dr. Morris:

The American Cleaning Institute (ACI)(1) is pleased to provide the following comments to the Environmental Protection Agency (EPA) on the proposed rule on Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act ("Prioritization Proposal"; 82 FR 4825; January 17, 2017). In a period in which the Agency might find itself challenged to use its resources judiciously, ACI encourages EPA to refine its vision for the prioritization pipeline it seeks to establish to be certain the process created will focus the Agency's attention on chemical substances, and conditions of use that present the greatest concerns to human health and the environment.

Summary of Comments

ACI supports EPA's efforts to articulate and establish a process for prioritizing substances for review under the amended TSCA. ACI encourages EPA to a) make clear the standards it will apply in the pre-prioritization process, b) use a flexible approach when interpreting how it will make the Low-Priority designation, and c) arrive at final prioritization procedures under the proposed "framework" rules that will enable the Agency to adopt a bold vision and approach by which EPA will make determinations to identify large numbers of Low-Priority substances swiftly using the information and data currently available on such substances. To arrive at that point, ACI recommends the Agency commit itself to considering as a whole the procedures being developed under both the Prioritization Rule and the proposed Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (Risk Evaluation Rule; 82 FR 7562; January

(1) ACI is a trade association for the $30 billion U.S. cleaning products industry. ACI members include the formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and oleochemical producers.

19, 2017). It is important to understand that the "procedures" articulated in the two proposed rules are inextricably linked. While the Agency may understand the infrastructure necessary, if not required by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA), to prioritize and evaluate chemicals on the TSCA Inventory, the approach described in the proposed Prioritization Rule suggests EPA will undertake prioritization as a piece meal approach on a chemical-by-chemical basis that will not enable the Agency to eventually prioritize and evaluate all substances that will appear on the TSCA Inventory of active substances. While the Proposed Rule notes that "…TSCA contemplates that, over time, all chemical substances on the TSCA Inventory will be prioritized into either High- or Low-Priority Substances, and that all High-Priority Substances will be evaluated," instead the proposal suggests that EPA will undertake an approach that will force the Agency to identify and focus on all conceivable uses for a substance, all potential opportunities for exposure and releases, and all potentially susceptive populations (82 FR 4825 at 4830). It would better serve the American public to have the Agency develop and execute a process that will initially identify and sort large categories of substances that can be considered to be of Low-Priority for risk evaluations *at this time*. This will help EPA fulfill the promise of the amendments to TSCA by giving consumers greater confidence in the products they purchase and use, and it would provide greater certainty for chemical suppliers and product manufacturers in the markets they are serving. ACI recommends EPA implement in the proposed pre-prioritization process a transparent procedure by which it sorts large numbers of substances for purposes of further consideration or for which EPA does not intend to do further screening work *at the present time* using methods and basic principles similar to those that were applied by the Canadian government under the Chemicals Management Plan, and by relying on designations EPA has already made explicitly and implicitly in previous exercises and in a number of current regulations under TSCA.

Comments on Prioritization Steps

The Agency has proposed four steps in prioritization which are illustrated in Figure 1 (below): 1) Pre-Prioritization, 2) Initiation, 3) Proposed Designation, and 4) Final Designation. There is a preparation step to feed the prioritization pipeline (Pre-Prioritization), followed by the three LCSA prescribed steps to get a chemical through the prioritization pipeline.

Conceptually, the approach presented in the figure below seems reasonable. However, ACI encourages EPA to make improvements to the pipeline process envisioned that will make it possible for EPA to use its limited resources as wisely as possible by screening out of the pipeline at the pre-prioritization stage as many substances as possible that do not require immediate attention from the Agency.

