HBCD (CASRN 3194-55-6)
Comments on Planning and Scoping

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Planning and Scoping (HHRA 2014)

- Planning and scoping contributes to development of a sound risk assessment (RA) that serves its intended purpose
- Provides context for the RA and the intended use of its results
- Is an important first step to ensures that each RA has a clear purpose and well-defined vision
- “Risk assessments should not be conducted unless –
  - they are designed to answer specific questions, and
  - that the level of technical detail and uncertainty and variability analysis is appropriate to the decision context.” (NRC 2009, 247)

Concerns with HBCD Planning and Scoping

- No information on environmental levels is provided; however, persistence is discussed.

- Detection in human tissues (breast milk, adipose, and blood) is noted. Assessment notes the suggestion of inhalation and ingestion of dust as being considered as a major source of exposure. Citation is a study that looked at fetal and placental tissue levels.

EPA Justification Not Well Supported

- "Given its potential for widespread human exposure, the IRIS Program is developing an assessment of HBCD to address multiple needs. Several activities that would benefit from the IRIS assessment of HBCD are presented below."
  - How does this lead to HBCD prioritization?
  - Is there any reason to believe levels are a concern?

Activities that would benefit from an IRIS Assessment:

1. IRIS assessment would be useful for rulemaking and risk assessment under TSCA (cites OPPT Action Plan) and TRI.

   TSCA 5B4 rulemaking was withdrawn.

   Draft SNUR released in 2012, no call for data; was focused on consumer textiles only.

   TRI does not require an IRIS value for listing.

EPA Justification Not Well Supported (2)

2. EPA is reviewing HBCD in the DfE program.

   A draft has already been released; no data needs are identified for HBCD.

3. EPA, FDA, and States issue fish advisories.

   To our knowledge no Federal or State Agency has identified HBCD as a high priority for a fish advisory.

4. HBCD was considered on the CCL3.

   Was part of the 7500 chemicals in the ‘universe; did not move forward as a top 600 priority; was not nominated and no public comments were received. See: http://water.epa.gov/scitech/drinkingwater/dws/ccl/upload/CCL3_Chemicals_Universe_08-31-09_508_v3.pdf.

5. IRIS values are used to develop Human Health Ambient Water Quality Criteria.

   No need has been identified.

EPA Justification Not Well Supported (3)

6. An IRIS assessment may be useful for EPA programs involved in waste management and site cleanups.
7. HBCD has been identified as a Substance of Very High Concern under REACH.

IRIS HBCD Prioritization

- Has a true EPA need been identified, or is it simply that an IRIS value might be useful for some future use?
  - IRIS assessments are resource intensive, costly and only a few are produced each year.
  - IRIS must ensure that the values developed are fit for purpose. Its not clear that a true purpose has been identified to justify conducting an IRIS level assessment.
  - Will health protective point estimates, that are not central estimates, be sufficient?
  - IRIS must ensure it will sufficiently characterize uncertainty and variability for the specific uses. This is hard to do when there is no clear use.

Planning and Scoping Must Be Robust

Five questions posed in HHRA Framework (from EPA 1997)

1. What are the overall purposes and general scope of the risk assessment? Are there legal limitations or other legal considerations? If so, what are they?

2. What risk assessment products (quantitative and qualitative) are needed by management for informed decision making? What is needed for other analyses (e.g., economic analysis)?

3. What resources are required, available or pending? Resources could include data or models, funding, personnel, expertise and/or coordination with other organizations.

4. Who will be involved in conducting the risk assessment, and what are their roles?

5. What schedule will be followed? This will include provision for timely input to the decision making process, as well as, timely and adequate internal and independent external peer review, where appropriate.

Questions and Discussion