

## § 1990.104

(5) Neoplastic transformation of mammalian cells in culture.

*Potential occupational carcinogen* means any substance, or combination or mixture of substances, which causes an increased incidence of benign and/or malignant neoplasms, or a substantial decrease in the latency period between exposure and onset of neoplasms in humans or in one or more experimental mammalian species as the result of any oral, respiratory or dermal exposure, or any other exposure which results in the induction of tumors at a site other than the site of administration. This definition also includes any substance which is metabolized into one or more potential occupational carcinogens by mammals.

*Secretary of HHS* means the Secretary of the United States Department of Health and Human Services, or designee.

### § 1990.104 Scientific review panel.

(a) *General.* At any time, the Secretary may request the Director of NCI, the Director of NIEHS and/or the Director of NIOSH to convene a scientific review panel (“the panel”) to provide recommendations to the Secretary in the identification, classification, or regulation of any potential occupational carcinogen.

(b) *Membership.* The panel will consist of individuals chosen by the respective Director(s). The panel will consist of individuals who are appropriately qualified in the disciplines relevant to the issues to be considered, and who are employed by the United States. The panel does not constitute an advisory committee within the meaning of section 6(b) or 7(b) of the Act, or the Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770).

(c) *Report.* The Secretary shall request that the panel submit a report of its evaluation within ninety (90) days after the appointment of the members of the panel. The Secretary shall place a copy of the report in the record of any relevant rulemaking undertaken pursuant to this part and allow an appropriate time for public review and comment. If a panel is not established or fails to file a timely report, or if the Secretary determines that it is necessary to proceed without waiting for

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the panel’s report, the Secretary may proceed in making any determination without such report.

(d) *Other aid and assistance.* Nothing herein precludes the Secretary from obtaining advice or other aid from any person or organization including NCI, NIEHS, and NIOSH.

### § 1990.105 Advisory committees.

The Secretary may appoint an Advisory Committee, pursuant to sections 6(b) and 7 of the Act, and 29 CFR part 1912, concerning any potential occupational carcinogen. The Secretary shall require the Advisory Committee to submit its recommendations to assist the Secretary in standard setting no later than ninety (90) days from the date of the Advisory Committee’s appointment, unless extended by the Secretary for exceptional circumstances. If an Advisory Committee fails to file a timely report, the Secretary may proceed in standard setting activities without such a report.

### § 1990.106 Amendments to this policy.

(a) *Initiation of review of this policy—*  
(1) *Secretary’s request.* No later than every three (3) years from the effective date of this part, or from the last general review, the Secretary shall request the Director of NCI, the Director of NIEHS and/or the Director of NIOSH, to review this part and render their opinions on whether significant scientific or technical advances made since the effective date of this part warrant any amendment to this part. The request shall ask that the answer be provided to the Secretary within one hundred twenty (120) days.

(2) *Recommendations by the institutes.* At any time, the Director of NCI, the Director of NIEHS and/or the Director of NIOSH may submit recommendations to the Secretary for amendments to this part whenever any of them believes that scientific or technical advances justify such amendments.

(3) *Petitions from the public.* (i) Any interested person may petition the Secretary concerning amendments to this part based upon substantial new issues or substantial new evidence.

(ii) For the purposes of this part, substantial new evidence is evidence which differs significantly from that

presented in establishing this part, including amendments.

(iii) For the purposes of this part, substantial new issues are issues which differ significantly from those upon 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