

§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 toxic effects under the criteria in paragraph (b)(3) (i) and (ii) of this section.

(iv) Has been shown to potentially cause developmentally toxic effects based on the weight of the evidence in short-term tests indicative of the potential to cause developmentally toxic effects.

20 February 2019

(4) The substance may cause significant adverse environmental effects under reasonably anticipated conditions of release because the substance:

(i) Has been shown by valid test data to cause significant adverse environmental effects at dose levels that could be of concern under reasonably anticipated conditions of release.

(ii) 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 significant adverse environmental effects at dose levels that could be of concern under reasonably anticipated conditions of release, 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) Has been determined, based on calculations using the substance's physical and chemical properties, to be potentially able to cause significant adverse environmental effects at dose levels that could be of concern under reasonably anticipated conditions of release.

(iv) Is known or can reasonably be anticipated, based on valid scientific data or established scientific principles, to be environmentally transformed to a substance which may have the potential to cause significant adverse environmental effects under the criteria in paragraph (b)(4) (i), (ii), and (iii) of this section.

(5) Concern exists about the health or environmental effects of one or more impurities or byproducts of the substance because the impurity or byproduct meets one or more of the criteria in paragraph (b) (1) through (4) of this section and either:

(i) The impurity or byproduct is a new chemical substance and may be present in concentrations that could cause adverse health or environmental effects under reasonably anticipated conditions of exposure or release.

(ii) Reasonably anticipated manufacture, processing, or use activities involving the substance for which a premanufacture notice has been submitted may result in significantly increased human exposure to or environmental release of the impurity or byproduct compared to exposure or release levels resulting from existing activities involving the impurity or byproduct.

(c) Designation of requirements. (1) When EPA decides to establish significant new use reporting requirements under this section, EPA may designate as a significant new use any one or more of the activities set forth in subpart B of this part. In addition, EPA may designate specific recordkeeping requirements described under subpart C of this part that are applicable to the substance.

(2) EPA may designate as a significant new use only those activities that (i) are different from those described in the premanufacture notice for the substance, including any amendments, deletions, and additions of activities to the premanufacture notice, and (ii) may be accompanied by changes in exposure or release levels that are significant in relation to the health or environmental concerns identified under paragraph (b) of this section.

(d) Procedures for issuing significant new use rules. (1) Significant new use requirements designated under this section will be listed in subpart E of this part. For each substance, subpart E of this part will identify:

(i) The chemical name.

(ii) The activities designated as significant new uses, which may include one or more of the activities described in paragraph (c) of this section.

(iii) Other specific requirements applicable to the substance.

(2) When EPA determines that a substance is a candidate for a significant new use rule under this section, it will notify the person that submitted the premanufacture notice for the substance no later than 7 calendar days before the expiration of the notice review period under §720.75 of this chapter. In providing this notice, EPA will describe the health or environmental concerns identified under paragraph (b) of this section and the activities under consideration for designation as significant new uses. Such notice may be by telephone, but in this event will be confirmed in writing no later than 30 days after completion of the notice review period.

(3) Federal Register documents issued to propose or establish significant new uses under this section will contain the following:

Extracted by GlobalMSDS Ltd

20 February 2019

- (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 the basis for action under this section.
 - (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.
- (4) 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.
- (i)(A) When EPA uses the direct final rulemaking procedure to issue a significant new use rule it will issue a direct final rule in the final rule section of the Federal Register following its decision to develop a significant new use rule under this section for a specific new chemical substance.
 - (B) The Federal Register document will state that, unless written notice is received by EPA within 30 days after the date of publication that someone wishes to submit adverse or critical comments, the SNUR will be effective 60 days from 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 after the date of publication 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 EPA will issue a proposed rule in the proposed rule section of the Federal Register. The proposed rule will establish a 30-day comment period.
 - (C) 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.
- (ii)(A) When EPA uses a notice and comment procedure to issue a significant new use rule, EPA will issue a proposed rule 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.
 - (B) 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.
- (iii)(A) 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.
- (1) The significant new use rule will take effect on the date of publication.
 - (2) Persons will be given 30 days from the date of publication to submit comments.
- (B) An interim final rule 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 (d)(4)(iii)(A)(2) of this section and promulgating final significant new use notification requirements and other requirements for the substance.

https://ecfr.io/Title-40/pt40.33.716#se40.33.716_13

Extracted by GlobalMSDS Ltd

20 February 2019

(e) Schedule for issuing significant new use rules. (1) EPA will issue a proposed rule, an interim final rule, or a direct final rule within 270 days of receipt of the 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) If EPA receives adverse or critical comments within the designated comment period following publication of a proposed rule or an interim final rule, EPA will either withdraw the rule or issue a final rule addressing the comments received.

[54 FR 31314, July 27, 1989, as amended at 60 FR 16316, Mar. 29, 1995]