

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 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.

PRIORITY SETTING

§ 1990.121 Candidate list of potential occupational carcinogens.

(a) *Contents.* The Secretary shall prepare a list of substances (the "Candidate List") which are reported to be present in any American workplace and which, on the basis of a brief scientific review of available data, may be considered candidates for further scientific review and possible regulation as Category I Potential Carcinogens or Category II Potential Carcinogens. For the purposes of this paragraph, "available data" means:

(1) The data submitted by any person;

(2) Any data referred to by the Secretary of HHS or by the Director of NIOSH, either in the latest list entitled "Suspected Carcinogens" or any other communication;

(3) Literature referred to in U.S. Public Health Service, Publication No. 149;

(4) Data summarized and reviewed in Monographs of the International Agency for Research on Cancer (IARC) of the World Health Organization;

(5) The Toxic Substances Control Act Inventory of Chemical Substances, published by the Administrator of EPA;

(6) The Secretary of HHS's Annual Report to the President and the Congress as required by the Community Mental Health Centers Extension Act of 1978, section 404(a)(9), 42 U.S.C. 285.

(7) Any other relevant data of which the Secretary has actual knowledge.

(b) *Tentative classification.* The Secretary may tentatively designate substances on the Candidate List as candidates for classification as Category I Potential Carcinogens or as Category II Potential Carcinogens, or may list substances without a tentative designation, based on the brief scientific review of available data for the purpose of initiating a more extensive scientific review.

(c) *No legal rights established.* The inclusion or exclusion of any substance from the Candidate List shall not be subject to judicial review nor be the basis of any legal action, nor shall the exclusion of any substance from the

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list prevent the regulation of that substance as a potential occupational carcinogen. The inclusion of a substance on the Candidate List and its possible tentative designation as a Category I Potential Carcinogen or a Category II Potential Carcinogen therein do not reflect a final scientific determination that the substance is, in fact, a Category I Potential Carcinogen or a Category II Potential Carcinogen. It is a policy determination based on the brief scientific review that the Secretary should conduct a thorough review of all relevant scientific data concerning the substance.

EFFECTIVE DATE NOTE: At 48 FR 243, Jan. 4, 1983, in §1990.121, paragraphs (a) and (b) were stayed in order to evaluate the impact of publishing the Candidate Lists and Priority List and to reconsider the criteria used in establishing the lists (see also 47 FR 187, Jan. 5, 1982).

§ 1990.122 Response to petitions.

Whenever the Secretary receives any information submitted in writing by any interested person concerning the inclusion or omission of any substance from the Candidate List, the Secretary shall briefly review the information and any other available data, as defined in §1990.121(a). The results of the Secretary's review shall be transmitted to the petitioner, together with a short statement of the Secretary's reasons therefor, and made public upon request.

EFFECTIVE DATE NOTE: At 48 FR 243, Jan. 4, 1983, §1990.122 was stayed in order to evaluate the impact of publishing the Candidate List and Priority Lists and to reconsider the criteria used in establishing the lists (see also 47 FR 187, Jan. 5, 1982).

§ 1990.131 Priority lists for regulating potential occupational carcinogens.

The Secretary shall establish two priority lists for regulating potential occupational carcinogens. One list should include approximately ten (10) candidates for rulemaking as Category I Potential Carcinogens; the other approximately ten (10) candidates for rulemaking as Category II Potential Carcinogens. The order of placement of substances on these lists will not reflect the Secretary's determination of the exact order in which these sub-

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stances should be regulated in rule-making proceedings but rather a policy determination that the Secretary plans to address some or all of these substances prior to proceeding with a thorough scientific review of data concerning other substances on the Candidate List. The inclusion or exclusion of any substance on these lists shall not be subject to judicial review or be the basis for any legal action. The Secretary may regulate a potential occupational carcinogen which has not been placed on these lists. The inclusion of a substance on either of these lists does not reflect a final scientific determination that the substance is, in fact, a Category I Potential Carcinogen or a Category II Potential Carcinogen.

EFFECTIVE DATE NOTE: At 48 FR 243, Jan. 4, 1983, §1990.131 was stayed in order to evaluate the impact of publishing the Candidate List and Priority Lists and to reconsider the criteria used in establishing the lists (see also 47 FR 187, Jan. 5, 1982).

§ 1990.132 Factors to be considered.

(a) The setting of priorities is a complex matter which requires subjective and policy judgments. It is not appropriate to establish a rigid formula or to assign predetermined weight to each factor. The identification of some of the elements is to guide the OSHA staff and inform the public on the development of priorities. It is not intended to create any legal rights with respect to the setting of priorities.

(b) Some factors which may be taken into account in setting priorities for regulating potential occupational carcinogens, when such data are available, are:

(1) The estimated number of workers exposed;

(2) The estimated levels of human exposure;

(3) The levels of exposure to the substance which have been reported to cause an increased incidence of neoplasms in exposed humans, animals or both;

(4) The extent to which regulatory action could reduce not only risks of contracting cancer but also other occupational and environmental health hazards;