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MEMORANDUM ON OSHA'S PROPOSED
GENERIC STANDARD FOR CARCINOGENS

In the Federal Register of October 4, 1977 (42 Fed. Reg. 54147), the Occupational Safety and Health Administration (OSHA) published proposed regulations for the identification, classification and regulation of toxic substances posing a potential occupational carcinogenic risk.

Abandoning its previous substance-by-substance approach to regulating carcinogens, an approach which has resulted in only four completed carcinogen rulemakings to date, OSHA, through these regulations, proposes to establish a vehicle and framework for future rulemakings which will enable it to move more expeditiously against suspect carcinogens. The regulations set forth criteria for determining whether a substance is a carcinogen, establish a classification scheme for suspect and known carcinogens and require certain regulatory actions to be taken following such classification. There are attached to the proposed regulations model standards to be used by OSHA as essentially fill-in-the-blank modules for standards on individual substances. Once adopted the proposed regulations

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will undoubtedly lead to a flurry of regulatory activity, the focus of which will probably be NIOSH's list of suspect carcinogens, numbering in excess of 2400.

The regulations represent OSHA's proposed resolution of many complex scientific^{1/} and legal issues. Once resolved in this rulemaking, those issues may not be open to further question in subsequent rulemakings on individual carcinogens. Thus, if OSHA decides in this rulemaking that there is no safe threshold for a carcinogen, that principle will be established and may not be questioned in subsequent rulemakings on individual substances. The criteria, classification scheme, and regulatory consequences in this proposal will apply to all subsequent OSHA rulemakings on suspect carcinogens. Indeed, given recent public pronouncements on the need for cooperation and harmonious policies between federal agencies on toxic substances, the OSHA proposal may well form the basis for a national approach to regulating carcinogens for all federal agencies.

I. COMMENTS AND HEARING DATES

Written comments on the proposed regulations and notices of intention to appear at the hearing must be postmarked on or before December 8, 1977. Direct testimony and supporting materials of persons intending to appear for more than 15 minutes at the hearing must be received no later than January 9,

^{1/} Attached hereto are eleven scientific principles which OSHA proposes to adopt in this rulemaking.

1978. OSHA need not file its testimony until February 28,
1978.^{1/} The hearing will commence on March 14, 1978.

II. INTRODUCTION

The regulations establish four categories for toxic chemicals of carcinogenic potential: Category I - confirmed carcinogens; Category II - suspect carcinogens; Category III - substances for which there is insufficient information to reach a conclusion on carcinogenicity; and Category IV - substances of carcinogenic potential not found in the American workplace. Mixtures containing carcinogens are also covered by the classification scheme without regard to the amount of carcinogenic impurities therein. The regulations will apply to all workplaces, including laboratories.

Upon receipt of information on a potentially carcinogenic substance from any interested person, or upon its own initiative, OSHA must publish within 30 days a notice of receipt in the Federal Register and provide an opportunity for public comment thereon. Within 90 days of publication, OSHA must classify the substance.

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^{1/} The Federal Register notice does not state whether OSHA intends to file or make available its supporting material, other than direct testimony, prior to February 28.

III. CATEGORY I - CONFIRMED CARCINOGENS

A. Criteria

The regulations create a presumption that a toxic substance is a Category I substance if it causes an increased incidence of tumors or decreases the latency period between exposure and onset in (1) humans, (2) two mammalian species, or (3) a single mammalian species if the test is replicated or if supported by short-term in vitro tests. The presumption is created without regard to whether tumors are benign or malignant, the dose given, or the route of exposure.

OSHA may also create a Category I presumption if it determines there is any other evidence which it believes is sufficient to classify the substance in Category I. The preamble to the regulations notes this may even include the results of a single well-conducted test in one animal species.

The presumption may be rebutted if OSHA determines that (1) the animal carcinogen data is the result of physical rather than chemical induction, (2) the route of exposure is "grossly" inappropriate to occupational exposure, (3) the data relied upon fit the Category II or III criteria, or (4) for some other reason the animal data are not scientifically relevant.

B. Regulatory Consequences

If OSHA classifies a substance as Category I, it must immediately issue an ETS following the model standard appended

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to the regulations. That standard provides that steps must be taken immediately to inform employees of the hazard and to reduce their exposure to the lowest level that can be quickly achieved. Within 50 days of classification, OSHA must then issue a proposed permanent standard which must also follow the model standard. The permanent standard will require exposure to be reduced to the lowest level feasible, or, if OSHA determines there is a "suitable" substitute, the substance may, in effect, be banned.^{1/}

None of the legal, scientific or regulatory issues which this generic rulemaking will resolve may be raised in a hearing on the permanent standard for an individual substance. Issues at such a hearing will be limited to (1) whether OSHA correctly classified or rebutted the classification presumption in accordance with the criteria stated in this proposal, (2) the determination of the lowest feasible exposure level or whether there are less hazardous suitable substitutes, (3) whether the characteristics of the particular substance require deviation from the model standard, and (4) the environmental impact of the proposed regulation.

^{1/} Where the evidence is sufficient to classify a substance on the NIOSH list of suspect carcinogens as a Category I substance but where the evidence is not relatively recent, OSHA states it may proceed directly to permanent rulemaking and not issue an ETS. Alternatively, it may proceed on a substance-by-substance basis rather than tackle all 2400 substances on the NIOSH list at once. However, neither of these approaches is authorized by the proposed regulations.

At the conclusion of the rulemaking, OSHA must promulgate a standard or reclassify the substance followed by issuance of a standard, if appropriate.

