

which the Secretary has reached a conclusion in the rulemaking establishing this part (including the conclusions reached in the preamble).

(iv) Each petition to amend this part shall contain at least the following information:

- (A) Name and address of petitioner;
- (B) The provisions which the petitioner believes are inappropriate;
- (C) All data, views and arguments relied upon by the petitioner; and
- (D) A detailed statement and analysis as to why the petitioner believes that the data, views and arguments presented by petitioner:

(1) Constitute substantial new issues or substantial new evidence; and

(2) Are so significant as to warrant amendment of this part.

(b) *Response to recommendations and petitions*—(1) *By the institutes*. Whenever any Director recommends an amendment to this part, the Secretary shall, within one hundred twenty (120) days after receipt of the recommendation, publish in the FEDERAL REGISTER, a notice which:

(i) States the reasons why the Secretary has determined not to commence a rulemaking proceeding to amend this part, in whole or in part, at that time; or

(ii) Commences a rulemaking proceeding to consider amending this part accordingly; or

(iii) Appoints an Advisory Committee as provided for by §1990.105 of this part and sections 6(b) and 7 of the Act.

(2) *By the public*. Within ninety (90) days, or as soon thereafter as possible, after receipt of a petition pursuant to §1990.106(a)(3), the Secretary shall:

(i) Refer the petition to the Director of NCI, the Director of NIEHS and/or the Director of NIOSH, in which case the provisions of §1990.106 (a)(1) and (b)(1) are applicable; or

(ii) Appoint an advisory committee;

(iii) Deny the petition, briefly giving the reasons therefor; or

(iv) Commence a rulemaking proceeding to consider amending this part accordingly.

(3) *On the Secretary's motion*. At any time, the Secretary may, on his own

motion, commence a rulemaking proceeding to amend this part.

[45 FR 5282, Jan. 22, 1980; 45 FR 43405, June 27, 1980]

THE OSHA CANCER POLICY

§ 1990.111 General statement of regulatory policy.

(a) This part establishes the criteria and procedures under which substances will be regulated by OSHA as potential occupational carcinogens. Although the conclusive identification of "carcinogens" is a complex matter "on the frontiers of science," (*IUD v. Hodgson* 499 F. 2d 467, 474 (D.C. Cir. 1974)), responsible health regulatory policy requires that criteria should be specified for the identification of substances which should be regulated as posing potential cancer risks to workers.

(b) The criteria established by this part are based on an extensive review of scientific data and opinions. The part provides for amending these criteria in light of new scientific developments. Decisions as to whether any particular substance meets the criteria or not will be consistent with the policies and procedures established by this part and will be based upon scientific evaluation of the evidence on that substance.

(c) This part applies to individual substances, groups of substances, or combinations or mixtures of substances which may be found in workplaces in the United States. In individual rulemaking proceedings under this part, the identity and range of substances and mixtures to be covered by the standard will be specified and the appropriateness of applying the available evidence to the range of substances and mixtures proposed for regulation will be subject to scientific and policy review.

(d) Potential occupational carcinogens will be identified and classified on the basis of human epidemiological studies and/or experimental carcinogenesis bioassays in mammals. Positive results in short term tests will also be used as concordant evidence.

(e) Potential occupational carcinogens will be classified and regulated in

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accordance with the policy. The scientific evidence as to whether individual substances meet these criteria will be considered in individual rulemakings. The issues which may be considered in these rulemakings will be limited as specified herein.

(f) This policy provides for the classification of potential occupational carcinogens into two categories depending on the nature and extent of the available scientific evidence. The two categories of potential occupational carcinogens may be regulated differently.

(g) The policy establishes a procedure for setting priorities and making them public.

(h) Worker exposure to Category I Potential Carcinogens will be reduced primarily through the use of engineering and work practice controls.

(i) Worker exposure to Category II Potential Carcinogens will be reduced as appropriate and consistent with the statutory requirements on a case-by-case basis in the rulemaking proceedings on individual substances. Any permissible exposure level so established shall be met primarily through engineering and work practice controls.

(j) The assessment of cancer risk to workers resulting from exposure to a potential occupational carcinogen will be made on the basis of available data. Because of the uncertainties and serious consequences to workers if the estimated risk is understated, cautious and prudent assumptions will be utilized to perform risk assessments.

(k) Where the Secretary determines that one or more suitable substitutes exist for certain uses of Category I Potential Carcinogens that are less hazardous to humans, a no occupational exposure level shall be set for those uses, to be achieved solely through the use of engineering and work practice controls to encourage substitution. In determining whether a substitute is suitable, the Secretary will consider the technological and economic feasibility of the introduction of the substitute, including its relative effectiveness and other relevant factors, such as regulatory requirements and the time

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needed for an orderly transition to the substitute.

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

§ 1990.112 Classification of potential carcinogens.

The following criteria for identification, classification and regulation of potential occupational carcinogens will be applied, unless the Secretary considers evidence under the provisions of §§ 1990.143, 1990.144 and 1990.145 and determines that such evidence warrants an exception to these criteria.

(a) *Category I Potential Carcinogens.* A substance shall be identified, classified, and regulated as a Category I Potential Carcinogen if, upon scientific evaluation, the Secretary determines that the substance meets the definition of a potential occupational carcinogen in (1) humans, or (2) in a single mammalian species in a long-term bioassay where the results are in concordance with some other scientifically evaluated evidence of a potential carcinogenic hazard, or (3) in a single mammalian species in an adequately conducted long-term bioassay, in appropriate circumstances where the Secretary determines the requirement for concordance is not necessary. Evidence of concordance is any of the following: positive results from independent testing in the same or other species, positive results in short-term tests, or induction of tumors at injection or implantation sites.

(b) *Category II Potential Carcinogens.* A substance shall be identified, classified, and regulated as a Category II Potential Carcinogen if, upon scientific evaluation, the Secretary determines that:

(1) The substance meets the criteria set forth in § 1990.112(a), but the evidence is found by the Secretary to be only "suggestive"; or

(2) The substance meets the criteria set forth in § 1990.112(a) in a single mammalian species without evidence of concordance.