4-983-2-24

Air Products and Chemicals, Inc.
Box 538, Allentown, PA 18105
(215) 481-4911

22 January 1981

Central Docket Section
Gallery 3, West Tower, Waterside Mall
401 M Street, S.W.
Washington, DC 20460

Attention: OAQPS-79-14

Gentlemen:

Air Products and Chemicals, Inc. submits additional supplementary comments on the proposed airborne carcinogen policy (44FR58642) pursuant to the notice of closing of the comment period as published at 45FR84827, December 23, 1980. These additional comments are attached.

We are concerned over the cryptic statement in the closure notice which says that "EPA has concluded that a further meeting of the SAB prior to finalization of the airborne carcinogen policy is unnecessary" (45FR84828). This further meeting was made necessary by the total rejection by the SAB of the principles embodied in the proposed policy (see the attached comments, Part IV, for further discussion), and the recommending of most of the CAG documents for extensive revision before the SAB would consider them. The Agency agreed at that time to return to the Board with revisions and further discussion. This action appears to be a violation of that agreement.

The Agency also agreed to seek adequate peer review for the IRLG/Regulatory Council policy on carcinogens, on which this Agency proposal is based, and now appears to have broken its word on that promise also. We are concerned that the Agency is attempting to denigrate the need for peer review.

It is not possible for the Agency to promulgate the proposed policy based on support from the record or on the actions of its advisory board. The alternatives left to the Agency are to withdraw the policy, as we have urged, or to modify it substantially to bring it into concordance with sound scientific principles. In this latter case, it will be necessary for the Agency to repropose a revised policy before it can take final action.

The Agency must either withdraw or repropose this policy; it will not be acceptable for it to continue to implement the proposal as an internal policy with no further formal action, for the reasons discussed in Part II of the attached comments.

Therefore, we submit the attached comments with the expectation that the Agency will withdraw the current proposal and repropose a more suitable policy for public consideration. This new policy should be a segment of a coherent national policy for a realistic program to address the causes and prevention of cancer. We cannot accept continued de facto implementation of a discredited proposal.

Please feel free to contact us if there are any questions regarding these or our earlier comments on this proposal.

Very truly yours,

AIR PRODUCTS & CHEMICALS, INC.

John T. Barr
Regulatory Response

JTB/rkw

bcc: G. H. Baise
R. C. Barnard
A. E. Greene
R. H. Schenck

ADDITIONAL SUPPLEMENTARY COMMENTS BY AIR PRODUCTS AND CHEMICALS, INC. ON THE PROPOSED AIRBORNE CARCINOGEN POLICY

Air Products has commented previously (1,2,3) on the proposed generic policy (4) for the Identification and Regulation of Airborne Carcinogens. This submittal will provide additional facts for the consideration of the Agency which have become available since the public meetings that were held in March, 1980.

I. Lack of Need for this Action

We have emphasized in our previous submittals the total lack of any demonstrated need for a generic carcinogen policy, in that there has been no supportable evidence placed on the record that connects either air pollution in general, or any specific pollutant, with an increase in cancer rate or incidence. If the record is, in fact, "in a shambles", as one Agency official has been quoted as saying, it is because the Agency has failed to provide any demonstrable need for its proposal.

New evidence continues to mount in support of this lack of correlation between air pollution and cancer in the general population. The American Cancer Society has released (5) an update on its 20-year prospective study of nearly one million persons, in which it concludes that "the study also found no evidence that certain factors were linked to cancer, such as air pollution and hair dyes." In another place it states: "Air pollution was not found to be a great culprit in causing lung cancer. General air pollution had little effect in a comparison between urban and rural people."

There also was published recently (6) the proceedings of a gathering of distinguished scientists held in 1979 which considered the relationship between our environment and cancer. This volume is too large to review in detail here, but some major points are worth mentioning. Devesa and Silverman presented national data on cancer incidence and mortality which quite contradict the claims that incidence has been rising in the United States recently. Phillips showed that selective diet and abstinence from tobacco and alcohol by some groups reduced the cancer incidence of those persons, while that of their neighbors was equivalent to the national average, thus effectively eliminating air pollution as a significant cause of cancer. On a similar theme, Rawson discussed the power of human epidemiology to distinguish between various causes of cancer. Goldsmith and Demopolous presented papers which discussed some of the lifestyle causes of the so-called "urban" effect on cancer rates. Several other papers also discussed the effect of life style, and especially diets and smoking on cancer rates. Cole and Merletti pointed out several of the faults of the "Estimates" paper on the projected incidence of occupationally-related cancer. The keynote paper by Cimino and Demopolous discussed the present state of knowledge regarding the various classes of determinants for cancer, and how this information should direct our fight against cancer. All of the papers in this symposium are of interest to those considering this proposal, and should be studied by the concerned parties.

