Points to Consider (PtC) When Preparing TSCA New Chemical Notifications

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Outline of Draft PtC

I. Purpose
II. General Information Requirements
III. New Chemical Process
IV. Risk Calculations
V. Focus meeting
VI. Standard Review
VII. Post-Submission
VIII. Pilot and comments received
I. Purpose

- PtC provides concise guidance to improve PMN submissions – largely based on existing documentation, e.g., Sustainable Futures (SF)
  - PtC should reduce delays and back and forth with submitters
  - Two common problems in submissions
    - Provided information does not allow for refinement of risk assessment
    - Useful information that is in the submitter’s possession is not provided at all → e.g., analog data
- Document sent out to industry participants for comment and as part of a pre-notice communication pilot
II. General Information Requirements

- Chemical identity
- Production, import and use
- There is not a base set of guideline testing (pchem, fate, ecotoxicity, human health) that must be provided
Focus on information that can improve and expedite review

- Consider a pre-notice consultation meeting
  - “Lower tier” than full PMN review

Covers all sections of risk assessment including chemistry, hazard, worker/consumer/general population exposure, environmental fate and ecological exposure

Includes descriptions of assumptions that are commonly made in the absence of information
III.b. New Chemical Process

- Know your chemical
  - Begin with p-chem followed by partitioning, absorption, metabolism, degradation...
  - Understand the chemical type for the submission and the relevant issues
    - Is the chemical likely to hydrolyze → the degradants will be important for ecotoxicity
    - Does your chemical fit in a new chemical category
      → Consider the described testing to determine potential data needs
III.c. New Chemical Process

- Examples of useful information
  - Particle size distribution
    - Strongly impacts worker exposure
      - Should target form of chemical that workers may be exposed to
    - In the absence of data, particles are assumed to be respirable
  - Descriptions of process information, particularly at submitter controlled sites
    - In the absence of data, EPA generic scenarios will be used to estimate worker exposures and releases → these estimates are intended to be conservative
III.d. New Chemical Process

- Human health hazard and ecotoxicity
  - Use physical chemistry to understand absorption and routes of exposure
  - Search for analogs and structural alerts
  - Know your chemical → understand metabolites and degradants
  - Is the data based on a guideline or related method
    - If not, EPA may ask for sufficient rationale for its use in the new chemical program
      - Non-guideline studies may be acceptable in certain situations
IV. Risk Calculations, V. Focus Meeting and VI. Standard Review

- Human health risk
  - Risk based on MOE for non-cancer (e.g., neurotoxicity) and slope factor for cancer

- Ecological risk
  - Acute aquatic risk – one day surface water concentration exceeds acute CoC
  - Chronic aquatic risk – twenty days or more of surface water exceedance above chronic CoC

- Focus meeting
  - Finalization of the initial risk assessment for the PMN

- Standard review
  - More in depth review of hazards and exposures for cases with complex concerns
VII. Post Submission Communication

- Please notify program manager of new submissions
  - Delays can occur due to large volume of communications across new chemical submissions
  - Please consider descriptive file names and separation of data into appropriate pieces when using CDX
- Consider use of binding option
- EPA may ask that you refine estimates of release and exposure based on
  - Control technology
  - Worker protections
  - Process descriptions
  - Use information
Additional Information

- Documentation was developed for the Sustainable Futures program
  - Contains description of most of the risk assessment process including models and tools
  - Gives insights on what types of engineering processes and releases will be calculated
  - EPA may request a rationale for changing release parameters away from the defaults typically entered into ChemSTEER™
EPA received comments from industry participants to improve clarity and utility of PtC.

Some comments requested expanded scope, but this is meant to be a concise introduction → see references for more details.
Several comments on use of model vs submitted data on the new chemical substance or analog data

- Risk assessment data hierarchy
  - High quality information on the PMN
  - High quality information on endpoint appropriate analog
  - Modeled data

Why isn’t submitted toxicity data used?

- Possible flaws in study or insufficient description of test material or system
- Submitted data doesn’t address all of the needed endpoints
  - Data submitted for algae and daphnia but modeled data indicates highest hazard concern for fish
EPA should provide a complete list of needed testing during pre-notice consultations

EPA is not in a position to provide a complete list at the pre-notice consultation stage

Testing recommendations for TSCA are commonly based on risk concerns via exposure pathways to identified populations (worker, consumer, general population, eco)

This requires all the steps of the risk assessment process, and these are not performed during the pre-notice consultation stage
Requests for lists of worst case assumptions

- Described in the Sustainable Futures material and defaults for the tools and models
  - ECOSAR™ and EPISuite™ have been programmed to provide conservative estimates
  - ChemSTEER™ allows for creation of conservative worker/release assessments
  - E-FAST™ can be run with SIC code options to evaluate low Stream-flow scenarios and the CEM model defaults to conservative consumer exposure assessments
EPA plans to seek further comments

After meeting all pre-publication requirements, EPA will update draft PtC document and create an official version for use

Once finalized, EPA encourages the use of the PtC document and pre-notice consultations to improve the efficiency of the new chemical program