Revised Suggested Audience Questions

TSCA

1. Currently to assure consistency in PMN assessments, the Office Director is directly involved in final review decisions. Over time, for the sake of efficiency, some of these kinds of decisions are typically delegated down to the Division level as part of the assessment practices and routines.

Is OPPT considering such changes to help make decisions more efficiently, and if so, what sorts of cases or issues might be delegated?

2. When evaluating "reasonably foreseeable," OPPT appears to rely mostly on the results of its modeling which generally are more conservative than engineering reports or other information the submitter does or can provide.

OPPT might review what information it finds useful or make suggestions to submitters about what information is more readily incorporated into the assessments – which might save time and review resources for all involved.

Is this a reasonable request to further articulate how to refine the issues around "reasonably foreseeable" exposures?

3. Generally stated endpoints such as "irritation" sometimes are unclear as to what it might mean for a risk that calls for some kind of mitigation.

One suggestion might be, now after the first two years of amended TSCA, to clarify how EPA is now assessing broadly stated endpoints is to have a public review of how certain terms how submitters and other stakeholders might anticipate useful information and how it might be used during EPA reviews?

4. As we all have learned new assessment requirements and review procedures, we still see what might be called "obvious errors" -- solids being assessed as liquids and vice versa, errors in production volume or release amounts, etc.

We understand that OPPT has gone through a lean process, but we have not seen a reduction in the error rate. What can OPPT do to help ensure that assessments are being reviewed for accuracy?

5. This question relates to the inhalation category for surfactants. EPA's category for all surfactants is informed solely by inhalation data for a single cationic surfactant that is also a pesticide active ingredient. Based on that "worst case," EPA sets a low POD for all surfactant PMNs that do not have inhalation data leading to stringent respiratory protection (*e.g.,* powered air supply APF 1000 respiratory protection).

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Both OPP and OPPT use conservative models as part of the standard risk assessment process. This can include "worst case" assumptions since exposure data may be limited, among other conservative estimates.

Sometimes this can lead, however, to outcomes which are difficult to understand: Example: inhalation assessments without inhalation data often lead to mitigation measures even if those surfactants are listed on the SCIL (Safer Chemical Ingredients List)?

One suggestion is for OPPT to review how it has sufficient data to designate a particular surfactant as "safer" when a surfactant in a PMN will be barred from any consumer use or any spray use.

FIFRA

1. Unlike many other nominees facing Senate confirmation, Assistant Administrator Dunn, you had broad bipartisan support at your confirmation hearing before the Senate Environment Committee. The Senators especially cited your work as Regional Administrator in New England -- Region 1. What lessons or approaches from the successful experience in Region 1 do you think will be most applicable to now being Assistant Administrator for OCSPP?

2. During the shutdown, not only did PRIA not get reauthorized, but also EPA reported that hundreds of pesticide registration applications were received on top of the already large workload in the pesticide program. When will EPA know and communicate the impact the shutdown and reduced fees have on previous deadlines, the need for extensions, and general impacts on decision time lines?

3. Regarding ESA, both the Bush and Obama Administrations devoted significant efforts trying to coordinate OPP reviews with the efforts of the Services. Now, EPA with USDA and the Services are working under a Memorandum of Agreement -- issued about a year ago -- to attempt to fashion a more workable and effective way of working together to meet the requirements of both ESA and FIFRA. Given the many competing priorities of both OPP and OPPT -- registration review, TSCA deadlines -- how do you plan to devote enough time, energy, and attention to bring the inter-agency process to a successful conclusion?

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