The 1980 International Symposium on Cancer was held in New York on the week of 14 September. At this time Shimkin reviewed (35) the findings of the 1979 Conference on the Primary Prevention of Cancer (36) which concluded that general air pollution had no detectable effect on cancer incidence, and found that, as the result of a study sponsored by the NCI, there were no new data to dispute that conclusion. Higginson gave the keynote address at the New York symposium (39), and emphasized the contribution that epidemiology has made to determining the causation of cancer, and also reiterated the insignificance of air pollution to cancer in the general populace. Sir Richard Doll (38) criticized the limitations which OSHA has placed on acceptable human epidemiology, and discussed the value of supportive negative results. In this context, Muir has said (39):

> "Although it is said to be impossible to prove a negative, if several epidemiological studies show that a given exposure does not appear to be associated with an increased risk, then it is likely that this exposure does not in fact carry a risk. It is unlikely that all the studies would be biased in the same direction or manner, in which event the results should converge towards the true mean. The International Agency for Research on Cancer recently considered this question and suggested that negative studies could be assessed by the following criteria.
>
> Analytical epidemiological studies showing no association between an agent and cancer ("negative" studies) should be interpreted according to criteria analogous to those used for "positive" studies. These would include absence of (a) identifiable negative bias, (b) negative confounding and (c) misclassification of exposure or outcome. In addition, it must be recognized that any study will have confidence limits around the estimate of association or relative risk. In a study regarded as "negative" the upper confidence limit may fall at a relative risk substantially above unity; in this case the study excludes only relative risks that are above this upper limit. This means that a negative study must be large to be convincing. Confidence in "negative" result, like for the "positive" result, is increased when several independent studies done under different circumstances are in agreement. Finally a "negative" study is only relevant for the exposure levels of the study and if sufficient time has elapsed since the first human exposure to the agent."

Beaumont and Hatch recently reported on a study of the power of several epidemiological studies on vinyl chloride (40) and discussed the conditions under which negative studies are convincing. Their analyses showed that properly designed studies are of value in the decision-making process.

A recent NCI monograph (41) contains fifteen papers from universities, government laboratories, and private institutions which emphasize the now well-recognized effect of private lifestyle on the risk of cancer. Religious groups such as the Mormons, Seventh-Day Adventists, Hutterites, and Protestant clergy showed substantially lower risk at sites recognized as reflecting abstinence from various social practices such as smoking, drinking, diet selection, and other optional lifestyles. The "urban

effect" was diminished greatly when viewed across several of these cohorts. Ethnic effects on lifestyle were also very apparent in comparisons made of the inhabitants of Hawaii and Alaska. Nowhere was there any evidence presented that industrially-related emissions of chemicals had a perceptible effect on cancer mortality.

There are those who claim that the incidence of cancer is increasing in this country. We are convinced that proper statistical analysis of the TNCS and SEER data will demonstrate just the opposite: a steady decrease in cancer incidence. In addition, these data support the evidence for no causal relationship between industrial emissions and cancer incidence. Nonindustrialized areas often have higher incidence rates than do heavily industrial areas (42).

We understand that the Office of Technology Assessment has engaged Sir Richard Doll and Dr. Petro to prepare an evaluation of current literature on the contribution of air pollutants to chronic health effects. This report should be released in the near future, and we request that it be made a part of the record at that time.

Thus, the Agency cannot fail to take into account the total absence of any epidemiological data connecting general or specific pollution of the environment outside of the workplace with cancer in the nonworking population. This lack of data completely removes any basis of need for this proposal.

Our position (1) that the need for a policy must be demonstrated before an Agency may act has been supported strongly by the recent Supreme Court decision on the OSHA benzene standard (7). In this case the court ruled that it was incumbent on that Agency to demonstrate a significant risk under the existing conditions before a new standard may be applied, and to show that the proposed reduction of exposure will provide a measurable abatement of that risk under feasible conditions. This Agency has done neither of these things in this matter.

The Court went on to point out that an Agency could, if it were to implement broad generic rules "limited only by the constraint of feasibility," take the position that a material "poses some risk of serious harm no matter how minute the exposure and no matter how many experts testified that they regarded the risk as insignificant," thereby taking to itself the "power to impose enormous costs that might produce little, if any, discernable benefit"(8). This is precisely the indefensible position which this Agency has proposed for itself when it requires the best available technology to be applied to limit the emissions of any suspect human carcinogen, regardless of evidence which shows no harm to the environment when less "draconian" controls may be applied.

The Court also felt that the mere existence of a generic policy based on such a philosophy warranted concern over its misapplication (9), and stated that such a policy abdicated the responsibility of the Agency to establish the need for the proposed standard, thus exceeding its authority (10).

This decision also reaffirmed the responsibility of the Agency to define for the public the meaning of significant risk (11) in its policy. We have noted (1) that this Agency has refused consistently to define its equivalent terms "ample margin of safety", or "acceptable residual risk", and this failure also has been criticized by the Center for Policy Analysis (12). The public must be informed as to the degree of safety which is proffered by any proposal so that it may judge its acceptability, and the Agency must define such key terms before a policy becomes enforceable. Chief Justice Berger (7) also pointed out the need to refrain from de minimus regulation, citing Alabama Power. This differentation between negligible and significant risks must be made in any policy decisions as to the scope of a generic rule. As Justice Berger said, "Perfect safety is a chimera; regulations must not strangle human activity in the search for the impossible." (The Commerce Department, in its comments to the Agency on this proposal, urged that a de minimus concept be incorporated to avoid regulating negligible risks [26]).

The Court has returned clearly to the agencies the burden of proof that a regulation is necessary (7), and this Agency has failed to meet that requirement in this case.

II. De Facto Application of this Proposal

Therefore, in view of the strong Court language that generic policies based on unproven assumptions (7) are not acceptable, it is apparent that the Agency cannot pursue its original proposal. Indeed, there is evidence that it already may have determined not to follow the normal course of promulgation, but simply to utilize the proposal as an internal policy as guidance in individual rulemaking procedures, and has actually done just that in the cases of radionuclides (13), organic solvent cleaners (22) and benzene (14) and is proposing to do so for six more substances (15). Further, we have been informed (21) by the Agency that its contractor is relying on the provisions of this proposed policy to prepare a five-year review of the existing vinyl chloride standard.

