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COMMENTS ON THE PROPOSED OSHA RULE ON IDENTIFICATION, CLASSIFICATION, AND REGULATION OF TOXIC SUBSTANCES POSING A POTENTIAL OCCUPATIONAL CARCINOGENIC RISK

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I. Introduction

Air Products and Chemicals, Inc., welcomes this opportunity to comment on the OSHA proposals regarding regulatory practices concerning materials posing a potential carcinogenic risk in occupational exposures. Careful control of any such exposure and the maintenance of safe working conditions are the responsibility of every employer and of each individual employee. To assure that appropriate control is established and maintained is of key importance to all of society and, hence, is a legitimate area for government regulation.

Such regulation, however, must not be based on misunderstanding or misrepresentation of the underlying evidence, or its interpretations must not be so rigid as to pre-empt sound judgment, must produce rational regulatory actions, must not exceed statutorially granted authority and must properly balance all of the significant factors bearing on the consequences that lead to or flow from the regulations themselves. In this regard we believe that the comments and recommendations presented by the American Industrial Health Council in this matter provide OSHA with a sound alternative course of action, and one that is a very much more satisfactory response to the difficult regulatory task, than that proposed by OSHA.

In this oral testimony we will touch upon four principal problems with the OSHA proposal taken from our more detailed written testimony, which also covers other matters of concern to us. The four points are:

(1) The OSHA proposed action will not utilize the best available scientific resources and information.

(2) The OSHA proposal is unsound administratively.

(3) OSHA does not have the legal authority to carry out several important parts of its proposal, nor should it have such authority.

(4) No balanced justification has been shown for the extent of the regulation that is proposed by OSHA.

II. The OSHA Proposal Will Not Utilize The Best Available Scientific Resources And Information

The broad sweep and rigid structure of the proposed regulation precludes proper evaluation of either the hazards or the best means of reducing these hazards for individual materials.

OSHA, by rote usage of the Emergency Temporary Standard Procedure, does not provide itself sufficient time for

a proper hazard study. Furthermore, OSHA does not now have, nor is it likely to be able to acquire, the necessary expertise for proper biomedical evaluation of such data as are available. OSHA must have the ability to integrate the relevant factors presented by the variety of advocates who seem to cluster around each important regulatory decision. Even a determination of the data needed to make a proper decision on the regulatory action required involves a tough scientific assessment on which OSHA needs outside help.

Regulatory proposals such as this one, because of their wide and repetitive application, must be especially sound, thoroughly reasoned, and flexible enough to be promptly responsive to changes or advances in scientific understanding. This is especially true in fields like toxicology in general and carcinogenics in particular, where the knowledge base is as yet comparatively weak and continuously evolving. Many observers, even testifiers at these hearings, imply that toxicology testing is developed to the point that its results are truly deterministic. This is rarely the case. Subjective judgments, gross extrapolations, and interpretations make up most of the texture of the scientific decision-making involved. This product (the scientific decision) then must be passed on to an at least equally subjective and uncertain regulatory

decision-making process. It is for this reason that we strongly recommend that the scientific evaluation of toxicological and epidemiological data in the classification of compounds and the determination of carcinogenic potency be completely separated from the regulatory decision-makers. These latter persons cannot be equipped to deal satisfactorily with the scientific uncertainties involved. They must deal with the political, ethical, and administrative pressures and processes involved in the weighing of the indicated hazards, costs, and societal benefits, and finally prescribe suitable workplace conditions. That should be seen as a sufficient task in itself.

We adhere to the principles that scientific data from all sources must be scrutinized in the light of the most current knowledge, and that it is the responsibility of OSHA to assure that state-of-the-art expertise is applied in this process. As written, OSHA's proposal would require OSHA to act on the basis of what may prove to be inadequate data or dubious scientific critique or appraisal, and neither is appropriate as a basis for the protection of people at work, customers, or neighbors, nor as grounds for dislocation of the industry.

OSHA must not cloak an administrative judgment in a fabric of biased or selected data, uncritical data

acceptance, faulty interpretations, or regulation by rote. Yet OSHA is in danger of doing this with its current proposal which, by policy, attempts to settle issues of scientific debate, not only now but for the future, and then regulates on this basis. Not only is this unsound, but it is contrary to the legislative mandate to OSHA that it use the latest and best scientific understanding available.

We believe that administrative judgments or positions of advocacy are ill-suited to the analysis of scientific data. Advocacy and political-ethical-social judgments are valid only when based upon data which have been subjected to prior competent scientific critique and interpretation.

For all of these reasons we strongly urge, toether with AIHC, that there be provided an independent panel of experts qualified to assess the scientific data which pertain to compounds under review. They should be selected for their ability to reach objectively based, scientifically sound judgments and interpretations concerning the toxicological data and its interpretation in terms of human health risk. Specific affiliation with industry, labor or others groups should represent no special barrier if the skill is needed and present.

An understanding of workplace circumstances of exposure and exposure control methodology is also important. The panel must be prepared to deal with the species selection, mechanisms of carcinogenesis, experimental design and prediction of human health risk. They are not to consider societal benefits of compounds, costs, alternatives, or any of the myriad legal-political-ethical variables which are the clear prerogative of the regulators.

