Ex. 2874
Proposed

PLAINTIFF'S EXHIBIT
AL-1539

BEFORE THE

UNITED STATES DEPARTMENT OF LABOR

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

WASHINGTON, D.C.

In Re:

The Proposed Regulation of the United States Occupational Safety and Health Administration for the Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk to Humans

OSHA Docket No. H-090

POST HEARING BRIEF FOR

THE AMERICAN INDUSTRIAL HEALTH COUNCIL

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Preliminary Statement

On October 4, 1977, the Occupational Safety and Health Administration ("OSHA") published the Proposed Regulation for the "Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk", 42 Fed. Reg. 54148 [hereinafter referred to as the "Proposed Regulation"], under the Occupational Safety and Health Act, 29 U.S.C. § 651 et seq. [hereinafter referred to as the "Act"].

OSHA began work on the Proposed Regulation in January 1976. (Wrenn Tr. 164.)[1/] In October 1976 a contract was entered into with Clement Associates, Inc. ("Clement"), a consulting firm to, inter alia, "examine and furnish alternative approaches and policies for the regulation of carcinogens . . . ." (Ex. 12A.) The contract also provided that Clement would "[d]evelop prototype regulations for controlling employee exposure to carcinogens found in the occupational environment."[2/] Id.

In January 1977 OSHA released a draft of proposed regulations substantially identical to the Proposed Regulation for comment by the National Advisory Committee on Safety and

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1/ References to the transcript of the hearing will be indicated as "Tr. ___." Exhibits to the Preamble to the Proposed Regulation will be indicated as "Preamble Ex. ___." Exhibits offered at the hearing will be indicated as "Ex. ___."

The statements filed on or before February 28, 1978, by persons wishing to testify, written statements by members of the public, and statements by OSHA witnesses were offered together as a single exhibit, Ex. 6. Additional statements or comments were filed during the hearing and as post hearing evidence was filed. For convenience the written statements of individual witnesses and written prepared testimony by witnesses will be referred to as "S. ___." Post hearing evidence will be identified by the person submitting the data as follows, e.g., "AIHC P.H."

2/ The National Institute for Occupational Safety and Health ("NIOSH") is designated under Section 20 of the Act, 29 U.S.C. § 669, as the research arm of OSHA. NIOSH is charged with, among other things, developing criteria for dealing with toxic materials, but was not consulted by OSHA when the Proposed Regulation was being drafted. (Tr. 2979.)

Health ("NACOSH").[1] This draft was not published in the Federal Register but was made available to the public on request. Two brief public meetings of NACOSH were held at which public comments were invited.[2] 42 Fed. Reg. 54182-54183. At these very brief hearings testimony was received from a number of witnesses.[3] On May 5, 1977, NACOSH adopted a resolution recommending that the draft be published for "information gathering and that neither the document nor the process be engaged for a rulemaking purpose at this time."[4] 42 Fed. Reg. 54183.

1/ NACOSH is an advisory committee established under Section 7(a) of the Act. 29 U.S.C. § 656(a).

2/ NIOSH received notice of the draft regulation when it was released to NACOSH. NIOSH filed a letter with NACOSH stating its intention to comment on the draft, but no such comments were filed.

3/ The transcript of the proceedings of the Subcommittee on Environmental Carcinogenesis of the National Cancer Advisory Board was filed as part of the record in the NACOSH proceedings.

4/ The NACOSH resolution stated:

> "1. The document can be adopted by OSHA as an administrative policy, and there should be such flexibility.
> 2. The document, even if adopted as a policy through the rulemaking process, would not deprive due process challenges when subsequent standards are promulgated.
> 3. The document identifies those issues upon which much debate has evolved and should continue, including the concept that some substances, although not always scientifically definable as carcinogens, must be addressed because of a regulatory obligation.

(Footnote continued on p. 4)

On July 13, 1977, OSHA entered into another contract with Clement to undertake a preliminary classification of substances in the 1976 Edition of the NIOSH Subfile of Suspect Carcinogens of the Registry of Toxic Effects of Chemical Substances ("NIOSH List" or "NIOSH Subfile") into OSHA's proposed Categories I, II, and III. (Ex. 12C.) On July 14, 1978, OSHA released the lists prepared by Clement placing substances in the NIOSH subfile in the OSHA categories on a tentative basis. (Ex. 132.)

The hearing began May 16, 1978, and ended July 25, 1978.

Statutes Involved

The relevant statutory provisions of the Act are Sections 3(8), 6, 7, 8(c), 8(g), 9, 13, and 20. 29 U.S.C. §§ 652(8), 655, 656, 657(c) and (g), 658, 662, and 669. The text of these sections of the statute is set out in Appendix A to this brief.

(Footnote continued from p. 3)

ISSUES WHICH NEED TO BE EXPANDED

1. Address adequacy of classification system.
2. Address carcinogenicity of impurities and mixtures.
3. Expand discussion on "other than animal testing" routes.
4. Anatomic and metabolic fate.
5. Decision on rate retention issue."

42 Fed. Reg. 54183.

Introductory Statement

The American Industrial Health Council ("AIHC") was formed with the objective of cooperating with government, labor, and the public in developing a sound policy for the control of exposure to carcinogens in the work place. 1/ To that end the AIHC developed "Recommended Alternatives to OSHA's Generic Carcinogen Proposal" [hereinafter referred to as "AIHC Alternative" or "the Alternative"]. The Alternative was originally released in draft form on January 9, 1978, to OSHA, unions, and the public for comment. A final copy reflecting comments on the draft was filed in these proceedings on February 28, 1978.

At the time of publication of the Proposed Regulation, OSHA published a one and one-half page pro forma Environmental Impact Statement.