We support a case-by-case evaluation of each proposed listing and regulation; we have urged that approach in many earlier submittals to the regulatory agencies. We cannot, however, agree that this discredited proposed philosophy be used as the basis for a regulatory policy. If agencies were to be permitted to implement proposals which they are unable to substantiate adequately for promulgation, the entire regulatory procedure would become a farce and a sham. Therefore, once having proposed this philosophy, the Agency must not implement it unofficially merely in an effort to avoid the judicial review which would come as the result of promulgation. This proposal ought to be promulgated, or abandoned, or reproposed for further public comments. Unofficial adoption and use is a perversion of the administrative procedures and a denial of due process to the public. Holingsworth has said (30) that this proposal "transcends the requirements of legal due process." More specifically, we believe it is a violation of Section 307 of the Clean Air Act, and of Section 533 of the Administrative Procedure Act.

We also agree that the long-needed peer review which the SAB subcommittee (15) is giving to the listing proposals under Section 112 of the Clean Air Act is proper, and we look on the establishment of this subcommittee as a useful, although temporary, first step toward the establishment of the Independent Scientific Panel which a large segment of the public has urged (16). We regret, however, that the Agency has concluded that further consultation with this group is "unnecessary" (45FR84828). Only when a Panel has been constituted which is completely free from the constraints of a particular agency, and whose results are available to all regulatory agencies, can we expect to obtain the maximum benefits of the scientific expertise which is available.

We cannot, however, support the practice of using the authority of this expert group to attempt to legitimize the implementation of a policy so lacking in scientific and legal bases that it cannot be promulgated.

III. Scientific Issues

Numerous scientific issues were presented in the development of the record in this proposal, and many of these were summarized in a recent letter to the Agency (17). This section will present additional data on some of these issues.

A. Benign Tumors

This Agency has adopted the position that any increase in any type of tumor in any test species is evidence of human carcinogenicity. This position, which was adopted as being "prudent," is contrary to a sizeable body of scientific opinion, as exemplified by a report of the National Academy of Science (18).

In that report, a special subcommittee, at the request of an Administrative Law Judge in a FIFRA hearing, was asked to review the human risk for some pesticides. Their report highlighted the conclusion that the concept of progress by benign nodular liver lesions in rodents to carcinoma is hypothesis only, and not a scientific fact. Similarly, the National Cancer Advisory Board has stated that "there is no simple or universal definition of either carcinoma or neoplasia. . . Each case must be considered on its own. . ."(19). Recently, doctors at Johns Hopkins University have determined physiological as well as pathological differences between benign and malignant human tumors. Among other differences, there is a substantially higher calcium content for the benign types (20). Thus, this "consensus opinion" of the regulatory agencies has no support in fact, nor do other similar unsupported hypotheses in use by the Agency, such as the reliability of in vitro, or short-term, tests. These have been adopted purely for regulatory convenience rather than their relevance to science.

B. Organ and Type Specificity

Similarly, epidemiology studies purporting to relate environmental factors to cancer incidence have tended to include all types of carcinomas in their evaluation, or at least all carcinomas in a

particular site, contrary to the principle of specificity which has shown that certain agents cause definite types of tumors at specific sites (23). This action not only confounds the efforts to determine the effect of specific agents, but dilutes the effect of the suspect substance by the variable background of tumors of other etiology. Some investigators are emphasizing the need for identification of the specific tumor (24), and we urge that this criterion be applied to all investigations of suspect carcinogens. Not to do so will result in much lower efficiency of the studies and will be very wasteful of epidemiological efforts.

C. Independent Scientific Panel

We are encouraged that the new special subcommittee of the Science Advisory Board (15) has undertaken to assure adequate peer review for the future proposed listings under Section 112, and look forward (2) to a resulting improvement in the quality of the risk assessments prepared for this purpose. This action by the Agency could be a useful first step toward an expert interagency Scientific Panel such as has been suggested by industry (16), Members of Congress (25), and other responsible groups, but the potential value of this action has been negated largely by the recent decision of the Agency not to utilize further consultation from the SAB in its decision on this proposal. Chief Judge Howard Markey states (27) that the courts are not the best arbiters of risk, and suggests that the Office of Technology Assessment be the review unit. The National Academy of Science has received a report from Professor Howard Riaffa of Harvard urging support for independent assessment groups (28), and Congress recently appropriated $500,000 for a study by the National Academy of Sciency of this approach.

We are beginning to see a broad awakening to the fact that the regulatory agency staffs are not the best place to do risk assessment studies, and a variety of solutions are being proposed. However, we continue to believe that one expert Panel will better serve the regulatory bodies by its ability to attract superior scientists, eliminate duplication between the various agencies requiring such services, and assure uniform interpretation of critical scientific evidence, and we urge the Agency to move toward further cooperation with the other agencies in establishing such a Panel.

It is interesting to note that the SAB subcommittee convened by this Agency totally rejected, properly we believe, any attempt by the Agency to draw it into regulatory, as opposed to scientific, considerations (15, transcript pages Vol. I:27, I:116, and II:17). Thus, it is following the very desirable policy of providing the regulators with the best scientific evidence for their consideration, but leaving the sociopolitical decisions to the regulators.

D. Application of Risk Analyses

We have commented above on the critique of the benzene risk assessment by the Center for Policy Alternatives (CPA) regarding the failure of the Agency to establish a policy relative to acceptable risk, or ample margin of safety. This study (12) also supports several points made by us in earlier submittals to the Agency on other problems in the application of current risk assessments.

