Bert Dinman - 7

MCA

MANUFACTURING CHEMISTS ASSOCIATION

1825 CONNECTICUT AVENUE, N. W. WASHINGTON, D. C. 20009 (202) 483-6126

WILLIAM J. DRIVER
PRESIDENT

file
For presentation
OSHA carcinogen
Testimony

3/18

March 9, 1978

To The Executive Contacts of MCA Member Firms

Dear Sirs:

Subject: MCA Testimony on Occupational Safety and Health Administration Cancer Policy

The enclosed MCA statement on OSHA's proposed generic regulation of carcinogens was delivered to OSHA on February 28. It stresses the need for risk/benefit analysis and supports many of the views and recommendations of the American Industrial Health Council. Public hearings have been scheduled by OSHA to begin May 16. Presentation of the MCA position at the hearings will be made by Dr. M. N. Johnson of BFGoodrich Company.

Sincerely,

W. J. Driver

Enclosure

PLAINTIFF'S
EXHIBIT
AL-1018

ALCOA0003956

WILMER, CUTLER & PICKERING
1666 K STREET, N.W.
WASHINGTON, D.C. 20006

CABLE ADDRESS: WICRING WASH., D.C.
INTERNATIONAL TELEX: 440-239
TELEX: 89-2402
TELEPHONE 202 872-6000

EUROPEAN OFFICE
5 CHEAPSIDE
LONDON, EC2V 6AA, ENGLAND
TELEPHONE 01-236-2401
TELEX: 851 883242
CABLE ADDRESS: WICRING LONDON

LLOYD N. CUTLER
JOHN H. PICKERING
HUGH R. H. SMITH
J. ROGER WOLLENBERG
CHARLES C. GLOVER, III
MARSHALL HORNBLOWER
HENRY T. RATHBUN
REUBEN CLARK
SAMUEL J. LANAHAN
A. A. SOMMER, JR.
WILLIAM R. PERLIN
SAMUEL A. STERN
ARNOLD M. LERMAN
ROBERT P. STRANAHAN, JR.
MAX O. TRUITT, JR.
JOEL ROSENBLOOM
HOWARD P. WILLENS
ANDREW T. A. MACDONALD
ROBERT A. HAMMOND, III
DANIEL A. MAYERS
TIMOTHY B. DYK
DAVID R. ANDERSON
J. RODERICA HELLER, III
ARTHUR F. MATHEWS

JAMES S. CAMPBELL
DENNIS M. FLANNERY
JAMES ROBERTSON
RAYMOND C. CLEVENGER, III
LOUIS R. COHEN
MICHAEL R. KLEIN
STEPHEN A. WEISWASSER
TIMOTHY N. BLACK
SALLY KATZEN
F. DAVID LAKE, JR.
PAUL J. MODE, JR.
STEPHEN F. BLACK
C. BOYDEN GRAY
RONALD J. GREENE
JAY F. LAPIN
GARY D. WILSON
C. LORING JETTON, JR.
WILLIAM T. LAKE
MICHAEL L. BURACK
MICHAEL S. HELFER
NEIL J. KING
ROBERT B. McCAW
A. DOUGLAS MELAMED

EZEKIEL G. STODDARD
ARTHUR Z. GARDINER, JR.
COUNSEL

BARBARA E. BERGMAN
STEWART A. BLOCK
LACALAND H. BLOOM, JR.
ALAN N. BRAVERMAN
LYNN BREGMAN
DANIEL L. BRENNER
RICHARD G. BURT
RICHARD W. CASS
JOHN F. COONEY
MICHELE B. CORASH
MARY CAROLYN COX
PATRICIA D. DOUGLASS
STEPHEN P. DOYLE
JAMES R. FARRAND
NANCY C. GARRISON
MARK L. GERCHICK
NEAL M. GOLDBERG
CORNELIUS J. GOLDEN, JR.
EDWARD T. HAND
ALLEN H. HARRISON, JR.
JOHN M. HARWOOD II
A. STEPHEN HUT, JR.
DAVID R. JOHNSON
JAMES T. KILBRETH, III
PAUL S. KOFFSKY
WILLIAM J. KOLASET, JR.
CANDACE S. KOVACIC

VICKI E. LAND
DONALD C. LANGEVOORT
GERALD J. LAPORTE
CHRISTOPHER R. LIPSETT
RICHARD A. LOWE
ROBERT A. MAJOR, JR.
BRUCE MAXIMOV
MARY A. McREYNOLDS
LOWELL B. MILLER
WILLIAM J. PERLSTEIN
PHILLIP L. RADOFF
WILLIAM R. RICHARDSON, JR.
RENÉ TOWNSEND ROBINSON
JOHN ROUMBAVILLE, JR.
MICHAEL S. SCHOOLER
GAIL P. SCHULZ
KAREN ROSER SCHWARTZ
ARTHUR B. SPITZER
ALAN B. STERNSTEIN
ARTHUR M. WEISBURD
CAROL DRESCHER WEISMAN
ALAN S. WEITZ
ALEXANDER F. WILES
ANN O. WILLIAMS
ROBERT G. WILSON
ROGER M. WITTEN

February 28, 1978

OSHA Office of Consumer Affairs
Room N-3633
U.S. Department of Labor
Third Street and Constitution Ave., N.W.
Washington, D.C. 20210

Re: Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk, OSHA Docket No. H-090

Gentlemen:

Enclosed herewith are eight copies of the Notice of the Manufacturing Chemists Association's Intention To Appear, and Comments of Manufacturing Chemists Association on OSHA's Proposed Generic Carcinogen Regulation.