In several public meetings, Agency personnel have shared EPA's conceptualization of the entire prioritization and risk evaluation process in the Pipeline of Chemical Review and Management, depicted in Figure 1. The Proposed Rule, however, does not reflect a commitment on EPA's part to operating the proposed prioritization pipeline in a manner such that "all chemical substances on the TSCA Inventory will be prioritized into either High- or Low-Priority Substances" in a timely manner. Moreover, the depiction does not reflect that Low-Priority designations can be revised based on information as it becomes available to EPA. EPA should consider modifying the illustration and adopting a more flexible approach by which it conceives of the Low-Priority designation as a means by which the Agency can, for the time being, put certain substances into a

category where a substance can remain until information becomes available to EPA that would prompt the substance being categorized differently.

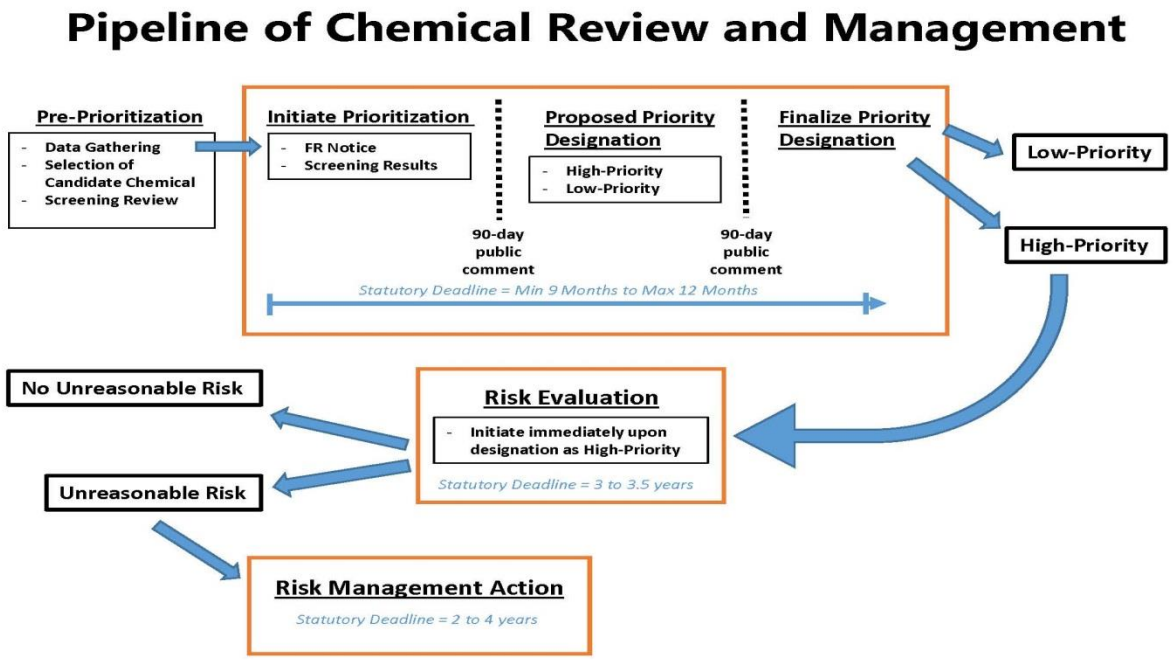

Figure 1. EPA conceptualization of the Pipeline of Chemical Review and Management

To assist with such an effort, EPA should adopt and apply in the final EPA Prioritization Process rule many of the methods and basic principles that were used by the Canadian government to effectively prioritize and evaluate all chemicals on the Canadian chemical inventory, the Domestic Substances List (DSL),(2) over a 15-year period from 2006-2020 under the Chemicals Management Plan.

We think it is reasonable for the Agency to commit itself to a 20-year time horizon to prioritize and evaluate all chemical substances on the active TSCA Inventory facilitated by examining batches of similar substances at a time, as was done in Canada. This will enable EPA to better identify and undertake more detailed evaluations on the better candidates for High-Priority designations and to concentrate on the conditions of use of greatest concern. To accomplish this, EPA should move swiftly to use the prioritization process to pragmatically sort out a large number of substances that should not be considered priorities for further EPA scrutiny *at this time*.

