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 Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (Docket No. **EPA-HQ-OPPT-2016-0654)**

Dear Dr. Morris:

The American Cleaning Institute (ACI)(1) is pleased to provide the following comments concerning the Agency's Proposed Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (TSCA) (the Proposed Rule).(2) ACI appreciates and supports the Agency's efforts to timely issue and seek public comment on this important Proposed Rule that will establish procedures that will affect the manner in which EPA will perform numerous Risk Evaluations under the law as amended by the Lautenberg Chemical Safety Act for the 21st Century (LCSA).

Summary of Comments

ACI encourages EPA to consider these comments to be complementary to ACI's comments on the proposed Prioritization Rule. We encourage EPA to consider the two operations, Prioritization and Risk Evaluation, to be closely linked and believe the Agency should use the processes as a means to swiftly sort out large groupings of chemicals and chemical-use combinations that do not require the most immediate attention and then to concentrate its Risk Evaluation resources and efforts on those substances and conditions of use that are the most likely to present the greatest risk on the basis of factors considered and identified during the prioritization process. This requires that the Agency must be willing to use a flexible approach that will enable EPA to sort large groups of substances in a manner that will recognize and temporarily remove from detailed consideration (or information gathering efforts) lower priority substances and conditions of use combinations. Likewise, the closer review of high priority substances requires the Agency to effectively and narrowly define the scope of the Risk Evaluations it intends to undertake. This is the most productive way in which EPA will be able to focus its limited resources on those chemical and use

(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.

(2) 82 Fed. Reg. 7562; January 19, 2017.

combinations of greatest concern. Doing so will permit EPA to undertake and complete Risk Evaluations more readily and will not unnecessarily obligate the Agency to identify and immediately assess all foreseen uses of a substance and all potential opportunities for exposures to a substance at the same time. ACI encourages EPA to avoid overburdening itself in favor of undertaking and completing more targeted Risk Evaluations in a credible manner that will rely on the information available to EPA and reflect the use of sound science while applying a weight of the evidence approach.

ACI's comments address the following:

- Clarifying early whether science policy issues need to be addressed
- Incorporating the concept of Tiered Evaluations
- Defining the scope and conditions of use for the Risk Evaluation
- The need to clarify terms, including making clearer at what points in the Risk Evaluation process EPA will use a weight of the evidence approach.
- The Agency's approach to determining information sources and availability, and the need to articulate the criteria for accepting manufacturer requests for evaluation
- Opportunities for public input
- The importance of peer review
- Comments regarding specific elements of the proposed text

Overview

In the Proposed Rule, EPA has acknowledged that risk evaluation is something the Agency has engaged in for a very long time using procedures that are well known to EPA personnel. The Agency recognizes that overly prescriptive framework regulations can limit needed flexibility for developing and completing Risk Evaluations. In that respect, we believe the Agency's proposal generally reflects a risk-evaluation process by which EPA can meet the requirements of LCSA, if EPA makes certain modifications before the final rule is issued. ACI thinks such modifications are needed to ensure the Agency will implement the Risk Evaluation process with the necessary flexibility to direct its efforts and resources to evaluating in a timely manner the most significant and meaningful conditions of use for High-Priority substances. There are a number of details of the proposed regulation for which ACI is providing comment below; our comments identify additional elements we believe will be important for the Agency to implement to be able to successfully complete high quality Risk Evaluations for a large number of chemicals that will be identified as "active" on the TSCA Inventory in the coming years. Many of these additional elements might not be appropriate to codify in the final regulation, but could be discussed in the preamble to the final rule and implemented through EPA policies, practices, and updates to its guidance documents.

Identify any Needed Science Policies and Guidance Immediately

Section 26(l) requires EPA to develop and issue policies and guidance necessary to implement the amended statute. Rather than doing so two years after enactment of the amendments, as the amendments permit, ACI recommends that EPA identify as soon as possible whether there are critical science policies and guidance documents that must be created or updated and commence

such modifications as soon as possible in order to fully operationalize the Prioritization and Risk Evaluation pipelines. It would be valuable for the Agency to identify those policies and indicate its schedule for seeking public input and issuing any new policies and updates to existing guidance in the very near future. Likewise, if the Agency does not intend to update existing policies and guidance documents, it should definitively say so.