One important point which has been discussed frequently in our written comments and in personal conversations with CAG staff is the presentation by CAG of a single numerical result, with the implication that it is the result, and without discussion of the error range or probability of correctness of the result. Alternatively, the Agency sometimes states a range, with no most probable value given (14). Figures are often given to one or two decimal places, thus indicating an unwarranted precision. As the CPA study points out, this can mislead seriously the layman, and perhaps the policymakers also, into placing greater reliance on the numerical value than is justified.

We have supported consistently the use of quantitative risk assessments in the development of priorities and evaluation of relative risks, but we urge that each assessment be made more useful by a careful discussion of all of the assumptions used in the development of the assessment and an evaluation of the error range of these assumptions at each step and in the aggregate. The most probable value should be stated, and the range of values at some statistical probability.

We agree, as CPA states, that human epidemiology should be used as the best available data whenever it is available. We have pointed out, however, that the uncritical use of these data can lead to unreliable results. The CPA (12), the Supreme Court (7) and the SAB subcommittee (15) all have noted the problems with some of the data in at least one of the epidemiological studies utilized by CAG. It is incumbent upon an Agency to assure the reliability of the data incorporated into its studies.

A further example of this unscientific adoption of data is illustrated by the failure to differentiate between the various types of leukemia cases in the base studies. As we pointed out above, type specificity is an accepted scientific principle of oncology, and failure to recognize this can weaken the credibility of an otherwise good study. Therefore, CAG must be more perceptive in its evaluation of its data bases.

We welcome the use of external peer review for Agency studies as was done in these cases, and we feel that consistent application of this action by a permanent mechanism such as the recommended independent Scientific Panel (1,16) will add greatly to the utility and credibility of the Agency proposals. We regret that the Agency appears to have decided not to use the SAB further in this instance.

Quantitative risk assessments must be an important part of the decision-making process, and the responsible policy-maker should require that he receive the very best data available so that his

decisions may be proper. We urge the Agency to continue to upgrade the quality of its risk assessment procedures, so that they may become an appropriate part of the process.

E. The Value of Short-term Tests

There has been much discussion of the stated intention of the Agency to use the positive results of short-term tests as confirmatory data for human carcinogenesis, and, in some instances, as the basis for regulation. A recent issue of EPA Journal carried an interview with the Dr. Cantlon, Chairman of the NAS Environmental Studies Board, in which he summarized the generally prevailing scientific evaluation of these tests (32):

> "The emergence of these quickie test techniques is a way to get away from testing on animals. But colonies of human or animal or bacterial cells simply do not respond the way a whole mouse or rat or monkey does because the cell colonies don't have kidneys, eyes, a liver, a brain, a gut, a stomach, or lungs, and both collectively and individually those organs behave differently to different combinations of compounds. There is no way that the quickie techniques will ever replace whole animal research. It just won't happen. However, preliminary screening and much basic research will be much enhanced by cell culture techniques."

Another reason why bacteria do not serve as adequate surrogates for humans is that there is a significant difference in the DNA structure between the species. In humans there are elements with no phenotypic function interspersed along the chains between segments with evolutionary functions (33). These "selfish" genes will alter the response of the cell to disturbing forces which attack the DNA strand as compared to cells which do not have these units (34).

Thus, while useful for screening programs, short-term tests are not an appropriate base on which to develop a regulatory decision.

IV. Suitability of the IRLG Guidelines

An attempt was made by the Agency staff to require the SAB subcommittee to comply with the so-called IRLG guidelines for the determination of animal carcinogenicity. The subcommittee would not allow itself to be bound by these rules, stating that "a committee from four government agencies does not write a handbook of science" (15, transcript page II:149). The committee chairman discussed the reliability of several specific policy points raised by the Agency staff, and his remarks are summarized briefly below (15, transcript pages II:6-14).

1. The results of a single test are acceptable - Reply: One well-done test might be acceptable, but those cited were not.

2. Negative studies were not considered - Reply: Negative data cannot be ignored.

3. Dose response is not necessary - Reply: Dose response is expected.

4. Results from tests with high incidence in the controls - Reply: High control incidence adds to the general disquietude over the tests.

5. Need for testing at MTD - Reply: MTD may or may not be important.

6. Need to test commercial mixtures - Reply: The feeling of need to test mixtures is sophistry.

Thus, the committee made it clear that it would not be bound by the guidelines, and that each substance would be considered on a case-by-case basis. It was eventually agreed that the Agency would revise the CAG risk assessments that had been submitted before the committee would give them further consideration. We now find that the Agency will not proceed with this agreement (45FR84828).

Other advisors to the Agency have criticized the Agency for the wasted time and effort it has put into attempts to prepare generic standards and rules. Richard Cooper told the Agency:

> "More generally, I am skeptical of the value of massive efforts to establish, with the force of law, agency policy on scientific subject matters ... My impression is that EPA's Cancer Principles did not have a happy history; and I predict that OSHA will conclude that the procedural advantages from its cancer policy will not be worth the costs in promulgating it."(29)

Ian Nisbet said, "I anticipate great difficulty in establishing generic test standards. I urge that test rules on specific chemicals should not be postponed into the indefinite future while generic standards are debated at length."(29)

The Director of the National Toxicology Program states (31) that "science and society have not yet arrived at a final consensus on the definition of a carcinogen either in the human population or in experimental animals ..."

Thus, the very wisdom of attempting to establish generic standards and rules such as this has been questioned seriously by the advisors chosen by the Agency. We urge the Agency to abide by their advice and withdraw this proposal.

REFERENCES

1. APCI Written Comments, OAQPS79-14-IV-D-65, February 7, 1980.

2. APCI Oral Statement, March 19, 1980. Boston, Mass. Transcript pages 187-212.

3. APCI Supplementary Comments, April 14, 1980.

4. 44 FR 58643.