OSHA did not undertake an economic analysis of the Proposed Regulation. OSHA stated that such an analysis would be made in rulemaking on individual substances. 42 Fed. Reg. 54182. In AIHC's view, an economic analysis of the Proposed Regulation should have been undertaken not only in compliance with the requirements of the National Environmental Policy Act of 1969, 42 U.S.C. § 4321 et seq. ("NEPA"), but also pur-

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1/ The membership of AIHC as of June 26, 1978, appears as Exhibit 81. A number of companies have joined AIHC since that date and membership is now approximately 120 companies. In addition to these member companies, AIHC has cooperative relationships with some 50 trade associations.

suant to directives of the President in Executive Orders No. 11821, 39 Fed. Reg. 41501 (November 28, 1974) and No. 12044, 43 Fed. Reg. 12660 (March 27, 1978).[1/] Consequently AIHC commissioned the Foster D. Snell Division of Booz, Allen and Hamilton, Inc., to undertake such an analysis. That analysis,- discussed infra, at 105, is entitled "Preliminary Estimates of Direct Compliance Costs and Other Economic Effects of OSHA's Generic Carcinogen Proposal on Substance Producing and Using Industries" [hereinafter referred to as the "Snell Report"].

Significant Post Hearing Developments

Regulatory Analysis. As pointed out above, OSHA did not undertake an economic analysis of the Proposed Regulation. On June 14, 1978 Organization Resource Counselors ("ORC") wrote to the Office of Management and Budget ("OMB"), the agency responsible for the implementation of the President's Regulatory Analysis Program, pointing out that OSHA's position that an economic analysis was not required under Executive Order 12044 was erroneous and requesting OMB to use its good offices to require OSHA to prepare an economic analysis. On July 25, 1978 OMB notified ORC that OSHA had "agreed that a regulatory analysis will be done for the generic standards and that [OMB] will

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1/ OSHA's failure to comply with NEPA and the Executive Orders is discussed infra, at 100.

continue to work with [OSHA] on the design of the analysis." (AIHC P.H.)

In a memorandum to Assistant Secretary Bingham dated August 3, 1978, Messrs. Morris and Wrenn summarized the agreement by OSHA to undertake a regulatory analysis of the Proposed Regulation, including an examination of "realistic alternative approaches." (AIHC P.H.) The memorandum continued:

> "In addition to this comparison of alternative approaches, the analysis would also look at alternative criteria for the categorization of substances within the generic standard. OSHA also will set forth for review the parameters which are included in a determination of feasibility. We think the analysis will demonstrate what issues are intended in the generic approach to be foreclosed from further rulemaking." Id.

As of the date of this brief, neither the regulatory analysis nor a draft or outline of the analysis has been made public.

The Benzene Decision. On October 5, 1978 the Fifth Circuit Court of Appeals unanimously decided to set aside the Occupational Safety and Health Standard for Benzene (the "Benzene Standard"). American Petroleum Institute v. Occupational Safety and Health Administration, ___ F.2d 80 (5th Cir. 1978). (A copy of the decision is attached as Appendix B. The decision will hereinafter be referred to as the "Benzene decision".) The decision bears directly upon many of the policy determinations being considered as part of the Proposed Regulation and demonstrates that OSHA should withdraw the Proposed Regulation and repromulgate a new proposal which complies with the statute. Because

of the importance of the decision, we are discussing it at the outset rather than piecemeal in various sections of the brief.

The core policy determination of the Proposed Regulation -- the control of exposure to confirmed or suspected carcinogens to the "lowest feasible level" -- was incorporated into the Benzene Standard and was the primary focus of the Fifth Circuit's decision. The factual premise for that policy determination in the Proposed Regulation -- that there presently exists no known safe level for exposure to a carcinogen -- also was the basis for the control of benzene in accordance with that policy. The provisions of the Benzene Standard clearly track the provisions of the model standards found in the Proposed Regulation.[1/]

The Court's ruling is particularly germane to the Proposed Regulation in light of the assumptions the court made in deciding to set the Benzene Standard aside. The Court accepted OSHA's determination that benzene is a leukomogen and that it is impossible to determine a safe or no-effect level for exposure to benzene or any other carcinogen. The Court accepted OSHA's cost estimates for industry implementa-

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1/ Compare 43 Fed. Reg. 5918 (February 10, 1978) with 42 Fed. Reg. 54148 (October 4, 1977) regarding adoption of policy to control exposure to lowest feasible level; 29 C.F.R. § 1910.1028(c)(1) and (c)(2) (published at 43 Fed. Reg. 5964) with Proposed Section 1990.160(c)(1) and (c)(2) (published at 43 Fed. Reg. 54189) regarding control of exposure from airborne concentrations and from dermal contact; and 29 C.F.R. § 1910.1028(k)(2)-(5) (published at 43 Fed. Reg. 5966) with Proposed Section 1990.160(p)(3) regarding labelling.

tion of the Benzene Standard and did not reach or discuss the petitioners' arguments concerning the infeasibility of the standard. The decision thus is based on statutory grounds rather than the particular facts pertaining to benzene.

In setting aside the Benzene Standard, the Fifth Circuit rejected OSHA's effectuation of the policy determination "to limit employee exposure to carcinogens to the lowest feasible level" where (as is the case with benzene and the Proposed Regulation) that determination is based simply upon factual findings that the substance is a carcinogen and that there is no known safe or threshold effect level of exposure for the substance. __ F.2d at 88. The Court found that for an occupational safety and health standard to be "reasonably necessary and appropriate to provide safe or healthful employment and places of employment," as required by Section 3(8) of the Act, 29 U.S.C. § 652(8), OSHA must "assess the expected benefits" from the standard and "determine whether [those benefits] bear a reasonable relationship to the costs imposed by the standard." __ F.2d at 90-91. In other words, OSHA must conduct some form of cost/benefit analysis, as advocated by AIHC and others.

The Court specifically found that in making the assessment of benefits OSHA could not assume "appreciable" benefits would accrue to employees by lowering exposure to a carcinogen, in this case benzene. Rather, OSHA must make a factul determination, supported by substantial evidence, as to the benefits to employees from the reduction of exposure required by the

standard:

> "Until OSHA can provide substantial evidence that the benefits to be achieved by reducing the [PEL] from 10 ppm to 1 ppm bear a reasonable relationship to the costs imposed by the reduction, it cannot show that the standard is reasonably necessary to provide safe or healthful workplaces." __ F.2d at 92.

In short, OSHA must "regulate on the basis of knowledge rather than on the unknown." Id.