Incorporate Greater Flexibility in Identifying Risk Evaluations' Scope, Conditions of Use

The Agency is proposing that a Risk Evaluation undertaken for any chemical substance would include all conditions of use (i.e., those known, intended and reasonably foreseen) within the scope of the evaluation. This could potentially waste EPA resources on reviews of lower priority, i.e., lower risk, lower exposure use scenarios, and thereby limit EPA's ability to take on and complete a significant number of Risk Evaluations unless EPA is committed to: a) identifying such low risk and low exposure use scenarios in the scoping process; b) making rapid determinations early in the risk evaluation process after confirming its findings of low risk and low exposure use conditions; and, c) making clear to the general public EPA's intentions to devote no additional Risk Evaluation resources to assessing those substances and conditions of use combinations after confirming its findings (unless *new* information becomes available that would justify modifying such a determination).

Public participation in the scoping phase will allow EPA to better identify ongoing uses, discontinued uses, and uses that EPA identifies as reasonably foreseen but (for economic or technological reasons) unlikely to occur (and thus unnecessary to consider further). ACI appreciates EPA's plan to make draft scoping documents available for comment not later than 45 days following a High-Priority designation and encourages the Agency to commit to a transparent process for determining the final scope of the Risk Evaluation. ACI encourages EPA to provide as many as 60 days for public comment on a draft scoping document, and not fewer than 45 days.

ACI interprets the LCSA amendments to TSCA as making clear that the determination of the scope of a Risk Evaluation is generally within EPA's discretion. ACI recommends the Agency adopt an approach under which EPA will define the scope of each Risk Evaluation on a case-by-case basis. ACI recommends EPA exercise its considerable discretion in the *prioritization* phase to identify certain conditions of use that are of comparatively low priority, and then (assuming EPA remains committed to performing Risk Evaluations for *all* reasonably foreseen uses) in the *scoping stage* of Risk Evaluation to identify the set of uses to be included. EPA should make clear its intention to concentrate the Agency's limited resources on evaluating in detail only those identified conditions of use with higher potential risks (in light of the attributes of the specific substances and its use patterns). Congress clearly intended the prioritization process and the scoping process to permit EPA to include *and exclude* conditions of use from the Risk Evaluation process. Accordingly, the statute permits EPA to reexamine chemicals and conditions of use when new or additional information becomes available to EPA.

The Proposed Rule reflects the Agency's assumption that considering all conditions of use for a substance will not be too burdensome because some conditions will require little time and resources to review before determining the risk is such that immediate movement to *risk management* is warranted. This implies an inherent bias of the rule drafters. It is equally possible, but apparently not within EPA's contemplation, that some identified conditions of use will present

low risks that they can be immediately classified as either "low priority" (and excluded at the outset of the Risk Evaluation phase from further review) or, after the initial phase of the Risk Evaluation process, can be determined "not likely to present an unreasonable risk" (such that no further review or dedication of EPA resources will be needed). The final rule should clarify this issue in such a way that the procedures themselves are not shaped to incorporate the implicit bias currently reflected in the Agency's proposal toward Risk Evaluation outcomes that require regulatory actions.

