Air Products

Date 8 January 1982

INTEROFFICE MEMORANDUM

Subject OSHA Cancer Policy

RECEIVED
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LAW DEPT.

To A. E. Greene — Corporate Safety and Environment
(Location, Organization, or Department)

From J. T. Barr — Regulatory Response
(Location, Organization, or Department)

cc: C. E. Blades, M. R. Chmura, W. L. Ent, H. H. Master, R. H. Schenck, L. B. Tepper, R. D. Wood

The long-awaited reopening of the OSHA cancer policy was published in the attached pages from the 5 January Federal Register. This stays the priority and Candidate list requirements, and reopens the scientific issues for discussion. Several "representative" issues are listed.

We will be active in this matter directly, and through CMA and AIHC. Comments and suggestions are solicited.

J. T. Barr

JTB/sjw

Attachment

(320)

AP00048547

the year of reclassification are treated as distributions to which section 301 applies. In addition, once a loan is reclassified under paragraph (c) of this section, its status as a contribution to capital can never change.

(e) *Illustrations.* The following examples illustrate the application of this section:

Example (1). Corporation M uses the calendar year as the taxable year. A is the sole shareholder of M. On March 1, 1986, A advances $73,000 to M, and M establishes an account payable to A in the amount of $73,000. The account payable is entered on the books of M but is not evidenced by an instrument. The account payable is not repaid within 120 days after the end of 1986. In addition, M has excessive debt within the meaning of § 1.385–6(g). Based on these facts, the account payable is classified as a contribution to capital.

Example (2). The facts are the same as in example (1), except that M does not have excessive debt. The account payable is classified as indebtedness. However, if M fails to pay (before April 1, 1987) interest at a reasonable rate on the account payable for the last 10 months of 1986, the account payable will be reclassified as a contribution to capital (effective retroactively to March 1, 1986).

Example (3). Corporation X, which has excessive debt, uses the calendar year as the taxable year. On January 1, 1985, X's sole shareholder advances $60,000 to X. The advance is entered on the books of X but is not evidenced by an instrument. X repays $40,000 of the advance on April 1, 1985 and the remaining $20,000 on October 1, 1986. The advance is not renewed or offset in any manner. Based on these facts, this section (other than paragraph (a)(2)(ii) thereof) does not apply to the $40,000 of the advance that was repaid on April 1, 1985. See paragraph (a)(2)(i) of this section. The remaining $20,000 is treated as a contribution to capital. Therefore, the $20,000 repaid on October 1, 1986 is treated as a distribution to which section 301 applies. Also, interest on the $40,000 repaid on on April 1 is imputed at the rate set forth in § 1.482–2(a)(2)(iii)(B)(*2*).

Example (4). B is the sole shareholder of corporation Y. On June 1, 1988, B makes a $40,000 noninterest-bearing unwritten advance to Y. The advance is repaid on November 30, 1988 and is not renewed or offset in any manner. Based on these facts, interest is imputed on the advance of the rate set forth in § 1.482–2(a)(2)(iii)(B)(*2*). Assume that the rate set forth in § 1.482–2(a)(2)(iii)(B)(*2*) is 12 percent per annum simple interest. Then $2,400 is imputed with respect to the period of the advance as interest income to B and as an interest expense of Y. However, apart from this imputation of interest, this section does not apply to the advance.

Example (5). Corporations S and T are wholly owned subsidiaries of corporation P. P, S, and T use the calendar year as their taxable year. On July 1, 1990, S makes a noninterest bearing advance of $50,000 to T. The advance is entered on the books of T but it is not evidenced by an instrument. The advance is not repaid within 120 days after the end of 1990. Based on these facts, S is treated as distributing $50,000 to P, and P is then treated as contributing this amount to the capital of T.

§ 1.385–6 Locked interests.

(a) *In general.* For purposes of the regulations under section 385, two or more distinct interests in a corporation are treated as separate even though title to one cannot be transferred without transferring title to the others. Thus, for example, if a corporation issues a bond with a nondetachable warrant, the bond and the warrant are treated as two separate interests in the corporation.

(b) *Illustrations.* The following examples illustrate the application of this section:

Example (1). On January 1, 1989, corporation X issues 20-year, $1,000 debentures with nondetachable warrants. Each warrant entitles the holder to buy 100 shares of common stock in X for $10 a share. Based on these facts, the debentures and the warrants are treated as separate interests.

