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Title 40 —Protection of Environment
Chapter I —Environmental Protection Agency
Subchapter R —Toxic Substances Control Act
Part 720 —Premanufacture Notification
Subpart D —Disposition of Notices

Authority: 15 U.S.C. 2604, 2607, and 2613.

Source: 48 FR 21742, May 13, 1983, unless otherwise noted.

§ 720.65 Acknowledgement of receipt of a notice; errors in the notice; incomplete submissions; and false and misleading statements.

(a) Notification to the submitter.

- (1)** EPA will acknowledge receipt of each notice by sending a letter via CDX or U.S. mail to the submitter that identifies the premanufacture notice number assigned to the new chemical substance and date on which the applicable review period begins as described in paragraph (a)(2) of this section.
- (2)** Before EPA sends an acknowledgement of receipt of a notice pursuant to paragraph (a)(1) of this section, EPA will conduct a pre-screen of the notice, typically taking 2-3 days and according to the criteria under paragraphs (b)(1) and (c)(1) of this section.
 - (i)** If EPA concludes that the notice contains errors warranting remedy or is incomplete, EPA will notify the submitter according to paragraph (d)(3) of this section. The applicable review period will not begin. Once the submitter corrects the errors or incomplete submission according to the requirements provided by EPA and re-submits the notice to EPA, EPA will follow the procedures of paragraph (a)(2) of this section.
 - (ii)** If EPA does not identify errors or determine the notice to be incomplete during screening, EPA will notify the submitter according to paragraph (a)(1) of this section. The applicable review period will begin on the date EPA received the complete notice.

(b) Errors in the notice.

- (1)** Within 30 days of receipt of the notice, EPA may request that the submitter remedy errors in the notice. The following are examples of such errors:
 - (i)** Typographical errors that cause data to be misleading or answers to any questions to be unclear.
 - (ii)** Contradictory information.
 - (iii)** Ambiguous statements or information.
- (2)** The applicable review period does not begin for notices containing errors that EPA asks the submitter to remedy until corrections are made following the procedures of paragraph (d) of this section.

(c) Incomplete submissions.

- (1)** A submission is not complete, and the applicable review period does not begin, if:

- (i) The wrong person submits the notice form.
 - (ii) The submitter does not sign the notice form.
 - (iii) Some or all of the information in the notice or the attachments are not in English, except for published scientific literature.
 - (iv) The submitter does not submit the notice in the manner set forth in § 720.40(a)(2).
 - (v) The submitter does not provide information that is required by section 5(d)(1)(B) and (C) of the Act and § 720.50.
 - (vi) The submitter does not provide information required by § 720.45 or indicate that it is not known to or reasonably ascertainable by the submitter.
 - (vii) The submitter does not submit a second copy of the submission with all confidential information deleted for the public file, as required by § 703.5(c).
 - (viii) The submitter does not include any information required by section 5(b)(1) of the Act and pursuant to a rule promulgated under section 4 of the Act, as required by § 720.40(g).
 - (ix) The submitter does not submit data which the submitter believes show that the chemical substance will not present an unreasonable risk of injury to health or the environment, if EPA has listed the chemical substance under section 5(b)(4) of the Act, as required in § 720.40(h).
 - (x) The submitter does not include an identifying number and a payment identity number as required by § 700.45(e)(3).
- (2) The submission may be declared incomplete if at any time during the applicable review period the submitter submits additional or revised information without demonstrating to EPA's satisfaction that the additional or revised information in the amended notice was not known to or reasonably ascertainable by the submitter at the time of initial notice submission (e.g., new information as described in § 720.40(f) or information from testing in progress at the time of the original submission, as described in § 720.50(a)(4)), unless it relates to administrative or non-substantive amendments (e.g., changing the technical point of contact) or amendments made at the request of EPA.
- (d) *Corrections to errors in the notice or incomplete submissions.*
- (1) If EPA receives an incomplete submission or seeks remedy of errors identified in a notice, EPA will notify the submitter within 30 days of receipt that the submission contains errors or is incomplete and that the applicable review period will not begin until EPA receives a correct and complete notice.
 - (2) If EPA obtains additional information during the applicable review period that indicates the original submission was incomplete, EPA may declare the submission incomplete within 30 days after EPA obtains the additional information and so notify the submitter.
 - (3) The notification that a submission contains errors or is incomplete under paragraph (d)(1) or (2) of this section will include:
 - (i) A statement of the basis of EPA's determination that the submission contains errors or is incomplete.
 - (ii) The requirements for correcting the errors or incomplete submission.

- (iii) Information on procedures under paragraph (d)(4) of this section for filing objections to the determination or requesting modification of the requirements for completing the submission.
- (4) Within ten days after receipt of notification by EPA that a submission contains errors or is incomplete, the submitter may file written objections requesting that EPA accept the submission as a complete notice or modify the requirements necessary to complete the submission.
- (5) EPA will consider the objections filed by the submitter and determine:
 - (i) Whether the submission was complete or incomplete, or whether to modify the requirements for completing the submission. EPA will notify the submitter in writing of EPA's response within ten days of receiving the objections.
 - (ii) If EPA determines, in response to the objection, that the submission was complete, the applicable review period will be deemed suspended on the date EPA declared the notice incomplete and will resume on the date that the notice is declared complete. The submitter need not correct the notice as EPA originally requested. If EPA can complete its review within 90 days from the date of the original submission, EPA may inform the submitter that the running of the review period will resume on the date EPA originally declared it incomplete.
 - (iii) If EPA modifies the requirements for completing the submission or affirms its original determination that the submission contains errors or is incomplete, or if no objections are filed, the applicable review period will begin (or if previously begun, will restart at Day 1) when EPA receives a complete notice.
- (e) **Materially false or misleading statements.** If EPA discovers at any time that a person submitted materially false or misleading statements in the notice, EPA may find that the notice was incomplete from the date it was submitted and take any other appropriate action.

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