Develop a Streamlined Program That Includes the Use of Tiered Risk Evaluations

The approach EPA has articulated in the proposed Risk Evaluation rule and in public discussions will require EPA to identify and undertake a thorough Risk Evaluation for all uses that are intended and reasonably foreseen for a substance, and to consider all potentially exposed subpopulations. Unless EPA is willing to incorporate greater flexibility and to exclude certain foreseen but potentially unlikely or lower-exposure conditions of uses from consideration, the proposed approach will lead to a resource intensive assessment process and necessitate that all EPA Risk Evaluations will require a similar level of effort. If EPA remains intent on doing its Risk Evaluations on all intended and reasonably foreseen conditions of use for a substance, ACI encourages a far more flexible approach, whereby certain conditions of use that will not require the same level of detailed review as other conditions of use are identified early in the Risk Evaluation process and can be classified as representing lower-risk scenarios in an open and transparent manner. The Agency should clarify in the final Risk Evaluation rule how it will adjust the procedures outlined in the Proposed Rule to accommodate the varying levels of detail and effort that will be appropriate for differing conditions of use. A common concept that has not been discussed in EPA's Proposed Rule is that of a tiered risk evaluation where the analysis can be tailored based on the data available and where outcomes of the evaluation can dictate whether additional data and information should be collected and more sophisticated analyses conducted. Embry et al. (2014) offer a roadmap for how just this sort of an approach might be implemented.(3),(4) We believe EPA should embrace the concept of tiered risk evaluation procedures and articulate its commitment to a tiered approach in the preamble to the final Risk Evaluation rule, and where appropriate in the final regulatory language. Such a tiered approach should involve EPA identifying those conditions of use which, based on readily available information, represent low exposure and/or low risk uses and devote only the resources needed to confirm this. Examples include conditions of use such as: a) the production and consumption of chemical intermediates in a manufacturing process stream, b) a chemical substance in a condition of use in which it becomes incorporated into an article from which it is unlikely to be released, and c) substances that are cured during use or (on the basis of their physical and chemical properties) are otherwise not likely to be bioavailable. Likewise, foreseen uses that are considered to be unlikely (due to technological or economic reasons) also can be excluded from further review. Examples of unlikely uses might include chemical manufacturing pathways that are more

(3) Embry, MR, AN Bachman, DR Bell AR Boobis, SM Cohen, M Dellarco, IC Dewhurst, NG Doerrer, RN Hines, A Moretto, TP Pastoor, RD Phillips, JC Rowlands, DC Wolf, JE Doe. 2014. Risk assessment in the 21st century: Roadmap and matrix. *Critical Reviews in Toxicology* 44(S3): 6-16. http://www.tandfonline.com/doi/full/10.3109/10408444.2014.931924

(4) http://www.risk21.org/

expensive than more commonly used methods, or the use of a substance in a consumer product which is foreseeable but unlikely because there are less expensive alternatives available that serve the same function. EPA need not devote Risk Evaluation resources to such low risk or unlikely conditions of use. If the Agency concludes it must consider and evaluate "all" foreseen uses in its final Risk Evaluation procedures, EPA should devote no more resources than are necessary to confirm the accuracy of the bases for such low-exposure and low-risk determinations and make public its decision to discontinue further review of those conditions of use on that basis. EPA should initially articulate its approach to addressing such low risk use conditions in the draft scoping document to be released for comment by the 45th day following a High-Priority designation. EPA is encouraged to make available additional findings identifying low risk conditions of use as it refines and focuses its Risk Evaluation (i.e., as information is taken into consideration and reviewed). Making such findings early in the scoping and Risk Evaluation process will encourage interested parties to provide to EPA information in their possession that confirms or contradicts EPA's assumptions. Such findings also lend themselves to making transparent EPA's intent to issue final determinations as soon as it can on chemical and conditions of use combinations that do not present an unreasonable risk.

The Agency Should Clarify the Phases in Which it Will Perform Weight of the Evidence Analyses, and How That Will be Documented

ACI considers the entire Risk Evaluation process to be subject to the provisions of Section 26 that obligate EPA to meet standards that will ensure the use of sound science. To reinforce EPA's commitment in this regard, ACI recommends the preamble to the final rule and the final rule language be amended to make clear the points in the Risk Evaluation process at which the Agency expects to perform weight of the evidence analyses. EPA also should include such information in the scoping document based on the information currently at hand. This will encourage EPA to articulate how the Risk Evaluation procedures being established will ensure the best available science is used in decision making. To do this, the final rule should identify the specific junctures in the Risk Evaluation proceedings at which EPA generally expects to undertake and apply a weight of the evidence approach for making determination. At a minimum, ACI believes these junctures should include a) the hazard evaluation phase, b) the exposure assessment phase, and c) the phases in which EPA is preparing draft and final Risk Evaluation documents. At those intervals, and elsewhere as appropriate, the weight of evidence should be evaluated by EPA in writing and should include a discussion on the strengths and limitations of the data and information available to EPA and how those strengths and weaknesses were vetted during consideration on the information and in reaching a determination. This also will allow EPA to state in the final rule that any weight of the evidence findings will be subjected to a credible and transparent peer review process.