(2) The Domestic Substances List (DSL) is a compilation of about 23,000 substances used, imported or manufactured in Canada for commercial purposes between January 1, 1984, and December 31, 1986 (before CEPA came into existence), at a quantity of greater than 100 kilograms per year. It includes discrete organic compounds, inorganic substances, organometallic substances, polymers, and unknown or variable composition complex reaction products or biological material such as acetone or iron.

Pre-Prioritization Provides an Opportunity for Sorting Substances for Prioritization

ACI recommends that EPA clarify in any final Prioritization Rule how it intends to perform the pre-prioritization process. It would be beneficial to the Agency, to the public interest community, and the regulated community if EPA made the pre-prioritization process transparent, and if EPA could articulate its intent to use the process to clearly identify those substances that do not merit further EPA scrutiny initially. This is a critical first step in the Agency's four-step prioritization process because once a substance moves officially into the prioritization pipeline, it is put on a course whereby the Agency has many deadlines and obligations that it must meet. EPA correctly understands that it must do preliminary assessment work (to ensure it has the information and data necessary) before classifying a substance as High-Priority for risk evaluation. We believe this pre-prioritization process provides EPA with an excellent opportunity to sort out large numbers of substances and thereby avoid embarking on a process whereby EPA will consider far too many substances to be High-Priority simply because the Agency considers it necessary to "default" to that classification when EPA cannot definitively consider a substance to be Low-Priority.

The Agency states in the preamble to the Proposal, "the overall objective of the process should be to guide the Agency towards identifying the High-Priority Substances that have the greatest hazard and exposure potential first."(3) We recommend the Agency modify its way of thinking and also treat the process as an integral way to identify for itself, and to inform the general public, the regulated community and non-governmental interest groups of which substances, and which conditions of use of those substances, are of a Low-Priority for further review by EPA in the near term. Unfortunately, the Agency's proposal reflects a bias toward using the pre-prioritization process to identify substances for which EPA expects to identify one or more conditions of use for which a "no unreasonable risk" determination is likely be made. The Agency should consider the pre-prioritization process as an opportunity to classify large numbers of substances as being low-priority candidates as a means by which an agency with significant resource needs might enable itself to credibly and in an open manner, target its limited resources on substances and uses that present the greatest concerns.

Applying Lessons from the Canadian Chemical Management Plan

One way to accomplish this is to employ in the pre-prioritization process a number of tools and approaches used by Canada which should serve as examples for how EPA might eventually prioritize and evaluate the *entire* TSCA Inventory of active substances. For example, one of the first exercises Canada implemented was a categorization of the 23,000 chemicals on the DSL. The result of the categorization, completed in 2006, was that about 4,000 of the 23,000 chemical substances on the DSL met the criteria for further attention, and roughly 19,000 chemicals did not need further action. This binary decision-making might be analogous to the High/Low-Priority Designation required under LCSA (and serve as a model for the pre-prioritization phase).

The 4,000 chemicals identified for further attention were broken into three tranches from highest to lowest priority that were addressed over three five-year periods (2006-2010, 2011-2015, 2016-2020). The Canadian government has initiated and completed assessments at various levels (tiers) of detail for thousands of the 4,000 chemicals warranting further attention. In order to execute that

(3) Prioritization Proposal at p. 4829.

multitude of assessments, the Canadian government developed the Risk Assessment Toolbox illustrated in Figure 2 (below) which allowed them to conduct a qualitative (science-based policy or broad-based approach) assessment or a quantitative assessment of varying degrees of complexity. This tiered approach has proven to be very pragmatic and efficient and should be seriously explored by EPA so that the Prioritization and Risk Evaluation processes are meaningful, efficient and effective. Applying these same principles and methods, EPA could use the pre-prioritization process to place large numbers of substances into certain broad categories, including some to be obvious candidates for Low-Priority, and thereby make clear which substances are not among those for which EPA considers risk evaluations must be undertaken *in the near term*. Given EPA's history of working cooperatively with Canada on chemical assessments, the Agency should place confidence in the methods used by Canada to sort and prioritize large numbers of substances.