Sincerely yours,

Andrew T.A. Macdonald

Andrew T.A. Macdonald

Enclosures

BEFORE THE
UNITED STATES DEPARTMENT OF LABOR
ASSISTANT SECRETARY OF LABOR FOR
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

In Re Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk	OSHA Docket No. H-090

NOTICE OF
MANUFACTURING CHEMISTS ASSOCIATION
OF INTENTION TO APPEAR

The Manufacturing Chemists Association (MCA) hereby gives notice of its intention to appear at the hearing in the above matter and respectfully states:

1. Appearances - Attorneys

John H. Pickering (202) 872-6200
Andrew T.A. Macdonald (202) 872-6306
Wilmer, Cutler & Pickering
1666 K Street, N.W.
Washington, D.C. 20006

Edmund B. Frost (202) 483-6126
General Counsel
Manufacturing Chemists Association
1825 Connecticut Avenue, N.W.
Washington, D.C. 20009

Appearances - Witnesses

M. N. Johnson, M.D. (216) 379-3298
B. F. Goodrich Company
500 S. Main Street
Akron, Ohio 44318

D. E. Ellison (804) 484-5000
Virginia Chemicals, Inc.
3340 West Norfolk Road
Portsmouth, Virginia 23703

Thomas J. McDonagh, M.D. (212) 398-3000
Exxon Chemical Company
1251 Avenue of the Americas
New York, New York 10020

J. M. Pardee (716) 724-4761
Eastman Kodak Company
343 State Street
Rochester, New York 14650

P. W. Simmons (517) 636-3353
Dow Chemical U.S.A.
2030 Abbott Road
Midland, Michigan 48640

2. Approximate Time Required for Presentation

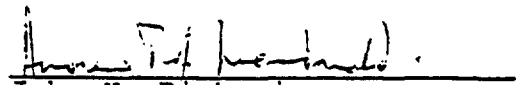
MCA anticipates that one hour will be required to present its materials. The above-named witnesses will appear as a panel under the chairmanship of Dr. Johnson.

3. Issues To Be Raised, Statement of Position and Documentary Evidence

There is being filed concurrently herewith a document entitled "Comments of Manufacturing Chemists Association on OSHA's Proposed Generic Carcinogen Regulation."

That document addresses the issues to be raised, the position of MCA and refers to documentary evidence.

Respectfully submitted,



John H. Pickering
Andrew T.A. Macdonald

Wilmer, Cutler & Pickering
1666 K Street, N.W.
Washington, D.C. 20006

Attorneys for Manufacturing
Chemists Association

February 28, 1978

BEFORE THE
UNITED STATES DEPARTMENT OF LABOR
ASSISTANT SECRETARY OF LABOR FOR
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

In Re Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk	OSHA Docket No. H-090

COMMENTS OF MANUFACTURING CHEMISTS ASSOCIATION ON OSHA'S PROPOSED GENERIC CARCINOGEN REGULATION

Communications with respect to this document should be sent to:

John H. Pickering
Andrew T.A. Macdonald
Wilmer, Cutler & Pickering
1666 K Street, N.W.
Washington, D.C. 20006
(202) 872-6000

and to

Edmund B. Frost
General Counsel
Manufacturing Chemists Association
1825 Connecticut Avenue, N.W.
Washington, D.C. 20009
(202) 483-6126

February 28, 1978

TABLE OF CONTENTS

TABLE OF CONTENTS
(continued)

BEFORE THE
UNITED STATES DEPARTMENT OF LABOR
ASSISTANT SECRETARY OF LABOR FOR
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

In Re Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk	OSHA Docket No. H-090

COMMENTS OF
MANUFACTURING CHEMISTS ASSOCIATION ON
OSHA'S PROPOSED GENERIC CARCINOGEN REGULATION

I. INTRODUCTION

The Manufacturing Chemists Association (MCA) is a non-profit trade association having 196 United States company members who account for more than 90% of the production capacity of basic industrial chemicals within this country. Many of these chemicals may fall within the scope of the regulation proposed by OSHA for the identification and regulation of potential carcinogens in the workplace. MCA, on behalf of its member companies, accordingly has a significant and substantial interest in the outcome of these proceedings.

MCA and its member companies recognize that the existence of potential carcinogens in the workplace is a matter of justifiable concern to OSHA, employees and employers

alike. But the fact that carcinogens are involved does not require that action be taken in a hasty manner. The use of industrial chemicals ranks low as a cause of cancer in human beings -- on the order of one to five percent.[1/] Of far greater significance in the national incidence of cancer are causes which lie generally (but not exclusively) outside the workplace, such as cigarette smoking and dietary intake. Nevertheless, MCA believes that all concerned have the obligation to examine carefully the question of carcinogenic substances in the workplace and, where a chemical has been objectively and scientifically established as a carcinogen, to reduce the exposure of workers to a level where the risk of cancer is acceptable to society.

The chemical industry takes its obligation seriously. For some years, member companies of MCA have funded research projects into the toxicology of specific chemicals. About five years ago, MCA began a project of administering special projects on individual chemicals in order to provide interested manufacturers and users an opportunity to support collective research testing. There are currently 16 projects under way with research being conducted at the laboratories of a member company or at the facilities of an independent organization. To give just a few cases, Acrylonitrile, trichloroethylene,

---

1/ International Agency for Research on Cancer of WHO, Annual Report, 1976.

epichlorohydrin and other chemicals are now under study. In addition to the individual research projects administered by MCA, companies in the industry, at the end of 1974, founded the Chemical Industry Institute of Toxicology (CIIT), as an independent organization whose aim is "the scientific, objective study of toxicological issues involved in the manufacture, handling, use and disposal of commodity chemicals." (The Chemical Industry Institute of Toxicology, May 1976.)

In these comments, MCA will not deal with every issue raised by OSHA's proposed regulation. Other organizations, such as the American Industrial Health Council (AIHC), and individual companies will collectively do so. MCA wishes, however, to comment on certain matters. We will note, by way of preserving the point for future argument on post-hearing briefs, that the proposed regulation exceeds the authority granted under the Occupational Safety and Health Act (the Act). In addition, and assuming the legality of OSHA's proposal, we will discuss (1) the timeliness of OSHA's action; (2) the necessity from both a legal and practical standpoint, of applying a relative risk/benefit analysis in any proceeding looking to the regulation of a chemical; (3) the question of suitable substitutes; and (4) the question of an alternative method of procedure.

II. OSHA's Proposed Regulation Is Beyond Its Statutory Authority.

The question whether OSHA has the authority to issue the proposed regulation is properly a subject for argument on post-hearing briefs. However, in order to emphasize and to preserve the legal points involved, MCA submits that the proposed regulation is beyond OSHA's statutory authority in at least the following respects.

