ALLENTOWN, PENNSYLVANIA 18105

24 February 1976

Docket Officer
Docket No. H-090
Technical Data Center
Room S-6212
U. S. Department of Labor
Third and Constitution Avenue, N.W.
Washington, D. C. 20210

Re: Proposed 29 CFR Part 1990

Dear Sir:

Air Products and Chemicals, Inc. submits herewith in quadruplicate its written comments on Proposed 29 CFR Part 1990.

We reserve the right to submit supplemental written comments during the post-hearing comment period.

If you have any questions about the enclosed, or require further information, please contact:

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Very truly yours,

AIR PRODUCTS AND CHEMICALS, INC.

By
Richard Tilghman
Executive Vice President

RT/JTB:ejb

Enclosure

WRITTEN COMMENTS

OF

AIR PRODUCTS AND CHEMICALS, INC.

ON THE

OSHA PROPOSED RULE ON

IDENTIFICATION, CLASSIFICATION AND REGULATION

OF TOXIC SUBSTANCES POSING A

POTENTIAL OCCUPATIONAL CARCINOGENIC RISK

VI. COMMENTS ON SPECIFIC ISSUES RAISED BY OSHA

A. The discussion of the proposed rules states on page 54160, that "there appears to be general agreement on some of the following major issues, and OSHA relies upon these concepts in preparing these regulations". We do not agree fully that there is general agreement with the way in which OSHA has stated these concepts, and provide the following comments, using the numbering system of the discussion.

1. Mammalian Species

We agree that we must rely on animal testing in the absence of human epidemiological data, and that mammals are more appropriate than non-mammals. We emphasize, however, that selection of the appropriate model and meticulous attention to experimental design and data analysis are essential. However, where adequate human data are available, they are to be preferred over animal tests.

2. Positive Vs. Negative Results

All properly conducted tests should have equal weight. There is no rational basis for any other

position. Above all, negative human epidemiology results, from a study that was conducted and evaluated properly, should have greater weight than a positive animal study. For example, a cohort of several hundred or a thousand humans, with proper matched controls and resonably estimated exposures, means far more in predicting the results of occupational exposure than does the result of a test of 50 or a hundred mice at exposures near the maximum tolerable dose.

The AIHC proposal speaks specifically to the many detailed criteria which must be examined for an animal study. When conflicting animal results are obtained, the Classification Panel should weigh all relevant data and determine where the preponderence of the evidence lies.

OSHA is incorrect in its reliance on DES as support for its position. Recent data have shown that females receiving high dosages of this material show increased incidence of breast cancer.

Testing at High Dose

OSHA has failed to consider a substantial body of recent metabolic data that shows, for some types of chemical carcinogens, a primary metabolic pathway that

can detoxify foreign materials. There are few materials that are not seriously toxic at some level; the concept of a maximum tolerable dose confirms this. Results obtained at extremely high dosages must be suspect, in and of themselves. Here, too, the AIHC has proposed general guidelines for acceptable dosages.

When the latency period exceeds the expected life span of the animal, and when the incidence of tumors cannot be distinguished from the normal background, then a no-effect level can be established, and this result has been reported in many cases. The regulatory action to be taken in such cases must contain a consideration of the incremental risk/benefit at the various possible levels of regulation; otherwise, resources are diverted without avail.

4. Organ Specificity

Organ specificity of carcinogens may provide important insights into mechanisms of action. Every effort must be made to understand such mechanisms so that any regulations which follow are grounded on data which are relevant to man and the real exposure situation. The important point is the mechanism of the carcinogen, whether it is a direct carcinogen or must be mediated

by a metabolic process, and the method of exposure. Thus, it is not correct to make a blanket statement regarding all materials as the same. This disregards the facts.

5. Statistical Significance

We agree completely with the statement that all results must be evaluated for statistical significance. No other approach would be appropriate. We note, however, that the proposal would accept "only suggestive" (defined as "less than persuasive, or not statistically significant") data as adequate for classification in Category II. This may be rebutted if the data are "less than suggestive". It is difficult to imagine what is meant by less than "not statistically significant". Thus, the body of the model standard is not consistent with the stated philosophy of OSHA. There is no justification for making important regulations with wide impact on the basis of insignificant data, and the proposal to do so seems ludicrous.