Example (2). The facts are the same as in example (1), except that each debenture can be surrendered on the exercise of a warrant in lieu of cash. The result is the same as in example (1).

Example (3). On January 1, 1990, corporation Y issues a 25-year, $1,000 debenture to individual A for $1,000 in cash. Y has no other debentures outstanding. The debenture pays interest at a rate of $100 a year; $50 is payable in all events and the other $50 is noncumulative and payable only if earned. Individual A owns 90 percent of the stock in Y, and the fair market value of the debenture is $1,000. Based on these facts, the debenture is treated as stock under § 1.385.6(d) (relating to hybrid instruments held proportionately).

Example (4). The facts are the same as in example (3), except that Y issues a $600 debenture together with four shares of preferred stock to A. The debenture pays fixed interest of $50 a year and has a fair market value of $600. Each share of preferred stock has a liquidation value of $100 and pays a noncumulative dividend of $12.50 a year if earned. In addition, Y is required to redeem the preferred stock at $100 a share at the end of 25 years. Assume that § 1.385–6(g) (relating to excessive debt) does not apply to the debenture. Based on these facts, the debenture is treated as indebtedness under § 1.385–4(a). The result is the same even if A cannot transfer title to the debenture without also transferring title to the preferred stock.

PART 15A—TEMPORARY INCOME TAX REGULATIONS UNDER THE INSTALLMENT SALES REVISION ACT

Par. 4. Section 15A.453–1(c)(8) is revised to read as follows:

§ 15A.453–1 Installment method reporting for sales of real property and casual sales of personal property.

* * * * *

(c) * * *

(8) *Coordination with section 385.* For rules regarding coordination with section 385, see § 1.385–1(b)(4).

PART 1 [AMENDED]

§ 1.482–2 [Amended]

Par. 5. Paragraph (a)(4)(ii) of § 1.482–2 is amended by removing "§ 1.61–12(c)(2)" and inserting in lieu thereof "section 171."

Par. 6. Paragraph (a)(5) of § 1.482–2 is amended by adding, immediately after the first sentence in the flush material following (ii), "(See, however, § 1.385–6(f)(2), under which the safe haven rates of paragraph (a)(2)(iii) of this section may, under certain circumstances, be safe harbor rates under the regulations under section 385.)"

Par. 7. The example in § 1.482–2(a)(8) is amended:

1. By removing "(see § 1.385–3(a)(1))" from the fourth sentence and inserting in lieu thereof "(see § 1.385–6(c)(1))"; and

2. By inserting immediately after the second sentence, "Assume that S's debt-to-equity ratio, determined under § 1.385–6 (h) and (j), exceeds 3:1 on the last day of the taxable year of issue."

Roscoe L. Egger, Jr.,
Commissioner of Internal Revenue.

[FR Doc. 81–37400 Filed 12–30–81; 3:04 pm]
BILLING CODE 4830–01–M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1990

[Docket No. H090C]

Identification, Classification and Regulation of Potential Occupational Carcinogens

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Advance notice of proposed rulemaking and proposal for partial stay pending completion of rulemaking proceedings.

SUMMARY: The Occupational Safety and Health Administration is considering rulemaking proceedings, under Section 6 of the Occupational Safety and Health Act of 1970 and pursuant to 29 CFR 1990.106(b)(3), to reevaluate certain provisions of the generic standard, Identification, Classification and Regulation of Potential Occupational Carcinogens—the "Carcinogen Policy"—29 CFR Part 1990. This reevaluation is to determine the need for modification based on recent Supreme Court

decisions, public requests for review and the Agency's own experience. The Agency is considering possible changes to improve the cost-effectiveness of regulation under the Policy to coordinate the Policy with relevant portions of Executive Order 12291. The provisions for scientific review, for setting priorities and making the selection of substances public, and for limiting the use of certain kinds of scientific evidence are also being evaluated. Comments are invited on the scope of the reevaluation of the Carcinogen Policy.

OSHA also proposes to stay the requirements of the Policy relating to the establishment and pubication of the Candidate List and Priority Lists for the duration of the comment period on this advance notice and during any rulemaking proceedings which may follow. Other provisions of the Policy will continue in effect under the terms of this proposed stay.

DATES: Comments on suggested changes to the standard must be submitted by April 5, 1982. Comments concerning the issuance of a stay on the requirements to establish and publish the Candidate and Priority Lists must be submitted by February 19, 1982.