The Court explained that sufficient "knowledge" of the benefits provided by a standard could be secured through appropriate risk assessment and quantification.[1/] While recognizing that "OSHA's assertion that present knowledge is insufficient to construct a valid dose-response curve for benzene may be correct," the Court found that "the record

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1/ Because the word "risk" was used with different meanings by the Fifth Circuit and various witnesses in this proceeding, it is important as a preliminary matter to define "risk" as that word is used in this brief and to distinguish "risk" from "hazard". "Risk" is used in this brief to refer to the scientific evaluation of data to determine its validity to establish qualitative human risk of cancer. "Risk" also encompasses evaluation of potency in relation to human risk, identification of the scientific extrapolation techniques, and an evaluation of the probability of occurrence.

"Hazard", in contrast, is used in the regulatory context, to mean the social danger presented by exposure to the substance. The determination by the Agency whether to regulate or not is based on the analysis of the Agency of the "hazard". "Hazard" thus encompasses the number of workers exposed, the level of exposure, and the characteristics of the substance to which the worker is exposed - both the physical characteristics and the relative potency of the substance. Hazard assessment is the function of the Agency.

See generally AIHC Alternative at 78-82.

reflects that preliminary assessments are now being made and that valid extrapolations will be possible as more is known about the effects of past exposure at higher levels." __ F.2d at 92 n. 23. Furthermore, until "rough but educated estimates of the extent of benefits" from reducing exposure could be developed based on human exposures or animal data, there would be insufficient evidence upon which to find a standard reasonably necessary. __ F.2d at 93.[1/]

The PEL for airborne concentrations of benzene was the primary focus of the Court's opinion, but challenges to the dermal contact and labelling provisions in the standard were considered and the Court's ruling setting aside these provisions was significant. The disposition of these challenges clearly demonstrates that each provision in a standard must be the subject of a finding, supported by substantial evidence, that the provision is "reasonably necessary" to provide workers protection.

The dermal contact provision in the Benzene Standard was set aside upon a finding that OSHA failed to demonstrate that it was "reasonably necessary" for the protection of workers:

> "Since entry to the body by dermal contact was not established, the record will not support a finding that the prohibition of all dermal contact with benzene will result

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1/ The court's decision underlines the conclusion (see discussion beginning infra, at 197) that OSHA should modify the Proposed Regulation to provide for risk quantification and hazard assessment.

> in quantifiable benefits in terms of a reduced risk of leukemia justifying the costs of the provision. Thus reasonable necessity is lacking here too." __ F.2d at 94 (emphasis added).1/

The Court stated that it would have applied the same criterion to the labelling provisions of the Benzene Standard but such an analysis became unnecessary once the provisions concerning the reduction of the PEL and the prohibition of dermal contact were set aside. These provisions were correctly viewed by the Court as tied to all the Benzene Standard's other requirements. However, in an effort to provide guidance to OSHA in promulgating future standards, the Court addressed the labelling issue.

The Fifth Circuit opined that OSHA could forbid employers from removing caution labels upon containers of benzene and benzene-containing products sold, distributed or otherwise leaving the employer's workplace; that authority, however, is limited to circumstances where "the labelling requirement as a whole is shown to be reasonably necessary to provide safe workplaces." __ F.2d at 99 (emphasis added). In short, just as for exposure limits and restrictions on dermal contact, OSHA must

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1/ It is notable that the Court reached this determination having before it information on costs which was made uncertain by OSHA's amendment of the Benzene Standard (promulgated on June 21, 1978, the day before oral argument) exempting from the scope of the standard work operations where the only dermal exposure to benzene is from liquid mixtures containing 0.5 percent or less of benzene by volume. Thus, the lack of a supportable finding of appreciable benefits was the primary basis for setting the provision aside.

find on the basis of substantial evidence that labelling will achieve a quantifiable health benefit for workers and that the benefits achieved will be reasonably related to the cost of such labelling. As in the Court's analysis of the PEL and dermal contact provisions, the Court stressed that a valid finding by OSHA that appreciable benefits would accrue to workers was the indispensable predicate to regulation. Thus, OSHA must as a threshold matter find that labelling is reasonably necessary or appropriate to inform employees of the danger of the substance found in the container and second, that it is reasonably necessary or appropriate for the labels to remain on the container to inform downstream employees of the danger of the substance found in the container.

Another aspect of the Court's decision is of great importance as it bears on OSHA's obligation to take affirmative action to secure data upon which to act. The analysis performed by the Court in determining that OSHA failed to establish dermal contact as a mode of entry of benzene into the body strongly suggests the invalidity of the primary procedural concept embodied in the Proposed Regulation. The Court recognized that there was evidence in the hearing record providing some support for OSHA's determination that benzene could enter the body through the skin. But testimony also established that through modern testing techniques a definitive answer could be provided to the question regarding the conditions under which skin absorption might occur and the nature of the substance which actually could be absorbed. The failure of OSHA to conduct the tests

necessary to answer these questions was viewed by the Court as directly contrary to the will of Congress:

> "OSHA's decision to regulate on the basis of dated, inconclusive data when modern experimental methods can quickly and efficiently provide reliable information contravenes the directive from Congress to promulgate standards on the basis of the 'best available evidence,' 'research, demonstrations, experiments, and such other information as may be appropriate,' and 'the latest available scientific data in the field.' 29 U.S.C.A. § 655(b)(5)." __ F.2d at 96.

Thus, the primary procedural concept in the Proposed Regulation -- OSHA's expressed intention to generically resolve many principles and concepts in this proceeding and to rigidly apply these principles and concepts in future rulemaking proceedings on specific substances -- flies in the face of the Fifth Circuit's ruling. It is clear that not only significant new data, but data reasonably obtainable must be considered by OSHA in promulgating occupational safety and health standards. Furthermore, assuming the answers to factual questions, such as whether a carcinogen may be absorbed through the skin, will be grounds for invalidating a standard. Rather than create such rebuttable presumptions, OSHA must find on the basis of substantial evidence that the carcinogen may be absorbed through the skin.

The Benzene decision underlines basic weaknesses of the Proposed Regulation. OSHA must find on the basis of valid supporting evidence that there are benefits in terms of reduced risk from control to the lowest feasible levels and those benefits must be quantified. OSHA has not done so. OSHA must then make the

determination whether the benefits justify the costs of the Proposed Regulation. OSHA has not done so. Finally, OSHA has the obligation to consider the best available evidence and to take affirmative steps to secure data reasonably available before making regulatory decisions. OSHA has done the opposite; the proposed policy decisions and presumptions of fact are designed to exclude new data and there is no procedure to secure reasonably available data. In short, if OSHA wishes to speed up its regulation of carcinogens in a valid manner, it must withdraw the Proposed Regulation and create a new regulatory scheme. OSHA has been provided such a scheme in the AIHC Alternative.

