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.

§ 720.75 Applicable review period and determination.

(a) ***Length of applicable review period.*** The applicable review period specified in section 5(a) of the Act runs for 90 days from the date EPA receives a complete notice, or the date EPA determines the notice is complete under § 720.65(d), unless the Agency extends the applicable review period under section 5(c) of the Act and paragraph (c) of this section.

(b) ***Suspension of the running of the applicable review period.***

(1) A submitter may voluntarily suspend the running of the applicable review period if EPA agrees. If EPA does not agree, the review period will continue to run, and EPA will notify the submitter. A submitter may request a suspension at any time during the applicable review period. The suspension must be for a specified period of time.

(2) ***Requests for suspensions.***

(i) A request for a suspension of 30 days or less may be made orally, including by telephone, or in writing, including by e-mail, to the submitter's EPA contact for that notice. Any request for a suspension exceeding 30 days must be submitted in the manner set forth in paragraph (b)(2)(ii) of this section. The running of the applicable review period will be suspended upon approval of the oral or written request by EPA.

(ii) Requests for suspensions exceeding 30 days must be submitted electronically to EPA via CDX using e-PMN software. Requests for suspensions of 30 days or less may also be submitted electronically to EPA via CDX using e-PMN software. See § 720.40(a)(2)(ii) for information on how to access the e-PMN software. The running of the applicable review period will be suspended upon approval of the request submitted electronically to EPA via CDX using e-PMN software by EPA.

(c) ***Extension of applicable review period.***

(1) At any time during the applicable review period, EPA may determine that good cause exists to extend the applicable review period specified in paragraph (a) of this section.

(2) If EPA makes such a determination, EPA will:

(i) Notify the submitter that EPA is extending the applicable review period for a specified length of time, and state the reasons for the extension.

(ii) Issue a notice for publication in the FEDERAL REGISTER which states that EPA is extending the applicable review period and gives the reasons for the extension.

(3) The initial extension may be for a period of up to 90 days. If the initial extension is for less than 90 days, EPA may make additional extensions. However, the total period of extensions may not exceed 90 days for any notice.

(4) The following are examples of situations in which EPA may find that good cause exists for extending the applicable review period:

(i) EPA has reviewed the notice and determined that there is a significant possibility that the chemical substance will be regulated under section 5(e) or section 5(f) of the Act, but EPA is unable to initiate regulatory action within the initial 90-day period.

(ii) EPA has reviewed the submission and is seeking additional information.

(iii) EPA has received significant additional information during the applicable review period, which was not known to or reasonably ascertainable by the submitter at the time of initial notice submission.

(iv) The submitter has failed to correct a notice after receiving EPA's request under § 720.65(b).

(d) ***Determinations.***

(1) Within the applicable review period, EPA will make one of the following five determinations, as set forth in section 5(a)(3) of the Act:

(i) The chemical substance presents an unreasonable risk of injury to health or the environment, as set forth in section 5(a)(3)(A) of the Act.

(ii) Information available to EPA is insufficient to permit a reasoned evaluation of the health and the environmental effects of the relevant chemical substance, as set forth in section 5(a)(3)(B)(i) of the Act.

(iii) In the absence of sufficient information to permit EPA to make such an evaluation, the chemical substance may present an unreasonable risk of injury to health or the environment, as set forth in section 5(a)(3)(B)(ii)(I) of the Act.

(iv) The chemical substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance, as set forth in section 5(a)(3)(B)(ii)(II) of the Act.

(v) The chemical substance is not likely to present an unreasonable risk of injury to health or the environment, as set forth in section 5(a)(3)(C) of the Act.

(2) EPA will take the following actions required in association with the determination:

(i) For determinations described in paragraph (d)(1)(i) of this section, EPA will issue the submitter an order to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance, or any combination of such activities, to the extent necessary to protect against an unreasonable risk of injury to health or the environment, as set forth in section 5(f) of the Act, or will issue a proposed rule under section 6(a) of the Act, as set forth in section 5(f) of the Act.

(ii) For determinations described in paragraphs (d)(1)(ii), (iii), or (iv) of this section, EPA will issue the submitter an order to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance, or any combination of such activities, to

the extent necessary to protect against an unreasonable risk of injury to health or the environment, as set forth in section 5(e) of the Act. EPA may issue an order under section 5(e) of the Act that requires certain testing to be conducted and presented to EPA after the applicable review period has concluded.

(iii) For determinations described in paragraph (d)(1)(v) of this section, EPA will issue the submitter a document containing EPA's final determination and will submit for publication in the FEDERAL REGISTER a statement of the finding, as set forth in section 5(g) of the Act. Upon EPA's issuance of the determination document, the submitter may commence the manufacture of the chemical substance without waiting for the end of the applicable review period.

(3) EPA may modify or revoke the prohibitions and limitations in an order issued under paragraph (d)(2)(i) or (ii) of this section after the applicable review period has ended if EPA receives additional testing, studies, reports, or other information that EPA determines, upon review, demonstrate that such prohibitions or limitations are no longer necessary to protect against an unreasonable risk of injury to health or the environment. Where such information demonstrates that the prohibitions or limitations of the order are not sufficient to protect against an unreasonable risk of injury to health or the environment, EPA may modify the order or take other action, as appropriate, to the extent necessary to protect against such risk.

(4) No person submitting a notice in response to the requirements of this part may manufacture a chemical substance subject to this part until EPA has issued a determination in accordance with paragraph (d)(1) of this section and taken the associated action required under paragraph (d)(2) of this section.

(e) ***Withdrawal of a notice by the submitter.***

(1)

(i) A submitter may withdraw a notice during the applicable review period by submitting a statement of withdrawal in a manner set forth in this paragraph. The withdrawal is effective upon receipt by EPA of the CDX submission.

(ii) ***Submission of withdrawal notices.*** EPA will accept statements of withdrawal only if submitted in accordance with this paragraph. Statements of withdrawal must be generated, completed, and submitted to EPA (via CDX) using e-PMN software. See § 720.40(a)(2)(ii) for information on how to obtain e-PMN software.

(2) If a manufacturer (including importer) which withdrew a notice later resubmits a notice for the same chemical substance, a new applicable review period begins.

[48 FR 21742, May 13, 1983, as amended at 53 FR 12523, Apr. 15, 1988; 58 FR 34204, June 23, 1993; 60 FR 34464, July 3, 1995; 71 FR 33641, June 12, 2006; 75 FR 786, Jan. 6, 2010; 78 FR 72827, Dec. 4, 2013; 80 FR 42746, July 20, 2015; 89 FR 102797, Dec. 18, 2024]