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reasonably ascertainable by the submitter. (1) Except as provided in paragraph (d) of this section, any person who submits a notice must describe the following data, including any data from a health and safety study, if the data are related to the effects on health or the environment of any manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance, of any mixture or article containing the new chemical substance, or of any combination of such activities:

(i) Any data, other than test data, in the submitter's possession or control.

(ii) Any data, including test data, which are not in the submitter's possession or control, but which are known to or reasonably ascertainable by the submitter. For the purposes of this section, data are known to or reasonably ascertainable by the submitter if the data are known to any of its employees or other agents who are associated with the research and development, test marketing, or commercial marketing of the substance.

(2) Data that must be described include data concerning the new chemical substance in a pure, technical grade, or formulated form.

(3) The description of data reported under this paragraph must include:

(i) If the data appear in the open scientific literature, a standard literature citation, which includes the author, title, periodical name, date of publication, volume, and pages.

(ii) If the data are not contained in the open scientific literature, a description of the type of data and summary of the results, if available, and the names and addresses of persons the submitter believes may have possession or control of the data.

(4) All data described by this paragraph are subject to these requirements, regardless of their age, quality, or results; and regardless of whether they are complete at the time the notice is submitted.

(c) [Reserved]

(d) *Data that need not be submitted*—(1) *Data previously submitted to EPA.* (i) A person need not submit any data previously submitted to EPA with no claims of confidentiality if the notice includes the office or person to whom the data were submitted, the date of submission, and, if appropriate, a standard literature citation as specified in paragraph (a)(3)(ii) of this section.

(ii) For data previously submitted to EPA with a claim of confidentiality, the person must resubmit the data with the notice and any claim of confidentiality, under § 720.80.

(2) *Efficacy data.* This part does not require submission of any data related solely to product efficacy. This does not exempt a person from submitting any of the data specified in paragraph (a), (b), or (c) of this section.

(3) *Non-U.S. exposure data.* This part does not require submission of any data which relates only to exposure of humans or the environment outside the United States. This does not exclude nonexposure data such as data on health effects (including epidemiological studies), ecological effects, physical and chemical properties, or environmental fate characteristics.

[48 FR 21742, May 13, 1983, as amended at 51 FR 15102, Apr. 22, 1986]

§ 720.57 Imports.

(a) Except as otherwise provided in this section, the provisions of this subpart C apply to each person who submits a notice for a new chemcial substance which he or she intends to import for a commercial purpose. In addition, each importer must comply with this section.

(b) EPA will hold the principal importer, or the importer that EPA determines must submit the notice when there is no principal importer under § 720.22(b)(2), liable for complying with this part, for completing the notice form and for the completeness and truthfulness of all information which it submits.

Subpart D—Disposition of Notices

§ 720.60 General.

This subpart establishes procedures that EPA will follow in reviewing notices.

§ 720.62 Notice that notification is not required.

When EPA receives a notice, EPA will review it to determine whether the

chemical substance is subject to the requirements of this part. If EPA determines that the chemical substance is not subject to these requirements, EPA will notify the submitter that section 5 of the Act does not prevent the manufacture or import of the substance and that the submission is not a notice under this part.

[48 FR 21742, May 13, 1983, as amended at 58 FR 34204, June 23, 1993]

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

(a) *Notification to the submitter.* 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 review period begins. The review period will begin on the date the notice is received by the Office of Pollution Prevention and Toxics Document Control Officer. The acknowledgment does not constitute a finding by EPA that the notice, as submitted, is in compliance with this part.

(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) Failure to date the notice form.

(ii) Typographical errors that cause data to be misleading or answers to any questions to be unclear.

(iii) Contradictory information.

(iv) Ambiguous statements or information.

(2) In the request to correct the notice, EPA will explain the action which the submitter must take to correct the notice.

(3) If the submitter fails to correct the notice within 15 days of receipt of the request, EPA may extend the notice period under section (5)(c) of the Act, in accordance with § 720.75(c).

(c) *Incomplete submissions.* (1) A submission is not complete, and the notification 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 on the notice form and 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 § 720.80(b)(2).

(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 40 CFR 700.45(e)(3).

(2)(i) If EPA receives an incomplete submission, the Director, or his or her delegate, will notify the submitter within 30 days of receipt that the submission is incomplete and that the notice review period will not begin until EPA receives a complete notice.

(ii) If EPA obtains additional information during the notice review period that indicates the original submission was incomplete, the Director, or his or her delegate, 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 is incomplete under paragraph (c)(2) (i) or (ii) of this section will include:

(i) A statement of the basis of EPA's determination that the submission is incomplete.

(ii) The requirements for correcting the incomplete submission.

