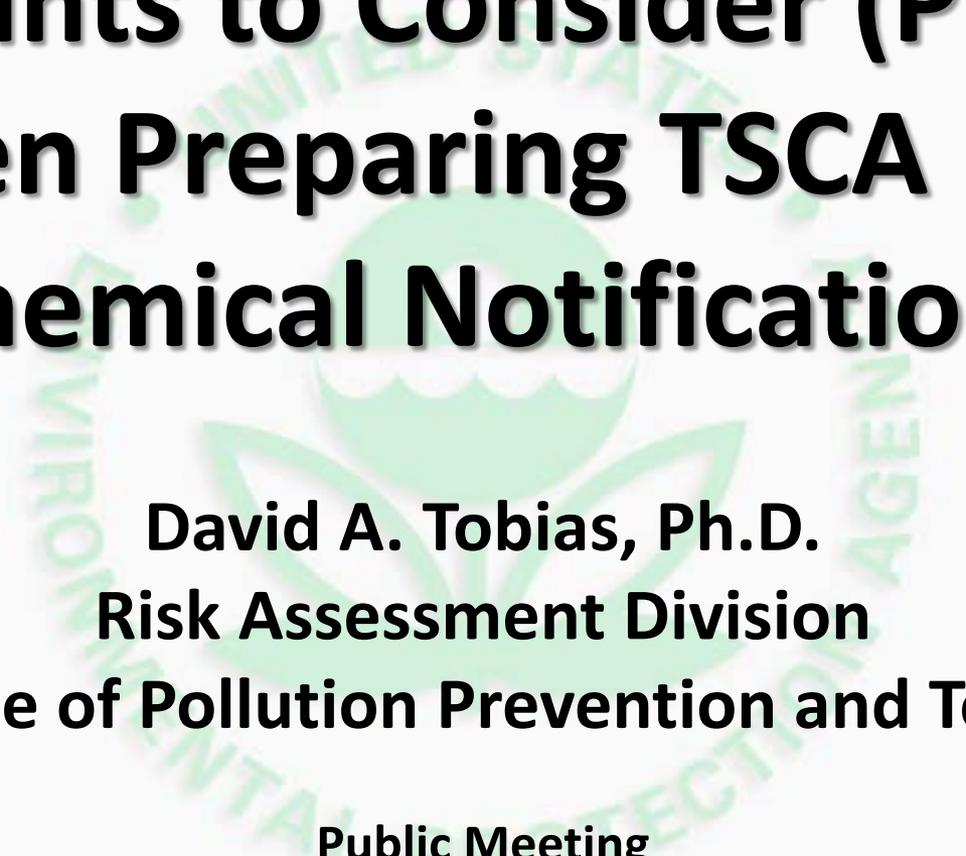




Points to Consider (PtC) When Preparing TSCA New Chemical Notifications



**David A. Tobias, Ph.D.
Risk Assessment Division
Office of Pollution Prevention and Toxics**

**Public Meeting
December 6, 2017**

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

III.a. New Chemical Process



- ▶ 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™

Comments Received on PtC



- 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

Comments Received on PtC



- 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

Comments Received on PtC



- 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

Comments Received on PtC



- Requests for lists of worst case assumptions
 - Described in the Sustainable Futures material and defaults for the tools and models
 - ECOSARTM and EPISuiteTM have been programmed to provide conservative estimates
 - ChemSTEERTM allows for creation of conservative worker/release assessments
 - E-FASTTM can be run with SIC code options to evaluate low Stream-flow scenarios and the CEM model defaults to conservative consumer exposure assessments

Next Steps



- 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