The proposal then states that there are further issues on which agreement is not assumed. We concur, and offer comments on these issues also.

6. Weight to be Placed on Benign Tumors

Any evaluation of the significance of benign tumors requires that at least three points be considered by the Classification Panel: 1) is there likelihood that this tumor type undergoes malignant transformation?; 2) is there evidence that the agent may also induce primary malignant disease?; 3) what is the evidence that the benign tumor might occur in man and cause injury on a mechanical or structural basis? Therefore, the Classification Panel should consider the type, location, and history of benign tumors, and the species and strain of the test animals in its evaluation of the seriousness of risk for each material under consideration. The AIHC Alternative Proposal goes into more detail on this point in its discussion of the duties of the Classification Panel.

Indiscriminate weighting of all tumors equally ignores the medical knowledge in this area and puts an unduly pessimistic interpretation on the facts.

Spontaneous Tumors

We agree with the position taken by OSHA that only a significant increase in naturally-occurring tumors should be considered positive, and that judgment be

mediated by a consideration of the natural frequency of occurrence. We do not agree that the higher the spontaneous rate the more appropriate the strain, because this makes the statistical analysis less precise. The most appppropriate strain is the one from which results are best extrapolated to man. This may or may not be the "most sensitive" strain. If "most sensitive" suggests a unique genetic or metabolic constitution, then the results may not be widely applicable.

8. Route of Exposure

We agree with OSHA in its two-point guiding principles on the relevant routes of exposure. The NIOSH list contains many substances which are there only because of tumors induced at the site of implantation in mice. These should be removed from the list and such "evidence" ignored.

9. Confirmation of Positive Tests

We agree with OSHA that confirmation of carcinogenicity in humans is adequate for regulation, and we believe that confirmation in two species of mammals, or one species by a replicated test is sufficient to require careful consideration of the need for regulation.

We do not agree that "only suggestive" evidence is adequate for regulation, as discussed above. Certainly there should be no regulation where "the evidence is inadequate to raise any concern...". It is as possible, from a statistical viewpoint, to get a false positive result as a false negative result. On the other hand, there may be occasion where a single, well conducted experiment could be given considerable weight by the Panel. Therefore, we believe that no rigid rule can be developed for this subject, and that each report must be examined carefully for its relevance.

However, it should be recognized that, in the long run, the question of a no-effect level loses it relevancy, although it will continue to be debated until our knowledge of cancer mechanism is much advanced. What is relevant is a thorough understanding of the risk/benefit proportion in each case and the detailed review of evidence for both risk and benefit. When one cannot prove that a no-effect level does or does not exist, then it is incumbent upon OSHA to estimate the risk at low levels of exposure and determine whether or not this risk, or probability of risk, is societally acceptable in the light of the societal benefits of production.

In addition to the foregoing numbered issues, the Proposal requests comments on several other points. Our comments are given below:

Page 54168 requests comments on the use of the principle of molecular structure to determine toxicity. We agree with the position of OSHA that this is not an adequate basis for regulation. Many examples exist in homologous series and isomeric compounds where one member differs widely from the other in its biological properties; and each case must be studied separately.

As pointed out earlier, we do not agree with the overall categorization and regulative procedure proposed by OSHA, and urge adoption of the AIHC alternative in its place.

Page 54175 requests comments on the use of reporting systems, recognizing the duplication of effort between this Proposal and other regulations. We believe that it is a proper function of an inter-agency commission to develop a single reporting system, available to all relevant agencies, that will maximize the security of the information submitted, and minimize the burden of recordkeeping and reporting for both the government and industry.

VI. Detailed Comments on the Proposed Model Standards

The detailed comments made here are in response to the request of OSHA, and as the result of study of the proposed rules. Failure to comment on a section does not imply approval of its promulgation in the context of the regulatory approach proposed by OSHA. A particular action may be appropriate for a particular application, but we repeat our statement that we do not believe the proposed rulemaking is proper, nor does it contribute to the solution of the problem at hand.

