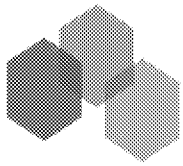

TSCA
NEW CHEMICALS
COALITION

January 19, 2018

Via Docket Submission

U.S. Environmental Protection Agency
Office of Pollution Prevention and Toxics
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Re: TSCA NCC Comments on EPA New Chemicals Review Process Documents; Docket Number EPA-HQ-OPPT-2017-0585

Dear Sir or Madam:

The Toxic Substances Control Act (TSCA) New Chemicals Coalition (NCC)[1] offers these comments in response to the U.S. Environmental Protection Agency's (EPA) request for comment on its process for reviewing new chemical substances under TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (82 Fed. Reg. 51415 (Nov. 6, 2017)). The input below builds on the oral comments made on behalf of the TSCA NCC during the December 6, 2017, EPA workshop.

EPA prepared three separate documents for discussion at the December 6, 2017, workshop: (1) Points to Consider When Preparing TSCA New Chemical Notifications; (2) New Chemicals Decision-Making Framework; and (3) New Chemicals Decision Guidelines Manual. The TSCA NCC is particularly pleased that EPA issued the second two documents that we believe make significant strides in providing transparency to new chemical submitters on how EPA assesses and reaches decisions on new chemical notifications. As the TSCA NCC noted to EPA before the December 6, 2017, workshop, while the information elements in the Points to Consider document are important, the identification of this information without more explanation does not provide the clarity, transparency, and understanding that affected companies need regarding EPA assessment and regulatory approaches under amended TSCA. Beyond knowing *what* to report in a submission, stakeholders need to understand *why* the information is needed by EPA assessors and *how* that information will be used by EPA and incorporated into a new chemical risk evaluation.

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[1] The TSCA NCC is a group of representatives from over 20 companies that have come together to identify new chemical notification issues under amended TSCA and work collaboratively with EPA and other stakeholders to address them.

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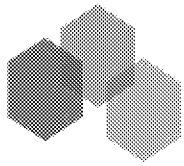


We offer below specific feedback on the three documents.

Points to Consider When Preparing TSCA New Chemical Notifications

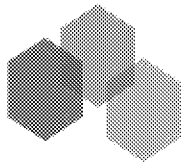
TSCA NCC members appreciate EPA's efforts in preparing the Points to Consider document. The document will assist submitters in preparing new chemical notifications that meet the requirements under Section 5 and facilitate EPA's review of the submission by ensuring that the information received accurately and completely reflects the intended manufacture, processing, distribution in commerce, use, and disposal of the new chemical substance. Below we identify additional considerations or revised text that we believe will strengthen the utility of this document for new chemical notifiers.

Section II: The TSCA NCC recommends that the section be expanded to include a discussion on analogs for notified chemicals. Specifically, EPA should provide guidance for submitters to consider in explaining and scientifically justifying the basis for any proposed analogs. This will provide EPA staff with clear indications as to why the submitter believes that EPA should consider and apply the analog in review of the new chemical. The TSCA NCC also recommends that EPA provide specific justification when EPA disagrees with the submitter's suggestion of analogs.

Section III, Part D, Subpart i - Human Health Hazard/Toxicity: The TSCA NCC urges EPA to expand on the language related to information needed for chemical substances that may be potentially respirable. In the document, EPA recommends that submitters consider whether information on the particle or droplet size may assist in EPA's assessment of respirability. We believe EPA should also consider other factors that could assist in its determination of respirability, such as viscosity and vapor pressure for liquids.

The TSCA NCC also suggests that an additional consideration be added in this section related to the potential for absorption, relevant or anticipated routes of exposure, and metabolic potential of the new chemical.

EPA should revise its bullet point that currently reads, "Justification for consideration of the analog for the endpoint(s) identified (e.g., similarity of structure, physical chemistry, toxicological data, as applicable)," to "Scientific justification for consideration of the analog for the endpoint(s) identified (e.g., similarity of structure, physical chemistry, toxicological data, metabolism, as applicable)."



The TSCA NCC urges EPA to consider the conclusions of other competent authorities, rather than relying solely on full studies on the analogs, and suggests that the guidance reflect this point.

Section III, Part D, Subpart ii – Environmental Fate: EPA should provide additional clarification on the two approaches offered for estimating fate parameters: (1) modeling and (2) use of physical-chemical properties. EPA should elaborate on and explain the difference between the two approaches and the reliability of information generated, particularly when a new chemical is not suitable for modeling.

Section III, Part D, Subpart iii – Aquatic (Environmental) Hazard/Toxicity: In its discussion regarding the use of the Ecological Structure Activity Relationships (ECOSAR) Predictive Model, EPA should provide clarity as to when the model should be used. The text could be interpreted to mean that EPA will use ECOSAR regardless of data included in the new chemical submission.

