4-988-L-A

OSHA Office of Consumer Affairs
Docket No. H-030
Room N. 3635
U.S. Department of Labor
Third Street and Constitution Ave., N.W.
Washington, D.C. 20210

Re: Proposed 29 CFR Part 1990
Notice of Intention to Appear

Gentlemen:

You are hereby notified that Air Products and Chemicals, Inc. ("Air Products") intends to appear and testify at the public hearing on the subject of the proposed rulemaking.

1. The name, address and telephone number of the person who will appear on behalf of Air Products is:

Richard Fleming
Executive Vice President
Air Products and Chemicals, Inc.
Box 538
Allentown, PA 18105
(215) 398-8582

Air Products' alternate witness will be:

John T. Barr
Assistant Director of Health
for Plastics
Air Products and Chemicals, Inc.
Box 538
Allentown, PA 18105
(215) 398-8343

2. The capacity in which [illegible] appear will be as a representative of Air Products.

3. The approximate amount of time required for Air Products' presentation is forty-five (45) minutes.

4. The specific issue which will be addressed is the substantial modification of the [illegible] because:

[redacted]

c. [redacted] is highly Wrong

d. [redacted] is Economically Infeasible

3. [redacted] products' position on the foregoing issues is as follows:

a. It is our judgment that regulations must derive from a meticulous and competent analysis of all available scientific data. Analysis must reflect the state of the art in all relevant fields, e.g., experimental design, comparative metabolism, biostatistics. In that the requisite skills are not strongly represented in regulatory agencies, and because scientific judgment should be separated from regulatory responsibility, we support an independent panel of experts, largely from academia, to evaluate all data pertaining to substances presented by OSHA for classification.

b. The Proposal is overly rigid, and fails to establish priorities for regulatory action. Substantially more than 100 substances on the NIOSH list can be expected to fall into Category I, overwhelming OSHA with required regulatory activity. Unsubstantiated submissions by interested persons automatically trigger the classification process. All Category I and II classifications automatically trigger regulatory action irrespective of the potency of the substances, the quality of the data or other information used for categorization, the degree of worker exposure or the number of workers [illegible]

c. OSHA has neither the authority nor the expertise to [redacted] "suitable substitutes" or the impact of [redacted] OSHA has no authority to ban substances by [redacted] OSHA has no authority to [redacted] employer's relations with personnel other [redacted] By foreclosing individual consideration of specific substances OSHA is virtually [redacted] Automatic recourse to an NTP for all Category I substances is contrary to law.

d. OSHA has failed to consider the economic feasibility of the proposed policy and the model standards issued thereunder. Incremental reduction in risk are rarely justified by the often astronomical expense of achieving that more adequate protection has been achieved.

6. [redacted] ... in lieu of ... position ... [illegible] ... will, however, submit detailed written comments on the proposal, and reserves the right to submit supplemental written comments during the post-hearing comment period.

Since the testimony of Air Products will be generally supportive of that presented by the American Industrial Health Council, and will refer to certain portions of the AIHC testimony, we request that the Air Products presentation be scheduled after the conclusion of the AIHC presentation.

If you have any questions about the enclosed, or require further information, please contact John T. Barr, whose address and telephone number appear in Section 1 of this letter.

Very truly yours,

AIR PRODUCTS AND CHEMICALS, INC.

By: [signature]
Richard Fleming
Executive Vice-President

RF/RHS:cab

[redacted]

Prepared Testimony

of

Richard Fleming
Executive Vice President
Air Products and Chemicals, Inc.

on the

OSHA Proposed Rule on

Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk

Comments on the Proposed OSHA

Regulation on Toxic Substances

Outline

I. Introduction

Air Products opposes the Proposal, supports AIHC, and offers comments.

II. The Proposal Will Not Utilize the Best Available Scientific Resources

An independent classification should be utilized to assure adequate evaluation of the facts.

III. The Proposal is Administratively Unsound

OSHA will be overwhelmed with mandated regulatory action. The proposal is unduly rigid, and a host of absurdities will result. The present regulatory powers are adequate.