When their critique has been completed, then and only then, should one pass the issue to the regulators for that phase of the decision-making process.

The panel must be placed where it is relatively protected from political, commercial, or economic pressure groups, non-scientific advocates of every persuasion, and inappropriate influence by the research funding hierarchy of the Federal Government. It must be capable of dealing with the frontiers of scientific development in relevant areas. Such a panel seems to us to be the best route to state-of-the-art critiques of scientific data adequate to form the foundation of important regulation.

In addition, one would hope that the toxic hazard assessments of this panel would be made available to,

and used by all of the standard-setting agencies of the Federal Government, and also of the individual states.

Inconsistencies in interpreting what the valid factual background tells us should not further complicate the differing regulatory needs, real or imagined, of our various agencies. In fact, several widely publicized efforts on the part of various parts of the Federal Government to coordinate their efforts in this regard have yet to show any real effect in producing a sound, common approach. It is hoped that OSHA will assure that any action they take as a result of these hearings will fit into a thoroughly developed and agreed Federal regulatory policy usable by all arms of the government in this important area.

III. <u>This Proposal Is Administratively Unsound</u>

OSHA has given, as its primary reason for this proposal, its concern that present procedures are too slow and require too much regulatory effort to be effective in protecting the health of workers; OSHA, therefore, intends to increase its capacity and, it supposes, its effectiveness in fulfilling its mission by these new rules.

We believe that precisely the opposite will result. This proposal is so rigid and unwieldy, and is so

insensitive to the real needs of society and to the state of medical science, that the future activity of OSHA will be even less productive than in the past if the proposal is promulgated. OSHA will be so overwhelmed with nondiscretionary rulemaking, and so constricted in its responses as the result of this action, that the regulatory output will be of far poorer quality. Worse than this, OSHA will visit these same problems on the society it is supposed to be serving.

It seems perfectly clear that the motivation for this proposal is administrative convenience, and that it is born because of OSHA's unwillingness or incapacity to perform the task to which it is assigned. Such motivation does not lead to good regulatory practice and, it would seem, would be ultimately rejected by our society.

Proposed Section 103 requires that there be regulatory action as the result of the receipt of any information, regardless of its quality or relevance, on any compound. This receipt of information sets in motion a chain of events that leads to categorization and rulemaking after publication of a notice in the Federal Register and a hearing. If the information is significant and adequate, the compound is placed in Category I and an Emergency Temporary Standard ("ETS") is published. If the information

is not significant, the compound is required to be placed in Category II. If the information is both insignificant and inadequate, the compound is placed in Category III. The Secretary has no alternative, and cannot question the source or the quality of the information received. Any rebuttal is permitted only at a public hearing which must be called within sixty days. This is not enough time to prove safety or even to validate the quality of the test on which the claim of carcinogenicity is based. All compounds are presumptively Category I unless rebutted, which rebuttal is largely academic when no negative test can take priority over a positive one, even if it involves a clear-cut human experience in the face of a questionable animal test, or obvious physiologic or metabolic explanations for disease in animals which are irrelevant to man.

OSHA has stated they expect 261 commercial compounds on the NIOSH Suspected Carcinogen List to be put in Category I, requiring immediate publication of an ETS, public hearings, and a permanent standard within six months. Obviously, all of these do not offer the same risk to the worker, or to the same number of workers, but, under this rule, all of them would require the same immediate regulatory action.

A glaring fault of this procedure is that the data used to establish this classification clearly are of variable quality, but no standard of quality is applied to positive test results. Since any rebuttal tests will have to meet good laboratory standard tests, it would seem reasonable to demand similar standards be met by tests used to indict a chemical. The classification system should contain this provision.

Every substance which has ever given a positive test in a rodent, regardless of the dosage, becomes a "potential occupational carcinogen" and presumptively in Category II at least, requires a notice of proposed rulemaking within sixty days of the promulgation of this rule. There are hundreds of these substances. (OSHA says two hundred at least, and there may be many hundreds more.)

All other substances for which "information" has been submitted fall into Category III, and require that NIOSH, EPA, CPSC, and FDA start an immediate search for information that will permit their reclassification into more restrictive categories.

These results certainly will give OSHA the "speedy approach" to rulemaking for which it professes a desire,

but it also is certain that it will increase, not reduce its workload, and it will certainly not improve the quality of its output.

If this scenario is permitted, at least two new public hearings will begin every workday for the six months the proposed rule allows between publishing the ETS's and promulgating the final standards for the Mandatory Category I materials alone. Thus, the rigidity of the proposed approach will totally contravene the spirit of the Proposal. A far better approach would be for NIOSH and OSHA to cooperate with the other regulatory agencies in establishing a uniform system of toxic hazard assessment and for setting priorities for regulation based on extent and degree of exposue, utilizing the best medical and scientific data on potency and mechanism of oncogenicity, which can respond to advances in knowledge as they develop.

Rigid application of these proposed rules leads to a host of absurdities with which OSHA must be prepared to deal if it persists in this rulemaking.