(a) The proposed rule is purportedly promulgated under Sections 4(b), 6(b), 8(c) and 8(g) of the Act. Section 4(b) has nothing to do with the proposed rule except insofar as it provides that safety and health standards promulgated under prior legislation are superseded by corresponding standards under this Act. Neither is Section 6(b) applicable here. That section provides only for regulations for occupational safety and health standards as defined in Section 2(b)(8) and arrived at in conformity with the criteria established by Section 6(b)(5). The proposed regulation is rather clearly neither a safety and health regulation as defined by Section 2(b)(8) nor a regulation applying the criteria under which Congress has delegated to OSHA the power to regulate. Section 8(c) deals primarily with the power of OSHA to require the keeping of records of accidents and illnesses, and thus does not involve the far more important aspects of the regulation, such as classification of carcinogens,

applicable testing methods, no-effect dose levels and the like. Finally, Section 8(g)(7), even if it be construed as not limited to a general power to regulate only on the subject matter of Section 8 -- "Inspections, Investigations and Recordkeeping" -- cannot provide the basis of authority to issue safety and health regulations outside the limits ordained by Congress under Section 6. Such a construction would mean that OSHA has a free hand to issue any regulation which will, in OSHA's sole judgment, ensure "safe and healthful working conditions." That construction would represent an unlimited delegation of legislative power and would raise a substantial constitutional question.

(b) Assuming, for the purpose of discussion, that OSHA has authority to promulgate the proposed regulation, that regulation is unlawful because:

(i) Its proposal to foreclose numerous contentions in future substance-by-substance cases, is directly contrary to the requirement set forth in the statute that standards be set on the best available evidence, including the latest scientific data in the field.

(ii) Its proposal to refuse to consider variations to the procedural structure announced, except by a petition to modify the proposed regulation itself, is contrary to that part of the Storer Broadcasting case[1/] which noted that the availability of a waiver from the FCC's rule preserved the lawfulness of that rule.

(iii) Its proposal that, under a Category I carcinogenic finding, an Emergency Temporary Standard shall automatically issue is in conflict with the requirements of Section 6(c) that such standard shall be issued only upon a finding that the substance poses a grave danger and that the emergency standard is necessary to protect the health of the worker. Such a finding cannot be made in the absence of a measurement of the risk involved.

(iv) The proposed regulation fails to consider economic impact which is an inherent part of the statutory test of the feasibility of an occupational safety or health standard.

(v) The proposed regulation is accompanied neither by an adequate Environmental Impact Statement nor by an adequate Economic Impact Statement.

1/ United States v. Storer Broadcasting Co., 351 U.S. 192 (1956).

MCA respectfully submits that the foregoing list of the legal infirmities of the proposed regulation must receive serious consideration by OSHA. MCA will address these matters fully in its post-hearing brief.

III. The Proposed Regulation Is Untimely and Should Await a Uniform Approach Formulated by All Responsible Government Agencies.

Several government agencies have statutory responsibility for the regulation of toxic and hazardous substances. As a result, American industry is faced with the problem of addressing itself to numerous proposed regulations, some of which are duplicative, while others present the possibility of conflicting obligations.

A current example is the regulation of benzene. That chemical is presently under regulation by OSHA, and under consideration for regulation by the Environmental Protection Agency (EPA), the Consumer Product Safety Commission (CPSC), and the Mining Enforcement and Safety Administration (MESA). In its recently published standard regulating occupational exposure to benzene,[1/] OSHA established a permissible exposure level of 1 part per million (ppm) on an 8-hour time weighted average basis with a ceiling level of 5 ppm in any 15-minute period and an action level of 0.5 ppm. In contrast, MESA has recently published a ceiling limit of 1 ppm for a 120-minute period applicable to underground coal mines.

1/ 43 Fed. Reg. 5918, February 10, 1978.

(Proposed 30 CFR Part 70.700, 42 Fed. Reg. 59294, 59299). To complicate matters further, MESA, without any apparent reference to EPA, has proposed that benzene vapor, among other listed air contaminants, be exhausted from coal mines through the return air course into the atmosphere (Proposed 30 CFR Part 70.700(g)).

These duplicating and/or conflicting requirements are in direct contrast with recent statements by government agencies to the effect that agencies should and will cooperate in order to produce reasonably consistent regulations. Thus, the Council on Environmental Quality was requested in the President's Environmental Message of May 23, 1977,

> "to develop an interagency program to eliminate overlaps and fill gaps in the collection of toxic chemicals data and to coordinate research and regulatory activities affecting them. This (Toxic Substances Strategy Committee) committee will serve as the principal forum for the development of Administration initiatives with respect to government-wide toxic substances strategy and policy." 42 Fed. Reg. 57866, November 4, 1977.

This request was enthusiastically endorsed by EPA, CPSC, OSHA and the Food and Drug Administration (FDA). Upon the signing of an interagency agreement on August 2, 1977, those agencies wrote to the President stating:

> "We have concluded that within our collective legislative mandates there are significant and exciting opportunities -- acting as a team -- to effectively control hazardous materials for the protection of public health. We have agreed to examine,

> assess and redesign, if necessary, the processes by which we collectively regulate the chemicals which impact upon people and the environment. We are particularly sensitive to the need to minimize duplicative (government) requests from industry . . . . Our goal is to make the regulatory process more efficient for other agencies, for industry and the public."

Despite the "significant and existing opportunities" which it recognized, OSHA now seems determined to proceed virtually on its own. Thus, its proposed regulation contains carcinogenicity standards even though a subgroup of the Interagency Regulatory Group (made up of EPA, CPSC, FDA and OSHA) is still attempting to establish common standards and guidelines for use in assessing new chemical testing regulations (including carcinogenicity testing) for interagency consistency and compatibility.[1/]

In view of the burden imposed by duplicative and/or inconsistent regulation, MCA believes that the proposed regulation should be held in abeyance until a uniform government approach can be formulated at least as to such matters as the identification and classification of carcinogens, the applicability of acceptable exposure levels, and the techniques of risk/benefit analysis to be applied. During the period of development of a uniform government approach, the public health will be fully protected by the procedures now avail-

---

1/ EPA: Interagency Agreement, 42 Fed. Reg. 54856-7, October 11, 1977; CPSC: Interagency Regulatory Liaison Group, Intent to Develop Compatible Testing Standards and Guidelines, 43 Fed. Reg. 1523, January 10, 1978.

able under the Act, sections 6(b) and 6(c) (relating to occupational safety and health standards), and under sections 8(e), 7, and 21 of the Toxic Substances Control Act (relating to reporting requirements, and court actions by the Administrator of EPA and other persons).