IV. The Proposal is Legally Wrong

OSHA does not have the authority to ban substances. The proposal is faulty because of imprecise definitions and is in conflict with several laws and Executive orders.

V. The Proposal is not Economically Feasible

No incremental justification is provided for the level of regulation proposed, nor have adequate economic or environmental inputs been prepared.

VI. Detailed Comments on Specific Issues raised by OSHA, and on the Model Standards

[Written testimony only.]

VII. Conclusion

We urge withdrawal of the Proposal and substitution of normal proceedings using the guidelines suggested by AIHC.

Comments on the Proposed OSHA
Regulation on Toxic Substances

I. Introduction

Air Products and Chemicals, Inc., opposes the proposal by OSHA to promulgate a new general regulation for toxic substances as published in 42FR54148. This position is based on the following points:

1. It will not utilize the best available scientific resources.
2. The proposal is unsound administratively.
3. OSHA does not have the legal authority to carry out several important parts of the proposal.
4. No economic justification can be shown for the extent of regulation that is proposed.

Our oral testimony will touch on each of these principal points; our written testimony contains more detailed information on each subject, and, in addition, addresses a number of other items which are of concern to us, including comments on issues raised by OSHA in this Proposal and detailed comments on the model standards.

We believe that carrying forward this Proposal, as written, would be a grave error on the part of OSHA from its standpoint alone. There is no need for this unnecessarily rigid Proposal, which will hamstring the operation of OSHA by forcing extensive regulatory activity for materials not significant industrially. As written, the Proposal will foreclose the incorporation of future advances in science in OSHA's regulatory process, and thus eventually require the repudiation of the resulting regulation.

We generally support the comments and recommendations made by the American Industrial Health Council in this matter, which we believe present a sound alternative course for OSHA to follow, and in addition, will offer some suggestions ourselves as to how OSHA should best proceed.

II. The OSHA Proposal will not utilize the best available scientific resources.

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 would not have the time nor does it have the expertise for proper biomedical evaluation of the data available, or the determination of the data needed to make a proper decision on the regulatory action required. We, therefore, support the proposal by AIHC for an independent Classification Panel to be charged with the scientific decision making. Such a panel could well serve the scientific appraisal needs of all agencies of the Federal government concerned with health regulation.

Generic regulations, because of their wide application, must be especially sound, thoroughly reasoned, and promptly responsive to advances in science. On this basis, we strongly recommend that the scientific evaluation of toxicological and epidemiological data in the classification of compounds and the determination of carcinogenic potency be entirely divorced from political, ethical, and administrative processes which weigh the indicated risk and societal benefits, and prescribe work practices or workplace conditions. We adhere to the principle 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. Inadequate data or dubious scientific critique or appraisal are appropriate neither as a basis for the protection of people at work, customers, or neighbors nor as grounds for dislocation of the industry.

Obviously, complete and impeccable data are not always available, and if one must choose between protection and no protection, one must err on the side of health conservation. But the necessary judgements must be administrative. OSHA must not cloak an administrative judgement in a fabric of biased or selected data, uncritical data acceptance, faulty interpretations, or regulation by rote. In other words, make policy judgements, if necessary but don't torture the data in an attempt to justify what is not justifiable. We have seen examples in which regulatory agencies have appeared to be less than objective or critical in their internal scientific evaluation of data: consider OSHA's examination of beryllium carcinogenicity data or EPA's appraisal of vinyl chloride epidemiological surveys and the ethylene oxide toxicity data. We believe that administrative judgments or positions of advocacy are ill-suited

to the analysis of scientific data. Advocacy and political-ethical-social judgements based upon such data may be appropriate when data have been subjected to prior competent critique and interpretation.

This means to us that there must be a panel of experts qualified to assess the scientific data which pertain to compounds under review. The composition of the panel must reflect state-of-the-art knowledge in such fields as biochemistry, comparative pharmacology, statistics, and epidemiology, to name but a few. For the most part members will come from academic institutions and the laboratories of the National Institute of Health or our National Laboratories such as Oak Ridge and Brookhaven. 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 other groups should represent no special barrier if the skill is needed and present. An understanding of work-place 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.

