

MANUFACTURING CHEMISTS ASSOCIATION

1825 CONNECTICUT AVENUE, N. W. WASHINGTON, D. C. 20009 (202) 483-6126

WILLIAM J. DRIVER
PRESIDENT

*Enclosed with
Klein. / Kohnen*

October 21, 1977

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J. E. McEVoy

To the Executive Contacts of MCA Member Firms

Dear Sirs:

Subject: OSHA Cancer Policy

A proposal for the regulation of generic carcinogens was published by OSHA in the October 4th Federal Register. ✓

Briefly, it is proposed to establish criteria for classifying materials as (1) carcinogens (2) suspect carcinogens (3) all other material or (4) carcinogens not found in the workplace. Rigid regulatory responses would be required in each case. An emergency temporary standard and proposed standard, both specifying lowest feasible exposure, would result from placing a material in the first category. Also in that case, no occupational exposure would be allowed if the Secretary of Labor determines a less hazardous substitute is available for certain uses. For substances in the second category, a standard would be promulgated or revised, if one exists, with an "appropriate" permissible exposure level to protect against acute or chronic effects of exposure. Model standards are provided for each of the above instances. Placement in the last two categories would result primarily in the exchange of information on these substances with other agencies.

This regulatory approach allows no flexibility to reflect different degrees of hazard, lacks sufficient guidelines for acceptability of toxicological data and fails to provide procedural safeguards before banning materials. Other aspects of the proposal of concern are the assumed OSHA doctrine that no safe level of exposure exists for carcinogens and the establishment of specification standards rather than performance standards.

The Board of Directors concurred in a plan proposed by the Synthetic Organic Chemical Manufacturers Association to form an ad hoc industry task force under whose direction (1) a record of testimony would be prepared such that it would be adequate in the event of future court review, (2) desired changes in the proposed regulation would be identified and recommended, (3) OSHA would be encouraged to make an economic impact analysis, and (4) other industry and non-industry groups would be enlisted for support of the position taken. Mr. Paul F. Oreffice,

AP00047960

president of Dow Chemical U.S.A. and a member of MCA's Executive Committee and Board, will lead this effort. It is likely one of the first steps will be to request a delay in OSHA's present deadlines of December 8 for initial comments, January 9 for a more complete record, and March 14 for hearings.

Senior Advisors on health and safety, headed by Mr. William H. Bricker, president of Diamond Shamrock Corporation, will continue to guide MCA activities in this area.

R. F. - *Ray Loyal*

Also, an MCA inter-committee task group will prepare a response to the OSHA proposal, coordinated with that of the industry ad hoc group.

We will keep you informed of developments.

Sincerely,

W. J. Driver
W. J. Driver

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[4510-26]

DEPARTMENT OF LABOR
Occupational Safety and Health
Administration

[29 CFR Part 1990]

IDENTIFICATION, CLASSIFICATION AND
REGULATION OF TOXIC SUBSTANCES
POSING A POTENTIAL OCCUPATIONAL
CARCINOGENIC RISK

AGENCY: The Occupational Safety and
Health Administration, Department of
Labor.

ACTION: Proposed rule and notice of
hearing.

SUMMARY: The Occupational Safety and Health Administration (OSHA) proposes a new general regulation concerning the identification, classification and regulation of toxic substances in American workplaces that may pose a carcinogenic risk to workers. This proposal is necessary to allow OSHA to deal in a comprehensive way with the important problem of worker exposure to many toxic substances which may be potential or confirmed occupational carcinogens. This broad rulemaking proceeding is intended to establish: new procedures and a regulatory framework for regulating exposures to potential occupational carcinogens; OSHA's scientifically based policies concerning the identification and classification of potential occupational carcinogens; and three model standards for use in specific rulemakings involving such substances. The three proposed model standards incorporate OSHA's views concerning which protective provisions are generally the most appropriate to protect employees permanently against exposure to categories of toxic substances, as defined, and, in the model emergency temporary standard, which protective provisions are necessary to protect employees from the danger of cancer and which can be instituted immediately. Once promulgated in this rulemaking therefore, these proposed procedures, identification and classification criteria, and, as qualified above, the provisions of the model standards will be consistently applied and, as discussed in this proposal, foreclosed from reconsideration in future regulatory activity pursuant to these proposed regulations.