Literal interpretation of the proposal could lead to a workplace ban on open burning, smelting, steel making, coal-fired boilers, internal combustion engines, smoking, broiling of meats, serving of saccharin, or handling of grain.

These absurdities arise because OSHA has not provided for risk/benefit calculations in its rules, nor has it provided for the exemption of low levels of impurities or mixtures in its effort to write one standard and be rid of the problem for all time. Careful re-thinking of the full implications of this Proposal is required by OSHA.

Much of OSHA's rigidity stems from their acceptance and espousal of the no-threshold theory of carcinogenic material exposure. I, personally, believe there is insufficient evidence to prove that thresholds do or do not exist, but, as we see it, the central issue is not the existence of a "threshold" but rather the level of risk. OSHA must make the effort to estimate risk and determine whether or not the risk is acceptable in terms of overall societal gain. OSHA must make the effort to determine whether or not additional controls are justifiable in terms of incremental achievements in risk reduction. We believe that it is a valid goal to reduce incremental risk to the point where it is statistically indistinguishable against the background of other risks which are voluntarily accepted as a part of life. Socially advantageous regulation is not achieved by committing huge added resources to reduction of exposures so as to obtain theoretical risks below background.

IV. The OSHA Proposal Is Legally Wrong

We believe the proposed standard to be legally defective in the following areas:

(1) It forecloses the use of the "best available evidence" by limiting the scope of future hearing and by requiring regulatory action on data that are merely "suggestive".

(2) It shifts the burden of proof from the proponent of a regulation.

(3) It would permit a ban of a substance - for which OSHA has absolutely no statutory authority.

(4) It proposes automatic use of the ETS, without the proof of "grave danger" - as is required by the act (OSHA).

In the drafting and enacting of the Occupational Safety and Health Act, Congress was quite specific on three of these four points, and the Administrative Procedures Act squarely places the burden of justification and proof on the proponent of a regulatory action.

OSHA is wrong in attempting to resolve scientific issues that cannot be resolved by scientists themselves and in proposing to ban materials. In both of these cases, Congress specifically called upon OSHA to do the opposite. The breadth of impact in these matters of contemplated OSHA action goes far beyond the limits of OSHA expertise or proper scope, and this was recognized by Congress. Finally, routine use of an ETS, without proof of grave danger distorts this key provision of the enabling legislation.

V. Economic Aspects

A critical deficiency of this proposal is the lack of an economic evaluation of the consequences, and the failure to perform any risk/cost/benefit analyses to assist in determining an optimum regulatory level.

We believe that a thorough case-by-case study with an appropriate economic analysis is required for each chemical to be regulated, and the absence of such consideration or analyses is a major failing of this proposal.

VI. Comments On Specific Issues

There is one final point which we wish to emphasize. As written, the regulation would cover every exposure no matter how slight or infrequent. We strongly urge that an action level be established below which most requirements of the standards would not apply, and separate provisions should be made for laboratory use of toxic chemicals. Similarly, exemption should be made for mixtures which do not contain enough of the toxic material to cause exposure above the action level with normal use. In addition, recognition should be made that it is necessary for service personnel and regulatory officials to enter regulated areas. These persons are not employees of the operator and, thus, their medical records are not under his control. Further details on these points are in our written comments in which we emphasize the need for a performance standard developed with the specific hazard posed by the material being considered, rather than a specification standard.

VII. Conclusion

In summary, then, we respectfully urge the consideration of the following points:

(1) Regulations must derive from a meticulous and competent analysis of all available

scientific data. Such analysis must reflect the state-of-the-art in all relevent fields; e.g., experimental design, comparative metabolism, biostatistics. In that the requisite scientific skills are not strongly represented in regulatory agencies, and that scientific judgment should be separated from the regulatory responsibility, we support an independent panel of expert scientists to evaluate all data pertaining to substances presented by OSHA for classification and to provide careful hazard assessment analyses to the regulators.

(2) In a comparable way, OSHA must carry out relative risk assessment, economic impact studies of societal needs, etc., in formulating its recovery action.

(3) The OSHA Proposal is overly rigid, and fails to establish priorities for regulatory action. It will decrease, not increase, OSHA's effectiveness as a regulatory body.

(4) The Proposal is defective legally in several areas.

(5) OSHA has failed to consider the economic feasibility of the proposed policy and the model standards issued thereunder, and it has not provided the required exemption for low exposures. OSHA should undertake to do both.

(6) OSHA should give careful consideration to the Alternatives proposal presented by AIHC.

(7) The regulatory agencies should work together to formulate a coherent Federal policy on carcinogens in keeping with the Executive Order of October, 1977.

(8) This OSHA Proposal should be withdrawn, and rule-making continued under normal procedures, with the assistance of the Classification Panel. A complete re-evaluation of OSHA's policies should be undertaken in light of the evidence obtained at this meeting. All too often meetings of this kind have been seen by some informed observers to have been nothing but a formal showcase, after which the agency has proceeded as it would. Hopefully the sincere effort put forth by all parties concerned here will make it evident that this should not happen in this case.