Other Advance Questions

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Public Access to Information

- TSCA section 5(d) – each PMN "shall be made available, subject to section 14, for examination by interested persons"; status?
  - Sanitized PMNs and their attachments can be requested directly from the EPA Docket Center at: Phone: (202) 566-1744; Email: docket-customerservice@epa.gov
  - EPA is working to create electronic dockets for PMNs
  - Sanitized versions of signed consent orders are available in ChemView and using the PMN search tool

Public Access to Information

- "TSCA section 5(g) – "statement of Administrator findings" requirement for each "not likely" determination is inadequate in light of definition of "best available science"; status to release documents with actual basis for finding?
  - Requirements in section 26(h) with respect to best available science do not dictate specific content of the statement of Administrator findings under section 5(g); determination documents are available at: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chemicals-determined-not-likely.
- Updates to EPA's PMN status database/table for tracking PMN status are not occurring
  - EPA is still updating its final determinations on the web.
  - Previous terminology used for interim status created confusion; EPA is developing revised terminology for interim status and intends to resume updating that column once the effort is complete.

Confidential Business Information

- TSCA section 14 – EPA's review of non-exempt CBI claims; status?
  - Per section 14(c)(3), EPA requires upfront substantiation of CBI claims
  - EPA is reviewing CBI claims as required under section 14(g)
  - On 1/19/17, FRN published giving submitters from 3/21 – 10/19/17 to substantiate all non-exempt CBI claims in submissions made from 6/22/16 – 3/21/17.
  - CBI claims in many submissions received during that timeframe have only recently been fully substantiated; we're reviewing & making determinations.

Confidential Business Information

- How can the public track review results, ensure timeliness; how will EPA disclose decisions on CBI claims?
  - Disclosures required under TSCA Section 26(j) are subject to the disclosure restrictions in Section 14
  - EPA's confidentiality determinations, and the substantiations pertaining to those determinations, may themselves contain CBI
  - EPA is considering how best to publicly communicate various aspects of CBI review efforts, including the release determinations.

Unique Identifier

- TSCA section 14(g)(4) - requires that EPA, among other things, "assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure…."; status?
  - Purpose of unique identifier is to provide a specific reference identifier that protects the confidentiality claim to the specific chemical identity for the claim duration, while providing a way for the public to identify other filings pertaining to that substance.
  - Per 5/8/17 FRN, EPA identified challenges re application of unique identifier requirements and requirement to protect specific chemical identify of valid CBI claims
  - 5/24/17 public meeting held to discuss issues; written comments accepted through 7/7/17
  - EPA is reviewing information collected and working to develop acceptable approach

Chemical Identity

- TSCA section 14(c)(4) – requires EPA develop guidance for generic names; status?
  - EPA has begun drafting guidance for generic names based on a review of statutory requirements, existing guidance, and current CBI review efforts for confidential chemical identities.

- TSCA section 8(b)(4)(C) – requires EPA "promulgate a rule that establishes a plan to review all claims to protect specific chemical identities of chemical substances on the confidential portion" of the TSCA Inventory; status?
  - EPA is engaged in the initial regulatory development processes to develop this required rule.

Risks to Exposed or Susceptible Subpopulations

- Evaluation of whether new chemicals "may present an unreasonable risk to a potentially exposed or susceptible subpopulation"
  - Relevant toxicity endpoints are compared to exposures that incorporate behavior patterns for subpopulations, as appropriate for the use and exposure scenarios for the chemical.
  - As an example, if a chemical has developmental concerns EPA will evaluate the drinking water exposures based on the higher amount of water consumed per body weight for young children if children are an exposed population.

Alternative Animal Testing

- TSCA section 4(h) – requires EPA to explain the basis for any decision that requires the use of vertebrate animals
- Request that EPA consider adding functionality to query ChemView by the decision reached and whether the use of animals is required, as well as to sort the output by date
  - EPA will explore the possibility of adding ChemView functionality as requested