

records which demonstrate establishment and implementation of a program that ensures compliance with any applicable disposal requirements.

(k) Records documenting establishment and implementation of procedures that ensure compliance with any applicable water discharge limitations under § 721.90.

[54 FR 31313, July 27, 1989]

Subpart D—Expedited Process for Issuing Significant New Use Rules for Selected Chemical Substances and Limitation or Revocation of Selected Significant New Use Rules

SOURCE: 54 FR 31314, July 27, 1989, unless otherwise noted.

§ 721.160 Notification requirements for new chemical substances subject to section 5(e) orders.

(a) *Selection of substances.* (1) In accordance with the expedited process specified in this section, EPA will issue significant new use notification requirements and other specific requirements for each new chemical substance that is the subject of a final order issued under section 5(e) of the Act, except for an order that prohibits manufacture and import of the substance, unless EPA determines that significant new use notification requirements are not needed for the substance.

(2) If EPA determines that significant new use notification requirements are not needed for a substance that is subject to a final order issued under section 5(e) of the Act, except for an order that prohibits manufacture or import of the substance, EPA will issue a notice in the FEDERAL REGISTER explaining why the significant new use requirements are not needed.

(b) *Designation of requirements.* (1) The significant new use notification and other specific requirements will be based on and be consistent with the provisions included in the final order issued for the substance under section 5(e) of the Act. EPA may also designate additional activities as significant new uses which will be subject to notification. Designation of additional activities as significant new uses will be

done in accordance with the criteria and procedures under § 721.170, or through a separate rulemaking proceeding.

(2) Significant new use requirements and other specific requirements designated under this section will be listed in subpart E of this part. For each substance, subpart E will identify:

(i) The chemical name.

(ii) The activities designated as significant new uses.

(iii) Other specific requirements applicable to the substance, including recordkeeping requirements or any other requirements included in the final section 5(e) order.

(c) *Procedures for issuing significant new use rules.* (1) EPA will issue significant new use rules under this section by one of the following three processes: direct final rulemaking, interim final rulemaking, or notice and comment rulemaking. EPA will use the direct final rulemaking process to issue significant new use rules unless it determines that, in a particular case, one of the other processes is more appropriate.

(2) FEDERAL REGISTER documents issued to propose or establish significant new uses under this section will contain the following:

(i) The chemical identity of the substance or, if its specific identity is claimed confidential, an appropriate generic chemical name and an accession number assigned by EPA.

(ii) The premanufacture notice number.

(iii) The CAS number, where available and not claimed confidential.

(iv) A summary of EPA's findings under section 5(e)(1)(A) of the Act for the final order issued under section 5(e).

(v) Designation of the significant new uses subject to, or proposed to be subject to, notification and any other applicable requirements.

(vi) Any modifications of subpart A of this part applicable to the specific substance and significant new uses.

(vii) If the FEDERAL REGISTER document establishes a final rule, or notifies the public that a final rule will not be issued after public comment has

been received, the document will describe comments received and EPA's response.

(3) *Direct final rulemaking.* (i) When EPA uses the direct final rulemaking procedure to issue a significant new use rule, it will issue a final rule in the FEDERAL REGISTER following its decision to develop a significant new use rule under this section for a specific new chemical substance.

(ii) The FEDERAL REGISTER document will state that, unless written notice is received by EPA within 30 days of publication that someone wishes to submit adverse or critical comments, the rule will be effective 60 days from the date of publication. The written notice of intent to submit adverse or critical comments should state which SNUR(s) will be the subject of the adverse or critical comments, if several SNURs are established through the direct final rule. If notice is received within 30 days that someone wishes to submit adverse or critical comments, the section(s) of the direct final rule containing the SNUR(s) for which a notice of intent to comment was received will be withdrawn by EPA issuing a document in the final rule section of the FEDERAL REGISTER, and a proposal will be published in the proposed rule section of the FEDERAL REGISTER. The proposal will establish a 30-day comment period.

(iii) If EPA, having considered any timely comments submitted in response to the proposal, decides to establish notification requirements under this section, EPA will issue a final rule adding the substance to subpart E of this part and designating the significant new uses subject to notification.

(4) *Notice and comment rulemaking.* (i) When EPA uses a notice and comment procedure to issue a significant new use rule, EPA will issue a proposal in the FEDERAL REGISTER following its decision to develop a significant new use rule under this section for a specific new chemical substance. Persons will be given 30 days to comment on whether EPA should establish notification requirements for the substance under this part.

(ii) If EPA, having considered any timely comments, decides to establish

notification requirements under this section, EPA will issue a final rule adding the substance to subpart E of this part and designating the significant new uses subject to notification.