A R G U M E N T

Introduction

The AIHC Alternative and OSHA's Proposed Regulation agree on a number of very important points. However, in AIHC's view, the record shows that OSHA's proposal is deficient both legally and scientifically. The purpose of this brief is two-fold: First, to point out the shortcomings of the Proposed Regulation and to indicate how the regulation can be brought into conformity with the law. Second, to demonstrate that the AIHC Alternative avoids the shortcomings of the Proposed Regulation.

The discussion in this brief is divided into five

general parts.

In Part One (Sections I - VII) we shall discuss the statutory and constitutional issues arising under OSHA's proposal. As a background to this discussion and in order to clarify the nature of the problem OSHA is addressing, we shall discuss briefly the evidence in the record as it bears on the issue of whether there is an occupational cancer epidemic due to industrial exposure of workers.

In Part Two of the brief (Sections VIII - X) we shall discuss the shortcomings, both scientific and legal, of OSHA's proposed classification system. We will address the evidence in the record which demonstrates that OSHA's proposal to make generic scientific decisions by administrative fiat is unsound and would "freeze" science in a way inconsistent with the statute.

Part Three (Sections XI - XIV) addresses the issues which arise by reason of the automatic and inflexible way in which OSHA proposes that regulatory action be taken. We shall discuss OSHA's lack of authority to issue an Emergency Temporary Standard without an appraisal of the risk as required by law. We shall review the evidence in the record which demonstrates that OSHA should undertake a quantitative risk analysis and consider how such an analysis should be used in setting exposure levels. And we shall also refer to the record and the statute regarding OSHA's obligation to establish priorities.

Part Four (Sections XV - XVII) deals with the impor-

tance of providing in the regulation for a determination in subsequent standards for exclusion of mixtures containing small quantities of a carcinogen and for determination of an action level. It also discusses three matters which are inappropriate in the Proposed Regulation: rate retention, a permit system and limitations on the use of company doctors. Finally, we point out that key words in both the Proposed Regulation and the proposed standards are impermissibly vague.

Part Five (Sections XVIII - XIX) will address the inadequacies of the proposed model standards.

AIHC believes that the defects in the Proposed Regulation are fundamental. Significant issues such as risk assessment are being decided in the Interagency Regulatory Liaison Group, not in this proceeding. The Agency's interpretation of the basic concept of feasibility will only be made public when the Regulatory Analysis is made public. Similarly, the Agency has not indicated clearly which issues it proposes to decide generically. To make these basic disclosures only in the Regulatory Analysis, as the Agency proposes, renders the notice meaningless since the record is closed. OSHA has commenced overlapping proceedings on access to medical records. AIHC believes that the only prudent course is for OSHA to propose a new revised regulation which corrects the deficiencies of the present proposal and allow public comment on that new proposal.

PART ONE

I

THERE IS NO OCCUPATIONAL CANCER EPIDEMIC

In the Preamble to the Proposed Regulation OSHA discusses the increase in cancer since 1900. 42 Fed. Reg. 54150. Unfortunately, the ambiguous way in which OSHA used the term "environmental factors" as the cause of cancer, together with the way in which OSHA discussed exposure to "man-made chemicals" in the context of a burgeoning "environmental" cancer problem, created the impression that OSHA was attributing the growth in cancer since 1900 to industrial exposure. This has lead to a significant volume of testimony addressed to the issue of whether there is an epidemic of cancer related to workplace exposure to man-made chemicals.

It is not our purpose to review this testimony in any detail. While cancer from industrial exposure is only a small part of the total cancer problem, nonetheless the part industrial exposure plays is important because any cause of cancer is important. It is AIHC's position that whenever a confirmed or highly probable cause of cancer is found in the workplace, there is good and sufficient reason to take prompt and stringent protective action prior to OSHA's promulgation of a standard. Should OSHA conclude that protective action taken by industry is insufficient, it can then insti-

tute regulatory proceedings. It is unnecessary to show that there is an actual or threatened epidemic in order to justify control over worker exposure to identified carcinogens.

Until the post hearing filing by OSHA on September 15, 1978, the statements in the record of government officials (not industry representatives) indicated that the relative contribution of occupational exposure to the total cancer burden was small: 1% to 5% was the most frequent estimate.[1/] Dr. Gori of the NCI and Dr. Wynder of the American Health Foundation in a study prior to this controversy concluded that most of the cancer burden was attributable to life style: diet, tobacco, alcohol and sunbathing, and attributed only about 4% to industrial exposure.[2/]

1/ The British Royal Society Study Group on Lay Term Toxic Effects, of which Sir Richard Doll is chairman, issued a report dated July, 1978. (A copy has been filed in Docket 090). That report states:

> "Many specific hazards of cancer have been traced to occupational exposures to chemicals in industry, though such hazards are not likely to account for more than about 1% of all cancers now occuring in the U.K. A few other cancers could be attributed to pollution by industrial products or industrial waste (e.g. respiratory cancer attributable to asbestos dust). New rapid tests for the detection of the carcinogenic potential of chemicals should enable sources of hazard to be reduced even further." (Id. at 7)(emphasis added).

2/ Ernest L. Wynder and Gio B. Gori "Contribution of the Environment to Cancer Incidence; an Epidemiologic Exercise," 58 J. Natl. Can. Inst. 825, 831 (1977). Reprint in AIHC Bibliography.

