

## 40 C.F.R. § 702.41

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### Evaluation requirements.

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- (a) *Considerations.* (1) Each risk evaluation will include all of the following components:
- (i) A Scope, including a Conceptual Model and an Analysis Plan;
  - (ii) A Hazard Assessment;
  - (iii) An Exposure Assessment;
  - (iv) A Risk Characterization; and
  - (v) A Risk Determination.
- (2) EPA guidance will be used, as applicable where it represents the best available science appropriate for the particular risk evaluation.
- (3) Where appropriate, a risk evaluation will be conducted on a category of chemical substances. EPA will determine whether to conduct an evaluation on a category of chemical substances, and the composition of the category based on the considerations listed in 15 U.S.C. 2625(c).
- (4) EPA will document that it has used the best available science and weight of scientific evidence approaches in the risk evaluation process.
- (5) EPA will ensure that all supporting analyses and components of the risk evaluation are suitable for their intended purpose, and well-tailored to the problems and decision at hand, in order to inform the development of a technically sound determination as to whether a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use within the scope of the risk evaluation, based on the weight of the scientific evidence.
- (6) The extent to which EPA will refine its evaluations for one or more condition of use in any risk evaluation will vary as necessary to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment.
- (7) To the extent a determination as to the level of risk presented by a condition of use can be made, for example, using assumptions, uncertainty factors, and models or screening methodologies, EPA may determine that no further information or analysis is needed to complete its risk evaluation of the condition(s) of use.
- (8) In general, EPA intends to determine whether a chemical substance does or does not present an unreasonable risk under all of the conditions of use within the scope of the risk evaluations, and intends to identify the individual conditions of use or categories of conditions of use that are responsible for such determinations.
- (9) Within the time frame in § 702.43(d), EPA will complete the risk evaluation of the chemical substance
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addressing all of the conditions of use within the scope of the evaluation. However, EPA may complete its evaluation of the chemical substance under specific conditions of use or categories of conditions of use at any point following the issuance of the final scope document, and issue its determination as to whether the chemical substance under those conditions of use does or does not present an unreasonable risk to health or the environment under those conditions of use. EPA will follow all of the requirements and procedures in this Subpart when it conducts its evaluation of the chemical substance under any individual or specific conditions of use.

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