4-9-4 INFORMATION COPY

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

WILLIAM J. DRIVER
PRESIDENT

RECEIVED
DEC 09 1977
LAW DEPT.

December 5, 1977

@ MCA Wash. D.C.
12/7/77
WMG

To The Executive Contacts of MCA Member Firms

Dear Sirs:

Subject: OSHA Cancer Policy

My letter of October 21 to you reported on steps to be taken in presenting industry views on proposals of the Occupational Safety and Health Administration (OSHA) for generic regulations in dealing with carcinogens. In response to requests for delay in the unreasonably short deadlines for responding to these proposals, OSHA announced in the Federal Register of November 29, that the December 8 and January 9 deadlines specified earlier have been delayed until January 30, 1978, when notification of intent to appear and portions of the record are due. The hearing has been rescheduled to begin April 4, 1978.

The American Industrial Health Council (formerly the Ad Hoc Committee) has now been formalized and is proceeding with preparations for an in-depth industry response to OSHA's proposal. While arguments are expected to rest on a sound scientific basis, economic considerations also will have a prominent role.

To assist companies in gauging the effect on their own operations, the Council asked the F. D. Snell Division of Booz, Allen & Hamilton to prepare guidelines for such an analysis. A copy is enclosed.

Also enclosed is a computer printout which attempts to both separate the major commercial chemicals from NIOSH's Tumorigenic Subfile and indicates EPA's ranking of the test results on which the listing was based.

In addition to estimating the cost of reaching the "lowest feasible" exposure in the workplace, the economic consequences of banning a product as proposed when the Secretary of Labor determines a less hazardous substitute is available, also should be calculated. In addition to the dollar costs, effects also should be presented in terms of jobs and international trade results.

It is important that each company make its views known to OSHA in writing and, if feasible, plan to make a representation at the hearing. The literal weight of such statements and the number received by an agency can, in the long run, influence its actions.

The MCA intercommittee task group addressing this matter is working closely with the Scientific Committee of the Council and has accepted the assignment of drafting that portion of the Council testimony dealing with risk/benefit. In addition, the task group is developing a proposed statement for MCA to present at the hearing.

As part of the overall effort, the MCA library has established a document center for the references cited in the OSHA proposals and others directly related. These voluminous materials are available for review at the library by member company representatives.

While these activities are expected to lead to timely industry participation in the proceedings on OSHA's cancer proposal, alone they are not enough. I urge every member company to submit views directly to OSHA on this vital matter and to participate in the April hearings.

Sincerely,

W. J. Driver

Enclosures

LAW DEPARTMENT

4-948

RECEIVED
MAR 15 1977
LAW DEPARTMENT

March 11, 1977

TO: Dr. H. J. Taufen
Executive

FROM: T. W. D'Alonzo
Legal Division

RE: Legal Analysis of OSHA's Proposed Regulation - Identification, Classification and Regulation of Toxic Materials Posing a Potential Occupational Cancer Risk to Workers

I. Compliance with the Administrative Procedures Act (5 USC 553, 556) and the Occupational Safety and Health Act (29 USC 655, 656).

The purpose of the Administrative Procedures Act (APA) is to formalize the rule-making process and give the public an opportunity to participate in that process and to assure fairness and mature consideration of rules and regulations of general application.

It has been held that agency action, which is ostensibly taken to promote the public good, must be founded upon the proper basis of congressional authority, rather than on mere good intention, personal insight, prejudice or predilection.

APA (§556) places the burden of proof on the proponent of the regulation and §655 (b)(5) of the Occupational Safety and Health Act (OSHA) provides that standards dealing with toxic materials shall be based on the "best available evidence". The mandatory presumption of Category I classification (§1990.10) effectively shifts the burden of proof to industry and the ability to classify a chemical as Category II on the basis of "suggestive" data is in contravention of OSHA.