Many of the difficulties apparent in the proposed rule arise from an attempt to prepare one blanket standard for all possible future regulations, and these problems emphasize the need for a case-by-case study at the proper time.

1900.0000 (b) Definitions: Authorized Persons

No provision has been made for entry of several categories of persons who must enter regulated areas, and are other than employees of the operator or representatives of the employees. These include local safety and enforcement officials, service personnel for telephones, fire protection systems, elevators, weighing devices, and the like, contractors' employees, and representatives of various regulatory agencies.

The exposure of these individuals is infrequent and unlikely to be severe. The enforcement of medical, hygiene, and other provisions of the proposed regulation is beyond the power of the operator, yet the presence of such persons is necessary.

(c) Permissible Exposure Limits

Paragraphs (c)(1) and (3) - No exposure is permitted for uses where substitutes exist. This is tantamount to a ban, even though the preamble states that there could be a completely closed system; in actuality, such a system does not exist. Does this ban carry back to a raw material for which some uses have suitable substitutes and some do not? How is the exposure to be ratioed?

Throughout this standard all references to the "lowest practical exposure" should be changed to the "permissible limit".

Paragraph (c)(2) - "The employer shall assure that no employee is exposed to eye or skin contact...". There always will be some material present in the atmosphere, even below the permissible exposure limit, and therefore, there will be eye and skin contact, at least with trace vapors. The only alternative is a totally impervious suit, even when the breathing concentration is within permissible limits.

"No contact" should be changed to "no contact with liquid above a concentration of _____%", or some similar modified statement.

Further, many, if not most carcinogens are site specific, and others require metabolic activation. Thus skin contact is not a universal hazard with all carcinogens. A case-by-case determination is necessary.

This proposal omits any mention of an action level, below which employee exposure does not trigger medical examination, routine monitoring, compliance programs, or recordkeeping. Circumstances differ greatly as to probable employee exposure depending on whether the toxic material is used in its pure form or is present as a trace impurity in one component. Furthermore, the lowest possible exposure will differ for various stages of processing or manufacturing, and one set limit will not be applicable to all operations. As we discussed above, occasionally, there are persons who are required to enter for safety reasons that will experience very short exposures.

Provisions should therefore be made for an action level of exposure, as has been done in past standards, below which exemption is granted for most provisions of the standard. The Secretary has continued this approach in the proposed acrylonitile (43FR2586) and benezene (43FR5918) standards.

The Secretary has omitted the supporting data for the statement on page 54174, column 3, that the ceiling must be no more than five times the permissible limit for a statistically sound protection of the employee. This conclusion should be explained, and its basis made available for comment.

Comment was requested in the Preamble (page 54174) on the proposed policy for setting exposure limits on toxic materials. There can be no justification for any procedure other than a case-by-case study of the appropriate and feasible exposure to that particular material at a particular finite concentration. This can be arrived at only after full and public review of the facts at a hearing.

(e) Exposure Monitoring

Paragraph e(1)(ii) - OSHA persists in requiring monitoring without regard to respirators. The purpose of monitoring is to provide knowledge of the exposure to the employee, and health data relative to that exposure, therefore, data taken under other circumstances are irrelevant and useless for documenting exposure-health correlation. Monitoring should reflect the exposure by inhalation for air-borne contaminants, except where exposure through the skin is known to be more important, and should be with regard to the air actually breathed.

(e)(6) - A major consideration in establishing feasible limits will be the availability of adequate and accepted analytical methods. The rule should reflect the need for properly demonstrated procedures.

(j) Protective Clothing

Paragraph j(1) - Again, reference should be to contact with material other than in a vapor form unless entry into the body through the skin is the principal hazard.

(l) Waste Disposal

Paragraph l - Disposal of large equipment in sealed bags is an obvious impossibility. The proper procedure is to decontaminate (if necessary) before removal from the regulated area. The same alternative should be allowed for waste, down to a predetermined allowable concentration.