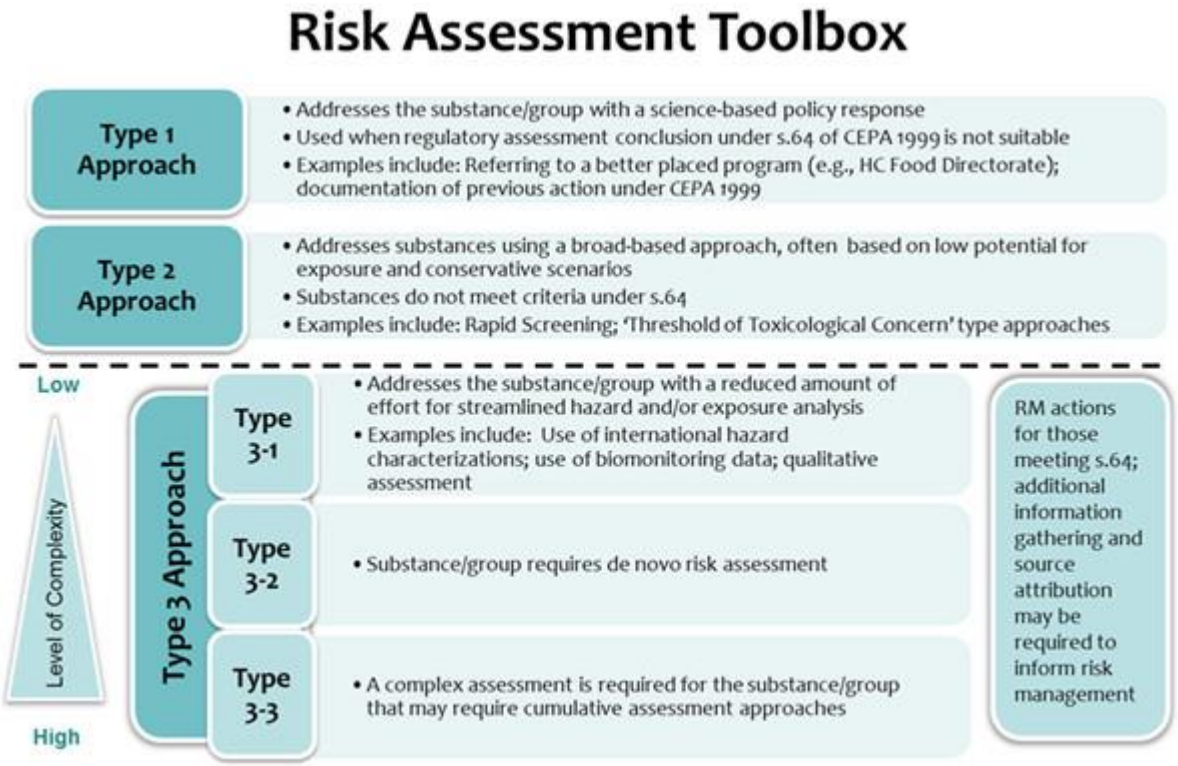

Figure 2. The Risk Assessment Toolbox developed for the Canadian Chemical Management Plan

Identifying Candidates Early for Potential Low-Priority Designations

With regard to potential Low-Priority Substances, the proposed rule states "…in identifying potential candidates for Low-Priority Substance designation, EPA is proposing that it will seek to identify chemical substances where the information indicates that hazard and exposure potential for 'all conditions of use' are so low that EPA can confidently set that chemical substance aside without doing further evaluation" (82 FR 4825 at 4830). We offer some suggestions below on how EPA could identify a substantial portion of the TSCA Inventory as Low-Priority Substances so that it can move on to the difficult work of assessing those substances that truly merit being High-Priority Substances. We reiterate that the amendments to TSCA make clear, that the Low-Priority Substance designation does not mean that EPA will *never* evaluate a particular chemical

substance just that it is not a priority for the current time horizon. EPA has discretion under the amended law to exercise its prerogative to propose moving a chemical from Low-Priority to High-Priority at any time based on information that has become available to EPA; ACI concurs with the regulatory language the Agency has proposed at §702.15 Revision of Designation.