5. American Cancer Society, Annual Report 1979. Special Report: Cancer Prevention Study.

6. Demopolous, H. B., and M. A. Mehlmon, Eds., "Cancer and the Environment." Pathatox Pubs., Park Forest South, Ill., 1980.

7. Industrial Union Dept. v. American Petrol. Inst., No. 78-911, July 2, 1980, pp. 31-32, 42 of the plurality slip opinion.

8. op. cit., pp. 34-35, of slip opinion.

9. op. cit., footnote 51, p. 35.

10. op. cit., p. 40.

11. op. cit., p. 2 of Chief Justice Berger's concurring opinion.

12. Ashford, N. A., D. Hattis, and W. Mendez, "Discussion and Critique of the CAG's Report on Population Risk Due to Atmospheric Exposure to Benzene", MIT Center for Policy Analysis, Boston, Mass., May 7, 1980.

13. 44 FR 76738, 27 December 1979.

14. 45 FR 34315, 22 May 1980, 45FR83449, 18 Dec., 1980, 45FR83952, 19 Dec., 1980, and 46FR1165.

15. Science Advisory Board, Subcommittee on Airborne Carcinogens, Transcript of Meeting September 4-5, 1980, Washington, DC.

16. American Industrial Health Council, Comments on this proposal, OAQPS 79-14-IV-D-66.

17. Batchelor, R., letter to W. Barber, EPA, June 6, 1980 on behalf of AIHC.

18. National Academy of Science, Subcommittee on Evaluation of the Carcinogenicity of Heptachlor and Chlordane, October 1977. See also: O'Connor, C. A., "The IRLG Approach to Carcinogenesis," Remarks to the Federal Bar Association, Second Annual Reform Conference, May 8, 1980, Washington, DC.

19. J.N.C.I., 58 461 (1977).

20. Siegelman, S. S., Am. J. Roentgenology, 1980 July.

21. Meeting of the SPI with EPA/TRW, 31 July 1980, Durham, NC.

22. 45 FR 39766, 11 June 1980.

23. Morton, W. E. "Epidemiology of Histological Types of Lung Cancer." Listing No. 269 in Current Cancer Research, National Cancer Institute, December 7, 1979, NTISUB/E/295-010. See also Archer, V. E., Listing No. 125, ibid.

24. Mushak, P., et al., "Health Assessment Document for Arsenic", External Review Draft, April 1980, EPA/ORD, Research Triangle Park.

25. "A Bill to Establish the National Science Council," Rep. Wampler HR 6521, 96th Congress, 2nd Session, "A Bill to Provide for a Federal Mechanism within the OSTP," Rep. Ritter, 96th Congress, 1st Session.

26. Chamber of Commerce, comments on this proposal, as quoted in Inside EPA, p. 9, September 19, 1980.

27. Markey, H., as quoted in Food Chemical News, p. 40, October 13, 1980.

28. Raiffa, N., as quoted in C&EN, p. 30, October 20, 1980.

29. Pesticide and Toxic Chemical News, p. 9, October 1, 1980.

30. Hollingsworth, J. G., Chemical Times/Trends, p. 63, July 1980.

31. National Toxicology Program "First Annual Report on Carcinogens," Washington, DC, July 1980, Vol. I, p. 2.

32. Cantlon, J. G., as quoted in EPA Journal, 6 (9) 27 (1980).

33. Doolittle, W. F., and C. Sapienza, Nature 284 601 (1980).

34. "How Selfish is DNA?", Nature 285 617-620 (1980).

35. Shimkin, M. B., "Industrial and Life-Style Carcinogens" 1980 International Symposium on Cancer, New York, September 14-18, 1980.

36. Wynder, E. L., Preventive Med., 9 163-332, 1980.

37. Higginson, J., "Epidemiology for Clues to Etiology" 1980 International Symposium on Cancer, New York, September 14-18, 1980.

38. Doll, Sir R., "The Interface Between Epidemiology and Cancer Control Policy," ibid.

39. Muir, C. S., Ann. NY A.S., 329 153 (1979).

40. Beaumont, J., "Power Considerations in Epidemiological Studies of Vinyl Chloride Workers," Hatch, M., "Power Considerations in Studies of Reproductive Effects Associated with Vinyl Chloride and Some Structural Analogies," at the Conference to Reevaluate the Toxicity of Vinyl Chloride, Polyvinyl Chloride and Structural Analogies, Bethesda, MD, March 20-21, 1980.

41. "Populations at Low Risk of Cancer," JNCI, 65 1050-1197 (1980).

42. SEER Program. DHEW Pub. No. (NIH) 78-1837.

A-79-13-A

Air Products

Air Products and Chemicals, Inc.
Box 538, Allentown, PA 18105
(215) 481-4911

22 January 1981

Central Docket Section
Gallery 3, West Tower, Waterside Mall
401 M Street, S.W.
Washington, DC 20460

Attention: OAQPS-79-13

Gentlemen:

Air Products and Chemicals, Inc. submits herewith additional comments on the ANPR for a generic work practice and operational standard for airborne carcinogens (44FR58662) pursuant to the closure notice for comments as given at 45FR84827.

Air Products has commented earlier (letter of 3 December 1979 to Docket A-79-13) on this ANPR. As we pointed out at that time, it is impossible to consider adequately an adjunct to a policy until that policy has been determined. We continue to hold that position. It is apparent that the Agency has not yet been able to show a need for a general airborne carcinogen policy (see our letter of even date to Docket OAQPS-79-14), and that the issue of an implementing regulation still is not ripe for decision.