IV. The Proposed Regulation Cannot Be Made Final Unless It Makes Provision for Determining an Acceptable Level of Occupational Exposure.

This section of MCA's comments dealing with risk/benefit analysis follows closely the presentation made by AIHC on that subject. It differs primarily in that it takes the position that, as a part of the risk/benefit approach, substantial weight should be given the concept of a no-effect level or permissible exposure level (PEL) as applied to individual chemicals. MCA believes that the PEL together with an additional safety factor represents a reasonable regulatory response. Unlike the zero exposure level which, subject to technological feasibility, is the approach advocated by OSHA, the MCA position is consistent with the Act as interpreted by the courts in the light of its legislative history.

A. There is no such thing as a risk-free society.

The OSHA preamble makes much of the uncertainties or difficulties with respect to confidence in any safe level of exposure to a known or suspect carcinogen. Implicit in this notion, if not explicit, is the concept that "safe" within the meaning of the Act means entirely risk free, and

the correlative notion that industrial or other useful activity can occur on a completely safe, risk-free basis. Neither proposition is warranted, attainable, or sustainable. There are risks associated with all human activity, and indeed there are risks associated with all efforts to avoid activity. Moreover, in enacting the Occupational Safety and Health Act of 1970, Congress explicitly recognized the impossibility of assuring American workers a risk-free workplace. It follows, therefore, that there is a legitimate role for the evaluation of relative risk and the acceptance of some degree of risk, a concept commonly regarded as "acceptable risk." Even in an emotional, fright-laden context such as cancer, sound public policy must take into account the inevitability of some risk, and the necessity of evaluating such risk not only against alternative risk but also in light of the benefits of the substance being regulated.

This portion of MCA's comments does not proceed on the illusory basis that risk-free industrial environment is attainable. Rather, it deals candidly with assessment of risk and benefits. A key aspect of the assessment of risk is the quantification of carcinogenic risk, that is, assessment of the likelihood of a carcinogenic event at a particular level of exposure. It is not presumed that there is presently any broad agreement on a particular method for quantification of such risk, or that any of the more frequently used or

advocated methods to quantify risk is precise. Indeed, the methods commonly used are generally regarded as erring considerably on the side of safety and conservatism with respect to the calculation of the occurrence of carcinogenic risk. The proposal proceeds on the basis, however, that efforts to quantify risks can serve a useful purpose in comparing risks of exposure to a particular chemical with other occupational risks and with other risks commonly encountered and accepted in our society.

B. The concept of risk measurement is inherent in the Act.

The Occupational Safety and Health Act requires that OSHA, in promulgating standards, "shall set the standard which most adequately assures, to the extent feasible . . . . that no employee will suffer material impairment of health or functional capacity." § 6(b)(5), 29 U.S.C. § 655(b)(5) (emphasis supplied). Both the legislative history of the Act and the decisions of several circuits establish that feasibility means not only technologically feasible but also economically and practicably feasible. Thus, in Industrial Union Department, AFL-CIO v. Hodgson, 499 F.2d 467 (D.C. Cir. 1974), the court, through Judge McGowan, stated:

> "There can be no question that OSHA represents a decision to require safeguards for the health of employees even if such measures substantially increase production

costs. This is not, however, the same thing as saying that Congress intended to require immediate implementation of all protective measures technologically achievable without regard for their economic impact. To the contrary, it would comport with common usage to say that a standard that is prohibitively expensive is not 'feasible.' Senator Javits, author of the amendment that added the phrase in question to the Act, explained it in these terms:

> As a result of this amendment the Secretary, in setting standards, is expressly required to consider feasibility of proposed standards. This is an improvement over the Daniels bill, which might be interpreted to require absolute health and safety in all cases, regardless of feasibility, and the Administration bill, which contains no criteria for standards at all. S. Rep. No. 91-1282, 91st Cong., 2d Sess., at 58; Legis. Hist. at 197.

The thrust of these remarks would seem to be that practical considerations can temper protective requirements. Congress does not appear to have intended to protect employees by putting their employers out of business -- either by requiring protective devices unavailable under existing technology or by making financial viability generally impossible." (499 F.2d at 477-78; footnote omitted.) 1/

1/ See also remarks of Senator Saxbe concerning the failure to consider the economic impact of standards based exclusively on technological ideals. Legislative history of the Occupational Safety and Health Act of 1970, Senate Committee on Labor and Public Welfare, 92nd Cong., 1st Sess., 321-327, (Comm. Print June 1971)

Other circuits are in full agreement. The Third Circuit refused to "impute to Congressional silence a direction to the Secretary to disregard the possibility of massive economic dislocation caused by an unreasonable standard."[1/] The Fifth Circuit required that "the promulgation of any standard will depend upon a balance between the protection afforded by the requirement and the effect upon economic and market conditions in the industry."[2/] And the Seventh Circuit, in reviewing a decision of the Occupational Safety and Health Review Commission, held that the word "feasible" in the OSHA standard at issue "must be given its ordinary and common sense meaning of 'practicable'" and that that "construction is in accord with the clear intent of Congress and the purpose of the Occupational Safety and Health Act."[3/]

MCA submits that the history of the Act and the interpretation given to it by the courts make it clear that the "zero level of exposure" which OSHA seeks to pursue does not meet the tests of economic feasibility and practicability. If standards are to be put in conformity with those tests, attention must be given to the extent of the risk which the standard seeks to control. For if a known

---

1/ AFL-CIO v. Brennan 530 F.2d 109, 123 (3rd Cir. 1975).

2/ Florida Peach Growers Ass'n v. United States Department of Labor, 489 F.2d 120, 130 (5th Cir. 1974).

3/ Turner Co. v. Secretary of Labor, 561 F.2d 82, 83 (7th Cir. 1977).

or suggested carcinogen presents only a minimal risk or a risk which is generally accepted by society, it is neither practicable nor economical to regulate it. For example, a substance may be a known or suspected carcinogen at high exposure levels, but at current PEL's has not been shown to be carcinogenic either in humans or in mammalian species. Under OSHA's approach that substance would be subject to a Category I or Category II classification without any measurement of the degree to which risk would be lessened by the application of a "lowest feasible exposure" regulation. Under the approach advocated by MCA, a scientifically determined PEL would be applied, subject to an additional safety factor, and risks and benefits comparatively measured in relation to that modified PEL. That method, MCA believes, would fully satisfy the purpose of the Act.