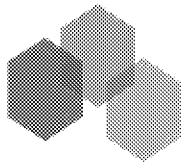
EPA should specify under what circumstances EPA will give preference to a ten-fold acute-to-chronic extrapolation or an ECOSAR predicted value in its derivation of chronic toxicity values for this endpoint. If EPA will default to whichever is more conservative, there is little incentive for submitters to perform aquatic toxicity testing.

EPA states that, as a general rule, it will consider that an organic new chemical substance has a low hazard if the log K_{ow} is greater than 8. EPA should specify whether it will use measured melting point, water solubility, or other measured physical-chemical data to improve the estimate of K_{ow}. EPA should also include examples of when this general rule would not apply. The TSCA NCC notes a number of circumstances when EPA assessors have excluded measured properties in the modeling calculations.

In the document, EPA explains that it may consider environmental aquatic hazard to be low for a specific toxicity endpoint value (96-h fish LC_{50}), if that value is greater than ten times the measured water solubility value or the measured water solubility value is less than 1 microgram/liter (< 1 part per billion). EPA should clarify that this also applies in the case of an ECOSAR estimate.

EPA notes that "information" related to environmental hazards for both short-term (acute) and long-term (chronic) exposures should be included in a new chemical submission. EPA should clarify whether ECOSAR estimates would be sufficient for this purpose.

EPA suggests that notifiers provide information on the percent of amine-nitrogen content for all relevant chemical substances (*e.g.*, polycationic polymers). The TSCA NCC



notes that EPA chemists routinely calculate this number. Rather than simply submitting the percent amine-nitrogen, the notifier could provide EPA with insight as to the limits of amine nitrogen intended or necessary for the functional use of the notified chemical.

EPA should revise the bullet point, "Provide justification for consideration of the analog for the endpoint(s) identified," to read, "Provide scientific justification for consideration of the analog for the endpoint(s) identified.

Section III, Part E: The TSCA NCC notes that potentially exposed or susceptible subpopulations are not mentioned in this section, which focused on exposure assessments.

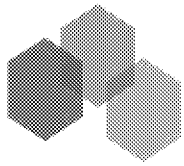
Section IV, Part B: In its discussion of chronic aquatic risk, EPA should provide clarification that the conservative criterion for potential chronic risk should not apply if it is known that the number of consecutive days for exceedance is lower than 20 (batch process).

Section VII, Part ii – Additional Information and Training: The TSCA NCC urges EPA to continue the Sustainable Futures program, and consider expanding it so that more parties can receive the training. We believe that stakeholders benefit greatly from this program and wish to see it utilized more robustly.

Input on New Chemicals Decision-Making Framework

The TSCA NCC applauds EPA in providing this document as part of the public review and comment on its new chemical review process. The Framework allows stakeholders to understand better EPA's approach in decision making for new chemical notices and is a solid first step in EPA's efforts to clarify its policies and procedures under new Section 5. Transparency and predictability are vital for a well-functioning New Chemicals Program, for submitters, for stakeholders, and for program efficiency. We provide below some thoughts and suggestions to strengthen the Framework document and EPA approaches.

Introduction: EPA should refrain from stating that the Lautenberg Act amendments require it to make affirmative determinations on Section 5 notices, as the term "affirmative" does not appear in the statute. The sentence in the EPA Framework document that currently reads, "The Lautenberg Act amendments to TSCA require that EPA make affirmative determinations on premanufacture notices received under section 5," should be revised to read, "The Lautenberg Act amendments to TSCA require that EPA make determinations on notices received under section 5."

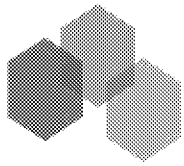


Footnote 3: The TSCA NCC supports the EPA statement that a reasoned evaluation will be able to shape hazard and exposure characterizations into either a quantitative or robust qualitative characterization of risk. We are concerned, however, with the statement, "This suggests that the level of uncertainty in a reasoned evaluation to inform a 'not likely' determination could be greater than that in an evaluation to inform a 'presents' determination." In our view, this could be read to mean that EPA will use the qualitative approach to support a "likely to present" determination but will be unable to do so for a "not likely to present" determination. The TSCA NCC suggests that EPA modify the language to state that in EPA's view the statutory language requires a greater degree of certainty for EPA to make a "presents unreasonable risk" finding.