The Agency's Approach to Determining Information Needs and Responsibility for Making Information Available Must Be Clarified; the Agency Should Articulate Criteria for Accepting Manufacturer Requested Evaluations

EPA has made it clear in the Proposed Rule that it will not undertake a Risk Evaluation at the request of a manufacturer unless the person submitting the request has all of the information EPA considers to be necessary in its possession (or capable of being produced). However, the Agency

has not provided a complete list of all of the information that it considers will be necessary for a Risk Evaluation. The Agency must articulate the criteria it will apply for accepting manufacturer requests for evaluation.

Nevertheless, EPA should not hold a manufacturer who submits a Risk Evaluation request responsible for having all information the Agency believes is necessary to be available. EPA should instead obtain information that EPA can easily obtain using Sections 8(a) and (d) to call in existing data. Section 4 also provides EPA with authority to gather information, if needed. EPA's subpoena authority under Section 11 should only be used in adversarial situations if EPA becomes aware that data might exist that have not been voluntarily submitted or submitted pursuant to a Section 8(a) and (d) rule requirement.

Moreover, ACI believes a manufacturer requesting a Risk Evaluation should be able to define the scope of the Risk Evaluation it is requesting, including the conditions of use. Whether the information the manufacturer submits is sufficient should be assessed based solely on the conditions of use the manufacturer is requesting be evaluated.

Finally, ACI believes the Agency should be able to reach a decision within 6 months whether or not it will accept a manufacturer's request for a Risk Evaluation.

Opportunities for Public Input

ACI supports the opportunities in the Proposed Rule for EPA to solicit and receive public input and recommends providing more than 30 days to comment on draft scoping documents and draft Risk Evaluations, especially if EPA intends all EPA Risk Evaluations will consider all conditions of use. In addition, ACI recommends the Agency's draft Risk Evaluation be made available within eighteen months of completion of the scoping document. This will ensure the Agency would issue the final scoping document 6 months following a High Priority designation, issue a draft Risk Evaluation 18 months later, and thus provide the Agency 12 months to complete the final Risk Evaluation.

The Importance of Peer Review

Rather than looking for instances in which peer review will not be needed, ACI recommends EPA should generally err in favor of conducting peer review of all significant elements of the Risk Evaluation in which scientific judgment is being applied (as discussed in greater detail below). At a minimum, ACI believes these junctures will include: a) the hazard evaluation phase, b) the exposure assessment phase, and c) the preparation of both the draft and final Risk Evaluation documents. Too often EPA receives comments during peer review that are easily dismissed without further scrutiny during preparation of a final assessment. ACI endorses EPA's commitment to include its peer review plan as part of the draft scope upon which public comment is sought. The results of peer review (including EPA's responses to comments received from peer reviewers) should become part of the record at each these critical intervals. While ACI recognizes EPA desires to retain the discretion not to conduct an elaborate peer review process for non-controversial determinations, ACI thinks it is reasonable and will instill greater confidence in the Agency's Risk Evaluation process if the final rule specifies the Agency's presumption that any final Risk Evaluation that concludes a substance and one or more on-going condition of use

presents an unreasonable risk will undergo a peer review involving an independent panel of experts. This is certainly consistent with the criteria EPA articulates in the preamble to the Proposed Rule (and as reflected in the Agency's Handbook and OMB's Information Quality guidance on peer review) because it is reasonable to expect that such a finding "will have or does have a clear and substantial impact on important public policies or private sector decisions" and therefore should be subjected to an objective peer review process.

