



# **RISK ANALYSIS, UNCERTAINTY, and the TOXIC SUBSTANCES CONTROL ACT**

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December 12, 2017

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# TSCA

## *Statutory Requirements*

- Risk Evaluations must contain:
  - Hazard Assessment
  - Exposure Assessment
  - Risk Characterization
  - Determination of Unreasonable Risk
- EPA must determine if a chemical presents an unreasonable risk of injury to health or the environment under conditions of use
  - Without consideration of cost or other non-risk factors
  - Including unreasonable risk to potentially exposed or susceptible subpopulation(s) determined to be relevant to the evaluation



# Unreasonable Risk

- To make a risk determination, EPA may weigh a variety of factors in determining unreasonable risk. The Administrator will consider ***relevant factors*** including, but not limited to:
  - the effects of the chemical substance on health and human exposure to such substance under the conditions of use (including cancer and non-cancer risks);
  - the effects of the chemical substance on the environment and environmental exposure under the conditions of use;
  - the population exposed (including any susceptible populations),
  - the severity of hazard (the nature of the hazard, the irreversibility of hazard), and
  - ***uncertainties.***



# Uncertainty Defined

## § 702.33 EPA Risk Evaluation Rule:

- *Uncertainty* means the imperfect knowledge or lack of precise knowledge of the real world either for specific values of interest or in the description of the system.



# Scope of Risk Assessment

§ 702.41(c)(5) - *An analysis plan.*

- The scope documents will include an analysis plan that identifies the approaches, methods, and/or metrics that EPA plans to use to assess exposures, effects, and risk, including associated **uncertainty** and variability for each risk evaluation. The analysis plan will also identify the strategy for using information, accepted science policies, models, and screening methodologies.



# Scientific Standards

**TSCA § 26(h): SCIENTIFIC STANDARDS** — In carrying out sections 4, 5, and 6, to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the ***best available science***, and shall consider as applicable—

(4) the extent to which the variability and ***uncertainty*** in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized;...



# Best Available Science Defined

**Best available science** – science that is reliable and unbiased. Use of best available science involves the use of supporting studies conducted in accordance with sound and objective science practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data)

- Additionally, EPA will consider as applicable:
  - The extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information
  - The extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture
  - The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented
  - **The extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized**
  - The extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models



# Risk Evaluation and Uncertainty

## § 702.41(b)(4) *Information and information sources*

- EPA must consider the extent to which the information reduces ***uncertainty***.

## § 702.41(d)(6):

- **Hazard identification** will include an evaluation of the strengths, limitations, and ***uncertainties*** associated with the reasonably available information.
- **Exposure Assessment** will include some discussion of the size, nature, and types of individuals or populations exposed to the agent, as well as discussion of the ***uncertainties*** in this information.





# Risk Characterization

**§ 702.43 (b) Risk Characterization summary.** The Risk Characterization will summarize, as applicable, the considerations addressed throughout the evaluation components, in carrying out the obligations under 15 U.S.C. 2625(h). This summary will include, as appropriate, a discussion of:

- **Considerations regarding *uncertainty* and variability.** Information about *uncertainty* and variability in each step of the risk evaluation (e.g., use of default assumptions, scenarios, choice of models, and information used for quantitative analysis) will be integrated into an overall characterization and/or analysis of the impact of the *uncertainty* and variability on estimated risks. EPA may describe the *uncertainty* using a qualitative assessment of the overall strength and limitations of the data used in the assessment.