On September 15 OSHA filed a document in the record entitled "Estimates of the Fraction of Cancer in the United States Related to Occupational Factors" [hereinafter referred to as the "Estimates Paper"].[1/] This paper purports to set forth a basis for revising the estimated cancer burden attributable to occupational exposure and concludes that an estimated 20% of cancer mortality will be occupationally related in forthcoming decades. (Estimates Paper at 24.)[2/]

AIHC believes that the Estimates Paper is fundamentally flawed and presents a false picture. It is doubly unfortunate that such a new frightful forecast should be presented on the last day for filing evidence without opportunity to question the contributors or to demonstrate the flaws in the estimate. A separate memorandum [hereinafter referred to as the "AIHC Reply"], filed with this brief, contains an analysis by AIHC of the Estimates Paper. In this brief we will summarize the

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1/ The contributors are: Kenneth Bridbord, M.D., NIOSH; Pierre Decoufle, Sc.D., NCI; Joseph F. Fraumeni, Jr., M.D., NCI; David G. Hoel, Ph.D., NIEHS; Robert N. Hoover, M.D., Sc.D., NCI; David P. Rall, M.D., Ph.D., NIEHS, Director; Umberto Saffiotti, M.D., NCI; Marvin A. Schneiderman, Ph.D., NCI; Arthur C. Upton, M.D., NCI, Director. Contributor to the Appendix: Nicholas Day, Ph.D., NCI, IARC.

2/ This figure was selected without explanation as a conservative estimate from a range of estimates of cancer as occupationally related varying from 18% to 38%. The Estimates Paper appears to conclude that there is no way to ameliorate this tragic and frightful forecast. The estimates are "future consequences of past exposure" (Estimates Paper at 16, emphasis in the original). Thus apparently no action by OSHA or any other agency can alter this terrible forecast.

points made in the AIHC Reply.

At the outset it is important to point out tht the Estimates Paper rejects the "one effect-one cause" explanation of cancer and embraces the concept of associated risk while calling it attributable risk. An inevitable consequence of this approach is that attributable causes of cancer exceed 100%. (Estimates Paper at 23.) Thus, for example, worker A who had exposure to asbestos and in uranium mining would have his death of lung cancer attributed both to asbestos and radioactivity exposures. Assume a ten worker cohort with workplace exposure as indicated in the following table and that all died of lung cancer:

Worker	Smoker?	Asbestos?	Uranium?
1	+	+	+
2		+	
3	+		+
4	+	+	
5			
6	+	+	+
7			
8	+	+	
9			
10	+		
	6	5	3

Six deaths would be attributable to smoking, five to asbestos and three to uranium - a total of 14 attributable deaths in 10 workers. The Estimates Paper would claim smoking accounted for 60% of the deaths, asbestos for 50% and uranium for 30%. We now have "attributed" 140% of the deaths without taking into account the attributable risk from genetic susceptibility, diet, alcohol, or exposure to other natural or synthetic carcinogens

in the environment or the body.[1/] Since cancer has attributable causes exceeding 100%, the 20% estimate of occupationally related cancer should not be considered in relation to 100% of the cases of cancer, as is the case with most previous estimates, but to some higher percentage number of all attributable causes. If one conservatively assumes that the total of attributable causes do not exceed 500%, the 20% figure translated to the normal 100% usage would be 4%.

In addition, the Estimates Paper has not addressed the critical question of prevention: whether removal or reduction of one attributable cause has any meaning, if the remaining attributable causes still exceed 100%.

In the same discussion, the Estimates Paper urges that the focus be on "causative factors". (Estimates Paper at 23.) However, the methodology of the Estimates Paper injects a note of confusion with regard to recommendations that OSHA make a risk estimate of the causative factors as part of the regulatory process. No meaningful risk estimate can be made

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1/ Several of OSHA's post hearing filings, including one by Dr. Saffiotti, a contributor to the Estimates Paper, were designed to show that the bionutrients, selenium, cobalt, calcium and estrogens which are essential to life are also contributors to the human cancer burden even at low essential levels. In addition, the calculations by Dr. Nisbet in his comment filed as part of the OSHA post-hearing evidence would indicate a very high risk for non-smokers from exposure to sidestream smoke. Thus each individual inherently has attributable risks from essential bionutrients and an inevitable risk from exposure to tobacco directly as a smoker or indirectly from sidestream smoke.

until a clear distinction is made between associated risk and attributable risk, between association and causation, and between preventable and attributable.

An increased associated risk does not necessarily mean the risk is attributable to exposure in a certain industry. Thus, hypothetical workers in a certain industry may have an increased relative risk of stomach cancer. If the etiological agent is diet, then the deaths are not attributable to occupational exposure. If the stomach cancer were truly attributable to occupational exposure, the mortality should drop by correcting the work environment. In this hypothetical example, correcting the work environment would have no effect because the workers carry an excessive relative risk which is associated with, but not caused by, workplace exposure. Removal of exposure would not prevent the cancer, but adding refrigeration might.

The lack of differentiation between relative risk and attributable risk must be eliminated in a sound methodology of risk analysis. Moreover, the methodology of quantification in the Estimates Paper has the following serious flaws which must be corrected before a sound risk assessment can be made:

(1) The Estimates Paper virtually disregarded dose-response relationships. The estimates were based on relative risk observations in select very high exposure cohorts and then that same risk ratio was applied to all potentially exposed workers without regard to the duration or level or probability of exposure for those individuals.

(2) The estimates of the number of individuals exposed are inappropriately large. The Estimates Paper relied largely on estimated numbers of potentially exposed workers from the National Occupational Hazard Survey ("NOHS") conducted by NIOSH between 1972 and 1974. The NOHS numbers are based on a survey of 5000 establishments and extrapolated to the entire workforce. The NOHS made no distinction between potentially and actually exposed workers or of levels of exposure.

(3) The calculated incidence rates are used in the Estimates Paper to approximate mortality without adjustments for cure rate, or competing causes of death, or shifts in the age structure of the U.S. population.

(4) The methodology of the Estimates Paper makes no attempt to eliminate multiple counting. The NOHS study identified 4.38 billion exposures for 38.2 million employees - an average of 115 potential exposures per worker out of the 198 hazards investigated. The Estimates Paper made no attempt to deal with this multiple counting. If the exposed population numbers in Table II are multiplied by the factor of 5 suggested in the Estimates Paper (Estimates Paper at 13), 59 million workers over 20 have been exposed to the six substances alone. In 1970, the total U.S. worker population over 20 was about 75 million.

(5) The risk ratios were calculated from select highly exposed cohorts and estimates on recent workplace conditions were ignored.

Asbestos. The principal example used for the analysis in the Estimates Paper is asbestos. This analysis is based on an estimated 8-11 million population exposed since World War II ("WW II"), including a cohort of 4,500,000 of WW II shipyard workers.[1/] Of this 8-11 million, 4,000,000 are estimated to have been heavily exposed and "probably" one million have died. (Estimates Paper at 8-9.) The invalidity of the methodology embraced by the Estimates Paper can be demonstrated by applying that methodology to the WW II cohort of shipyard workers.