The proposed regulation mandates a presumption of Category I classification after the Secretary receives information satisfying the criteria detailed in §1990.10. Such classification shall take place within a maximum of 60 days of receipt of the information and no sooner than 30 days after notice of such receipt is published in the Federal Register. The Secretary must classify the product as Category I or rebut the presumption after allowing a minimum of 30 days for comment on the Federal Register notice. Thirty days is a grossly insufficient time to generate data and information for submission.

If a product is classified as Category I, the Secretary must issue an Emergency Temporary Standard (ETS) which is exempt from compliance with the APA. A Notice of Proposed Rule Making must be published within 60 days of the Category I classification and the Secretary, on his own initiative or on objection and request for a hearing, must schedule a hearing subject to the APA.

The basic intent of the APA is frustrated through the proposal's limitations on the issues to be considered at such a hearing. The proposal would exclude any evidence or testimony at the hearing on the appropriateness or scientific and medical soundness of the basic definitions giving rise to the original classification ("multi-test evidence", "mutagenic", "potential occupational carcinogen" and "toxic material", none of which are defined in the Occupational Safety and Health Act).

II. Arbitrary and Capricious.

It may be safe to assume that the proposed regulatory definitions for "toxic material", "mutagenic", "multi-test evidence" and "potential occupational carcinogen" will fail to achieve significant scientific and medical consensus and, indeed, may be viewed as an oversimplification and of little guidance or utility.

A second layer of confusion and ambiguity is imposed with the definition of "suggestive" test data and the consequences flowing from the application of that novel

legal standard. The definition is indeed exclusive; and notwithstanding the vagueness of the regulatory definition, "suggestive" studies will only succeed in moving a Category I product to Category II.

The proposal therefore creates the legally and scientically absurd situation where "less than persuasive" (inadequate?) or "not statistically significant" (statistically insignificant?) data may be found by the Secretary to be insufficient to support a Category I classification, but because of the proposal, can only be reclassified to Category II, subjecting that product to Category II regulatory consequences.

The legal and economic harm perpetrated by this is compounded and aggravated by foreclosure under the proposal of any further debate, evidence or testimony regarding those definitions at a Category I or II hearing.

This situation results from arbitrary and capricious decision making by OSHA within the proposal.

A tangible economic harm will result from the regulatory consequences flowing from these definitions; and the single opportunity to comment on them prior to publication of the final regulation is, in my opinion, violative of due process.

This regulation is an unsuccessful attempt at solidifying and melding admittedly shallow and constantly expanding scientific and medical knowledge with legal principles;and, justice and fairness to business, labor and government dictates as great precision and flexibility as possible with regulatory action based on the best available data and information. The regulation should, therefore, anticipate expansion and development in this area and provide a mechanism for consideration of such new information and data at the hearing level for Category I and Category II classifications.

The proposal also has a built-in prejudgment of Category I and Category II classifications. Notwithstanding OSHA's "best evidence" requirement in setting standards, the only time under the proposal that the Secretary is required to transmit his findings to the National Cancer Institute and the Environmental Protection Agency is when a chemical has been placed in Category III, and then only to solicit information which would indicate a step up to Category I or II. It would seem advisable to do this for all three classifications and request also any information which would indicate a lower rather than higher classification.

III. Emergency Temporary Standard For Exposure (ETS), Model Standard (MS) For A Category I Toxic Material

Should the employer record employe exposure above the ETS and MS limits, he must notify and inform each affected employe of that circumstance. This requirement will undoubtedly increase the number of workmen's compensation claims filed and increase the employers' burden of proof in doubtful or spurious claims. Given the low level of knowledge of the etiology of cancer and the variety of factors external to the workplace which may or do affect the incidence of this disease, the employers' burden of disproving a causal relationship between the employment and the disease will be impossible.

