§ 1990.112

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 needed for an orderly transition to the substitute.


§ 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 where the results are in concordance with evidence 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 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:** Paragraphs (a) and (b) of §1990.121 were stayed at 48 FR 243, Jan. 4, 1983, 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).

§ 1990.131 **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 substances should be regulated in rulemaking 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:** Section 1990.131 was stayed at 48 FR 243, Jan. 4, 1983, 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 consider the criteria used in establishing the lists (see also 47 FR 187, Jan. 5, 1982).
§ 1990.133 Regulation of 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;
5. Whether the molecular structure of the substance is similar to the molecular structure of another substance which meets the definition of a potential occupational carcinogen;
6. Whether there are substitutes that pose a lower risk of cancer or other serious human health problems, or available evidence otherwise suggests that the social and economic costs of regulation would be small; and
7. OSHA will also consider its responsibilities for dealing with other health and safety hazards and will consider the actions being taken or planned by other governmental agencies in dealing with the same or similar health and safety hazards.

§ 1990.133 Publication.

(a) The Secretary shall publish the Candidate List in the Federal Register at least annually.

(b) The Secretary shall publish the Priority Lists in the Federal Register at least every six months and may seek public comment thereon.

(c) The Secretary may periodically publish in the Federal Register a notice requesting information concerning the classification and establishment of priorities for substances on the Candidate List together with a brief statement describing the type of information being sought.

§ 1990.141 Advance notice of proposed rulemaking.

(a) Within thirty (30) days after OSHA initiates a study concerning the economic and/or technological feasibility of specific standards that might be applied in the regulation of a potential occupational carcinogen, the Secretary will normally publish, in the Federal Register, a notice which includes at least the following:

1. The name of the substance(s);
2. The scope of the study, including where possible,
   i. Affected industries,
   ii. Levels of exposure being studied,
   iii. The anticipated completion date of the study;
3. A brief summary of the available data on health effects;
4. An estimate of when the Secretary anticipates the issuance of a proposal;
5. An invitation to interested parties to provide relevant information;
6. A statement that persons wishing to provide OSHA with their own study should complete it within 30 days after the anticipated proposal date; and
7. A statement of the procedural requirements that must be met before substantial new issues or substantial new evidence will be considered in the proceeding pursuant to § 1990.145.

(b) Where the Secretary determines to discontinue a feasibility study, the Secretary should publish, within 30 days, a notice in the Federal Register so indicating.

§ 1990.142 Initiation of a rulemaking.

Where the Secretary decides to regulate a potential occupational carcinogen, the Secretary shall initiate a rulemaking proceeding in accordance with one of the following procedures, as appropriate.

(a) Notice of proposed rulemakings (section 6(b) of the Act)—(1) General. The Secretary may issue a notice of proposed rulemaking in the Federal Register, pursuant to section 6(b) of the Act and part 1911 of this chapter. The notice shall provide for no more than a sixty (60) day comment period, and may provide for a hearing, which shall