Assuming conservatively that all the "probable" million deaths occurred in the WW II cohort, one would conclude that 3.5 million exposed workers are still alive. While it appears probable that the WW II cohort was heavily exposed, it is reasonable to allocate the 3.5 million by assigning only 4/10 or 4/7 as heavily exposed and the balance as lightly exposed.[2/] The heavily exposed sub-cohort then is between 1.4 million and 2 million. Using standard mortality rates and assuming the shipyard cohort had the same distribution of men and women workers as the WW II civilian workforce there would be 131,000 deaths expected in

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1/ The basis for the figure of 8-11 million exposed workers has not been explained. In the Estimates Paper the number is referenced through reference (9) to reference (11), which is a speech by Secretary Califano, a rather unusual form of circular reference.

2/ Total exposed 8-11 million less one million dead leaves 7-10 million of which 4 million were heavily exposed. 4/10 of 3.5 million equals 1.4 million; 4/7 of 3.5 million equals 2 million.

this cohort in 1976.[1/] The period since WW II is a long enough latency period (see Estimates Paper referfence 15) for a significant number of deaths to have occurred as a result of asbestos exposure. Seven-to-ten percent of the deaths would be expected to be due to mesothelioma, the "marker" disease for asbestos exposure. On this assumption there would have been 5,200 deaths predicted from mesothelioma among the heavily exposed and over 900 among the less heavily exposed for a total of more than 6,100 deaths annually in the WW II cohort.[2/] This projected epidemic has not materialized.

Surveillance Epidemiology and End Results ("SEER") data for total incidence of mesothelioma for all sites, sexes and races are as follows:

SEER Areas	Total	1973	1974	1975	1976
Connecticut	52	9	13	16	14
New Orleans	12	-- 3/	1	7	4
Atlanta	2	--	--	--	2
Detroit	63	10	22	14	17
Iowa	43	10	15	11	7
Hawaii	6	1	1	4	0
New Mexico	21	5	5	7	4
San Francisco	95	26	22	20	27
Seattle	41	--	11	15	15
Utah	17	2	4	6	5
Total	352	63	94	100	95

1/ On this assumption one third of the shipyard cohort would be women, a conservative estimate since women live longer than men. The detailed calculations to derive the number of deaths is set out in the analysis in the AIHC Reply.

2/ This is the lower bound depending on whether 7% or 10% is used and depending on whether the total exposed population is 7 million or 10 million. The range is about 6,000 to nearly 9,000.

3/ Dashes indicate the area was not in the SEER program in that year.

The SEER population represent about 10% of the U.S. population. Disregarding the fact that the SEER population may have an unusually large number of cases of mesothelioma since five of the areas have a significant shipbuilding industry, these data would indicate a national incidence in 1976 of about 900-1000 cases of mesothelioma, compared to the 6,000 expected deaths in the WW II cohort alone forecast by the methodology in the Estimates Paper.[1/] While the gross cancer statistics may not be "inconsistent" as the Estimates Paper asserts with its total estimates of occupationally related cancer (Estimates Paper at 22), it is extremely difficult to reconcile the forecast of mesothelioma incidence using the methodology in the Estimates Paper with the SEER data.

If one assumed that the WW II cohort had a higher proportion of heavily exposed workers the number of mesotheliomas forecast for 1976 could easily exceed 10,000. However, the assumption that a large number were heavily exposed would also lead to the conclusion that most of the cohort would now be dead.[2/] In

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1/ See "Lung Cancer After Employment in the Shipyards During World War II" published by Blot, Harrington, Toledo, Hoover, Heath and Fraumeni, September 21, 1978 in the New England Journal of Medicine. The authors, two of whom are contributors to the Estimates Paper, found an excess of lung among shipyard workers but the incidence of mesothelioma was no higher than the national average, thus indicating that something other than asbestos exposure may be involved.

2/ See Selikoff, I.J. and Hammond, E.C. "Multiple Risk Factors In Environmental Cancer", "Persons at High Risk of Cancer" at 467-483 (1975). Dr. Selikoff reported that 71% of his cohort of New Jersey asbestos insulation workers on the union rolls in 1943 had died by 1973 and 56% of the cohort of amosite workers first employed in 1941 had died by 1973.

that event, predictions for the future in the Estimates Paper are in error, since the predicted number that "probably" died before 1978 would exceed 1,000,000. Moreover, if the shipyard cohort had the high risks attributed to the heavily-exposed sub-cohort in the Estimates Paper, mesothelioma should have appeared in epidemic proportions in the Third National Cancer Survey, which was not the case.

Chromium (VI). The risk ratio used by the Estimates Paper is questionable. The risk ratio is based on studies of workers heavily exposed between 1945-1955 in the manufacture of chromates from chrome ore using the alkali roasting process. Such exposure conditions no longer exist. Moreover, the Enterline study (referenced in the Estimates Paper) showed a steady decline in the Standard Mortality Rate ("SMR") over the period of observation from 2090 in 1941-1955 to 475 in 1956-1960. Further, the NIOSH Criteria Document for chromium (VI) confirms the pattern of decreased risk at Allied's Baltimore chrome works. There the SMR declined from 680 in 1932-1941 to 160 in 1952-1961, with no cases observed for the period 1961-1974. 1/

The Estimates Paper uses the NOHS figure of 1.5 million workers exposed to chromium. The NIOSH Criteria Docu-

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1/ A recent report on chrome pigment workers found no excess risk among workers with "low exposure" in two factories (exposure dates 1932-1954 and 1948-1967); nor was excess risk found over all exposure levels in a cohort employed during 1955-1967. Some excess of respiratory cancer was found in men with early and heavy exposures. Hayes, R., "A Study of Chromate Production Workers" 1978 Ph.D. (Epidemiology) Thesis, the Johns Hopkins University (I. Press) (1978).

ment (1975) concluded that only 175,000 workers are directly exposed to chromium (VI). Even that figure includes exposure to chromium (VI) compounds where carcinogenesis is merely "inferred". (Criteria Document Table III-5.)[1/]

There is no reasonable basis for using a risk ratio derived from a cohort of workers highly exposed under conditions not found in the industry for many years and apply that risk ratio to a highly inflated exposed-population figure.