OSHA invites written comment on these proposed regulations and all of the issues raised or implicit therein. In that regard, OSHA has scheduled an informal public hearing for the receipt of oral testimony as well, as pointed out below.

DATES: Written comments concerning the proposed set of regulations and notices of intention to appear at the hearing must be postmarked on or before December 8, 1977; all materials and direct written testimony of witnesses

*Later additional subparts to this Part may be added to include other generic approaches to other toxic substances, such as, for example, those posing a potential occupational teratogenic or mutagenic risk.

which will be introduced into the hearing record by any party must be filed by no later than January 9, 1978; an informal hearing is scheduled to begin March 14, 1978.

FOR FURTHER INFORMATION CON-
TACT:

Mr. James Foster, Office of Public Affairs, OSHA, Third Street and Constitution Avenue NW, Room N3641, Washington, D.C. 20210 (202-323-8151).

SUPPLEMENTARY INFORMATION: Pursuant to sections 6(b), 8(c), and 8 (g) of the Occupational Safety and Health Act of 1970 (the Act) (84 Stat. 1593, 1599, 29 U.S.C. 655, 657), the Secretary of Labor's Order 8-76 (41 FR 25059) and Title 29 of the Code of Federal Regulations (CFR), Part 1911, it is proposed to amend Title 29 of the CFR by adding at this time a new Part 1990, a subpart A to Part 1990 to deal with the identification, classification and regulation of toxic substances, in general, and a subpart B to Part 1990 to deal with the identification, classification and regulation of toxic substances, as defined, for which there is reported to be evidence of carcinogenic potential to humans. These regulations would apply to all employments in all industries covered by the Act, including general industry, construction, maritime and agriculture. OSHA requests the submission of written comments, data and arguments from interested persons on the variety of scientific, technical and procedural issues addressed or implicit in this proposal. In addition, an informal hearing has been scheduled to provide an opportunity for presentation of evidence concerning the issues and to facilitate the conduct of this rulemaking.

This proposed set of regulations attempts to deal with one of the most important issues OSHA faces, namely the exposure of workers to toxic substances which may be potential or confirmed occupational carcinogens. At the outset, OSHA recognizes that some 1,500 to 2,000 agents have been identified by the National Institute for Occupational Safety and Health (NIOSH) as being "suspect carcinogens" (Suspected Carcinogens, HEW Publication No. (NIOSH) 77-149, December, 1976). By definition, this means that NIOSH has found some scientific evidence, of varying degrees of quality and quantity, identifying those substances as having potential carcinogenic activity, based on observations in human populations or on results from experimentation with laboratory test animals. Yet, OSHA has completed regulatory activity for only 17 of those substances since its creation on April 29, 1971. OSHA recognizes that in regulating occupational exposure to potential carcinogens, many gaps remain in our knowledge of cancer, its causes, prevention and cure. However, to wait for years to resolve these issues scientifically without some consistent and workable system for the regulation of toxic substances, for which there is evidence of a carcino-

genic potential to humans, would be, we believe, inconsistent with OSHA's statutory obligations and unacceptable to all.

Thus, OSHA proposes an orderly and comprehensive set of regulations to identify, classify and regulate potential carcinogens in American workplaces. This action is based upon three basic propositions, namely:

1. That the term "carcinogen," although perhaps difficult to define as a matter of science, must be defined for purposes of overall regulatory activity.

2. That a toxic substance, determined as a carcinogen in a mammalian test animal system, as defined, is to be treated as a policy matter as posing a carcinogenic risk to humans.

3. That when OSHA is dealing with a toxic substance, identified as a carcinogen, as defined herein, the permissible exposure limits will be set as low as feasible. In cases where there are suitable substitutes that are found to be less hazardous to the worker, no occupational exposure to the toxic substance will be permitted. In other words, unless there is evidence submitted in this rulemaking sufficient to convince the Secretary of Labor that this general policy is incorrect namely, that there is presently no means to determine a safe exposure level to a carcinogen, the permissible exposure limits will be set as low as feasible or occupational exposure will not be permitted in certain cases, both determinations to be made in the individual rulemakings conducted pursuant to this subpart.