Overall Framework: EPA references workplace practices and exposure controls as part of its consideration of conditions of use for a notified new chemical substance. The TSCA NCC reminds EPA of the points articulated in the TSCA NCC's December 1, 2017, letter to Jeffery Morris (EPA) regarding workplace exposure controls and regulations under the Occupational Safety and Health (OSH) Act. As stated in the Framework document, EPA should rely on the information provided by the submitter in a safety data sheet (SDS) on recommended personal protective equipment (PPE) and/or engineering controls to protect workers from potential exposure and incorporate those factors into the intended condition of use determination for the new chemical substance. Furthermore, EPA should recognize that the Occupational Safety and Health Administration (OSHA) has the statutory authority and extensive regulatory scheme, as well as its enforcement mechanisms, to govern workplace chemical exposures, including exposure to new chemicals. These include:

- OSHA's detailed regulations for use of PPE when needed to further limit exposures beyond that afforded by OSHA's preferred approach of engineering and process controls. The regulatory standard, for example, requires use of respiratory protection to protect employees from exposure to air contaminants above an exposure limit, or where such protection is otherwise necessary to protect employee health. The standard places a range of OSHA enforced responsibilities on employers, requiring that a written program of respiratory protection must be in place, including procedures for respirator selection, use, fit, testing, and so forth, training in use and hazards, and medical evaluations of employees who use such PPE.

- The General Duty clause of the OSH Act that, among other provisions, requires every employer to furnish to each of its employees a workplace free from recognized hazards that cause, or are likely to cause, death or serious physical harm. The "likely to cause" aspect of the General Duty

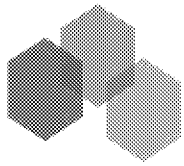


requirement is particularly relevant to new chemicals given the limited information that is often available.

If the PPE and engineering controls are considered as part of the conditions of use, they should also be considered in EPA's decision regarding imposition of risk management requirements. We remind EPA that, as discussed in the referenced letter, under TSCA Section 5(f)(5), it is required to consult with OSHA before requiring workplace protections under Sections 5(e) and (f). EPA can inform the submitter and OSHA of its hazard assessment and EPA's views on exposure limits and PPE and EPA can publish such information (for example, using its ChemView database), and point to such information using an Inventory Flag so that other manufacturers or processors are aware of EPA's concerns and address those concerns in their own workplace safety assessments. We believe that absent extraordinary circumstances, EPA should rely on OSHA's pervasive and established requirements and enforcement mechanisms to ensure workplace protections for new chemicals. It is frequently the case that the new substance is less hazardous than an existing substance it is intended to replace. If two substances both require gloves, goggles, and a particular respirator to ensure a safe workplace, but one has a Section 5(e) order and/or a significant new use rule (SNUR) requiring such protection and the other applies these workplace protections based on the General Duty clause and OSHA's regulations, there is little to be gained, and much to be lost by the unequal TSCA regulatory burden that disfavors the safer new chemical alternative. We look forward to further discussion with EPA on the points raised in our letter.

The TSCA NCC supports the Framework document statement that identification of "reasonably foreseen conditions of use will be fact- or knowledge-specific: that is it will be based on evidence, knowledge, or experience leading EPA to foresee conditions of use different from those described in the submission" and that EPA "should try to minimize speculation when identifying reasonably foreseen conditions of use." Additional language that clarifies that "reasonably foreseen" is not the same as "any imaginable" condition of use should be included.

The TSCA NCC also supports the proposed approach to address concerns with reasonably foreseen conditions of use, but not the intended conditions of use as described in a submission, through the use of SNURs. The TSCA NCC is aware that some non-governmental organizations (NGO) have raised concerns with this approach but the TSCA NCC does not believe these concerns are valid. The concept that persons using a chemical would be unknown to EPA and therefore unable to have enforcement applied is ill-conceived. Parties using a chemical are required to have an SDS and provide to an inspector upon request, which would trigger any questions as appropriate. While testing cannot be imposed via a non-order SNUR as it can via a SNUR based on an order, EPA can and does discuss testing needs in SNURs and if there is a need to impose testing, EPA has that authority under Section 4. Like consent orders, SNURs can be reopened if EPA comes to understand new toxicity or risk issues. SNURs apply



to all parties using the chemical in question, whereas consent orders only apply to the signatories and a SNUR is typically written to have the same binding effect on a premanufacture notice (PMN) that a Section 5(e) consent order can. The TSCA NCC notes that in its "non-order SNUR" approach, EPA does not make its final determination until the SNUR is published in final, so non-exempt commercial activity is prohibited until the SNUR is in place.

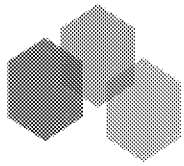
"Not Likely to Present Unreasonable Risk" Section: The TSCA NCC is concerned that EPA does not explicitly mention the role of analog information in making a "not likely to present unreasonable risk" decision. Analog information is clearly identified as a consideration in an EPA determination of "presents unreasonable risk." The TSCA NCC believes that analog data can and should be relied on for either "presents" or "not likely to present" determinations, but suggests that this section be expanded to include how analog data can support a "not likely to present unreasonable risk" decision.

