

(b) *Substantial new evidence.* Notwithstanding any other provision of this part, the Secretary will consider in a rulemaking proceeding on a specific substance any arguments, data or views which he determines are based upon substantial new evidence which may warrant the amendment of one or more provisions of this part. For the purposes of this part, "substantial new evidence" is evidence directly relevant to any provision of this part and is based upon data, views or arguments which differ significantly from those presented in establishing this part, including amendments thereto.

(c) *Petitions for consideration of substantial new evidence*—(1) *Petition.* Any interested person may file a written petition with the Secretary to consider "substantial new evidence" or one or more "substantial new issues" which contains the information specified in paragraph (c)(2) of this section. The Secretary shall treat such a petition as a request to amend this part, as well as a petition to consider "substantial new evidence".

(2) *Contents.* Each petition for consideration of "substantial new evidence" or one or more "substantial new issues" shall contain at least the following information:

(i) Name and address of the petitioner;

(ii) All of the data, views and arguments that the petitioner would like the Secretary to consider;

(iii) The provision or provisions that petitioner believes are inappropriate or should be added to this part in light of the new data, views, and arguments;

(iv) A statement which demonstrates that the data, views, and arguments relied upon by petitioners are directly relevant to the substance or class of substances that is the subject of a rulemaking or an Advance Notice of Proposed Rulemaking;

(v) A detailed statement and analysis as to why the petitioner believes that the data, views, and arguments presented by the petitioner:

(A) Differ significantly from those presented in the proceeding(s) which establish this part;

(B) Are so substantial as to warrant amendment of this part; and

(C) Constitute a new issue or new evidence within the meaning of paragraphs (a) and (b) of this section.

(3) *Deadline for petitions.* (i) Petitions which comply with paragraph (c) of this section, shall be filed in accordance with the schedule set forth in the Advanced Notice of Proposed Rulemaking.

(ii) In extraordinary cases the Secretary may consider evidence submitted after the deadline if the petitioner establishes that the evidence relied upon was not available and could not have reasonably been available in whole or substantial part by the deadline and that it is being submitted at the earliest possible time.

(d) *Secretary's response.* (1) The Secretary shall respond to petitions under this paragraph in accordance with § 1990.106.

(2) Whenever the Secretary determines that the "substantial new issue" or the "substantial new evidence" submitted under this paragraph is sufficient to initiate a proceeding to amend this part, the Secretary shall:

(i) Issue a notice to consider amendment to this part and not proceed on the rulemaking concerning the individual substance until completion of the amendment proceeding; or

(ii) Issue a notice to consider amendment to this part and consolidate it with the proceeding on the individual substance.

§ 1990.146 Issues to be considered in the rulemaking.

Except as provided in § 1990.145, after issuance of the advance notice of rulemaking, the proceedings for individual substances under this part shall be limited to consideration of the following issues:

(a) Whether the substance, group of substances or combination of substances subject to the proposed rulemaking is appropriately considered in a single proceeding;

(b) Whether the substance or group of substances subject to the rulemaking meets the definition of a potential occupational carcinogen set forth in § 1990.103, including whether the scientific studies are reliable;

(c) Whether the available data can appropriately be applied to the substance, group of substances or combination of substances covered by the rulemaking;

(d) Whether the data, views and arguments that are submitted in accordance with §1990.144 are sufficient to warrant an exception to this part;

(e) Whether the data, views and arguments that are submitted in accordance with §1990.145 are sufficient to warrant amendment of this part;

(f) Whether the potential occupational carcinogen meets the criteria for a Category I Potential Carcinogen or a Category II Potential Carcinogen.

(g) The environmental impact arising from regulation of the substance;

(h) Any issues required by statute or executive order;

(i) The determination of the level to control exposures to Category I Potential Carcinogens primarily through the use of engineering and work practice controls including technological and economic considerations.

(j) The determination of the appropriate employee exposure level, consistent with the Act's requirements, for Category II Potential Carcinogens;

(k) Whether suitable substitutes are available for one or more uses of Category I Potential Carcinogens and; if so, the no occupational exposure level to be achieved solely with engineering and work practice controls and other issues relevant to substitution; and

(l) Whether the provisions of the proposal and of §§1990.151 and 1990.152 (model standards) are appropriate, except as limited by §1990.142 and whether additional regulatory provisions may be appropriate.

[45 FR 5282, Jan. 22, 1980, as amended at 46 FR 5881, Jan. 21, 1981]

§ 1990.147 Final action.

(a) Within one hundred twenty (120) days from the last day of any hearing or ninety (90) days from the close of any post hearing comment period, whichever occurs first, the Secretary shall publish in the FEDERAL REGISTER:

(1) A final standard based upon the record in the proceeding; or

(2) A statement that no final standard will be issued, and the reasons therefor, or

(3) A statement that the Secretary intends to issue a final rule, but that he is unable to do so at the present time, including:

(i) The reasons therefor; and

(ii) The date by which the standard will be published, which may not exceed one hundred twenty (120) days thereafter.

(iii) The Secretary may issue no more than one such notice, unless the Secretary determines that (A) new evidence which was unavailable during the rulemaking proceeding has just become available; (B) the evidence is so important that a final rule could not reasonably be issued without this evidence, and; (C) the record is reopened for receipt of comments and/or a hearing on this evidence. This paragraph does not require the Secretary to consider any evidence which is submitted after the dates established for the submission of evidence.

(b) The failure of the Secretary to comply with the required timeframes shall not be a basis to set aside any standard or to require the issuance of a new proposal on any individual substance.

(c) The final standard shall state whether the substance or group of substances subject to the rulemaking is classified as a Category I Potential Carcinogen or as a Category II Potential Carcinogen. If the classification differs from that in the notice of proposed rulemaking, the Secretary shall explain the reasons for the change in classification in the preamble to the final standard.

(d) If the substance is classified as a Category I Potential Carcinogen, the final standard shall conform to the provisions of §1990.142(a)(2)(iii). If the final standard contains other provisions that substantially differ from the proposed provisions, the Secretary shall explain the reasons for the changes in the preamble to the final standard.

(e) If the substance is classified as a Category II potential carcinogen, the final standard shall conform to the provisions of §1990.142(a)(3)(iii). If the final standard contains other provisions that substantially differ from the proposed provisions, the Secretary shall explain the reasons for the changes in the preamble to the final standard.