C. Consideration by OSHA of risks and benefits will bring consistency to the federal scheme for regulation of public safety and health.

The risk/benefit provisions of the Consumer Product Safety Act, the Medical Devices Amendments of 1976 to the Federal Food, Drug and Cosmetic Act and the Toxic Substances Control Act have been set forth in detail in the "Alternatives" document filed by AIHC and need not be repeated here. But it should be noted that Congressional emphasis on the measurement of risks and benefits continues. Thus, in the Saccharin Study and Labeling Act which was enacted in November 1977 Congress required the Secretary of Health, Education and Wel-

fare to conduct certain studies which would consider, among other things, the benefits and risks to the public of foods containing carcinogens or other toxic substances and instances where restriction or prohibition of such substances are out of line with the risk/benefit relationship. (Public Law 95-203, § 2(a)(i)(B), (C), and (D).).

In light of the Congressional mandate to apply or to consider analysis of risk and benefit from carcinogens in other areas of regulation--especially in the regulation of food--it is inconceivable that such analysis should be ignored by OSHA in the regulation of the workplace.

D. Risk and benefit considerations are commonly considered or accepted by government agencies and by society at large.

1. Government Agencies

The FDA has a broad mandate to assure the safety of all food. Nevertheless, that agency has allowed numerous food substances to remain available for consumption even though the scientific literature tends to show that each is carcinogenic in at least one species of mammalian test animals. Such food substances include the following:

Egg yolk and egg white 1/

1/ J. Szepsenwol, Proc. Soc. Exp. Bio. and Med. 116:1136 (1964).

Vitamin D2 1/

Calcium 2/

Lactose and maltose 3/

Selenium 4/

Beverage alcohol 5/

OSHA itself is required to assure the health and safety of the workplace. Yet it has taken no steps to prohibit smoking in the workplace even though smoking is the primary cause of lung cancer today. And neither FDA nor OSHA, within their respective areas of responsibility, has prohibited the consumption of bacon or ham (nitrosamines), broiled meats (benzo-a-pyrene), peanuts or peanut butter (aflatoxin). Indeed, FDA, with full knowledge of the carcinogenicity of aflatoxin, has set guideline tolerances

---

1/ G. H. Gass and W. T. Allaben, 1 RCS J. Med. Sci. 5:477 (1977).

2/ L. Krook, L. Lutwak, K. McEntee, Guest Editorial, "Dietary Calcium, Ultimobranchial Tumors and Osteopetrosis in the Bull", 22 Am. J. Clinical Nutrition, No. 2, pp. 115-118 (Feb. 1969).

3/ K. Yamagiwa, Japanese J. Cancer Res. 46:No. 1 (1955) 48:555 (1957).

4/ 38 F.R. 10458 (April 27, 1973); 39 F.R. 1355 (Jan. 8, 1974).

5/ 38 F.R. 10460 (April 27, 1973); 39 F.R. 42748, 3d Col. (Dec. 6, 1974).

for aflatoxin in milk, peanuts and corn, acknowledging a potential of 66 lifetime cancers per 100,000 persons. (Food Chemical News, November 14, 1977, pp. 3-4).

Finally, in the Saccharin Study and Labeling Act, Pub. L. 95-203, 91 Stat. 1451 (1977), Congress declined to permit an immediate ban on saccharin despite the fact that Canadian studies purport to show that saccharin is carcinogenic, and despite the fact that prior existing law (the Delaney amendment) prohibits its use as a food additive.

2. Society

In everyday life, men and women are exposed to risks, of cancer or other fatality, which are unrelated to chemicals and which appear to be generally accepted or tolerated by society. Those risks have been set forth in detail in the "Alternatives" document of AIHC and will not be repeated in full here. It must be noted, however, that those "acceptable" risk invoke activities which are assumed both voluntarily and involuntarily.

On the involuntary side, for example, much of the population of the United States cannot avoid a risk of 1.5 in 100,000 of contracting cancer from natural sea level backgrounds of radiation. Other activities which, in a practical sense cannot be avoided, also pose risks of fatal cancer from radiation. Frequent airline passengers run a risk of up to 1.5 in 100,000 from cosmic radiation. That

risk is in addition to risk from radiation at sea level. The average U.S. diagnostic X-ray poses a risk of 1 in 100,000. Involuntary risks of fatality not involving cancer are higher. Thus, the risk of accident to a frequent passenger in commercial flying is 10 per 100,000. Risk of death by automobile accident (including risk to pedestrians) is 22 in 100,000. For pedestrians separately, it is 40 in 100,000.

On the voluntary side, risks are generally higher and run from as low as 1.0 in 100,000 for drowning when fishing, to 500 in 100,000 when sunbathing (curable skin cancer) to 1200 and 1300 per 100,000 for automobile and horse racing respectively. Yet society accepts these risks and perhaps encourages them as evidenced by the popularity at least of watching the last two activities mentioned. And what society accepts or tolerates should be part of the evaluation of risk by OSHA. 1/

E. The regulation should establish general criteria for the analysis of risks and benefits.

There are probably many possible approaches to the question of the risk involved in exposure to known or suggested carcinogens. MCA will focus on three.

1/ For risk measurements on this page and the preceding page, see Testimony of Richard Wilson.

First, there is the approach of OSHA which seeks ultimately a zero-exposure level within the limits of technology.[1/] MCA believes that that approach is wrong. Zero exposure is a moving target and will vary with advances in technology. Under zero exposure theory, industry would be required to increase its protective engineering systems each time the limits of detectability are lowered, and without regard to the question whether the workplace is in fact made safer by the more stringent standard which would be applied. That approach does nothing for the employee. It merely adds to expenditure, and increases the price of the product. It may lead to concentration of industry and lay-off of employees. It does not square with the purpose of the Act and the interpretations of the courts.

1/ OSHA does go through an economic impact analysis in deference to the rulings of the courts. But, with all respect to OSHA, the analysis seems to be merely a listing of dollar amounts rather than a thoughtful comparison of risk vs. cost, or cost vs. benefit.

