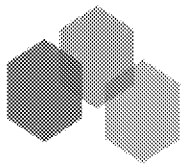

TSCA
NEW CHEMICALS
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January 23, 2018

Via E-Mail

Jeffery Morris, Ph.D.
Director, Office of Pollution Prevention and Toxics
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1300 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

Dear Jeff:

This letter is submitted on behalf of the Toxic Substances Control Act (TSCA) New Chemicals Coalition (NCC), a group of company representatives that have identified specific issues related to new chemical review at the U.S. Environmental Protection Agency (EPA) under amended TSCA. The TSCA NCC was formed to work collaboratively with you and others at EPA to resolve these issues while still achieving mandated deadlines and timely chemical reviews.

We are well aware of and grateful for EPA staff's efforts to address the backlog of premanufacture notices (PMN) that initially resulted after new TSCA was enacted. As we stated during the December 6, 2017, EPA workshop, we are alarmed that EPA's review of PMNs considered since TSCA was amended has resulted in "not likely" determinations for only ten percent of the notifications submitted. This contrasts sharply with the >80 percent that were dropped without regulation under old TSCA. While we recognize and understand EPA's obligation under new TSCA to make determinations and take necessary actions, we do not agree with the implication that the vast majority of PMNs were under-regulated under old TSCA. We believe that EPA's current practice of imposing restrictions may be inappropriate and, in many cases, is based on a review process that lacks transparency and on legal and/or scientific principles that are, for the most part, entirely unspecified. This lack of clarity has inspired regulatory results that to us seem anomalous.

For example, there are six process steps and/or meetings that are part of EPA's review of a PMN -- (1) Chemistry Review and Search Strategy (CRSS); (2) Structure Activity

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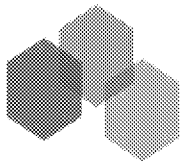

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Team (SAT); (3) Engineering and Exposure Assessments; (4) Focus meeting; (5) Risk Assessment Division (RAD) Disposition meeting; and (6) Division Directors meeting. We believe it would be helpful to confirm that in each of these steps the appropriate parameters and interpretations for "reasonably foreseen" conditions of use are identified so that they can be applied consistently. These criteria should not be subject to change between steps or applied differently by EPA staff or managers. A request from EPA senior management to new chemical review staff to describe the reasonably foreseen conditions of use of a particular chemical should be quickly and easily answerable, and the same answer should be provided at all points during the review process. Similarly, the review process should be based on a clear and consistent understanding of what is considered a reasonably foreseeable (as opposed to any foreseeable) use, and that understanding should be consistently applied during the review process.

Within the SAT, it would be helpful to obtain a better understanding on whether staff at this step in the PMN review process might conclude "insufficient information" exists and, if so, how staff makes "low/moderate/high" calls for health and ecotoxicity concerns. We believe that any default exposure/release assumptions that are applied should be compiled, shared, and reviewed to ensure all such assumptions have been appropriately peer or expert reviewed. Furthermore, we have noticed a number of cases in which information provided in a submission was ignored or missed or in which assessors made errors in the information input to EPA models. While we recognize the resource constraints that EPA is operating under, such errors exacerbate the problem, requiring additional effort for EPA reviewers to rerun models and revise the various reports. This problem may be a result of or compounded by the organization of assessment teams that do not provide for redundancy of expertise.

Recognizing that amended TSCA states that any "unreasonable risk" should be managed "to the extent necessary," EPA new chemical review staff should be able to explain clearly exactly how any proposed management action satisfies the "to the extent necessary" standard, but does not exceed it. EPA should also be able to provide documentation of coordination with the U.S. Occupational Safety and Health Administration (OSHA) for any proposed workplace exposure control measures, as required under TSCA Section 5(f)(5).

We offer these as illustrative examples of the types of issues TSCA NCC wishes to explore with EPA. We believe our members are well suited to share with EPA other examples that merit discussion and believe that our collective experience with the new Section 5 process,

and thoughts and observations on it, will assist EPA in developing a robust, transparent, and legally defensible process.

The TSCA NCC membership appreciates that you are aware of concerns on the high percentage of regulated new chemicals and will be reviewing new chemical assessment decisions for the time being. We offer below several questions as potential discussion starters between you and the PMN review staff.

- At each step in the PMN process, how are reasonably foreseen uses identified and differentiated from "any possible" conditions of use?
- How much of a driver are reasonably foreseen uses in precluding "not likely" determinations?
- How and on what basis does the SAT make its low/moderate/high hazard calls? What is the role of uncertainty in these judgments?
- Under what circumstances would EPA make a "not likely" determination if SAT makes a moderate or high hazard call?
- What role do chemical analogs pay within the SAT deliberations? How does SAT assess the appropriateness of analogs?
- How do the number of SAT low/moderate/high calls post amended TSCA compare with prior statistics?
- Is there a summary of default assumptions used for exposure/release estimations?
- What kinds of risks are attributed to chemicals with insufficient information?

- If testing is proposed, how are elements of Section 4 (tiered testing, animal welfare issues) considered and incorporated?

- If workplace exposure controls are required, how did the required coordination with OSHA occur?

- If restrictions are proposed, how are those assessed to be "to the extent necessary"?

Thank you for your consideration of these suggestions. We hope you find them helpful.

Sincerely,

Kathleen M. Roberts

cc: Nancy B. Beck, Ph.D., DABT (via e-mail)