Arsenic.[2/] In 1974 OSHA instituted regulatory proceedings to set exposure standards for arsenic. After extensive hearings a standard was published May 5, 1978. 43 Fed. Reg. 19583. The Estimates Paper neither referred to nor cited the extensive data in that record. In the Inflationary Impact Analysis filed April 28, 1976, OSHA made the following estimates of employee exposure to arsenic:

> "4. Employment and Exposure Figures
>
> Employment in all industries directly or indirectly involved in the commercial cycle of arsenic is about 660,000 employees. About 70 to 75 percent of these are production workers and, therefore, potentially exposed to inorganic arsenic. However, a large number of employees included in these figures work in areas where exposures to inorganic arsenicals are very low or non-existent. Relatively few employees are

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1/ The NIOSH Criteria Document (Table XI-3) lists a large number of occupations where there is potential chromium exposure including downstream users where exposure is low and of shorter duration. The National Academy of Sciences study on chromium (1975) found no increased lung cancer risk in the user industries.

2/ There is scientific controversy as to whether arsenic is a carcinogen.

> directly exposed to inorganic arsenicals. Estimates of the affected industries at any one time currently ranges from 1500-1700, for exposure levels of 0.1 mg As/m3 and above, to almost 7000 for exposure levels of 0.004 mg As/m3 and above. Most of the exposed workers are in the copper smelters (especially ASARCO-Tacoma) and wood preserving industries, where exposure levels are also the highest."

OSHA considered and rejected the NOHS 1,500,000 exposed population figure used by the Estimates Paper. That number, OSHA noted, may include some industries that have discontinued use of arsenicals or which involved exposure to organic arsenic.[1/] It is also apparent from the range of exposures which OSHA found that use of a risk ratio derived from smelter workers grossly overstates the risk to "the large number of workers" in OSHA's 660,000 exposed worker population where OSHA found exposures "to inorganic arsenicals are very low or non-existent." The error is doubled by the use of the NOHS estimate in the Estimates Paper.

Nickel. The risk factor used in estimates for nickel is also exaggerated. A 1977 study by Doll, a reassessment of the study referenced in the report, states that the 6-fold excess was confined to persons exposed before 1930 and that no significant excess was seen among persons first exposed during the period 1930-1944 after process changes had been implemented.[2/]

1/ The use of arsenic in agriculture and glassmaking has significantly declined in recent years. Organic arsenic has not been implicated as a carcinogen.

2/ Doll, R., Matthews, J.D., Morgan, L.G. "Cancers of the Lung and Nasal Sinuses in Nickel Workers; A Reassessment of the Period of Risk," Brit. J. of Industr. Med. 34:102-105 (1977).

Moreover, recent work on U.S. workers exposed to nickel since WW II has found no increased association with lung cancer.[1/]

Benzene. The Estimates Paper uses the NOHS figure of 2,000,000 as the exposed population. However, only 48,500 of that population are employees with "full time" exposure. Moreover, the Economic Impact Statement in which Arthur D. Little assesses the economic impact of an OSHA proposed regulation of benzene, estimates that there are 800,000 employees in service stations where exposure is "well below 1 ppm on an 8-hour basis" (at D-4, 4-21).

The Estimates Paper proposes to apply a single risk ratio derived from a single study of highly exposed workers to this heterogeneous population. That study of some workers exposed in a pliofilm plant in Ohio 1940-1949 has been severely criticized. Seven cases of leukemia of various cell types were found among 746 workers. The study, however, did not report the absence of cases among 404 other workers at the plant. There is serious doubt as to the level of exposure at the plant. Records from the Ohio State Laboratory indicate levels of 500 ppm in places where workers spent considerable amounts of time and testimony at the OSHA hearing indicated clothing of workers were drenched, containers of benzene were open and direct contact with benzene was frequent. This would indicate an exposure

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1/ Bernacki et al., "Investigation of Exposure to Nickel and Lung Cancer Mortality: Case Control Study at Aircraft Engine Factory," Am. Clin. Lab. Sci. 8(3):190-194 (1978).

considerably above 10-15 ppm assumed in the study, a level which requires sophisticated equipment for detection.

Thus a risk ratio derived from a flawed study was applied to a population with widely varying exposures, a large segment of which had exposures at very low levels.

Petroleum Products, Including Aromatic Hydrocarbons.

The Estimates Paper uses an estimate of 3,900,000 as the exposed population.[1/] On the assumption that this population coincides with the NOHS category, this population includes only about 60,000 workers with a "full time" exposure in about 30 different industries.

The unreliability of an estimate using a risk ratio derived from a study of coke workers exposed to arsenic, aromatic amines, and ammonia in addition to PNA's, across industries with very different exposures is apparent. The observations in reference 16 are based merely on association in a survey of Los Angeles County. A cross section study of this kind provides no basis for extrapolation across the United States.

Thus an inappropriate risk ratio was applied across a wide range of industries with unexplored ranges of exposure.

1/ This number is stated to be derived from reference 16 but there are no such estimates in that article. Reference 18 gives 2.9 million as the estimated exposed population, a number which is taken from the NOHS data. The Draft Summary of the Estimates Paper released four days earlier gives 3,000,000 as the estimated exposed population.

