

§ 702.17

does not meet the High-Priority Substance definition.

§ 702.17 Effect of designation as a high-priority substance.

Final designation of a chemical substance as a High-Priority Substance under § 702.11 initiates a risk evaluation pursuant to subpart B of this part. Designation as a High-Priority Substance is not a final agency action and is not subject to judicial review until the date of promulgation of the associated final rule under section 6(a). Designation as a High-Priority Substance is not a finding that the chemical substance presents an unreasonable risk.

Subpart B—Procedures for Chemical Substance Risk Evaluations

SOURCE: 82 FR 33747, July 20, 2017, unless otherwise noted.

§ 702.31 General provisions.

(a) *Purpose.* This subpart establishes the EPA process for conducting a risk evaluation to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment as required under TSCA section 6(b)(4)(B) (15 U.S.C. 2605(b)(4)(B)).

(b) *Scope.* These regulations establish the general procedures, key definitions, and timelines EPA will use in a risk evaluation conducted pursuant to TSCA section 6(b) (15 U.S.C. 2605(b)).

(c) *Applicability.* The requirements of this part apply to all chemical substance risk evaluations initiated pursuant to TSCA section 6(b) (15 U.S.C. 2605(b)).

(d) *Enforcement.* Submission to EPA of inaccurate, incomplete, or misleading information pursuant to a risk evaluation conducted pursuant to 15 U.S.C. 2605(b)(4)(B) is a prohibited act under 15 U.S.C. 2614, subject to penalties under 15 U.S.C. 2615 and Title 18 of the U.S. Code.

§ 702.33 Definitions.

All definitions in TSCA apply to this subpart. In addition, the following definitions apply:

40 CFR Ch. I (7–1–23 Edition)

Act means the Toxic Substances Control Act, as amended (15 U.S.C. 2601 *et seq.*).

Aggregate exposure means the combined exposures to an individual from a single chemical substance across multiple routes and across multiple pathways.

Best available science means 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:

(1) 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;

(2) The extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;

(3) The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;

(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; and

(5) The extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies or models.

Conditions of use means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

EPA means the U.S. Environmental Protection Agency.