

Message

From: Beck, Nancy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=168ECB5184AC44DE95A913297F353745-BECK, NANCY]
Sent: 3/11/2018 3:19:12 PM
To: Cox, Kevin [kcox@nsf.org]
CC: mwhittaker@toxservices.com [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f63b7262223e4c33a1ca6606254d1372-mwhittaker@toxservices.com]; Phelka, Amanda [aphelka@nsf.org]
Subject: RE: SOT TSCA Session questions

Kevin,
I'm arrived. Had some great food last night and am ready for the day.
The questions below seem very applicable and I can be ready to respond to them.

See you all soon,
Nancy

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Ex. 6
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From: Cox, Kevin [mailto:kcox@nsf.org]
Sent: Saturday, March 10, 2018 6:34 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Cc: mwhittaker@toxservices.com; Phelka, Amanda <aphelka@nsf.org>
Subject: SOT TSCA Session questions

Greetings,

Safe travels to San Antonio if you haven't already arrived! For tomorrow's session, Amanda, Meg and I have the prepared below questions for the open discussion following your remarks. The idea is to ask a few of the below questions prior to opening session up to questions from the audience. If you have any questions/concerns with any of the below questions, please let me know.

- 1) Is there a recommendation for when external parties should begin to prepare risk evaluations according to the available guidance? Is there an anticipated date by which the first EPA prepared risk evaluation will be available to serve as an example?
- 2) It is mentioned in the guidance document for external parties that there is the potential for a consensus-based standard to be developed to provide greater assurance that risk evaluations would meet the requirements of TSCA and the EPA quality standards. What strategy would the EPA employ to prepare the standard?
- 3) Based on experience, there is a good chance that individuals without the required expertise will prepare and submit evaluations that do not meet either TSCA requirements or EPA quality standards. Has there been any consideration given to how the EPA will ensure that risk assessors external to the EPA conducting risk evaluations are sufficiently competent to do so? Perhaps a similar structure to that used by SaferChoice and the third-party profilers?

- 4) Is there an anticipated need of the agency to collaborate with an outside party or parties that can be vetted by the EPA to either prepare risk evaluations with greater certainty that they will meet the quality expectations or for these outside parties to peer review external party risk evaluation submissions before review by EPA staff?
- 5) EPA's June, 2017 "Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluations Under the Toxic Substances Control Act" does not specifically address conflict of interest, which has the potential to impact third party risk evaluations. In November, 2017, FDA released their draft Best Practices for Convening a GRAS Panel. This guidance outlines conflicts of interest that would preclude an independent and object GRAS assessment—which is critical to protecting public health. To ensure similar objectivity in third party reviews conducted under TSCA, would EPA consider issuing similar guidance? If not, why not?

Thank you!

Kevin



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