§ 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)(i) 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 which 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.

(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, 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.
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(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 sub-
stance, including any amendments, deletions, and additions of activities to
the premanufacture notice, and (ii) may be accompanied by changes in ex-
posure or release levels that are signif-
ificant in relation to the health or en-
vironmental 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 sig-
nificant new uses, which may include
one or more of the activities described
in paragraph (c) of this section.
(iii) Other specific requirements ap-
licable to the substance.

(2) When EPA determines that a sub-
stance is a candidate for a significant
new use rule under this section, it will
notify the person that submitted the
premanufacture notice for the sub-
stance no later than 7 calendar days
before the expiration of the notice re-
view period under §720.75 of this chap-
ter. 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 sig-
nificant 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 re-
view period.

(3) Federal Register documents
issued to propose or establish signifi-
cant new uses under this section will contain the following:
(i) The chemical identity of the sub-
stance or, if its specific identity is claimed confidential, an appropriate
generic chemical name and an access-
ion number assigned by EPA.
(ii) The premanufacture notice num-
ber.
(iii) The CAS number, where avail-
able and not claimed confidential.
(iv) A summary of the basis for ac-
tion under this section.

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

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

(vii) If the Federal Register docu-
ment establishes a final rule, or noti-
ifies the public that a final rule will not
be issued after public comment has
been received, the document will de-
scribe 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 rule-
making 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 sig-
nificant new use rule it will issue a di-
rect 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 spe-
cific 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(s) will be effective
60 days from date of publication. The
written notice of intent to submit ad-
verse 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 re-
ceived 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 no-
tice 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.

(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]

§ 721.185 Limitation or revocation of certain notification requirements.

(a) Criteria for modification or revocation. EPA may at any time modify or revoke significant new use notification requirements for a chemical substance which has been added to subpart E of this part using the procedures under §721.160 or §721.170. Such action may be taken under this section if EPA makes one of the following determinations, unless other information shows that the requirements should be retained:

(1) Test data or other information obtained by EPA provide a reasonable basis for concluding that activities designated as significant new uses of the substance will not present an unreasonable risk of injury to human health or the environment.

(2) EPA has promulgated a rule under section 4 or 6 of the Act, or EPA or another agency has taken action under another law for the substance that eliminates the need for significant new use notification under section 5(a)(2) of the Act.

(3) EPA has received significant new use notices for some or all of the activities designated as significant new uses of the substance and, after reviewing such notices, concluded that there is no need to require additional notice from persons who propose to engage in identical or similar activities.

(4) EPA has examined new information, or has reexamined the test data or other information or analysis supporting its decision to add the substance to subpart E of this part under §721.170 and has concluded that the substance does not meet the criteria under §721.170(b).

(5) For a substance added to subpart E of this part under §721.160, EPA has