ADDRESSES: Comments, data and information should be submitted to the Docket Officer, Occupational Safety and Health Administration, Docket No. H090C, Room S6212, U.S. Department of Labor, 3rd St. and Constitution Avenue NW., Washington, D.C. 20210, where they will be available for inspection and copying.

FOR FURTHER INFORMATION CONTACT: James Foster, Occupational Safety and Health Administration, Room N3637, U.S. Department of Labor, 3rd St. and Constitution Avenue NW., Washington, D.C. 20210, telephone (202) 523-8148.

SUPPLEMENTARY INFORMATION:

Background

OSHA published the standard, Identification, Classification and Regulations of Potential Occupational Carcinogens—the "Carcinogen Policy"—as 29 CFR Part 1990 on January 22, 1980 (45 FR 5001 *et seq.*) The stated purposes of the Policy are to streamline the regulatory process and provide predictable an uniform criteria for identifying and regulating substances as occupational carcinogens.

The Policy includes criteria and scientific policies for identifying and classifying a substance as a potential occupational carcinogen. It includes a screening and priority setting process to be followed in determining whether a proposed standard on a potential carcinogen should be issued. Guidelines are included on the substantive provisions of a proposed standard and are generally non-binding except for provisions giving preference to engineering and work practice controls. Certain procedures are included for issuing advance notices of proposed rulemaking, and for considering new scientific information and for setting time periods for comments and actions. Provisions are also included for amending the Policy and for scientific review by government scientists outside OSHA. The Policy does not, by itself, regulate specific substances. For a detailed explanation of the Policy see 29 CFR Part 1990, 45 FR 5001, January 22, 1980, as amended by 46 FR 4889, January 19, 1981.

On August 12, 1980, OSHA published a Candidate List (45 FR 53872) as part of the priority setting process. OSHA listed the substances which were candidates for further scientific review after conducting a brief scientific review of "available positive data" (as defined in the Policy, 45 FR 5209 and § 1990.121).

Since its effective date of April 21, 1980, the Policy has been modified in light of the Supreme Court's decision in *Industrial Union Department, AFL–CIO* v. *American Petroleum Institute (IUD* v. *API)* 448 U.S. 607 (1980). Provisions of the Policy that were inconsistent with that decision regarding OSHA's benzene standard, were deleted (46 FR 4889, January 19, 1981). Among the deleted provisions was one that required worker's exposure to carcinogins automatically to be set at the lowest feasible levels. Another provision that was deleted automatically characterized all carcinogens as presenting a grave danger. Furthermore, the Agency published additional proposed amendments to the Policy on January 23, 1981, (46 FR 7402), which were later withdrawn (46 FR 19000, March 27, 1981).

The Carcinogen Policy remains the subject of several court challenges. These challenges have been consolidated in the United States Court of Appeals for the Fifth Circuit in *American Petroleum Institute et al.* v. *OSHA et al.*, Nos. 80–3016, et al. The litigation is still in a preliminary stage, and no decision on the legal merits of the Policy has issued, nor is expected in the near future.

Reasons for Considering a Proposed Rulemaking

OSHA is considering reevaluating the Carcinogen Policy for a number of reasons, including the following:

1. To assure consistency with Supreme Court decisions.
2. To consider more cost-effective means of achieving the regulation of occupational carcinogens.
3. To consider modifications based on OSHA's experience under the existing policy e.g., the priority system, and additional policy considerations.
4. To consider and respond to any advances or changes in the science of carcinogenesis, including quantitative risk assessment, occurring since the closing of the record in 1979.
5. To respond to the requirements of Executive Order 12291.

Summary of Issues for Which Submissions of Comments, Data and Information are Requested

This summary is representative only. OSHA invites the submission of comments and data on all aspects of the Policy.

1. How should OSHA consider the cost-effectiveness of provisions which are incorporated into a standard regulating carcinogens under the Policy?

The Policy preamble and standard do not explicitly address methods of obtaining required levels of employee protection at lower cost. Appropriate areas for consideration of cost-effective approaches may include methods of compliance with the exposure limits in a standard. One such approach might utilize a combined strategy of engineering controls, work practices, personal protective equipment and medical surveillance. Greater use of action levels, percentage exclusions (see the discussion at 45 FR 5242) and performance language in the model standard, if one is to be retained, also may increase cost-effectiveness. In addition, more performance oriented standards may encourage cooperative efforts between employees and employers, which should lead to better protection in a more cost-effective manner. OSHA solicits comments on the approaches suggested, and any other suggestions to incorporate considerations of cost-effectiveness into this Policy.

