Diethyl Phthalate (DEP)
Comments on Planning and Scoping

Nancy B. Beck, PhD, DABT
April 23, 2014
EPA April Bimonthly Meeting

American Chemistry Council

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 DEP Planning and Scoping

- EPA does not use most recent available information.
  - EPA estimates production is 10-50 million lbs; 2012 CDR indicates production volume is 5.6 million lbs.
  - Many citations > 10 years old; assessment provides links but dates of citations are not transparent.
- EPA provides no context for occurrence data.
  - What is significance of surface water levels? (0.01-0.5ug/l)
  - What are levels found in soil and groundwater? (4-5% occurrence)
- DEP does not bioaccumulate; quick biodegradation.
- EPA “findings” inconsistent with NHANES data
  - MEP levels dropped 42% (Zota et.al. 2014, EHP)
  - Levels in children about 50% less than adults.
    - EPA states that infants and children “may be especially vulnerable because they have higher exposure levels and are exposed through critical developmental stages.”

EPA Justification Provides Limited Details

- "Given the documented widespread human exposure to DEP, the IRIS Program is developing an assessment of DEP to address multiple needs."
  - How does this lead to DEP prioritization?
  - Is there any reason to expect that exposure is a concern?

Identified Needs:

1. For risk assessments and to define remediation goals at Superfund and RCRA sites.
   - No citations for RCRA concerns provided.
   - Are there other screening values that could be used?
2. Because DEP was considered in CCL3 but not included.
   - DEP nominated amongst 7500 chemicals but did not move forward within the top 600.
3. Because of unique children's exposures and potential sensitivities, is a priority for OCHP.
   - What are specific needs?
   - How ensure values provided are fit-for-purpose?

Has EPA Considered Available Agency Data?

2010 screening level characterization conducted for DEP and DMP concluded:

- The acute oral (rats and mice), dermal (guinea pigs) and inhalation (rats) toxicity in animal studies is low.
- Oral repeated-dose and reproductive toxicity data in rats and mice show effects at 750 mg/kg/day (decreases in body weight) and 3250 mg/kg/day (reduced litter size), respectively. The NOAELs for these studies were 150 mg/kg/day and 1625 mg/kg/day, respectively.
- Maternal toxicity is seen at oral (dietary) doses of 1910 mg/kg/day (decreased body weight), with a NOAEL of 200 mg/kg/day.
- Skeletal variations are observed at the highest tested dose of 3210 mg/kg/day.
- DEP not mutagenic when tested in vitro in bacteria and does not induce chromosomal aberrations when tested in vitro.
- DEP is not a skin or eye irritant in rabbits.
- DEP is negative in one-year initiation/promotion cancer studies (dermal route of exposure) in mice.
- The NTP reported negative results in rats and equivocal results in mice in separate two-year dermal cancer studies.

http://www.epa.gov/oppt/chemrtk/hpvis/hazchar/Category_%20Phthalate%20Esters_March%202010.pdf

DEP Prioritization

- IRIS assessments are resource intensive and costly; only a few are produced each year.
- Use 2010 screening evaluation.
  - Are exposures truly a high priority concern for children and adults?
- Ensure that the values developed are fit for purpose.
  - Are health-protective point estimates sufficient?
- Ensure that IRIS will sufficiently characterize uncertainty and variability for the specific uses.

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