Relatively little attention was given to this ANPR during the hearings and comments on the senior issue of the proposed policy. We continue to believe, for the reasons stated earlier, that the Agency should not act on this matter until the overall policy is finalized. The inability of the Agency to demonstrate a need for the carcinogen policy carries through to this issue also; if there is no need for a carcinogen policy, there is no need for implementing standards. Whatever may be the decision on the policy, the control methods must be determined on a case-by-case study, and generic standards are most appropriate.

Furthermore, the New Source Performance Standards now being developed for the synthetic organic chemicals manufacturing industry in the areas of fugative emissions, storage, transport and loading, etc. (SAN 1112, 1613, etc.) will cover the substances most likely to be regulated by this proposal, making it duplicative.

Therefore, we urge the Agency to withhold any actions on this ANPR until the Agency has been able to demonstrate a need for the overall policy for the control of potential airborne carcinogens.

Very truly yours,

AIR PRODUCTS AND CHEMICALS, INC.

John T. Barr
Regulatory Response

JTB:jas

921 N-3

bcc: A. E. Greene
R. H. Schenck

4-944-L-A

Air Products

Air Products and Chemicals, Inc.
Box 538, Allentown, PA 18105
(215) 481-4911

25 November 1980

Docket Office, H-009A
Room S6212
Department of Labor
200 Constitution Avenue, N.W.
Washington, DC 20210

Gentlemen:

Pursuant to the OSHA Carcinogen Policy (45 FR 5002), OSHA has published for comment (45 FR 53672, 67594) a list of candidate substances for possible future regulation. Air Products and Chemicals, Inc. submits herewith comments on this list.

We are gratified to see that OSHA has responded to the urging of many persons from industry and academia to organize its regulatory efforts and establish priorities for future activity. The lack of such an effort in the past has impeded seriously the effective control of workplace exposure. We are greatly disappointed, however, in the apparent lack of serious scientific scrutiny of the data base for the preparation of this list, and urge that the development of the forthcoming priority lists be the result of a more serious review of the facts.

I. It appears that OSHA has not truly applied even the requisite "brief scientific review" to a number of lists from other agencies which have been incorporated by reference into this list, including one by the EPA/CAG (reference f in the OSHA notice). Regarding this list, one of the principal authors has stated that CAG deliberately gives weight to any evidence or report of carcinogenicity without regard to the quality of the data:

> "This is in effect the general approach. I would emphasize one particular point, which I think certainly must have struck you in going through these documents, and that is the emphasis on the conservative approach to the evaluation of data. This has been a deliberate sort of thing. It's been adopted right from the start. What I mean is that the tendency is to give weight to evidence for carcinogenicity, that is, to lean over in the direction of giving weight to evidence for carcinogenicity, which, even when there are certain amounts of reservations in this regard." Roy Albert, statement at meeting of the Science Advisory Board, Subcommittee on Airborne Carcinogens, September 4, 1980, Transcript at pp. 23-24. (Emphasis added.)

Thus, OSHA has accepted an unbalanced appraisal of carcinogenicity in at least this instance. It is important to note that the members of the SAB subcommittee were extremely critical of the quality of the data presented on several of the substances of the EPA/OSHA list, and remanded them to CAG for revision before there would be further consideration.

II. This uncritical approach has lead to the inclusion on the list of many substances for which the data are poor or nonexistent. A few typical illustrations are given below.

A. Nickel and its compounds. This group of substances is included by OSHA on the candidate list. The data summary sheet specifically includes nickel metal among the suspect substances, based on alleged high incidence of nasal cancer among nickel ore miners and processors in which nickel metal is not a component. Gadbold, et al., (J.O.M. 21 (12) 799 [1979]) report no excess of mortality or cancer deaths among a group of 1,600 workers exposed to the metal and which were followed for up to 25 years. Selikcoff and coworkers (Science, 209 420 [1980]) suggest that the excess deaths among miners are due to the asbestos-bearing rock that accompanies the ore. It is clear that the positive animal results are obtained with only some crystalline, non-soluble types of compounds, and not soluble materials (Costa and Mollenhauer, Science 209 517 [1980], Costa and Mollenhauer, Cancer Research, 40 2688, [1980]). Nickel compounds are a normal component of the body and natural foodstuff. It is difficult to think of a substance less likely to be carcinogenic than metallic nickel, and a logical consequence of a conclusion that it is would be the banning of the ordinary five-cent piece. Careless listings such as this harm the credibility of the entire procedure.

Similar comments can be made regarding the inclusion of cadmium in "Cadmium and Its Compounds".

B. Formaldehyde

The data summary sheet states that a final decision must be deferred until completion of the "suggestive" study which prompted inclusion of this substance. Therefore, it seems that the proper step would have been to delay listing until a subsequent semiannual revision of the list, rather than placing it on the list now. Both bioassay and epidemiological studies are underway at this time, and any action on this substance should be deffered until these are completed.

C. Ethylene Oxide

The principal evidence for listing is a supposed exposure of mice to bedding thought to be contaminated with the substance, after which an excess of tumors were seen. This evidence falls far short of being adequate for regulatory action, particularly in light of the other cited negative data, and the substance ought not to have been listed on this basis.

D. Saccharin and Safrole

Regulation of these substances could place OSHA in the anomalous position of prohibiting an employee to come into occupational contact with a material that may well have been eaten, with full regulatory approval, during a lunch or coffee break. Again, all scientific credibility is lost when a policy requires even the consideration of such substances.