Opportunities for Identifying Candidates for Low-Priority Substance Designations

In addition to the methods and principles applied in Canada's Chemical Management program, there are additional opportunities for EPA to make some simple decisions in the pre-prioritization phase that could readily lead to designation of substantial numbers of chemicals as candidates for Low-Priority. The approach in the proposed Prioritization Rule, in which EPA characterizes the Low-Prioritization designations as being "rigorous" and requiring EPA to determine "that under no condition of use" will the substance meet the High-Priority standard, suggests EPA does not want to create, much less enhance over time, the initial list it will generate of 20 Low-Priority Substances. However, there is considerable value to EPA, to the public interest community, to the chemical producer and user sector, and to consumers in general for EPA to signal that, while there may be thousands of chemicals potentially active in commerce in the U.S., the vast majority of them do not pose unreasonable risks to the public or the environment.

EPA's focus on moving chemicals through the prioritization pipeline by taking into consideration all foreseen conditions of use and then only considering for the Low-Priority designation those substances for which it can conclude that *all* conditions of use identified *or foreseen* do not present an unreasonable risk will inevitably and unnecessarily burden the prioritization process and weigh it down. The Agency can make significant progress initially if it would seek to establish simplified categories and groups of chemicals that need not receive the kind of detailed initial use-by-use screening for every chemical substance that EPA appears to contemplate in its proposed rule.

Inactive Substances Should be Initially Identified as Low-Priority. As a matter of policy and pragmatism, the Agency could articulate in its final rule that it will use the pre-prioritization to screen out inactive substances and will consider them as candidates for Low-Priority designations. Unless EPA becomes aware through an Inventory rule Notice of Activity Form B that an inactive substance with the potential to present an unreasonable risk will soon be manufactured or imported, the substance should be identified as Low-Priority. Further, in the absence of new information, only when the Agency has completed its review of all substances it has designated as High-Priority should EPA *consider* reclassifying an inactive substance as a High-Priority for risk evaluation.

Low Volume Substances Should Be Initially Identified as Low-Priority. Many active chemicals may not pose unreasonable risks simply because they are used in such low quantities and, therefore, need not require the *immediate* attention of EPA risk evaluators. Thus, we recommend EPA initially consider designating chemical substances that were not reported under the Chemical Data Reporting (CDR) during either the 2012 or 2016 cycles to be of a Low-Priority for risk evaluation. A clear, open and transparent pre-prioritization process that specifies such substances will not initially be considered as "High-Priority" for risk evaluation will provide sufficient incentive to persons who are in possession of data that contradicts EPA's proposed Low-Priority designation to provide it to EPA, potentially making a change in the proposed designation warranted. Of course, the statute makes clear, and the final Prioritization Rule will articulate, that at a later date, EPA could identify and propose to designate as High-Priority such a substance if information becomes available to the Agency (e.g., information consistent with the statutory

criteria of changes in a pattern of use or increases in production volumes) to warrant a proposed reclassification.

Rely on EPA Program Determinations that Have Already Identified Low-Priority Substances and Which Enable EPA to Identify New Uses That May Present Unreasonable Risks. Clear opportunities are available for identifying candidates for Low-Priority Substance designations in a transparent pre-prioritization process in which EPA takes advantage of risk evaluation efforts the Agency has already performed and those in which it already is engaged under the law and its various TSCA programs. Examples include:

Safer Chemical Ingredients List. We recommend the Agency capitalize on the assertions it has made when generating the Safer Chemical Ingredients List (SCIL) by identifying the substances listed as candidates for Low-Priority Substance designation (82 FR 4825 at 4830). It is logical that EPA should propose that the entire SCIL be designated as Low-Priority substances. In addition, the Agency could consider close analogs to SCIL chemicals as Low-Priority substances. It appears that EPA has already made Low-Priority determinations for SCIL chemicals because the Agency encourages industry use of them in consumer use products and encourages consumers to favor products manufactured with the substances on the SCIL.