It is not my intent to dwell upon such issues as whether or not exposure to the Category I carcinogens, aflatoxin (in agriculture) or saccharin (in soda making) constitutes a "grave danger." Some regulators and the Congress evidently do not think so. However I am interested in the work by Dow showing that vinyl chloride administered at high levels saturates normal detoxification mechanisms and enters a pathway which leads to the production of carcinogenic metabolites. I would like to see these data weighed by an expert panel and observe the regulatory consequences. Do the enzymatic systems responsible for cancer induction also operate at low levels of exposure? If so, what is the significance of that fact? If not, what is the significance? When this critique has been completed, along with others of equal importance, then and only then, should one pass the issue to the regulators for their phase of the decision-making process.

I recognize that the determination of the most effective placement of the panel within the organizational pattern of the Federal government is a difficult matter. However, except for the jurisdictional and territorial imperative concerns of specific organizations, the placement of the panel is not of great importance. But the panel must be placed where it is immune to political, commercial, or economic pressure groups, environmental advocates of every persuasion, and 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. I do not see other routes to state-of-the-art critiques of scientific data adequate to form the foundation of important regulation.

In addition, one would hope that the activities of this panel would be made available to, and used by all of the standard-setting agencies, the Federal Government, and also the individual states. We are now faced with a morass of overlapping and inconsistant regulation being developed on an ad hoc basis. The early promises of cooperation from the IRLG have not yet borne fruit. All further regulatory action regarding health risk/benefit

assessment should be done under a coherent and consistent policy which is utilized by all of the agencies concerned, with the assistance of the best scientific thinking that this nation can provide.

III. This Proposal is Administratively Unsound

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 unwieldly, 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. 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.

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. (See Section III.) The Secretary has no alternative, and cannot question the source or reliability of the information received. Any rebuttal is permitted only at a public hearing. All compounds are presumptively Category I unless rebutted.

It is implicit throughout the proposed rule, and explicit in the third column of page 54181, that all existing carcinogens will be subject to new rulemaking procedures. Thus every substance presently listed in Subpart Z of Part 1910 will require an immediate ETS, to be followed by public hearings and a new permanent standard within six months of the promulgation of this rule.

In addition, there are over 160 commercial compounds on the NIOSH Suspected Carcinogen List with which carcinogenic response has been reported in two or more species. These are required 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.

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, requiring a notice of proposed rulemaking within 60 days of the promulgation of this rule. There are hundreds of these substances.

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 professed 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.

An official of OSHA has been quoted in the December 1977 issue of Job Safety and Health as saying "A preliminary review of the NIOSH list of suspected carcinogens indicates about 100 would belong to Category I. Another 300-400 would belong to Category II, and the remainder would be in Category III or IV." If this estimate is correct a new public hearing will begin almost every workday for the six months the proposed rule allows between publishing the one hundred-plus ETS's and promulgating the final standards for the mandatory Category I materials alone.

The rigidity of the proposed approach will totally contravene the spirit of the Proposal. It forces diversion of the resources of OSHA, industry, and society as a whole, toward substances which may have no practical significance in the total carcinogen problem, and precludes a rational approach to serious problems.

A far better approach would be for NIOSH and OSHA to cooperate in determining a system of priorities for regulation based on extent and degree of exposure, utilizing the best medical and scientific data on potency and mechanism of tumorgenicity, and which can respond to advances in knowledge as they develop. This can best be done through the independent Classification Panel suggested by many which would assist OSHA in the development of priorities through a careful evaluation of toxic potential.

The immense workload caused by this Proposal will be further exaggerated by the selection of the standards by which OSHA will categorize the suspected carcinogens. Compounds are required to be put in Category II where the data are "only suggestive" (1990.111(b). Suggestive is defined as "less than persuasive or not statistically significant..." (1990.102.) Thus statistically insignificant data require a permanent standard and a public hearing (1990.122.). The rationale to support such a course is very difficult to discern.