"Insufficient Information to Permit a Reasoned Evaluation" Section: The TSCA NCC notes that determinations under Section 5(a)(3)(B)(i) are based on health and environmental effects. As such, EPA should delete reference to "exposure potential" in the discussion of data adequacy.

Furthermore, the TSCA NCC reminds EPA of the need to develop information that will be needed to inform decisions on prioritizations of existing chemicals. In the event EPA determines that it has insufficient information to permit a reasoned evaluation of a new chemical substance, but close analogs of that substance are active in commerce, EPA could consider testing on the category, cluster, or class of substances, rather than simply placing the testing burden on the new chemical. This approach reduces the "bias" against new chemicals and builds off of EPA's previous efforts to develop categories, such as the category evaluations conducted under the High Production Volume (HPV) Chemicals Challenge.

Additional Thoughts and Comments: EPA should expand the Framework to include discussion on Section 5 exemptions.

EPA should provide stakeholders with assurance that "reasonably foreseen" conditions of use do not equate to "any possible conditions of use." As noted in the TSCA NCC oral comments from the December 6, 2017, workshop, EPA appears to be proposing regulation for every substance for which EPA has identified a hazard other than low hazard for both health and the environment. Such a "hazard-based" approach cannot possibly be the correct interpretation of TSCA as reformed; otherwise Congress would have not left the risk-based standard in place for the "not likely" determination in the TSCA amendments.



EPA should provide more clarity on the level of certainty needed on hazards and conditions of use for EPA to reach a "not likely" determination.

While the TSCA NCC understands and appreciates that each new chemical submission is unique and requires its own evaluation, EPA should strive to include additional case studies or examples in the Framework document.

As noted in the TSCA NCC oral comments at the December 6, 2017, workshop, and as discussed in written communications with EPA, the TSCA NCC recommends that EPA provide written guidance on the use, applicability, and legal effect of the "polymer flags" that are being used by EPA in the case of a PMN for a polymer that meets the polymer exemption criteria.

Outline for New Chemicals Decision Guidelines Manual

As requested, the TSCA NCC is providing input on sections that should be added to the outline for the New Chemicals Decision Guidelines Manual, as well as other suggested edits.

Section 1.6 - Affirmative Determinations, Risk Management and Regulatory Options:

- Delete the term "affirmative" as it does not appear in the statute.
- Add "OSHA Consultation Section 5(f)(5)."
- Add "Section 5(h) Exemptions."

Section 7.0.2 - Testing Strategies:

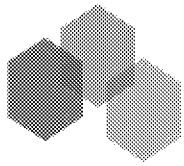
- Add "and Adverse Outcome Pathway Information."

Section 7.1 - Development of New Categories:

- Revise to two separate units: (1) "Updating of Existing Categories" and (2) "Development of New Categories."

Section 8.0.2 - Selection and Use of Analogs:

- Revise title to read "Selection and Use of Analogs and SAR Analysis."



Section 8.2.3 - Use of Models:

- Revise title to read "Use of Models and SAR Analysis."

Section 8.2.4 - Selection and Use of Analogs:

- Revise title to read "Selection, Scientific Justification, and Use of Analogs and SAR (QSAR and SAR) Models."

Section 9 - Environmental Fate:

- Include a section, "Overview of Environmental Fate."

Section 10 - Chemical and Biotechnology Exposure Assessment:

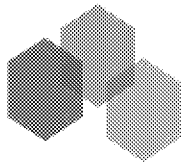
- The TSCA NCC believes this section needs more depth and explanation.
- Add "Overview of the Exposure Assessment Process."
- Add "Human Exposure Assessment."
- Add "Occupational Exposure Assessment."
- Add "Relationship to OSHA Hazard Communication, SDS, and General Duty."
- Add "General Population and Consumer Exposure Assessment."
- Add "Potentially Exposed Subpopulations."
- Add "Susceptible Subpopulations."
- Add "Environmental Exposure Assessment."

Section 11 - Exposure-Based Policy for Chemicals:

- Add "Overview."
- Add new section -- "Role of Section 26 Sound Science Provisions" before current Section 12.

Section 14 - Risk Management:

- Add "Section 5(f)(5) OSHA Consultation."
- Exemptions.



Section 14.2 - Statutory Determinations:

- Revise to read "Statutory Determinations, Regulatory Actions, and SNURS on PMNs."

Appendix A - Chemical Categories:

- Revise to two separate appendices: (1) "Existing Chemical Categories" and (2) "Guidance/methodology to formulate and use categories."

The TSCA NCC looks forward to continuing to work with EPA to strengthen the Section 5 program. Thank you for the opportunity to provide these comments.

Sincerely,

Kathleen M. Roberts
TSCA NCC Manager