E. Diethylstilbestrol

This, and other substances on the list such as phenacetin, are regularly prescribed or used pharmaceuticals, and are so noted by OSHA. The situation is even more disturbing than that of the substances discussed under D above.

F. Methyl Iodide

This substance has as its last recorded production volume the total of 18,000 lb/yr. It, and many other similar low-volume products on the list, surely do not merit serious consideration as a significant hazard to the workplace.

Therefore, it appears that the "brief scientific review" afforded this listing has not been adequate to prepare a realistic list of potentially dangerous substances. Considerable doubt is thrown on the credibility data base for the remaining items on the list after consideration of these few examples.

III. We note the absence on this list of a number of substances such as ethanol, caffeine, tobacco and its combustion products, and many other naturally occurring materials, for which the evidence of carcinogenicity is much more substantial, and to which many more employees are exposed, than for the majority of the items on the list. We are concerned that the Agency has not surveyed adequately the possibilities for inclusion on the list, and that other materials potentially more serious carcinogens than those listed here, may have been omitted.

It would be of value to the public if the Agency would describe more fully than it has the procedures used by its contractors, and the qualifications of the persons engaged by them in the preparation of this list. At the present, the public has received little information on, and no input into, the development of this candidate list.

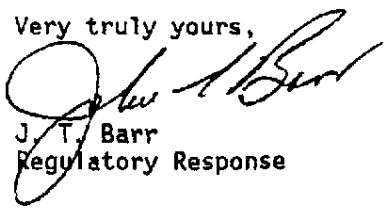
IV. Therefore, we would urge that the development of the priority lists involve a full scientific review of the data, rather than an uncritical acceptance of supposition and myth. OSHA has not published its criteria for placement on the priority lists, and we urge that it do this, either before or at the time of publication of that list. Simple reiteration of the broad principles of the Policy is not adequate for understanding of the procedures used in this step.

V. The Supreme Court has ruled (Ind. Union Dept. vs Am. Petrol. Inst., No. 78-911) that regulatory action requires a demonstration of harm under existing conditions as a threshold finding. Certainly we can expect that one of the necessary steps in placing a substance on the priority list will be a demonstration of need for that listing, based on occupational risk, and not simply a selection of likely prospects from a collection with such inadequate support as this list has.

VI. We urge the Agency to accept the recommendation of Air Products and many other commentors on the Policy to establish a credible and competent panel of independent scientists to review carefully and thoroughly the scientific basis on which substances are chosen for the Priority List, and possible subsequent regulation. The Agency is certain to receive, as the result of this request for comments, a substantial body of data of varying quality and relevance to its task. The problem of reviewing and evaluating this data will be great, and this will also be a suitable task for the Panel. Lacking this expert scientific support, the Agency undoubtedly will continue to face challenges of its decisions, and the regulatory process will be delayed.

We appreciate the opportunity to comment on this phase of the implementation of the Policy, and hope that you will feel free to call on us if any questions arise regarding these comments.

Very truly yours,



J. T. Barr
Regulatory Response

JTB/jas

bcc: A. E. Greene
R. H. Schenck
D. Kliever - Cleary, Gottlieb, Steen & Hamilton

Air Products and Chemicals, Inc.
Box 538, Allentown, PA 18105
(215) 398-4911

18 December 1978

Mr. Tom Hall
OSHA Office of Consumer Affairs
Room N-3635
U.S. Department of Labor
Third Street and Constitution Avenue
Washington, D.C. 20210

Re: Docket H-090

Dear Mr. Hall:

Pursuant to the order by Administrative Law Judge Green in the matter of Docket H-090 extending the comment period on specific items until 19 December 1978, we herewith submit our comments on the regulatory analyses of a Proposed Policy for the Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk, copy dated 10/17/78 and submitted into the record 24 October 1978.

It is our belief that this analysis is defective and not in compliance with the requirements for such an analysis nor with the agreement made by OSHA to prepare this particular analysis. Therefore, the analysis should be rejected, and the record declared incomplete in this matter. Facts substantiating this belief are contained in the attachment.

Sincerely yours,

J. T. Barr (ajw)
John T. Barr

JTB/sjw
Enclosure

bcc: R. Fleming

Summary

OSHA has failed to produce an acceptable Regulatory Analysis of its proposed regulations and should withdraw the existing analysis and prepare one which conforms to the applicable Executive Order and to OSHA's own regulations. The present document is no more than an attempted apology for the proposed regulation and involve apparent misconstruction of evidence produced at the hearing. The inability of OSHA to produce an adequate analysis emphasizes the inappropriate nature of the proposal.

I. The Present Document is Inadequate

A. It Fails in its Discussion of Alternatives.

Less than ten percent of the document is concerned with the discussion of alternatives, and those considered are those presented at the hearing, and are not, apparently, alternatives considered by OSHA during its preparation of the proposal. Thus, the public is deprived of any insight into the OSHA decision making process, and of any assistance which might derive from the knowledge that OSHA brings to this matter.

B. The Alternatives Discussed were Misrepresented.

The document grossly misrepresents the AIHC proposals as a) imposing an extra-agency regulatory body, when it in reality offers expert scientific advice to the agency and b) implies that AIHC has suggested regulation of only proven human carcinogens, when this is incorrect.

C. The Analysis Fails to Recognize the Major Reason for its Preparation.

1. The statement in the summary that only the differential costs between regulatory policies need be discussed illustrates the failure to comprehend that the principal objection to this type of proposal is that under it certain matters can never be debated, and this foreclosure is a loss of due process which must not be permitted.