2. Is it proper or appropriate for OSHA to retain the requirement for setting a no-exposure level where a suitable substitute exists for a use or a process of a potential occupational carcinogen?

The Policy now requires OSHA to assess whether the significance of the carcinogenic risk warrants the imposition of a no-exposure level for uses or processes involving a carcinogen, where a suitable substitute exists. Industrial hygienists generally state that substitution is a preferred compliance strategy because it

:cludes the possibility of exposure :m mechanical breakdown or human :ror. Some commenters suggest that it .s difficult to evaluate the suitability of substitutes and that considerable disruption to industrial processes may occur when substitutes originally deemed to be suitable replacements are not actually adequate. It is also argued that this provision is unnecessary, since market pressure would generally force substitution when it is feasible. OSHA invites additional comments on these issues.

3. Should OSHA amend the provisions for the review and utilization of negative (non-positive) animal and human data?

Under the current policy, negative (non-positive) data are given less evidentiary value than positive data in making Agency decisions on identifying, classifying and regulating substances as potential occupational carcinogens. The basis for this preference is the scientific generalization that positive studies are mot persuasive than negative studies. Moreover, it is alleged that negative studies typically have a low degree of sensitivity for detecting an increased risk of cancer.

The Policy provides that only positive data will be used in the initial screening of the large number of chemicals in order to determine which will be placed on the Candidate List for further scientific review. The preamble states that for purposes of creating Priority Lists the Secretary is "to thoroughly review all of the relevant and meaningful scientific and technological evidence" (45 FR 5210).

The Policy also provides that (except for significant risk determinations) negative studies in humans must meet stringent criteria before consideration. Negative animal studies are to be evaluated in relationship to positive studies in the same species, but uot in relationship to positive studies in different species.

Comments are requested on the appropriate procedures for evaluating the relationship between positive and negative data. Should these procedures, which currently give positive and negative data different weights at different stages in the regulatory process, be modified? If so, what scientific criteria are appropriate for evaluating negative studies and for determining their relative weight in the decision-making process?

4. Should OSHA alter or continue its process for reviewing data on the substantial number of substances for which there is some evidence of carcinogenicity, and for setting priorities?

The Policy establishes a three stage review process for screening the substantial number of substances for which there is some evidence of carcinogenicity. The first stage, limited to a brief review of certain available data, culminates in the preparation and publication of a Candidate List. OSHA completed that stage and published the first Candidate List of approximately 200 substances in August, 1980. Public comment was requested and reviewed.

At the second stage, OSHA performs a more searching scientific review, and applies priority factors set out in § 1990.132, which include the estimated number of employees exposed, their levels of exposure, and the levels reported to cause an increased incidence of neoplasms. The second stage culminates in the selection of ten Category I and ten Category II substances for inclusion on two Priority Lists. OSHA has not yet prepared these lists for public comment.

At the third stage, the Assistant Secretary for Occupational Safety and Health selects high priority substances for rulemaking, as appropriate, based on the application of the priority factors, scientific judgment, policy considerations and public comment received after publication of the Priority Lists.

Suggestions have been received which argue that the review process should be divided into separate scientific and regulatory stages, and that an outside panel should perform the scientific evaluation. In addition, required publication of the Candidate List, and especially the Priority Lists, has been seriously questioned. The basis of the concern is that the Lists are preliminary since they are published before OSHA fully evaluates all available evidence. A serious concern is that the public will perceive the Lists as the Government's conclusions that substances are carcinogens, possibly leading to undue and unwarranted concern or "cancer scares."

Comments are also requested on the screening and priority setting process, established in the current Policy. What have been the effects of the publication of the Candidate List in August 1980? Suggestions are requested on methods of involving the public in the screening and review process prior to rulemaking, without publication of the lists (or results) at varying stages of the process.

5. How should OSHA incorporate the provisions of Executive Order 12291, including cost/benefit analysis, in its priority setting process?

The Supreme Court, in *American Textile Manufacturers Institute (ATMI)* v. *Donovan*, 101 S. Ct. 2478 (1981) permits OSHA to utilize cost/benefit analysis in setting priorities. Executive Order 12291 (46 FR 13193, February 19, 1981) sets an analytic framework for performing cost/benefit analysis and evaluating regulatory alternatives. Some of the factors listed in the Policy for setting priorities would be relevant to performing cost/benefit analysis. They include whether controlling a carcinogen would reduce other occupational and environmental risks and the costs. Comments are requested on the appropriate framework for incorporating a cost/benefit approach in the prioritization process. Comments are also requested on incorporating the analytic framework of Executive Order 12291 in the priorities setting process of the Policy consistent with *ATMI* v. *Donovan*.