C. Model Standard

1. Emergency Temporary Standard

The model ETS requires employers to identify exposed employees, measure their exposures, inform them of the hazards of exposure, provide medical examinations and reduce exposures to the lowest level feasible that can be achieved within the shortest possible time through any combination of engineering, work practices and personal protection equipment control.

2. Permanent Standard

The permanent standard is similar in many respects to the ETS with two principal exceptions concerning substitutes and compliance methods.

The permanent standard provides that if OSHA determines there is a less hazardous "suitable" substitute, it can require no exposure to the suspect carcinogen. This may, in effect, amount to a ban for many substances. The term "suitable" is nowhere defined by OSHA.

The permanent standard also mandates a preference for engineering and work practice controls over less costly personal protective controls (e.g., respirators) as methods for complying with the exposure limits unless the employer

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proves such controls are not feasible. Engineering and work practice controls must first be utilized even if they do not bring exposures within the required limits. Although the term "feasible" is nowhere defined in the regulations, there is no indication that OSHA intends the term to include economic as well as technical considerations.

IV. CATEGORY II - SUSPECT CARCINOGENS

A. Criteria

If OSHA determines that a Category I presumption should be rebutted because the evidence is only "suggestive" of carcinogenicity, i.e., scientific concern is raised but the evidence is not persuasive or statistically significant, it must classify the substance in Category II.

In addition, a Category II presumption is raised if a substance, without regard generally to dose or route of exposure, causes an increased incidence of tumors, benign or malignant, or decreases the latency period in a single experiment in a single mammalian species or if there is other evidence to convince OSHA that the substance should be in Category II.

The grounds for rebutting the presumption are essentially the same as those for rebutting a Category I presumption.

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B. Regulatory Consequences

Within 60 days of publication of its classification decision, OSHA must publish a notice of proposed rulemaking generally following the model standard appended to the regulations. For such substances, permissible exposures will be set to reduce worker exposure to a level low enough to prevent acute or non-carcinogenic chronic effects. OSHA must also notify other federal agencies of its decision and request their assistance in conducting further research and in developing additional data.

Again, the issues at the hearing on the proposed standard are limited to those issues to which Category I hearings are limited. At the conclusion of the hearing, OSHA must issue a standard or reclassify the substance and issue a standard, if appropriate.

C. Model Standard

The model standard for Category II substances retains OSHA's present permissible exposure limit for the substance if there is one. If the present level is inadequate, or, if no limit exists, OSHA will set an appropriate level based on acute or chronic, but non-carcinogenic, effects of the substance. The standard also imposes monitoring, medical surveillance, recordkeeping and employee training and education requirements on employers. In addition, engineering and work practice controls are preferentially mandated over personal protection controls, unless the employer can prove they are not "feasible."

V. CATEGORY III - INSUFFICIENT DATA

Any substance which is not classified in Category I or II is to be classified by OSHA as Category III. Category III is intended to include those substances for which there are insufficient data to make a finding of carcinogenicity or lack thereof.

OSHA must transmit to EPA and other federal agencies its findings with respect to a Category III determination along with a request that such agencies determine whether they have additional information which might bear on reclassification of the substance.

VI. CATEGORY IV - FOREIGN TOXIC SUBSTANCE

If OSHA determines that a substance would be a potential occupational carcinogen but for the fact that it is not found in an American workplace, it must publish appropriate notices in the Federal Register and, upon receipt of information that the substance is, has been, or will be in the American workplace, initiate standard-setting procedures.

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Attachment

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SCIENTIFIC PRINCIPLES UPON WHICH OSHA EXPLICITLY RELIED

In explaining the scientific bases for the proposed regulations OSHA explicitly^{*/} set forth eleven principles upon which it relied in drafting the regulations. The first five of the principles are ones on which OSHA believes there to be general agreement in the scientific community. The next six are ones on which OSHA believes scientific experts to be less fully in agreement. Should the proposed regulations be adopted without amendment, these principles would apply to all subsequent OSHA rulemakings.

1. The only animal test data upon which OSHA will rely are mammalian test data.
2. Positive studies in any mammalian species will generally supersede negative studies in another species. Positive animal data will generally supersede negative human data.
3. Testing of substances at high exposure levels is required to overcome statistical insensitivities.
4. There can be no presumption that the organ affected in animal experiments would necessarily be that at risk in man.
5. The size of animal experimental groups must be adequately large to permit statistical evaluation.
6. As much weight should be placed on an experiment in which only benign tumors are observed as upon experiments in which both malignant and benign tumors are observed.

^{*/} There are, of course, other principles or theories upon which OSHA relied which are implicit in the proposal.

7. The results of experiments demonstrating increased incidence of tumors in treated animals should be interpreted as positive evidence of carcinogenicity regardless of the spontaneous tumor incidence provided that the experiments are sufficiently well controlled and the increase in incidence is statistically significant.
8. Tumors from dermal, inhalation, injection (with tumors at distant sites) and oral exposures are relevant to occupational exposure. Tumors induced only at the site of application are generally irrelevant to occupational exposure unless the substance is distributed systemically.
9. Much greater weight should be placed on positive results that have been replicated in another study than on a single unconfirmed result.
10. As a regulatory matter, there can be no "safe" or "no-effect" threshold level. Exposure limits must accordingly be set at the lowest level feasible.
11. Risk quantification for purposes of evaluating the expense and level of control considered feasible in light of the risk posed by a particular substance should, if at all, be considered only at the point of considering the feasibility of the regulatory provisions of a particular standard, not the risk as determined pursuant to these proposed regulations.

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