(iii) Information on procedures under paragraph (c)(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 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)(i) EPA will consider the objections filed by the submitter. The Director, or his or her delegate, will determine 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 the Director, or his or her delegate, determines, in response to the objection, that the submission was complete, the notice 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, the Director, or his or her delegate, may inform the submitter that the running of the review period will resume on the date EPA originally declared it incomplete.

(iii) If the Director, or his or her delegate, modifies the requirements for completing the submission or concurs with EPA's original determination, the notice review period will begin when EPA receives a complete notice.

(d) *Materially false or misleading statements.* If EPA discovers at any time that 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.

[48 FR 21742, May 13, 1983, as amended at 75 FR 785, Jan. 6, 2010]

§ 720.70 Notice in the Federal Register.

(a) *Filing of* FEDERAL REGISTER *notice.* In accordance with section 5(d)(2) of the Act, after EPA receives a notice, EPA will file with the Office of the Federal Register a notice including the information specified in paragraph (b) of this section.

(b) *Contents of notice.* (1) In the public interest, the specific chemical identity listed in the notice will be published in the FEDERAL REGISTER unless the submitter has claimed chemical identity confidential. If the submitter claims confidentiality, a generic name will be published in accordance with § 720.85(a)(3).

(2) The categories of use of the new chemical substance will be published as reported in the notice unless this information is claimed confidential. If confidentiality is claimed, the generic information which is submitted under § 720.87(b) will be published.

(3) A list of data submitted in accordance with § 720.50(a) will be published. In addition, for test data submitted in accordance with § 720.40(g), a summary of the data will be published.

(4) The submitter's identity will be published, unless the submitter has claimed it confidential.

§ 720.75 Notice review period.

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

(b) *Suspension of the running of the notice review period.* (1) A submitter may voluntarily suspend the running of the notice review period if the Director or his or her delegate agrees. If the Director 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 notice review period. The suspension must be for a specified period of time.

(2) A request for suspension may only be submitted in a manner set forth in

this paragraph. The request for suspension also may be made orally, including by telephone, to the submitter's EPA contact for that notice, subject to paragraph (b)(3) of this section.

(i) *Older notices.* Requests for suspension for premanufacture notices submitted before April 6, 2010 must be submitted on paper either via U.S. mail to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001 or submitted via courier to the Environmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004.

(ii) *Newer notices.* For notices submitted on or after April 6, 2010, EPA will accept requests for suspension only if submitted in accordance with this paragraph:

(A) Requests for suspension may be submitted on paper on or before April 6, 2011. All paper-based requests for suspension must be generated using e-PMN reporting software and be completed through the finalization step of the software, and e-PMN software must be used to print the request for suspension for submission to EPA. Paper requests for suspension must be submitted either via U.S. mail to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001 or submitted via courier to the Environmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004.

(B) Requests for suspension may be submitted as electronic files on optical disc on or before April 6, 2012. All requests for suspension submitted as electronic files on optical disc generated using e-PMN reporting software and be completed through the finalization step of the software, and e-PMN software must be used to print the request for suspension for submission to EPA. Paper requests for suspension must be submitted either via U.S. mail to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001 or submitted via courier to the Environmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004.

(C) Requests for suspension may be submitted electronically to EPA via CDX. Such requests must be generated and completed using e-PMN reporting software. See § 720.40(a)(2)(iv) for information on how to obtain e-PMN software.

(3) An oral request for suspension may be granted by EPA for a maximum of 15 days only. Requests for a longer suspension must only be submitted in the manner set forth in this paragraph.

(4) If the submitter has not made a previous oral request, the running of the notice review period is suspended as of the date of receipt of the written paper request, electronic request on optical disc, or CDX submission by EPA.

(c) *Extension of notice review period.* (1) At any time during the notice review period, EPA may determine that good cause exists to extend the notice 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 notice 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 notice 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 notice 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 notice review period.

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

(d) *Notice of expiration of notice review period.* EPA will notify the submitter that the notice review period has expired or that EPA has completed its review of the notice. Expiration of the review period does not constitute EPA approval or certification of the new chemical substance, and does not mean that EPA may not take regulatory action against the substance in the future. After expiration of the statutory notice review period, in the absence of regulatory action by EPA under section 5(e), 5(f), or 6(a) of the Act, the submitter may manufacture or import the chemical substance even if the submitter has not received notice of expiration.

(e) *Withdrawal of a notice by the submitter.* (1) A submitter may withdraw a notice during the notice review period by submitting a statement of withdrawal in a manner set forth in this paragraph. The withdrawal is effective upon receipt of the written paper request, electronic request on optical disc, or CDX submission by EPA.