Second, there is an approach which might be termed a "no-action level of risk." Under that concept, a measurement of the probability of cancer would be made at the permissible exposure level in effect at the time. If the risk of cancer is less than that currently accepted by society as being inevitable or present in well-controlled industrial or other operations, then OSHA should so find and decline to regulate further.

Third, while MCA sees considerable merit in the second approach and believes it to be reasonable, it advocates a position in between. Thus, MCA believes that where it has been objectively and scientifically determined, with regard to a given chemical, that a no-effect dose level exists, then a permissible exposure at a slightly lower level should be regarded as completely acceptable if a risk/benefit analysis shows that it is warranted.

V. OSHA Should Not Consider Issues of Substitutes.

In proposed § 1990.112, the consequences of a category I classification include a provision that:

> "When it is determined that there are suitable substitutes for certain uses or classes of uses that are less hazardous to humans, on the basis of the best available evidence, the proposal shall permit no occupational exposure for such uses or classes of uses." (42 Fed. Reg. 54185).

Expressed differently, proposed § 1990.112 would effectively give to OSHA the power to dictate to American industry what chemical substances are to be used in the workplace. Authority for such action is not to be found in the Act. Indeed, it would be contrary to the provisions of the Act, since, in the absence of any definition, it reflects only the technological and scientific finding that chemical A is less hazardous than chemical B for which it may be substituted and that therefore chemical B must be banned. But, as MCA has shown earlier in this statement, technological conclusions are not enough. There remains the question of whether it is economically and practicably feasible to substitute one chemical for another.

An equally serious problem with the proposed regulation is the lack of any definition of "suitable substitute." MCA questions whether any workable definition could be developed. Suppose, for example, that a substitute is deemed suitable if it is economically and functionally the genuine equivalent of the substance for which it is substituted. Does that cover the situation where the substitute for a Category I carcinogen is compatible with the process of one manufacturer but not with the process of another? Is the second manufacturer to be required to shut down and lay off his employees? If the substitute requires modification of

the process of manufacture, what will be the effect on small business and the employees of small business? Will competition, actual or potential, be adversely affected? Will substitution tend to increase concentration in a particular product? Will substitution cause an increase in the price of the product to the consumer? If the substitute is a new chemical, how much is known about it compared with the chemical in use?

MCA submits that OSHA is neither authorized nor equipped to handle the complexities of a situation which, in effect, requires it to decree which substances shall be used by industry. If a chemical in use is found to be carcinogenic, OSHA should regulate that substance within acceptable risk levels. It should not impose its judgment as to suitable substitutes over that of the manufacturer.

MCA wishes to emphasize that the American chemical industry continuously seeks new products and new processes which are better than existing ones. It has a built-in motivation to develop new substances and to withdraw or substitute them where hazards to health or safety have been validly established. For example, methylbromine was withdrawn from the residential fumigation market; Chlorothene (R) was substituted for carbon tetrachloride as a solvent; and alpha-naphthylamine was substituted for beta-naphthylamine.

MCA does not contend that the record of industry has been a perfect one. But hasty action by government, induced by unconsidered criticism, may also lead to errors. For example, in response to the demand for flame retardant treatment of children's nightwear, TRIS was applied to fabrics. Yet, TRIS was subsequently banned by the Consumer Product Safety Commission on the ground that it is a potential carcinogen in humans. Methylchloroform was substituted for perchloroethylene in dry cleaning and has led to alleged problems involving ozone levels. Today there is a contention that sodium nitrite should be banned in the processing of bacon. But, Professor Tannenbaum is reported as having said that, depending on conditions during distribution, the absence of nitrites in bacon would present the risk of death to consumers through botulism poisoning.[1/] He is also reported as having said that to "substitute" a freezing process for the use of nitrites would require an increased use of energy which, in turn, would add to the atmosphere substances more hazardous than the substance removed.[2/]

1/ S. Tannenbaum, Professor of Food Chemistry, Massachusetts Institute of Technology, reported in Food Chemical News, December 26, 1977, pp. 29-31.

2/ Ibid.

VI. The Proposed Regulation Should Be Substantially Modified.

The AIHC has filed with OSHA a document entitled AIHC Recommended Alternatives to OSHA's Generic Carcinogen Proposal. MCA has reviewed AIHC's submission and is in general agreement with it. MCA notes first the recommendation of AIHC that a Data Evaluation and Classification Panel be established which will make determinations concerning the carcinogenicity of substances. The concept behind the creation of a Panel is that the question of carcinogenicity should be decided, not by the agency which is to regulate the use of a substance, but by a group of scientists collectively recognized as experts in such fields as toxicology, metabolism, pharmacokinetics, cancer research and therapy, epidemiology and occupational medicine. MCA is in agreement with that proposal and would support a coordinated cancer data and classification panel consisting of both governmental (excluding OSHA) and non-governmental individuals of acknowledged scientific competence. Such a panel, in MCA's opinion, would be in general conformity with the thinking of the National Research Council when it recommended that the entity making the determination of carcinogenicity - - -

> ". . . should be, to the extent possible, credible to both management and labor; therefore, it should not be involved in the regulatory process. But it must not be so removed from the realities of the workplace that it cannot make an appropriate assessment of risk, or at least announce its decision in a form that can be translated to a specific occupational situation." 1/

In addition to the concept of a Panel, MCA wishes to emphasize a few points.

A. Relative potency of carcinogens and no-effect levels.

The AIHC Alternatives document proposes that carcinogens be ranked according to potency so that regulatory priorities may be established and the extent of regulatory control measured. MCA agrees with AIHC.

In the proposed rule, OSHA has decided to treat all demonstrated carcinogens the same for regulatory purposes. Thus, consideration of the potency of the tumorigenic response does not enter into the action that OSHA will require of industry when many chemicals of varying degrees of biological activity are classified into category I for regulatory purposes.

1/ "Informing Workers and Employers about Occupational Cancer," National Research Council, Washington, D.C., prepared for Occupational Safety and Health Administration (June 1977). NTIS, PB-269-599, p. 20.