In short, utilizing best available and generally accepted scientific knowledge to establish the carcinogenicity of a substance, OSHA proposes, in general, to rely on evidence from human epidemiological studies, adequately designed and conducted animal studies, or both. The degree of conclusiveness of such data may permit regulation of the toxic substance as a Category I toxic substance or a Category II toxic substance. This set of regulations also provides for the classification of toxic substances for which further development of data may be needed before any regulatory activity as to carcinogenicity is concerned (Category III Toxic Substances) or for toxic substances which OSHA believes are not found in American workplaces although the evidence shows that if they were, they would be classified pursuant to this subpart (Category IV Toxic Substances). The classifications of Category I and II toxic substances will require OSHA to initiate appropriate regulatory action, through the means of one or more of the three model standards, to control or eliminate exposure to the toxic substance, by way of engineering controls, work practices, respirators or simple housekeeping procedures. The content and format of these model standards, as pointed out below, are to be followed in subsequent rulemakings pursuant to this subpart, except where OSHA determines that unique properties of the toxic substance require deviations, additions or changes from the general requirements found in the model standards.

For full text call Dawn Spickler Ext: 7996

AP00047962

October 5, 1977

KEPONE CANCELLATION HEARING ON ACCESSIBLE PRODUCTS TO BE DISMISSED

Accepting almost verbatim the arguments by the Environmental Protection Agency counsel that parties filing objections to the cancellation of accessible Kepone products have not set forth any factual basis upon which a hearing would be required, presiding Administrative Law Judge Edward B. Finch has granted EPA's motion to dismiss the case and ordered the parties to file their proposed findings, conclusion and order (See Sept. 14, Page 2).

In explaining his decision that the Kepone registrants have not met the requirements of the Rules of Practice for filing objections to a proposed cancellation, Finch stated:

"EPA's actions in the April 11, 1977, Notice of Intent to Cancel and the July 21 modification were supported by a thorough analysis and weighing of the risks and benefits of the EPA Scientific Advisory Panel, the U.S. Department of Agriculture and the Agency's Pesticide Program Office. Petitioners' responses to these Notices do not challenge the factual basis underlying the Agency's position in these notices, nor do they challenge the way the Agency reached its conclusion from the supporting data.

"The detailed exposure and risk analysis, the benefit analysis and the Agency's assessment of risks and benefits go unchallenged by the Petitioners who seek a hearing before the Agency. The objections made by Petitioners are either vague and without foundation or immaterial."

Finch acknowledged that the basic argument made by most of the firms opposing cancellation concerned the impact that cancellation would have on them as small business and observed that "impact on the manufacturer is not a relevant consideration." To back up his position, he quoted the Interim Guidelines for Economic Impact Analysis of Proposed Regulatory Actions to Control Carcinogenic Pesticides, which says:

"The impacts on pesticides manufacturers are not germane to this type of regulatory decision, in which risk of the use of a pesticide is compared to the benefits of those uses."

In denying the parties' request for a hearing, Judge Finch ordered that the parties file their proposed conclusions and order no later than Oct. 14, 1977.

3 → OSHA CANCER POLICY TO WEATHER RULEMAKING; BENIGN TUMORS GET LOTS OF WEIGHT

A procedure for identifying, classifying and regulating potential carcinogens in U.S. workplaces was scheduled to be published in the Oct. 4 Federal Register by the Occupational Safety and Health Administration (OSHA).

AP00047963

The procedure, which was vigorously debated at a Washington, D.C., symposium in June (See June 8, Page 12), contains essentially the same features as the draft discussed earlier.

According to the proposal, OSHA would classify chemicals into one of four categories. Placement of a chemical into Category I would prompt immediate issuance of an OSHA "emergency temporary" standard forcing reductions in worker exposures, medical surveillance as well as other "model" actions which would be taken for all Category I substances. Within 60 days of the classification, OSHA would begin rule-making in an effort to propose a permanent standard reducing exposure to the "lowest feasible" level, in terms of technology, or prohibiting exposure entirely if a "suitable" substitute existed.