(5) *Interim final rulemaking.* (i) When EPA uses the interim final rulemaking procedure to issue a significant new use rule, EPA will issue an interim final rule in the final rule section of the FEDERAL REGISTER following its decision to develop a significant new use rule for a specific new chemical substance. The document will state EPA's reasons for using the interim final rulemaking procedure.

(A) The significant new use rule will take effect on the date of publication.

(B) Persons will be given 30 days from the date of publication to submit comments.

(ii) Interim final rules issued under this section shall cease to be in effect 180 days after publication unless, within the 180-day period, EPA issues a final rule in the FEDERAL REGISTER responding to any written comments received during the 30-day comment period specified in paragraph (c)(5)(i)(B) of this section and promulgating final significant new use notification requirements and other requirements for the substance.

(d) *Schedule for issuing significant new use rules.* (1) Unless EPA determines that a significant new use rule should not be issued under this section, EPA will issue a proposed rule, a direct final rule, or an interim final rule within 180 days of receipt of a valid notice of commencement under §720.102 of this chapter for any substance for which the notice of commencement was received on or after October 10, 1989.

(2) Unless EPA determines that a significant new use rule should not be issued under this section, EPA will issue a proposed rule, a direct final rule, or an interim final rule within 1 year of October 10, 1989, for any substance for which the valid notice of commencement under §720.102 of this chapter was received before October 10, 1989.

(3) If EPA receives adverse or critical significant comments following publication of a proposed or interim final rule, EPA will either withdraw the rule

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or issue a final rule addressing the comments received.

§ 721.170 Notification requirements for selected new chemical substances that have completed premanufacture review.

(a) *Selection of substances.* In accordance with the expedited process specified in this section, EPA may issue significant new use notification and recordkeeping requirements for any new chemical substance for which a premanufacture notice has been submitted under part 720 of this chapter if EPA determines that activities other than those described in the premanufacture notice may result in significant changes in human exposure or environmental release levels and/or that concern exists about the substance's health or environmental effects.

(b) *Concern criteria.* EPA may determine that concern exists about a substance's health or environmental effects if EPA makes any one of the following findings:

(1)(i) The substance may cause carcinogenic effects because the substance:

(A) Has been shown by valid test data to cause carcinogenic effects in humans or in at least one species of laboratory animal.

(B) Has been shown to be a possible carcinogen based on the weight of the evidence in short-term tests indicative of the potential to cause carcinogenic effects.

(C) Is closely analogous, based on toxicologically relevant similarities in molecular structure and physical properties, to another substance that has been shown by test data to cause carcinogenic effects in humans or in at least one species of laboratory animal, provided that if there is more than one such analogue, the greatest weight will be given to the relevant data for the most appropriate analogues.

(D) Is known or can reasonably be anticipated, based on valid scientific data or established scientific principles, to be metabolized in humans or transformed in the environment to a substance which may have the potential to cause carcinogenic effects under the

criteria in paragraphs (b)(1)(i) (A), (B), or (C) of this section.

(ii) No substance may be regulated based on a finding under paragraph (b)(1) of this section unless EPA has also made the finding under § 721.170(c)(2)(ii).

(2) The substance has been shown by valid test data to cause acutely toxic effects in at least one species of laboratory animal or is closely analogous, based on toxicologically relevant similarities in molecular structure and physical properties, to another substance that has been shown by valid test data to cause acutely toxic effects in at least one species of laboratory animal, provided that if there is more than one such analogue, the greatest weight will be given to the relevant data for the most appropriate analogues.

(3) The substance may cause serious chronic effects, serious acute effects, or developmentally toxic effects under reasonably anticipated conditions of exposure because the substance:

(i) Has been shown by valid test data to cause serious chronic effects, serious acute effects, or developmentally toxic effects in humans or in at least one species of laboratory animal at dose levels that could be of concern under reasonably anticipated conditions of exposure.

(ii) Is closely analogous, based on toxicologically relevant similarities in molecular structure and physical properties, to another chemical substance that has been shown by valid test data to cause serious chronic effects, serious acute effects, or developmentally toxic effects in humans or in at least one species of laboratory animal at dose levels that could be of concern under reasonably anticipated conditions of exposure, provided that if there is more than one such analogue, the greatest weight will be given to the relevant data for the most appropriate analogues.

(iii) Is known or can reasonably be anticipated, based on valid scientific data or established scientific principles, to be metabolized in humans or transformed in the environment to a substance which may have the potential to cause serious chronic effects, serious acute effects, or developmentally