6. Should the Policy specify methods or techniques of quantitative risk assessment and significant risk determinations?

The Policy preamble has an extensive discussion of risk assessment techniques and uncertainties (45 FR 5178–5201). As amended in light of *IUD* v. *API*, the Policy permits OSHA to consider all relevant evidence in making risk assessments §1990.111(j) as amended at 46 FR 4889) for purposes of priority setting and to assess the significance of the risk in rulemaking. However no specific methods of performing risk assessments or significant risk determinations are contained in the language of the Policy.

Comments are requested on techniques of quantitative risk assessment, and their reliability. In addition, comments are requested on methods of assessing the significance of the risk, and the value of incorporating guidelines on these matters into the Policy.

Other Matters

In addition to specific responses to the questions posed in this notice and to other relevant issues, and in accordance with the provisions of the Regulatory Flexibility Act (Pub. L. 96–354, 95 Stat. 1164, 5 U.S.C. 601 *et seq.*) and Executive Order No. 12291, OSHA also requests information regarding the economic impact which any changes might have on affected industries and, in particular, small businesses.

The preamble to the final Carcinogen Policy concluded that economic analysis would be performed at the later stage of regulating specific carcinogens. This conclusion was based on the availability of data at that time and on the argument that no direct cost burdens are imposed by the Policy.

Representatives of industry argued that economic analysis should be performed at the earlier policy stage to indicate possible overall economic effects, and that this would show that a cost-benefit approach to regulation should be adopted.

Subsequently, in two major decisions, the Supreme Court substantially changed the legal context of this debate. In *IUD* v. *API, supra*, the Court held that the Agency had to demonstrate significant risk before regulating hazards. Consequently, OSHA eliminated provisions of the Policy which would automatically require the Agency to reduce workers' exposure to the lowest feasible level without consideration of the significance of the risk. In *ATMI* v. *Donovan, supra*, the Court held that the OSH Act requires that exposure levels be reduced to levels limited by the significance of the risk and by feasibility but not by cost-benefit considerations.

Within this changed context, and the applicable Administration policies stated in Executive Order 12291, OSHA requests comment on what is the appropriate kind of economic analysis for an amended Policy? If the Policy should concentrate on scientific issues and leave specific regulatory policy issues to individual rulemakings, would the same comments apply? Should modifications to the Policy be made to facilitate economic analysis at all stages and, if so, what changes are recommended?

OSHA concluded that environmental issues are to be considered in the context of regulation of specific carcinogens. The Agency prepared an environmental impact statement, however, which generally and qualitatively assessed the impact of specific policies on the internal and external environment (see discussion at 45 FR 5254, January 22, 1980). OSHA requests the public to submit comments and data concerning the environmental impact of any suggested changes to the Policy.

Proposed Partial Stay Pending Reevaluation and Rulemaking

Pending the reconsideration of the entire Policy, including any related rulemaking, OSHA hereby proposes to stay the provisions of the Policy requiring OSHA to establish and publish in the Federal Register the Candidate List and the Priority Lists. These provisions of the Carcinogen Policy are found in 29 CFR 1990.121, 122, 131 and 133. OSHA believes that these provisions should be stayed so that the Agency can fully evaluate the actual impact of the published Candidate List, the possible impact of publishing the Priority Lists (before any further publication occurs), and the underlying criteria for inclusion of substances of these Lists.

At this time OSHA believes that a stay should be limited to the provisions concerning the Candidate and Priority Lists, and that all other provisions of the Cancer Policy should continue in effect during this period of reconsideration.

OSHA invites the public to comment on this proposal to issue a partial stay. OSHA will carefully evaluate all comments, which are submitted on time, before it determines whether such a stay should be issued.

Comments on the proposed partial stay must be submitted by February 19, 1982. Comments on possible changes to the Policy must be submitted by April 5, 1982. All comments should be sent to the Docket Officer, Occupational Safety and Health Administration, Docket H090C, Rm. S6212, U.S. Department of Labor, 3rd St. and Constitution Ave. NW., Washington, D.C. 20210.

Authority

This document was prepared under the direction of Thorne G. Auchter, Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue NW., Washington, D.C. 20210. It is issued pursuant to Sections 6(b), 6(c) and 8(g) of the Occupational Safety and Health Act (84 Stat. 1593; 29 U.S.C. 655), 29 CFR 1990.106(b)(3), and the Administrative Procedure Act.

