

§ 702.45

identified populations (including any potentially exposed or susceptible sub-population(s)) identified in the final scope document published pursuant to § 702.41(c)(8) and ecological characteristics for the conditions of use within the scope of the risk evaluation;

(2) Describe whether aggregate or sentinel exposures under the conditions of use were considered and the basis for their consideration;

(3) Not consider costs or other nonrisk factors;

(4) Take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the condition(s) of use of the chemical substance; and

(5) Describe the weight of the scientific evidence for the identified hazards and exposures.

(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:

(1) *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.

(2) *Considerations of data quality.* A discussion of data quality (e.g., reliability, relevance, and whether methods employed to generate the information are reasonable for and consistent with the intended use of the information), as well as assumptions used, will be included to the extent necessary. EPA also expects to include a discussion of the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models used in the risk evaluation.

(3) *Considerations of alternative interpretations.* If appropriate and relevant,

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where alternative interpretations are plausible, a discussion of alternative interpretations of the data and analyses will be included.

(4) *Considerations for environmental risk evaluations.* For environmental risk evaluations, it may be necessary to discuss the nature and magnitude of the effects, the spatial and temporal patterns of the effects, implications at the individual, species, population, and community level, and the likelihood of recovery subsequent to exposure to the chemical substance.

§ 702.45 Peer review.

The *EPA Peer Review Handbook* (2015), the Office of Management and Budget Final Information Quality Bulletin for Peer Review (OMB Bulletin), and other available, relevant and applicable methods consistent with 15 U.S.C. 2625, will serve as the guidance for peer review activities. Peer review will be conducted on the risk evaluations for the chemical substances identified pursuant to 15 U.S.C. 2605(b)(4)(A).

§ 702.47 Unreasonable risk determination.

As part of the risk evaluation, EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under each condition of uses within the scope of the risk evaluation, either in a single decision document or in multiple decision documents.

§ 702.49 Risk evaluation timeframes and actions.

(a) *Draft risk evaluation timeframe.* EPA will publish a draft risk evaluation in the FEDERAL REGISTER, open a docket to facilitate receipt of public comment, and provide no less than a 60-day comment period, during which time the public may submit comment on EPA's draft risk evaluation.

(b) *Final risk evaluation.* (1) EPA will complete a risk evaluation for the chemical substance under the conditions of use within the scope of the risk evaluation as soon as practicable, but not later than 3 years after the date on which the Agency initiates the risk evaluation.

(2) The Agency may extend the deadline for a risk evaluation for not more