Components of a Risk Evaluation – Aggregate or Sentinel Exposures

The Agency notes that TSCA requires the Risk Evaluation to document whether the Agency has considered aggregate or sentinel exposure, and the basis for those decisions. First, it is not clear from the Proposed Rule whether the Agency understands that this is not an either/or determination. EPA has within its discretion to consider both aggregate *and* sentinel exposures (and to consider either, or neither). The proposed regulatory text defines *Sentinel Exposure* to mean "the exposure(s) of greatest significance, which may be the plausible maximum exposure to an individual, population (or subpopulation), or the environment to the chemical substance of interest (or any combination thereof)." ACI believe the term should be *Sentinel Exposure**s*** because there may be multiple sentinel exposures which might be aggregated as part of the Risk Evaluation. The example might be that of a chemical substance contained in a variety of products. The products might fall into four categories. A sentinel product considered to have the highest exposure potential among those products in the same category might be selected for evaluation (e.g., exposure modeling) and the sum of the exposures from several sentinel products from several use categories would represent the aggregate of such sentinel exposures (assuming there were no other sources of exposure to the chemical substance).

If the Agency intends to assess potential aggregate exposures for a chemical, ACI recommends that EPA exclude from consideration those sentinel and aggregate exposures involving uses of substances that are not within the Agency's TSCA jurisdiction. Thus, exposures to a substance from its uses in foods, drugs, cosmetics, pesticides, and tobacco products should be excluded from TSCA Risk Evaluations.

Additional Topics for Which Comments Were Requested

In the Proposed Rule, the Agency requested comments in some specific areas for which ACI offers the following:

a. *Redefining scientific terms*. ACI agrees with the Agency that it is unnecessary to redefine a number of scientific terms related to risk evaluation. In particular, there is significant discussion regarding "weight-of-the-evidence" or weight of evidence (WoE). We appreciate the reference to the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) which referred to the WoE approach as ". . . a process by which trained professionals judge the strengths and weaknesses of a collection of information to render an overall conclusion that may not be evident from consideration of the individual data." ACI interprets the concept similarly and thinks it is not necessary to define WoE in the final regulations. Further, ACI appreciates the discussion of the National Toxicology Program's "systematic review" tool and the distinction EPA draws with respect to WoE.

ACI believes the amendments to TSCA require the Agency to apply a weight-of-evidence approach throughout its Risk Evaluation process, including if a tiered approach is applied. Moreover, ACI expects, and the amendments to TSCA require, that all such assessments will be orderly and take into consideration the best available scientific information. Systematic review of the kind described in the proposal will most significantly have a place in more complex and higher tier hazard assessments. When ruling out low risk and low exposure conditions of use for further review in simplified or lower tier risk assessment, a less systematic approach would be appropriate.

b. *Margin of exposure*. ACI believes the margin of exposure (MOE) approach has its place among the many tools that EPA may use in risk characterization. However, in using an MOE approach, the Agency should not prescribe a single MOE value which would be used in all of its Risk Evaluations to compare the dose-response:exposure ratio, but instead select an appropriate MOE value based on uncertainty factors associated with the strength of the evidence and the nature of the studies in the toxicology database. We see the MOE approach as a "mid-tier" approach along the tiered risk assessment spectrum. The Agency should develop its own Risk Evaluation toolbox that would include such tools as probabilistic risk assessments at the higher tier and consider application of a threshold of toxicological concern (TTC) approach when little hazard data might be available. Responsible decisions to exclude low risk low exposure scenarios from further consideration can still be made applying these methods.

c. *Systematic Review*. We do not believe the Agency should prescribe *in the regulations* a specific systematic review approach for hazard identification. However, when conducting a higher tier hazard identification it is appropriate to utilize systematic review. The approach used in those situations should be transparent and consistent across the various Risk Evaluations. ACI believes it would be useful for the Agency to issue the appropriate science policies and guidance documents quickly so its approach to systematic review is readily transparent.