Signed at Washington, D.C., this 29th day of December 1981.

Thorne G. Auchter,

Assistant Secretary of Labor.

[FR Doc. 81-37473 Filed 12-31-81; 8:45 am]

BILLING CODE 4510-26-M

DEPARTMENT OF DEFENSE

Department of the Army

32 CFR Part 585

Army General Counsel's Honors Program; Policy and Procedures

AGENCY: Department of the Army, DOD.

ACTION: Proposed rule.

SUMMARY: This regulation would establish policy and procedures governing the Army General Counsel's Honors Program. This program selects highly qualified attorneys to file vacancies that occur periodically in the Army General Counsel's Office. This regulation describes the program requirements and application procedures.

DATE: Written comments submitted on or before February 4, 1982, will be considered.

ADDRESSES: Written comments should be addressed to Office of the General Counsel, Department of the Army, Washington, D.C. 20310.

FOR FURTHER INFORMATION CONTACT: LTC Thomas W. Taylor, (202) 695-0562.

(10 U.S.C. 3012, 3065)

December 23, 1981.

John O. Roach, II,

The Department of the Army Liaison Officer with the Federal Register.

Part 585 is proposed to be added as follows:

PART 585—THE ARMY GENERAL COUNSEL'S HONORS PROGRAM

Sec.

Authority: 10 U.S.C. 3012, 3065

§ 585.1 Purpose.

This regulation prescribes policy, acceptance criteria, and procedures for applicants applying for the Army General Counsel's Honors Program.

§ 585.2 Applicability.

(a) This regulation applies to all qualified individuals, with or without military status, who may be considered for active duty as commissioned officers under Army General Counsel's Honors Program.

(b) This regulation applies to the Active Army, the Army National Guard, and the US Army Reserve.

§ 585.3 Related references.

Related publications are listed below. (A related publication is merely a source of additional information. The user does not have to read it to understand this regulation.)

(a) AR 40-501 (Standards of Medical Fitness).

(b) AR 135-100 (Appointment of Commissioned and Warrant Officers of the Army).

(c) AR 381-20 (US Army Counterintelligence (CI) Activities).

§ 585.4 Responsibility.

The Office of the General Counsel will consider all qualified applicants for the Army General Counsel's Honors

4-958-2-1

Air Products

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

17 March 1981

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Docket Officer, Docket H-090A
Occupational Safety and Health Administration
Room S-6212, U.S. Department of Labor
3rd and Constitution Avenue, N.W.
Washington, D.C. 20210

Gentlemen:

Air Products and Chemicals submits herewith its comments on the proposed amendments to the Carcinogen Policy, as noticed at 46FR7402, 23 January 1981.

We believe that this policy, even after the proposed amendment, fails to conform to the Supreme Court decision, and should be withdrawn or suspended for reconsideration. Our reasons for this belief are described in the attached comments.

Please feel free to contact us directly if you have any questions regarding this submittal.

Very truly yours,

John T. Barr
Manager, Regulatory Response

JTB/sjw

Attachment

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

Comments on the Proposed Amendments to
Identification, Classification and Regulation
of Potential Occupational Carcinogens
46FR7402
23 January 1981
Docket No. H-090A

Air Products and Chemicals, Inc. herewith submits its comments on the proposed amendments to the OSHA "Cancer Policy" of 45FR5002 and 43403 (29CFR1990.101 et seq.) as noticed at 46FR7402, 23 January 1981. We believe that it is appropriate and proper for OSHA to make an "affirmative" effort to bring the Cancer Policy into compliance with the Supreme Court decision on benzene (IUD v. API), and we welcome the intent of this proposal. However, we do not believe that these proposals are adequate to accomplish that purpose, nor do we believe that the Policy "is now fully consistent with the law" (p. 7403, col. 2). Neither do we believe that the deletions of January 19 (46FR4889), even with the current proposals, are adequate to remove the deficiencies of the Policy which required the filing of the petition for review (API et al., v. OSHA, Fifth Circuit, 80-3018 et al., AIHC v. Marshall, Fifth Circuit, 80-1880, and others). Therefore, we believe that the entire policy should be withdrawn for serious reconsideration of all of its features. Nevertheless, we will present specific comments on this proposal as a matter for the record.