Section 5(h) Exemption Chemicals. EPA's has already made risk determinations concerning a number of substances under the TSCA program that are sufficient to support their nominations to be designated as Low-Priority. These include:

1. Polymers that qualify for the exemption from PMN reporting and from the CDR reports (40 CFR 711.6(a)(1)).

2. Substances excluded from PMN and CDR reporting (40 CFR Part 720.30) including for example, certain by-products meeting the exclusions and site limited non-isolated intermediates.

3. Substances that are used primarily in laboratory applications under controlled conditions, such as those that are used as chemical reagents and substances generally used for research and development, including all conditions of use that are already regulated pursuant to the Occupational Safety and Health Administration's Occupational Exposure to Hazardous Chemicals in Laboratories standard (29 CFR 1910.1450).

Substances that are the subject of voluntary phase-out agreements with EPA as well as substances for which significant final new use rules have been issued and remain in effect. These substances should be described in a transparent pre-prioritization process as being candidates for Low-Priority designations at this time because the Agency has taken actions already intended to mitigate risks. EPA can propose to re-designate such substances on a case-by-case basis if it acquires information indicating that new exposures or new uses may present an unreasonable risk and when EPA does not have the capacity to learn of such uses before they occur through the SNUR notification process.

Micro-organisms. EPA should also consider for pre-prioritization purposes advising the general public that it will not initially consider micro-organisms to be candidates for High-Priorities for risk evaluation. EPA's new chemicals biotechnology regulatory program is sufficient for purposes

of alerting EPA to new micro-organisms and new uses and provides EPA the opportunity and the authority to intervene to prevent uses from occurring that may present an unreasonable risk.

EPA Should Rely on Evidence of Low Risk from Other Agencies. A number of ingredients that are found in food are also often used to manufacture non-food products, including cleaning products. This is evidenced again by virtue of such listings on the SCIL such as sodium chloride (table salt), D-glucose (table sugar), and olive oil. EPA should extend this concept to designate as candidates for Low-Priority those substances on the TSCA Inventory that also have been identified in U.S. Food and Drug Administration regulations to be generally recognized as safe (GRAS) for use in food. Direct human exposures to these chemicals in foods are likely to be much greater than the kind of indirect exposures that might be anticipated from their use in formulated products or articles. For the purposes of making decisions in the pre-prioritization phase and seeking nominations for large numbers of substances to be considered Low-Priority, the Agency should rely on FDA GRAS determinations and similar findings by other regulatory agencies and authoritative bodies.

EPA Should Be Judicious About How it Makes High-Priority Substance Designation

ACI agrees with the Agency about the importance of using the High-Priority designation only for those substances for which it has the data and information necessary to reach that determination. Unfortunately, the proposed rule provides little insight into how EPA will determine what it considers to be "sufficient information" for making a prioritization determination. ACI encourages EPA to provide greater clarity on the information sufficiency issue *before* issuing a final Prioritization Rule, and once this has been made public, the Agency should seek public comment on a) what EPA will consider are the data which will be "sufficient" (i.e., to be minimally necessary) for the Agency to propose a prioritization determination, and b) how EPA intends to use its information gathering authority under Sections 4 and 8 of the amended law in the pre-prioritization process. The absence of a complete and robust data set for a chemical substance should not *per se* be determinative that the substance must be given a High-Priority designation, especially if the conditions of use for the substance involve minimal or no exposures and environmental release. The lack of guidance on this feature of the Prioritization Proposal creates a "black box" approach which leaves much to EPA's discretion while providing no transparency on the pre-prioritization process. It also provides little incentive for the regulated community to voluntarily provide additional information during the pre-prioritization process.