Any mention of the October 5, 1978 decision on the benzene standard by the 5th Circuit is notably absent from the analysis. In this decision the court said in part: "

> We are not persuaded by OSHA's argument that this standard should be upheld since the lack of knowledge concerning the effects of exposure to benzene at low levesl makes an estimate of benefits expected from reducing the permissible exposure level impossible.* The statute requires all conditions imposed by a standard to be reasonably necessary to provide safe or healthful employment, and it requires decisions to be based on "the best available evidence," "research, demonstrations, experiments, and such other information as may be appropriate," "the latest scientific data in the field," and "experience gained under this and other health and safety laws." By

---

*Although OSHA asserts that risk quantification at low exposure levels and therefore estimates of expected benefits from the standard cannot presently be made. OSHA has provided us with a Preliminary Report on Population Risk to Ambient Benzene Exposures, recently released by the Environmental Protection Agency, which attempts to extrapolate from the results of the Infante study a determination of the risk of leukemia to the general population at the exposure level of 1 part per billion. In addition, the petitioners introduced at the rulemaking proceeding a preliminary risk assessment for occupational exposure to benzene at 10 ppm and 1 ppm based on the studies at higher exposure levels relied on by OSHA. Finally, OSHA's economic consultant testified that it could perform a cost-effectiveness analysis for the benzene standard; an analysis which would have included some kind of risk quantification. Although OSHA's assertion that present knowledge is insufficient to construct a valid dose-response curve for benzene may be correct, the record reflects that preliminary assessments are now being made and that valid extrapolations will be possible as more is known about the effects of past exposure at higher levels.

requiring the consideration of such kinds of information, Congress provided that OSHA regulate on the basis of knowledge rather than on the unknown. But see Society of Plastics Industry, Inc. vs. OSHA, 509 F.2d 1301, 1308 (2d Cir. 1975). Until OSHA can provide substantial evidence that the benefits to be achieved by reducing the permissible exposure limit from 10 ppm to 1 ppm bear a reasonable relationship to the costs imposed by the reduction, it cannot show that the standard is reasonably necessary to provide safe or healthful workplaces.

This does not mean that OSHA must wait until deaths occur as a result of exposure at levels below 10 ppm before it may validly promulgate a standard reducing the permissible exposure limit. See Florida Peach Growers Association, Inc. vs. United States Department of Labor, 489 F.2d 120, 132 (5th Cir. 1974). Nevertheless, OSHA must have some factual basis for an estimate of expected benefits before it can determine that a one-half billion dollar standard is reasonably necessary."

There could not be a clearer statement of the position taken by a great number of witnesses at the hearing: OSHA must provide now a reasonable analysis of the benefits to be attained from its proposal. Inability to do so merely emphasizes the inappropriate nature of the proposal.

2. On page 54 of the analysis the time-worn canard of the PVC industry "crying wolf" is resurrected. No one should know

better than OSHA the falseness of this gossip, for it was OSHA who altered the vinyl chloride limits from the proposed "non-detectable" to the actual 1 ppm PEL, thus making a reasonable degree of compliance possible. Adequate regulatory analysis would avoid such situations, and would prevent such misunderstandings on the part of the public by showing clearly the differences in various degrees of regulatory action.

D. The Analysis has Ignored Alternatives to Major Policy Issues

1. Such statements as "cancer has come to be recognized as a major occupational health hazard," "environmental exposures are prominent contribution to cancer conversation," "large number of carcinogenic substances," and "increasing rapidly" are present in the apology section of the analysis, and are without adequate support in the record. The analysis misquotes the HEW report on page 17 by stating that 20% of the cancer incidence "can be attributed" to occupational exposure, when this report estimates that in the future, as much as 20% may possibly be attributed to occupational exposure, of which 17% is postulated to be from asbestos, not a matter for consideration in this proposal. Thus, no alternative to a major policy position has been contemplated despite evidence supporting such alternative positions.

2. Similar fixed positions are taken in regard to various scientific matters, and the analysis contradicts itself in regard to the

reliance to be placed on animal testing in statements made on pages 43 and 36. In fact, the difficulties in scientific matters recited on pages 34-37 are excellent argument for the need for a scientific panel as proposed by AIHC. So long as OSHA persists in demanding that science be frozen as of today in order to lighten its administrative load, we can expect no agreement on the many details which flow out of such an arbitrary position.

II. This Analysis Should be Rejected and a More Appropriate Analysis Prepared

We agree with the Regulatory Analysis Review Group's comments on this analysis which said in part, "OSHA (should) complete a more comprehensive and analytical regulatory analysis and consider modifying its proposal".

Thus, we urge OSHA to withdraw this analysis and present another which truly offers a competent discussion of the options and incremental benefits of actual alternatives to this proposal.

Until such an analysis is made a part of the record, it is incomplete and not in compliance with Executive Order 12044, The 5th Circuit Decision in the case of benzene, nor the statutes establishing the agency.

Air Products

BOX 538
ALLENTOWN, PA 18105
PHONE: 215-398-8343

from the desk of

JOHN T. BARR

14 December 1979

R. Boone - Arcair
J. H. Body
D. Brown
A. J. Diglio
W. L. Ent
R. Fleming
P. Fong
G. G. Handley
D. C. Keehn
J. C. Novak
J. H. Robertson
R. H. Schenck
W. N. West

I have learned today that OSHA has established the following schedule for its carcinogen policy.

January 15 - 10:00 AM; written summaries and unsigned copies available at a public gathering.

- 11:00 AM; signed copy to be delivered to the Federal Register.

Seven to ten days before this - oral summary to be presented to a public gathering.

Later this month - press release on the above schedule.

JTB

AP00048596