I. Adequate Definitions are Lacking

The central theme of this proposal is that of significant risk, yet no definition is offered, nor is there any discussion of how the presence or absence of significant risk is to be determined. This is left for case-by-case consideration (p. 7403, col. 3.) Therefore it is impossible to evaluate the meaning of the key issue for rulemaking, the "lowest feasible level which is reasonably necessary or appropriate to eliminate significant risk." (Proposed 1910.111(h) et seq.)

A correct grammatical interpretation of that phrase would indicate that the intent is to reduce the risk until it is insignificant, although that is nowhere stated clearly. Even if that interpretation is proven to be correct, we are left with an undefined division between significant and insignificant, an area where OSHA states that it has little experience (p. 7403, col. 3.) This makes it all the more important that some indication of the meaning of this term, or at least the method which will be used to arrive at the meaning, be presented to the public for evaluation. Otherwise, there is little in this proposal which will have meaning for the public, or those to be regulated.

We would urge OSHA to consider the comparative risks of voluntary and involuntary lifestyles, the precision and accuracy of the methodologies which it is considering using, and the statutory mandate of "material impairment" to arrive at a general definition of this term "significant." Without that, informed comment cannot be prepared by the public. Both the plurality and concurring opinions of the Court supported the position of excluding de minimus risk. The Agency must devise and propose some rational process for recognizing that level of risk.

In addition, OSHA should clarify the intent of the term "eliminate." The same problems exist with the use of the term "reduce" in proposed Sec. 111(k), as applied to the requirement for substitutes - some quantitative evaluation of the amount of reduction is necessary for an understanding of this proposal.

II. Failure to Consider all Available Evidence is Capricious and Arbitrary.

The explanation in the preamble of the intent of proposed 1990.132 states that "(t)he Secretary is not required to take into account every factor or weigh them in particular ways in setting priorities..." (p. 7404, col. 2.) Not only is this an arbitrary and capricious act which will result in misordering of priorities and thus placing an undue burden on some substances, but we are concerned that it reflects the policy of the Secretary in other matters as well. This is justified by the use of the same wording in Sec. 146(i) which deals with the determination of significance of risk. All available data must at least be considered in every regulatory action. To do otherwise violates due process, and the Administrative Procedures Act, and results in a "taking" of the property of those who have an interest in the regulatory process.

The present position of the policy is a continuation of a refusal to separate properly the scientific and regulatory functions. The insistance on "prudent and conservative" methods of scientific evaluation is another way of asserting a biased outlook. There is a place for prudence and conservatism, and that is in the regulatory arena. The regulator is expected to be a prudent and conservative, and it should not be necessary to so state. However, his decisions should be supported by the best scientific evaluations possible, and to interject political philosophy into the scientific area is indefensible.

Persistence in the use of "prudence and conservatism" results in the regulator not having at his disposal adequate facts for proper decision-making. This has occured in the Environmental Protection Agency, when it attempted to measure the health risk of several wood preservatives, and was forced to state that "The Agency believes that the model tends to overstate the actual risk in this case because of adjustments and assumptions made to handle uncertainty in a conservative manner." Each time that risk was discussed, that Agency had to add a statement that the estimate was "subject to the caveats stated earlier regarding the high estimated levels of quantitative risk," 46FR13023-4. Therefore, the Secretary will not be able to demonstrate a proper or adequate consideration of the elimination of significant risk if he must acknowledge that the model used was faulty.

Proposed Sec. 1990.132(b)(4) must be amended by insertion of the word "all" before "other" in that paragraph.

Similarly, proposed Sec. 1990.146(i) must be amended in the same manner.

III. Criteria for use of Data are Inappropriate.

Proposed Sec. 1990.143 contains a provision that data which do not meet the criteria of 1990.144 or 145 for the classification of a substance

may be used in the risk assessment of that substance. We believe, as stated in Part II above, that all available data must be considered in all regulatory decision-making. This belief is emphasized by this proposed contradictory position that data suitable for measuring the quantitative nature of the risk posed by a substance are not satisfactory for a qualitative assessment of its hazard. It is illogical positions such as this that has required the petition for review of the entire Policy in which we have joined.

We believe that the position taken by the Agency on the criteria for data to be considered in the classification is unscientific and arbitrary. In view of the refusal of the Agency to reconsider those criteria at this time (p. 7403, col. 3), and because of the unreasonably rigid requirements for a petition to amend the Policy (Sec. 1990.106 and 145) we had no alternative but to seek judicial relief, as we have done. This action only confirms our position that the Secretary has acted arbitrarily.