These public hearings are to be held 30 to 60 days after publication of the notice that the information

has been received (1990.103(2)). This period is totally inadequate for either the public or OSHA to obtain data, evaluate it, and to prepare and review testimony. OSHA has been developing this Proposal for well over a year, and yet it finds that it cannot have its testimony ready until 45 days after the period when the public must have submitted its documents, and more than five months after publication of the proposal.

In addition, the testing and reporting requirements of TSCA will force a great deal of data of varying degrees of reliability and significance to be reported, adding to the burden already placed on the administrative mechanism from already published information.

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.

Saccharin will fall in Category I, and thus must be banned if there is a suitable substitute. There are substitutes, thus, the handling or serving of saccharin must be banned in any place under the jurisdiction of OSHA, at a time when Congress denies FDA the power to ban the ingestion of the material.

All dried vegetable matter, when burned, generates polycyclic compounds and vinyl chloride, in trace amounts. Thus open fires and smelting must be banned. Similarly, the use of coal as a fuel must be forbidden, and the steel industry must be shut down, since we can buy it from abroad.

Internal combustion engines cannot be permitted, since electrical drives are technically feasible.

Handling of peanuts and several major grain and nut crops would not be permitted because of the aflatoxin-producers that grow on them in storage. Substitutes exist, so these crops must be banned. Yet, the FDA permits human consumption at measurable concentrations.

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.

Present Procedures are Adequate. OSHA already has more than adequate regulatory power to accomplish its assinged task. In this Proposal OSHA has criticized itself for poor performance and used this as a justification for this Proposal. The facts are that OSHA has only recently turned its attention to health matters, and in the past had concentrated on the encodification and enforcement of a great number of industrial concensus standards.

A major source of difficulty in the area of health-related regulation has been the perennial dispute as to whether or not there is a threshold level for response to materials which at higher levels are shown to be carcinogens. There is evidence on both sides of the issue, and we are not likely to achieve consensus on the matter in the course of these hearings. I suspent that in the final analysis some carcinogens will be shown to have a no-effect level of exposure, others perhaps may not. Again it appears that the elucidation of mechanisms of disease induction will prove the issue since we cannot ever test a sufficient number of animals to establish conclusively that cancer cannot possibly occur.

As we see it, the central issue is not "threshold" but rather level of risk. OSHA must make the effort to estimate risk and determine whether or not the risk is acceptable in terms of over-all 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 part of life. Socially advantageous regulation is not achieved by committing resources to reduction of exposures so as to obtain theoretical risks below background. It is obviously appropriate to consider the commitment of societal resources to the reduction of the background, but that is quite another matter.

IV. The OSHA Proposal is Legally Wrong

Section 655(b)(5) of the Occupational Safety and Health Act provides that standards dealing with toxic materials shall be based on the "best available evidence" and the "latest available scientific data". Even if it were conceded that the Proposal reflects the best available current scientific thinking on carcinogens (which we

most certainly do not concede), the Proposal is defective in that it forecloses consideration of advances in scientific thinking which may have occurred by the time of rulemaking on a particular chemical. In fact, the inclusion of laboratories under the general standard will seriously hamper future research into the mechanisms and possible prevention of cancer.

Proposed Section 1990.111 violates the "best available evidence" requirement of the Act by requiring Category II regulatory action on the basis of data that is merely "suggestive".

Section 556 of the Administrative Procedures Act places the burden of proof on the proponent of a regulation. Proposed Section 1990.110 improperly shifts the burden of proof to industry through its presumption of Category I classification. OSHA does not have legal authority to do this.

Proposed Section 1990.114(a) permits the Secretary to determine whether there are suitable substitutes for a Category I substance, and to set a no exposure limit for any use or class of use for which suitable substitutes

are available. A no-exposure limit would result in OSHA's banning of the substance, an action for which there is absolutely no statutory authority. An exposure level is either the lowest feasible level, or it is not; to require on exposure level lower than the lowest feasible level is contrary to Section 665(b) (5) of the Act, which requires that standards be feasible.