(m) Hygiene

Paragraph m(2)(ii) - The question of an employer assuring that employees, and especially female employees, shower after each shift is something that cannot and should not be done. Provisions for shower facilities, and a requirement to change clothes is all that can be done. There, and elsewhere throughout the standard, the word "assure" should

be changed to "require". If OSHA wishes to create a legal obligation to shower, as stated on page 54177, column 3, the regulation should be directed toward the employee.

Here, too, the problem of an all-inclusive regulation is apparent. OSHA has pointed out that even with a material of the low volatility of benzene, showers are not necessary (page 54177).

(n) Medical Surveillance

Paragraph n(5)(vi) - The only information on prior examinations that can be provided by the employer are from those given by that employer. Any other medical history can only be obtained by the employee.

(p) Signs and Labels

Paragraph p(3)(i) - Here, too, there should be an exemption for trace concentrations of raw materials or solvents remaining in an otherwise nontoxic product. The limit should be set at those residues which will not give concentrations above the permissible level at the next point of use.

(q) Recordkeeping

Paragraph (q)(3)(iii) - OSHA has effected a change in policy regarding delivery of medical data directly to the employee. Previous rules have supplied this information through the employee's physician, and this should continue.

It is completely unclear as to what is meant on page 54179, column 3, of the preamble in regard to "(d) the environmental variables that could affect the measurement of employee exposure...". No such requirement is contained in the corresponding section of the proposed standard itself. This should be fully explained and made subject to comment.

The preamble on page 54180, second column, also has a requirement for transmittal of records by registered mail to NIOSH, while no such requirement is present in the proposed standard. This statement in the preamble should be deleted, because even a few years records are too voluminous to be accepted by the Postal Service.

The discussion of this paragraph is incorrectly labelled "g" in the preamble, not "q".

(i) Emergency

An emergency is defined in paragraph (b) as any "unexpected exposure...in excess of the ceiling limit". Each emergency is to be reported within 24 hours, in compliance with (d)(2), and (i) requires a written plan and an alarm.

The use of the ceiling as the threshold for emergency situations is preposterous. Each and every time the ceiling is exceeded, whether or not the employee is actually exposed to that amount, or is protected by respiratory equipment or clothing, will require a written report. This will undoubtedly occur frequently during the first phases of the engineering compliance program, and OSHA will be deluged with meaningless reports.

The purpose of this requirement is totally obscure. The ceiling will be so far below the acute effects level that there is no medical justification, and it is well above the permissible limit, so the employee has already withdrawn or donned protective equipment, and the actual exposure is not a factor.

The numerical definition of an emergency in terms of ambient concentration has been found in the case of vinyl chloride to be unworkable, and this provision should be withdrawn.

4-988-L-A

bc: J. T. Barr
J. Novak
R. H. Schenck

FEB 17 1977

15 February 1978

OSHA Docket Office
Docket No. S-250
Room S6212
Department of Labor
3rd Street and Constitution Ave., N.W.
Washington, D.C. 20210

Sir:

In response to the request for comment in the 13 December 1977 Federal Register on proposed revisions to 29 CFR part 1910, Air Products and Chemicals, Inc., provides the following comments:

1. We support the intention of the Secretary to simplify and improve part 1910 by elimination of unnecessary requirements. In particular, we support the proposed deletions in 1910.1017, Vinyl Chloride, of the requirement for preparing a daily roster, (e)(2), and for maintaining it 30 years (m)(2)(ii).

2. We recommend that two further deletions be made in the Vinyl Chloride standard and in other comparable standards. These are:

   A. Delete the phrase "without regard to respirators" in 1910.1017(d)(2) and elsewhere. Monitoring air not breathed by the employee vitiates all benefit from the exposure and record-keeping program. No possible use can be made of records that do not reflect actual personnel exposure.

B. Delete the phrase "by registered mail" from 1910.1017(m)(2)(ii). The U.S. Postal Service will not accept as registered mail a package large enough to hold even a few years' records. Thus, shipment must be by a parcel service.

Very truly yours,

Richard Fleming
Executive Vice President