We believe that the proper remedy for this action is to apply a uniform and fair criteria to all decisions under this policy which assures that all relevant and valid data are considered in all portions of the rule-making. In this manner, this proposed amendment to 1990.143 and 144 would be unnecessary. It is totally illogical that data useful in measuring the extent of a risk should not also be held useful in determining if that risk exists, and the benzene decision clearly states that the same standards apply to identification and classification as to regulation.

IV. Substitutes are not Given Comparable Risk Abatement Treatment.

As stated above in Part I, proper definitions are lacking to permit definitive interpratation of this proposal, but application of ordinary rules of grammar indicates that the proposed abatement of risks for which there may be substitutes is not given equal treatment with those for which there may not be substitutes.

Each place in the proposal where there is discussion of possible use of substitutes, the action to be taken is described as "to reduce" or "lower" the risk. See, e.g., 1990.132(b)(7), .142(a)(2)(iii), .146(1), and .151(e). Elsewhere, the action prescribed is to "eliminate" significant risk. The Court did not differentiate between risks for which there may or may not be substitutes. Therefore, the requirement of the Court that the significance of the risk be considered applies here as well. The primary matter for consideration is whether the use of substitutes will eliminate significant risk, that is, make it insignificant, and not whether it reduces or lowers it. It is the degree of lowering, not the direction of change, that is important.

Therefore, each place where the verbs "reduce" or "lower" are used to describe the abatement of risk to be achieved by the imposition of substitutes, those verbs should be replaced by "eliminate," in order to bring this proposal into compliance with the decision of the Court. A mere lowering of the risk is not adequate justification for the requirement of the use of substitutes, for unless the risk is eliminated it simply results in the substitution of one risk for another.

V. These Amendments Alone are not Adequate to Conform the Policy to the Court Decision.

As stated earlier, we do not believe that the Policy "is now fully consistent with the law." Many other changes are required to achieve this consistency. Some of them are discussed below.

A. The keystone upon which OSHA built its rationale for the now overturned benzene standard was a report by a NIOSH employee. It is now recognized that many of the statements in that report, and many of the conclusions which OSHA made based upon it, are erroneous (Plurality slip opinion p.11 and footnote 16, IUD v. API). These proposed amendments contain no provision which will prevent another standard based on invalid "data" or assumptions. In order for it to carry out successfully the explicit mandate and the spirit of the Court decision on benzene, it is incumbent on OSHA to assure adequate review of the validity of not only its own scientific evaluations of evidence, but that of the data on which these conclusions are based. We and others have urged OSHA during the hearing on the policy to draw upon the scientific community for review of these specific scientific issues. The Agency responded with an optional panel of government employees (1990.104), thus failing to obtain either the expertise or the dispassionate viewpoint which is available to it in the broader scientific community. Therefore, unless the Agency takes some steps to obtain competent scientific review of all the data relevant to a rulemaking, it runs the risk of again violating the Court mandate to make a supportable finding that the standard is reasonably necessary.

B. There are numerous references in the Court decision concerning the vague, and possibly unconstitutional, nature of the Act, and especially Sec. 6(b)(5). See generally the Plurality Slip Opinion at pps. 34-35 and footnote 51, and J. Rehnquists concurring opinion at pps. 4-5 and p. 17. This is not the responsibility of the Agency, except in that it has taken no action to seek a Congressional remedy of the problem. But, if the Agency wishes to utilize the authority of this section of the Act, it is incumbent upon it to avoid further judicial displeasure, in view of this warning of the defect. This could best be accomplished by a clear and definitive statement of its intended interpretation of this clause, in light of the Court statements. This would include not only precise definitions of the key terms in this proposal which were described in Part I above, but also of those most frequently invoked by the Agency (see p. 7404, col. 1, for example) such as "material impairment," "reasonably necessary" and "safe" or "healthful." A careful exposition of intent, with opportunity for public comment, will give the Agency a reasonable basis on which to place decision making.

VI. Conclusions.

We believe that the proper action for the Agency at this time is to withdraw or suspend this policy for complete reconsideration. Failing that, we have recommended several changes in the instant proposal;

1. Provide for public comment proper definitions of several key words and phrases.

2. Ensure that all available valid evidence is considered in all decisions.

3. Establish proper criteria for the validity of the evidence.

4. Give equal treatment to the consideration of the extent of abatement to be obtained through the use of substitutes by other means.

5. Make a distinct separation between the scientific and regulatory decision functions.

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