The proposal states that a chemical would be considered a Category I substance if it has been found to cause benign or malignant tumors in "(1) humans, or (2) two mammalian test species, or (3) a single mammalian species, if those results have been replicated in the same species in another experiment, or (4) a single mammalian species if those results are supported by short-term tests." A substance may be classified as Category I also if the OSHA Secretary "finds that any other evidence is sufficient to convince him that the toxic substance should be classified as Category I."

"The agency proposes to place as much weight on an experiment in which only benign tumors are observed, as upon experiments in which both malignant and benign tumors are induced," the proposal declares.

Proposal Defines "Replication" of a Positive Finding in One Test Species

On replication, the proposal states that a positive result -- benign or malignant tumors -- would be considered to have been replicated "if a similar significant increase in tumor incidence is induced in the same or different strain of the particular species so long as the experiments were carried out independently (i.e. at the least, with independent sets of control animals)."

This means that if OSHA were to rely on bioassay data generated by tests on only one species or strain of animal, "replication" would not be accomplished if the finding of "statistically significant" numbers of tumors was based on data from only one set of "historical" control animals (See Aug. 3, Page 34).

The other "sufficient" evidence upon which the OSHA Secretary may base a Category I classification, the proposal states, could include evidence that a substance "generates non-statistically significant but extremely rare or unusual tumors, such as brain tumors, that might not otherwise, standing alone, meet the other criteria for Category I classification. This might also include evidence from a single, exceptionally well conducted test on one animal species."

Category II classification would mean that a substance has been found to be positive in an "unreplicated experiment in a single mammalian species," or that the OSHA Secretary again has found evidence "sufficient" to justify placement of the substance into Category II. Category II classification would prompt no emergency temporary

AP00047964

October 5, 1977

standard, but a permanent standard would have to be proposed no later than 60 days after the classification, and the standard would have to reduce exposure to a level "low enough to prevent acute or chronic toxic effects."

It is the intent of the proposal to promulgate a "model" emergency temporary standard, as well as model standards for Category I and Category II substances, respectively. Any substance-specific deviations from the models would have to be justified and explained by OSHA, the proposal states.

In rulemaking on permanent standards for Category I and II substances, issues to be left open for discussion would be limited so that the proceedings will not be bogged down by "traditional" regulatory arguments such as the inapplicability of animal test data to humans, threshold levels, etc.

For Now, OSHA Won't Correlate Structures to Find Suspect Carcinogens

"At least at this time," the proposal states, "OSHA does not propose to rely upon structural similarities between known carcinogens and other substances" when considering regulation of the "other" substances (See Sept. 7, Page 15). However, the proposal notes that this issue may be rendered "moot" by Environmental Protection Agency testing requirements under the Toxic Substances Control Act (TSCA) which may, in fact, be based on "molecular or structural similarities."

Category III substances would be those where there is insufficient data to permit a higher level of classification, and Category IV substances would be those chemicals which could fall into any of the other categories but are not found in U.S. workplaces.

At a press briefing Oct. 3 devoted to the proposal, Labor Secretary Ray Marshall said the "generic" cancer policy would be better than OSHA's past policy of attempting to regulate substances one-by-one. "Trying to control carcinogenic substances on a case-by-case basis is like trying to put out a forest fire one tree at a time," Marshall said.

Also at the briefing, the Society of the Plastics Industry (SPI) distributed a statement saying it was in "fundamental disagreement with OSHA's apparent intent to rush to unequivocal enforcement judgments on the basis of limited scientific knowledge of carcinogens."

SPI said the proposal "is nothing more than an attempt by a regulatory agency to devise a quick fix method of dealing with the admittedly difficult task of reducing the risks of occupational cancer. No push button formula will provide the right answers," SPI said.

Acrylonitrile was mentioned at the briefing as one substance which OSHA would consider as Category I (See May 25, Page 21).

OSHA Secretary Eula Bingham said OSHA would not wait for the proposal to be promulgated in final form before proceeding with regulation of substances believed to pose carcinogenic risk. She said she hoped other Federal agencies would consider OSHA's policy in each agency's respective deliberations over suspect carcinogens.

AP00047965