That there are differences in potency between carcinogens is a well-established fact and is illustrated in Table I (with accompanying references). A reference quoted on page 54165 of the OSHA proposed rule as published in the Federal Register is the WHO Technical Report 546, p. 11 which states "[c]hemical carcinogens can vary in potency in comparable test systems by a factor as high as 10^7". This indicates the wide range in potency of various carcinogens, e.g., from aflatoxin to saccharin. On page 40 of the 1977 Threshold Limit Values listed annually by the American Conference of Governmental Industrial Hygienists, it is stated "[s]ubstances occurring in the occupational environment found carcinogenic for animals may be grouped into three classes, those of high, intermediate and low potency". Thus, differences in potency of animal carcinogenesis are recognized and different threshold limit values for individual carcinogens dependent upon their potency are proposed. Clearly all experimental carcinogens do not present the same risk and therefore do not require the same regulatory response.

In connection with no-effect levels, OSHA has taken the position that any exposure to a potential carcinogen must be considered to be attended by a risk and that there is no safe or no-effect level for a carcinogen. Yet contrary opinions can be documented in the literature. Since it is still not clearly accepted at this time whether a no-effect threshold exists, another approach is to determine the carcinogenic dose at which the specific effect appears beyond the limits of human life. This would serve as a tolerable carcinogenic dose.

- Druckrey on page 75:[1/] ". . . in carcinogenesis at continuous exposure with all substances tested and without regard to the organ of tumor development, clear dose-effect and time relationships exist". On page 78: "With very low dosage the induction time can be longer than the life expectancy, which apparently is the limiting factor in carcinogenesis. Every assessment of the potential risk of carcinogenesis, therefore, must take into account both factors: dose and time . . ."

1/ References are listed in Table 2, attached.

- On page 12 of the WHO Technical Report 546 is stated: "The possible existence of a threshold to the effects of both chemical carcinogens and mutagens should be envisaged".
- On page 14 of the same publication a statement of L. Friedman, former Director of the Division of Toxicology of the Bureau of Foods, FDA, is quoted: "It may be envisaged that a threshold for carcinogenic activity exists".
- Weisburger and Weisburger discussed the observation that " - - there are doses for which no tumors are seen over the average life span. Were the animals to live longer, tumors could be predicted to occur".
- Jones and Grendon stated: "Low dosage exposure at some levels is virtually without risk because the expected life span of those exposed is exceeded by the time necessary for low concentrations of altered cells to develop into cancers".
- Bingham and Bingham and Falk discussed thresholds in cancer induction and the modifying effects of cocarcinogenesis. Agents that are cocarcinogenic, promoters or accelerators do result in a shift in the cancer incidence and the induction period and, thus, in the threshold. They do not eliminate the

threshold, however, as these agents are also governed by the same biologic factors and conditions that govern the action of a simple carcinogen.

- Others who have given support to the threshold concept are Stokinger, Gehring and Blau, Truhout, Goldwater, Olson and Zapp.

B. Extrapolation of animal data to humans.

AIHC has proposed a thorough and careful approach to the methodology to be applied in animal testing and to the conclusion to be drawn. MCA agrees.

OSHA in its proposal recognizes that in determining hazards to man based upon animal data, sound judgmental decisons are required which take into account all available data and which cannot be done by simple categorization and standardization. The OSHA document is replete with references to the need for sound judgments and the difficulties in making such.

- "The correct interpretation of hazards to human health is sometimes extraordinarily difficult." (p. 54158).
- "The evaluation of carcinogenic hazards for man is based on a judgment of all available information: on bio-assay, on toxicological, metabolic and pharmacologic studies, on the extent and

route of exposure of man, and on epidemiologic studies . . . ." (p. 54166).

- "The particular characteristics of these animals and the results obtained may require additional evaluation." (p. 54164).
- "The assessment of the carcinogenic activity of a chemical depends on a variety of parameters. These include not only the total number of tumors induced but also their multiplicity, latent period, morphologic type, and degree of malignancy." (p. 54163).

While thus recognizing the complexity of the problems in several instances, OSHA has proceeded to ignore that complexity in this proposal.

1. Testing at high doses

The OSHA proposal states (p. 54161) that testing at constant high exposure levels at or approaching the maximum tolerated dose level is not inappropriate and is indeed required. However, the use of such large doses can lead to metabolic overload and may in fact produce a "fictitious over-estimate

of hazard".[1/] The pharmacokinetics and the metabolic pathway of a chemical can change with the dose and not be truly representative of events at lower doses. Miller and Miller have noted that "[m]ost of the human chemical carcinogens, with the exception of the alkylating agents, must be metabolically activated, and all chemical carcinogens appear to undergo metabolic deactivation in vivo".[2/] If metabolism is involved in the initial events leading to tumor formation, then this may also be influenced by exposure levels. It has been suggested for vinyl chloride, for instance, that at high concentrations a different pathway of metabolism could predominate having toxic and/or carcinogenic consequences. Thus, the use of massive doses in chemical carcinogenic testing in animals can be deemed unscientific, and using the results of such studies to make regulatory decisions without explaining the metabolic consequences of such experiments is not advisable.

2. Reliance on replicated test on a single species

In the preamble of the regulation, OSHA refers to a conclusion of a joint committee of the Food and Agriculture Organization and the World Health Organization

---

1/ Gehring, P.J. and Blau, G.E., "Mechanisms of Carcinogenesis: Dose Response." J. Environ. Path. Toxicol., 1, 163-179 (1977).

2/ "Chemical Carcinogenesis," Chapter 1, p. 74. Marcel Dekker, Inc., New York, 1974.

which recommended that "investigation of the tumor incidence in a chronic toxicity test . . ." should be performed, which ". . . should involve the study of animals of two species (e.g., rats and mice) . . . ." (42 Fed. Reg. 54158). Yet, OSHA now proposes that a chemical will be classified in category I if it is shown to produce cancer in "a single mammalian species if those results have been replicated in the same species in another experiment." (§ 1990.110, 42 Fed. Reg. 54185). MCA regards that position as scientifically unsound since interspecies variation in response may be a factor in the development of a positive result in the one species. "Species variation in metabolism can occur in respect to the speed at which metabolism occurs and the metabolic pathways employed and these arise mainly because of interspecies differences in enzymatic control."[1/] The more sound scientific procedure would be to use two (or more) mammalian species that biologically handle the material qualitatively and/or quantitatively as similarly as possible to man.