This is especially critical given the "default to High-Priority" preference that the Agency has built into the Prioritization Proposal and its decision-making processes whereby for any substance for which EPA has insufficient information to make a definitive Low-Priority designation for all conditions of use (intended and foreseen) and for all potentially susceptible subpopulations. ACI recommends EPA instead adopt the more practical and flexible approach we have encouraged above whereby EPA can make clear that it intends to consider revisiting initial Low-Priority designations when information becomes available that would encourage a re-classification.

The sufficiency of information criteria for making a prioritization determination would represent a lesser burden to Agency staff if EPA would consider information sufficiency on a conditions of use basis, and permit itself to make High- and Low-Priority designations on the same basis. It is clearly within the Agency's discretion under the amended law to designate as a High-Priority a limited set of conditions of use which warrant a Risk Evaluation. EPA's preference for making a

High-Priority determination based on a chemical-by-chemical basis and in contemplation of all subpopulations and for all known and reasonably foreseen uses at one time will slow EPA's progress and force the Agency to seek exhaustive information through the use of Test Rules and Administrative Orders and lead it to undertake needless reviews. This approach will become a self-imposed and unnecessary burden on EPA notwithstanding that Congress provided EPA with sufficient authority to reach prioritization decisions (and perform Risk Evaluations) on a chemical and conditions of use basis.

Consideration of Substitutes

The Prioritization Proposal states in the Policy Objective "EPA may also consider the relative hazard and exposure of a potential candidate's likely substitute(s) in order to avoid moving the market to a chemical substance of equal or greater risks."(4) Later, the Prioritization Proposal states, "…given EPA's objective to avoid simply moving the market to substitute chemical substances of equal or greater risks, EPA requests comment on whether and how information on the availability of chemical substitutes should be taken into account during this phase of the prioritization process." While the Agency may have a policy objective of avoiding "moving the market" toward substitutes of equal or greater risk, we do not believe the Prioritization or Risk Evaluation processes are the places where such considerations should occur. First, the Agency would have to establish as part of it "pipeline" the criteria for what constitutes a "substitute" and a means by which chemicals would be weighed against the criteria – a new process as yet unarticulated. While the Agency's policy is to avoid encouraging use of substitutes of equal or greater risk that does not mean all substitutes would themselves qualify as Low-Priority chemicals using the criteria EPA seems intent on applying. Moreover, the Agency would need to "bundle" for review all potentially High-Priority substances with their potential substitutes for both Prioritization and Risk Evaluation as part of that pipeline. This appears to be in conflict with the proposed regulatory language in §702.7(b) "…it is EPA's general objective to select those chemical substances with the greatest hazard and exposure potential first" for High-Priority Substance designation. It is not hard to imagine that if EPA carried out such an approach, the Risk Evaluation pipeline could be rapidly filled with a majority of substances which received their High-Priority Designation by virtue of their potential as a substitute for "the real" High-Priority Substance of interest but which the Agency was unable to designate to be a Low-Priority substitute. ACI recommends the consideration of substitutes is more appropriately left for the risk management process as Section 6(c) of the statute envisions.

Conclusion

ACI appreciates this opportunity to provide comments and information on the proposed Prioritization Rule. We encourage EPA to consider more carefully and to exercise its capacity to make swift determinations about entire categories of substances which can be treated as candidates for Low-Priority designations until such time as the Agency becomes aware of information related to risks or exposures that would warrant reconsideration of the Low-Priority designation. If EPA adopts a more practical and pragmatic approach, it can significantly simplify its prioritization

(4) Prioritization Proposal at p. 4829.

process and more readily devote its limited resources to work on reviews of substances and conditions of use that are of a higher priority to evaluate.

ACI looks forward to further engagement with EPA on this and other matters related to the implementation of the Lautenberg Chemical Safety Act for the 21st Century.

Sincerely,

Paul C. DeLeo
Associate Vice President, Environmental Safety