d. *Peer review*. ACI encourages EPA to commit to using peer review on determinations where a substance and use condition are moving forward toward an unreasonable risk determination that could lead to a regulatory outcome. In contrast, peer review might not be necessary when EPA is identifying in a lower tiered risk assessment obvious low-risk use conditions (e.g., for a site limited intermediate) for which there is little need for expert assistance and detailed scientific review. ACI agrees with the Agency when it notes that it "expects that there will be individual circumstances where a chemical substance is found to not present an unreasonable risk or that findings are similar or the same as other jurisdictions (states or countries) that have reached similar conclusions based on the same information" and a peer review would be unnecessary. We agree with the Agency that peer review is appropriate in cases where the Risk Evaluation concludes that a chemical substance in a condition of use presents an unreasonable risk, and in cases of Risk Evaluations involving "novel, controversial, or precedent-setting science with significant interagency interest." However, the Agency should make transparent such policy determination and identify in the final rule those instances in which it intends to exercise its discretion not to propose using an independent peer review panel process. At a

minimum, ACI believes the junctures in which an independent peer review process should be preferred must include: a) the hazard evaluation phase, b) the exposure assessment phase, and c) the preparation of both the draft and final Risk Evaluation documents for substances and use conditions for which EPA intends to make an unreasonable risk determination that will lead to a risk mitigation regulation.

e. *Reliance on existing guidance and procedures for conducting Risk Evaluations*. ACI agrees that the Agency need not codify specific guidance on the use of particular modeling methods or techniques. The state of the science changes, and EPA must be able to adapt to fulfil its obligations under Section 26 to use the best methods available for the information available to the Agency. Nevertheless, EPA should take this opportunity to identify, refresh and republish any guidance documents related to risk assessment it considers to be outdated upon which it intends to rely to support the TSCA Risk Evaluation process. EPA also should advise and solicit public input at five year intervals as Section 26 requires revisions that are necessary for such documents and guidance and science-policy positions that will influence the long-term administration of the program.

Comments regarding specific elements of the proposed text for the CFR

a. The Agency proposed §702.39(a)(5) reads:

The extent to which EPA will refine its evaluations for particular conditions of use in any Risk Evaluation will vary as necessary to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment.

The notion of "refinement" is fundamental to the tiered risk evaluation approach for which ACI advocates. The Agency appears to acknowledge that it will use a tiered approach to streamline the identification of lower risk conditions of use and substances for which more detailed assessments are not needed. We believe it would be valuable for the Agency to provide greater detail regarding the use of tiered risk evaluations in the final rule and future guidance in this area.

b. The Agency proposed §702.39(a)(6) reads:

EPA may conduct a Risk Evaluation on a chemical substance in phases to allow the Agency to proceed with risk management on particular conditions of use.

ACI agrees with the Agency's proposed approach. However, the example given in the subsection which follows references the potential to use this approach to expedite risk management action. We believe this reflects an underlying bias that all substances and use conditions to be reviewed will be shown to present unreasonable risks. We believe it would be useful for the Agency to overtly state, and the regulation to also note, that the EPA has the authority and intent make a preliminary finding of no unreasonable risk for certain conditions of use while other conditions of use might remain under evaluation.

c. The Agency proposed §702.39(e)(5)(ii) (environmental health exposure assessment) reads:

Exposures considered will include individuals as well as communities, depending on the chemical substance and the ecological characteristics involved.

We recommend that EPA substitute "individual species populations" for "individuals" as ecological risk assessment more commonly considers populations rather than individuals, except in the case of endangered species which should be outside of the scope of TSCA Risk Evaluations.

d. In §702.41(b)(4), reference to <u>individuals</u> should be removed so that the text reads:

For environmental risk evaluations, it may be necessary to discuss the nature and magnitude of the effects, the spatial and temporal patterns of the effects, implications at the species, and community level, and the likelihood of recovery subsequent to exposure to the chemical substance.

* * *

ACI appreciates this opportunity to provide comments and information on Procedures for Chemical Risk Evaluations under TSCA and looks forward to further engagement with EPA on this and other related matters of LCSA implementation.

Sincerely,

Paul C. DeLeo
Associate Vice President, Environmental Safety