3. Laboratories

MCA believes the OSHA should make special regulations for laboratories which are engaged in research or which produce small batches of chemical reagents on special

---

1/ Smith, R.L., "The Problem of Species Variations," Ann. Nutr. Alim., 28, 335-349 (1974).

and limited individual orders. Apart from the possibility (noted by AIHC) that OSHA's proposals might lead to impeding important research on health problems, the research, small batch producing and quality control laboratories are already operated under controlled conditions and do not require the type of regulation which may be appropriate for the general workplace.

VII. CONCLUSION

The Manufacturing Chemists Association and its member companies are concerned, no less than OSHA, that the American industrial workplace be made as safe and healthful as is reasonably possible. That concern arises not only from an obligation to obey the law as announced in the Occupational Safety and Health Act and other statutes; it is also based on the long-held belief that a reasonably safe and healthful workplace is a more productive and efficient workplace.

Neither legal obligation nor enlightened self-interest, however, require or suggest that MCA and its members acquiesce in the regulation proposed by OSHA. As presently proposed, OSHA's regulation is defective in a number of respects.

It exceeds the limits of the authority delegated to OSHA by Congress.

Because of insufficient interagency consultation, it creates the likelihood of inconsistent regulation by the government.

> It fails to make provision for the comparative evaluation of the risk and the benefit involved in taking regulatory action.
>
> In suggesting the requirement of substitution for existing chemicals, it enters an area where it has little expertise and which is properly a matter for decision by industry.

The foregoing is not to say that MCA is opposed to any regulation which would identify, classify and control carcinogens in the workplace. On the contrary, a regulation which would produce a reasonably uniform and practical approach to the problem would be welcome.

TABLE 1

Relative Potency of Carcinogens in Animal Tests

	Organ	Chemical	Potency	Dose	Reference
1.	Liver	Trichloroethylene	Weak	869-2339 mg/kg/day - oral	(1)
2.	Urinary tract	Nitrilotriacetic acid	Weak	15,000 ppm - oral	(2)
3.	Urinary tract	Trisodium salt of nitrilotriacetic acid	Weak	15,000 ppm - oral	(2)
4.	Liver	Chlordecone (kepone)	Moderate	30-60 ppm - oral	(4)
5.	Liver and kidney	Chloroform	Moderate	600 mg/kg - oral	(5)
6.	Lung	Bis-chloromethyl ether	Potent	1.0 ppm - inhalation	(6)
7.	Liver	Carbon tetrachloride	Weak	1250-2500 mg/kg oral	(9)
8.	Liver - human Stomach, kidney and liver - rat	Aflatoxins	Potent	500 µg/kg - oral	(6a)
9.	Liver	Nitrosamines	Potent	milligrams - oral	(7)
10.	Skin	Benzo(a)pyrene	Potent	0.3% solution - dermal	(3)
11.	Skin	1,2-Benzanthracene	Weak	dermal	(3)
12.	Bladder	2-Naphthylamine	Potent	oral	(6b)

References: see next page

REFERENCES FOR TABLE 1

1. National Cancer Institute Carcinogenesis Technical Report Series No. 2. 1976. b. Carcinogenesis Bioassay of Trichloroethylene. DHEW. Publ. No. (NIH) 76-802.

2. Bioassays of Nitrilotriacetic Acid (NTA) and Nitrilotriacetic Acid, Trisodium Salt, Monohydrate ($Na_3NTA \cdot H_2O$) for Possible Carcinogenicity (DHEW Publ. No. (NIH) 77-806). National Cancer Institute, Carcinogenic Bioassay Program Resources Branch, Bethesda, Maryland (January 1977).

3. Eckardt, R. E., Industrial Carcinogens, A. J. Lanza, Ed., Grune and Stratton, New York (1959).

4. FDA Report. DHEW, NIH. Report on Carcinogenesis Bioassay of Technical Grade Chlordecone (Kepone) (April 8, 1976).

5. A. Laskin and M. Kuschner, The Experimental Induction of Lung Cancer in Laboratory Animals. Abstr. Paper, APCA Meeting, Cleveland, Ohio (June 11-16, 1967).

6a. Butler, W. H. and Barnes, J. M. Carcinoma of the Glandular Stomach in Rats Given Diets Containing Aflatoxin. Nature 209:90 (1966).

b. IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Man. Some Naturally-Occurring Substances, Volume 10. IARC, Lyon, France (1976).

7. Chemical Carcinogens. Charles E. Searle, Ed. ACS Monograph 173, American Chemical Society, Washington, D.C. (1976).

8. Report on Carcinogenesis Bioassay of Chloroform. National Cancer Institute, Carcinogenesis Bioassay and Program Resources Branch, Bethesda, Maryland (March 1, 1976).

9. Lawley, P. D, Chemical Carcinogenesis. C. E. Searle, Ed. Chapter 4. Carcinogenesis by Alkylating Agents (1976).

TABLE 2

Druckrey, H., "Quantitative Aspects in Chemical Carcinogenesis". In "Potential Carcinogenic Hazards from Drugs; Evaluation of Risks". (R. Truhout, ed.) UICC Monograph Ser. Vol. 7, Springer-Verlag, Berlin and New York, 1967.

Weisburger, J.H. and Weisburger, E.K., "Food Additives and Chemical Carcinogens: On the Concept of Zero Tolerance", Fd. Cosmet. Toxicol. 6, 235-242, 1968.

Jones, H.B. and Grendon, A., "Analysis of Mathematical Models Used in Data Extrapolation". Clin. Toxicol. 9, 791-797, 1976.

Bingham, E., "Threshold in Cancer Induction. If They Exist, Do They Shift?" Arch. Environ. Health 22:692-695, 1971.

Bingham, E. and Falk, H.L., "The Modifying Effect of Cocarcinogens on the Threshold Response". Arch. Environ. Health 19:779-783, 1969.

Stokinger, H.E., "The Case for Carcinogen TLV's Continues Strong". Occup. Health Safety 46, 54-58, 1977.

Gehring, P.J. and Blau, G.E., "Mechanisms of Carcinogenesis: Dose Response". J. Environ. Path. Toxicol. 1, 163-179, 1977.

Truhout, R., "Can Permissable Levels of Carcinogenic Compounds in the Environment be Envisaged?" Ecotoxicol. Environ. Safety 1, 31-37, 1977.

Goldwater, L.J., Olson, R.E., and Zapp, J.A., Testimony at OSHA Hearings on Benzene, Exhibits 149C, 149D and 149E.