
40 C.F.R. § 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.

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