The ETS and MS require that employers "assure" that employes use respirators, when required under the standards. Additionally, the MS requires that employers "assure" that employes wear protective clothing, skin and eye protective equipment, that employes remove contaminated clothing and equipment only in change areas, that such clothing and equipment is not removed from the change area except by authorized personnel, that employes working in regulated areas wash their hands and faces prior to eating and shower at the end of the shift, that food and beverages are not present nor consumed in regulated areas and that cosmetics not be applied in such areas.

The choice of the word "assure" is significant, and represents a departure from the obligation placed on the employer in previously published standards. The Asbestos Standard (29 CFR Part 1910.1001) places on the employer the obligation of providing and requiring the use of protective clothing and equipment. The use of the word "assure" rather than "require" places a much greater burden on the employer; particularly in light of the OSHA provisions governing the assessment of fines for violations of a published standard (29 USC §666).

The employer's options in this regard are limited and the burden of "assuring" use of the protective clothing and equipment rests more appropriately with the employe, who will have an appreciation for its use as a result of the training programs mandated by the proposal. The obligation on the employer, as established in present standards, should be one of requiring use of the equipment and clothing.

The proposed ETS would require that the employer achieve employe exposure below the permissible level set by the ETS by any "practicable" combination of engineering controls, work practices and personal protective devices. Engineering controls, to include substitution of less hazardous materials, enclosure of the process and local exhaust ventilation, where "feasible" must be instituted under the ETS. The cost of compliance with the ETS could be significant and the employer could, under the proposal, be operating under an ETS within 60 days of the receipt of information or data by the Secretary giving rise to the classification. This circumstance underscores the inadequacy of the comment period prior to classification by not allowing a sufficient period to analyze the data or information submitted to the Secretary and to prepare information to be submitted in response.

Of serious concern also is the failure of the proposal to protect the confidentiality of processes or areas which can be observed by employe representatives who may have no connection or affiliation with the employer.

IV. Toxic Substances Control Act

The authority of the Environmental Protection Agency (EPA) under the Toxic Substances Control Act (Public Law 94-469) is defined in such a way as to not conflict with or preempt any standards published by OSHA. Therefore, this proposal will, if published in final form, not be preempted by any regulations issued by EPA under the Toxic Substances Control Act.

It is therefore possible and probable that the manufacturer of a new product or an old product for a new use will have to run the regulatory gauntlet twice; first, to secure marketing approval from EPA under the Toxic Substance Control Act; and again at a later date before OSHA when any member of the public submits data which may be "suggestive" (as described above) at best under the proposed regulation.

If marketing approval has been secured from EPA, any later OSHA regulatory activity regarding the same product should be only on the basis of information not considered by EPA or which was compiled after the date of EPA's approval.

V. Compliance with Executive Order 11821 (November 27, 1974)-Economic Impact Statement.

By Executive Order, major proposals for the promulgation of regulations must be accompanied by a statement certifying that the economic-inflationary impact of the proposal has been evaluated. The Director of the Office of Management and Budget (OMB) is charged with this responsibility and OSHA is subject to the Order. The analysis must consider:

(a) the cost impact on consumers, business and markets;

(b) the effect on productivity of wage earners and businesses;

(c) the effect on competition; and,

(d) the effect on supplies of important products or services.

When the regulation is published in the Federal Register in proposed form, OSHA will indicate whether it considers the regulation to be major or minor. If major, the Agency will undertake the economic analysis which will be reviewed by OMB. If minor, MCA should be prepared to take issue with that determination.

TWD/cb

cc: Mr. S. M. Turk
Mr. T. R. Hunt

4/.985 L 15

LEGAL ARGUMENTS

1. OSHA has neither the authority nor the expertise to determine "suitable substitutes" The suitability of the substitute depends upon circumstances.
2. OSHA has no authority to ban chemicals by requiring zero emissions.
3. OSHA has no authority to regulate an employer vis a vis third parties
4. OSHA has no authority to require labels etc on the employer's workplace.
5. By foreclosing individual consideration of specific chemicals OSHA is violating administrative due process.
6. Action level - small concentrations