(i) *Older notices.* Statements of withdrawal for premanufacture notices submitted before April 6, 2010 must be submitted on paper either via U.S. mail to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001 or submitted via courier to the Environmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004.

(ii) *Newer notices.* For notices submitted on or after April 6, 2010, EPA will accept statements of withdrawal only if submitted in accordance with this paragraph:

(A) Statements of withdrawal may be submitted on paper on or before April 6, 2011. All paper-based statements of withdrawal must be generated using e-PMN reporting software and be completed through the finalization step of the software, and e-PMN software must be used to print the statement of withdrawal for submission to EPA. Paper statements of withdrawal must be submitted either via U.S. mail to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001 or submitted via courier to the Environmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004.

(B) Statements of withdrawal may be submitted as electronic files on optical disc on or before April 6, 2012. All statements of withdrawal submitted as electronic files on optical disc must be generated using e-PMN reporting software and be completed through the finalization step of the software. Optical discs containing electronic statements of withdrawal must be submitted by courier to the Environmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004.

(C) Statements of withdrawal may be submitted electronically to EPA via CDX. Prior to submission to EPA via CDX, such statements of withdrawal must be generated and completed using e-PMN reporting software. See § 720.40(a)(2)(iv) for information on how to obtain e-PMN software.

(2) If a manufacturer or importer which withdrew a notice later resubmits a notice for the same chemical substance, a new notice 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 33641, June 12, 2006; 75 FR 786, Jan. 6, 2010]

§ 720.78 Recordkeeping.

(a) Any person who submits a notice under this part must retain documentation of information in the notice, including (1) other data, as defined in § 720.50(b), in the submitter's possession

or control; and (2) records of production volume for the first three years of production or import, the date of commencement of manufacture or import, and documentation of this information. This information must be retained for five years from the date of commencement of manufacture of import.

(b)(1) Persons who manufacture or import a chemical substance under § 720.36 must retain the following records:

(i) Copies of, or citations to, information reviewed and evaluated under § 720.36(b)(1) to determine the need to make any notification of risk.

(ii) Documentation of the nature and method of notification under § 720.36(c)(1) including copies of any labels or written notices used.

(iii) Documentation of prudent laboratory practices used instead of notification and evaluation under § 720.36(b)(2).

(iv) The names and addresses of any persons other than the manfacturer or importer to whom the substance is distributed, the identity of the substance to the extent known, the amount distributed, and copies of the notifications required under § 720.36(c)(2). These records are not required when substances are distributed as impurities or incorporated into an article, in accordance with paragraph (d) of this section.

(2) A person who manufactures or imports a chemical substance under § 720.36 and who manufactures or imports the substance in quantities greater than 100 kilograms per year must retain records of the identity of the substance to the extent known, the production volume of the substance, and the person's disposition of the substance. The person is not required to maintain records of the disposition of products containing the substance as an impurity or of articles incorporating the substances.

(3) Records under this paragraph must be retained for 5 years after they are developed.

(c) Any person who obtains a test-marketing exemption under this part must retain documentation of information in the application and documentation of compliance with any restrictions imposed by EPA when it granted the application. This information must be retained for five years from the final date of manufacture or import under the exemption.

[48 FR 21742, May 13, 1983; 48 FR 33872, July 26, 1983, as amended at 51 FR 15102, Apr. 22, 1986; 58 FR 34204, June 23, 1993]

Subpart E—Confidentiality and Public Access to Information

§ 720.80 General provisions.

(a) A person may assert a claim of confidentiality for any information which he or she submits to EPA under this part.

(b) Any claim of confidentiality must accompany the information when it is submitted to EPA.

(1)(i) For information submitted on the notice form, the claim(s) must be asserted on the form in the manner prescribed on the notice form.

(ii) When a person submits information in an attachment, the claim(s) must be asserted in the attachment as described on the notice form.

(2) If any information is claimed as confidential, the person must submit, in addition to the copies specified by § 720.40, a sanitized copy of the notice form (or electronic submission) and any attachments.

(i) The notice and attachments must be complete. The submitter must designate that information which is claimed as confidential in the manner prescribed on the notice form, via EPA's e-PMN software. See § 720.40(a)(2)(iv) for information on how to obtain e-PMN software.

(ii) The sanitized copy must be complete except that all information claimed as confidential in the original must be deleted. EPA will place this sanitized copy in the public file.

(iii) If the person does not provide the sanitized copy, or information in a health and safety study (except information claimed as confidential in accordance with § 720.90), the submission will be deemed incomplete and the notice review period will not begin until EPA receives the sanitized copy or the health and safety study information is included, in accordance with § 720.65(c)(1)(vii).

(c) EPA will disclose information that is subject to a claim of confidentiality asserted under this section only