Proposed Section 1990.112 provides for the mandatory issuance of an Emergency Temporary Standard at the time a substance is classified as Category I. This provision directly conflicts with Section 665(c)(1) of the Act which reserves the extraordinary ETS procedure (which is exempt from the due process protections of the Administrative Procedures Act) for instances of "grave danger".

Automatic and routine resort to an Emergency Temporary Standard in the case of every Category I substance, without regard to the degree of danger presented, is contrary to the Act, and constitutes a denial of administrative due process.

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 cost/benefit analyses to assist in determining an optimum regulatory level.

We have participated in the industry-sponsored economic evaluation of this proposal conducted by Booz-Allen, and have identified 17 materials of interest to us in their list of 99 most important chemicals that were abstracted from the NIOSH suspect carcinogen list. Three of these are products, the remainder are raw materials. We have attempted to estimate the cost of compliance, over and above our present expenditures for the protection of our employees, and find that we are unable to do so with any precision. In fact, we are unable to predict accurately to what level we can reduce exposures, much less the cost to do so.

We do know that we are spending in excess of thirteen million dollars in capital alone on environmental health programs for one chemical, vinyl chloride, and we cannot predict how much more would be required to achieve some yet-to-be defined lowest feasible exposure.

We believe these costs to be representative in an industry for which we represent only 4 percent of the capacity. And we do know that the best available data assures us that we have achieved a situation where there is no present significant risk to our employees.

The very least that industry can expect before it expends resources that may be many times that necessary to provide adequate protection to its personnel is that some justification be provided for the incremental expenditure in terms of its necessity to produce an improved quality of life. This OSHA has steadfastly refused to do while holding to the position that only zero exposure can be acceptable.

There is no question that these funds should be spent if it is clear that the material in question constitutes a significant danger to health. It is not clear, however, that unlimited resources should be expended merely because OSHA will not take sufficient time to explore the appropriate regulatory requirements for a particular material.

We believe that a thorough case-by-case study with an appropriate economic analysis is required for each chemical to be regulated. The absence of adequate consideration of risk/benefit analyses is a major failing of this proposal.

VI. Comments on Specific Issues

Our written submittal contains comments on the specific issues raised by OSHA in the preamble to the proposed regulation, and several detailed comments on the draft model standard. In the interest of time these will not be presented orally, but we request your serious consideration of these comments.

One point we do wish to emphasize here. 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 officers 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.

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. Analysis must reflect the state of the art in all relevant fields, e.g., experimental design, comparative metabolism, biostatistics. In that the requisite skills are not strongly represented in regulatory agencies, and that scientific judgement should be separated from the regulatory responsibility, we support an independent panel of experts, largely from acadame, to evaluate all data pertaining to substances presented by OSHA for classification.

2. The Proposal is overly rigid, and fails to establish priorities for regulatory action. Substantially

more than 100 substances on the NIOSH list can be expected to fall into Category I, overwhelming OSHA with required regulatory activity. Unsubstantiated submissions by interested persons automatically trigger the classification process. All Category I and II classifications automatically trigger regulatory action irrespective of the potency of the substances, the quality of the data, the degree of worker exposure, or the number of workers exposed.

3. OSHA has neither the authority nor the expertise to determine "suitable substitutes" or the impact of their imposition. OSHA has no authority to ban substances by requiring zero emissions. OSHA has no authority to regulate an employer's relations with persons other than his employees. By foreclosing individual consideration of specific substances OSHA is violating administrative due process. Automatic recourse to an ETS for all Category I substances is contrary to law.

4. OSHA has failed to consider the economic feasibility of the proposed policy and the model standards

issued thereunder. Once reasonable protection has been achieved a major effect is not justified to achieve further incremental reductions.

5. The regulatory agencies should work together to formulate a coherent federal policy on carcinogens in keeping with the Executive Order of October 1977.

6. This proposal should be withdrawn, and rulemaking continued under normal procedures, with the assistance of the Classification Panel. A complete reevaluation of OSHA's policies should be undertaken in light of the evidence obtained at this meeting.