

June 14, 2017

Via E-Mail

Nancy B. Beck, Ph.D., DABT  
Deputy Assistant Administrator  
Office of Chemical Safety and Pollution Prevention  
U.S. Environmental Protection Agency  
1201 Constitution Avenue, N.W.  
Washington, D.C. 20002

Dear Dr. Beck:

Thank you for visiting with Charlie Auer, Rich Engler, and me on Tuesday. We greatly enjoyed our discussion, welcomed the opportunity to visit briefly on topics of shared interest, and appreciate your devoting time to our discussion.

To memorialize briefly a few of the many topics we touched upon, we took the liberty of noting them below, in no particular order. We would be pleased to continue our discussion, after June, as your schedule permits.

**Open a Docket to Submit TSCA “Fixes”** -- As we discussed, many stakeholders are thinking hard about creative solutions to some Toxic Substances Control Act (TSCA) implementation challenges. To ensure stakeholders know that the U.S. Environmental Protection Agency (EPA) is solicitous of suggestions and proposed solutions, it may wish to open a docket to house all such suggestions. A docket, the opening of which would be noted in the *Federal Register* and on EPA’s website, would provide a convenient and transparent means for allowing stakeholders to review and consider suggestions, build upon them, and jump-start the development of other solutions based on docket submissions. As an example of such TSCA fixes, we briefly reviewed the paper we developed on the “Use of the Chemical Name in Managing New Chemical Polymers.” The paper has been provided to Dr. Jeff Morris and others in the Office of Pollution Prevention and Toxics (OPPT).

**Establish a TSCA FACA Committee** -- The National Pollution Prevention and Toxics Advisory Committee (NPPTAC) sunset years ago after the non-governmental organization community elected to withdraw. We have suggested to the Office of Chemical Safety and Pollution Prevention leadership many times over the past three years resuming a Federal Advisory Committee Act (FACA) committee focused on TSCA regulatory, policy, and program implementation issues. We renew that request here. Such a committee would operate in parallel to and complement the Science Advisory Committee on Chemicals. The Pesticide Program Dialogue Committee has been an enormously successful mechanism to identify, discuss, and resolve issues of concern to the pesticide community. There is every reason to



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believe a similar FACA committee would be effective in addressing TSCA issues, especially in light of Lautenberg. While we appreciate EPA's investment of time in public hearings, they seldom provide the venue needed for thoughtful, reflective discourse on complicated issues, such as the meaning of key statutory terms (*e.g.*, "not likely," "reasonably foreseeable"). A FACA committee would provide such a venue and ensure continuity of consideration on an on-going basis.

**Attend Focus and Other New Chemicals Meetings** -- We encouraged that you make an effort to drop in, without advance notice, on the key meetings that occur with regularity during the new chemicals process to get a flavor of the nature and the level of the discussion. The list could include both technical and regulatory meetings. The former includes both initial (Chemistry Review and Search Strategy (CRSS), Structure Activity Team (SAT), and Focus) and late stage meetings while the latter includes the Options meeting and the Division Directors meeting. We believe this would be a very useful and informative use of your time. You might also find it useful to review examples of the reports produced after these meetings to get a sense of how the discussion is captured and documented. We appreciate how busy you are, but there is no substitute for the real-time experience this opportunity would provide.

**Ensure Legal Review of All Consent Orders** -- As we discussed, the EPA consent order template may need reviewing by legal counsel. We suggest that all consent orders be reviewed by counsel as a matter of routine.

**15-Day Review Period** -- Jeff Morris' PowerPoint indicates that EPA is dispensing with the "action letter" approach and sending consent orders directly to submitters and requesting a response within 15 days. We suggested to you that requiring a response within 15 days is not possible without also providing submitters a substantive and meaningful summary of the basis of EPA's risk issues. EPA must provide a sound science justification for its determination; justification should include the Focus, CRSS, SAT, engineering/exposure, and reports developed after the Focus meeting (*e.g.*, during Standard Review). The reports would be sanitized of any non-submitter confidential business information (CBI) (*e.g.*, information on premanufacture notification analogs), but can provide critical visibility into EPA's hazard, exposure, and risk assessments of the new chemical substance. We suggest that OPPT work over time to improve the clarity and transparency of the reports, which are cryptic given their current focus almost exclusively on an internal audience. Reports can also be redesigned to make it easier to sanitize information that is CBI to the submitter. Another suggestion is that EPA, after promulgation of the fees rule, adopt the practice of timely providing submitters with copies of reports on all cases as a matter of routine.

**New Chemical Category Documents** -- We also briefly discussed the lung toxicity category documents that we recently received and indicated that we planned to submit comments. We encouraged that EPA consider an effort to update and improve the documents on

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relevant categories and to provide an informal public review step. Many of the other categories in the OPPT Chemical Categories document are quite dated. Given new TSCA, the documents play a more significant role in EPA's determinations and testing strategy; reviewing, updating, and including discussion of the tiering strategy for testing will be important in meeting the sound science provisions in Section 26.

Sincerely,

A handwritten signature in black ink, appearing to read 'Lynn L. Bergeson', with a long horizontal flourish extending to the right.

Lynn L. Bergeson  
Charles M. Auer  
Richard E. Engler, Ph.D.