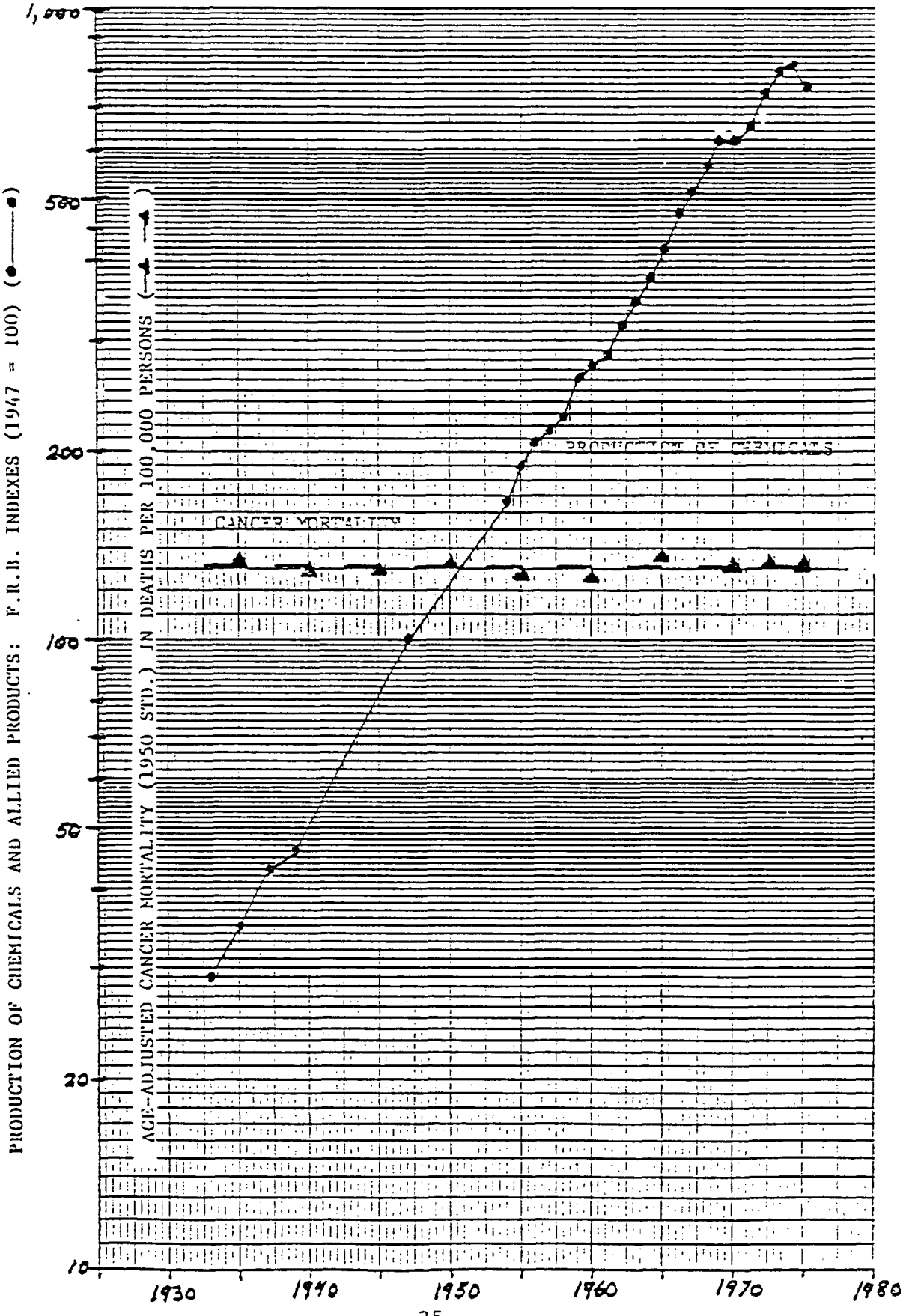
Four days before the Estimates Paper was made part of the record a "Draft Summary" was released. There are significant unexplained differences between the Draft Summary and the final document. Most important, the Draft Summary contained estimates for excess deaths from exposure to (1) coal tar pitch volatiles and coke oven emissions, (2) vinyl chloride, and (3) iron oxide. The Estimates Paper states that these were excluded from the final document because of difficulty in matching data on relative risk to the number of workers exposed. (Estimates Paper at 15.) Vinyl chloride illustrates why the Estimates Paper had difficulties relating relative risk to the number of workers exposed. On the basis of a NOHS exposed population of 2,260,000, the Draft Summary predicted 1940 excess cancers per year most of which would be hemangiosarcoma, the "marker" disease for vinyl chloride monomer exposure. The NOHS data used in the Draft Summary include exposure in some 30 to 40 industries most of which are downstream handling polyvinyl chloride rather than the monomer. The forecast in the Summary of yearly deaths using the NOHS population exceeds by a factor of almost 30 all the known cases of angiosarcoma world wide (about 70) since vinyl began to be manufactured more than 30 years ago. It is to be regretted that the data on other substances in the Estimates Paper were not also reexamined since those data suffer from the same difficulties which led to the withdrawal of estimates on the three substances.

Finally, the Estimates Paper asserts that the increase in production of synthetic organic chemicals is too recent to be

reflected in current cancer statistics. The chart prepared by Professor Jandl indicates that there is no detectible relationship between cancer mortality in the U.S. and the spectacular growth in the chemical industry since 1930.

A chart reproduced on page 35 prepared by Dr. Jandl compares the annual production of chemicals and allied products (using the Federal Reserve Board indices rather than simple poundage) and cancer mortality in the United States. The chart shows that the growth of the chemical industry in the United States has not been associated in any way with an increase in cancer mortality.

FIGURE 10B.
ANNUAL PRODUCTION OF CHEMICALS (1933-1975) VS.
ANNUAL CANCER MORTALITY (1935-1975)



II

OSHA'S AUTHORITY DOES NOT EXTEND TO PROMULGATION OF AN INFLEXIBLE "GENERIC" RULE FOR A WIDE VARIETY OF SUBSTANCES FOUND IN DIVERSE INDUSTRIES

The Proposed Regulation is broad and sweeping. It proposes to establish a single generic classification for all substances which under its inflexible criteria present a human carcinogenic risk. It would apply to all employment covered by the Act, "including general industry, construction, maritime and agriculture." 42 Fed. Reg. 54148. It purports to cover not only this enormous diversity of workplaces, but substances which range in form from solids, liquids, dusts and gases, and range in potency by a factor of a millionfold and more. 42 Fed. Reg. 54165. (Dr. Upton Tr. 318-319.) There are more than 2,400 substances in the NIOSH subfile of "Suspect Carcinogens" to which the Preamble to the Proposed Regulation refers. The variety and range are enormous.

Moreover, the Proposed Regulation proposes to establish a rigid and inflexible set of regulatory consequences which will flow automatically from the classification system without regard to the enormous diversity of workplaces and substances. No distinction is made in the regulatory scheme between exposure to the substances themselves as distinguished from exposure to minute quantities of the substance which may be present in mixtures.

While AIHC believes that it is appropriate for OSHA to issue generic regulations within the limits and subject to

the criteria approved by the courts (see discussion infra, at 43), the OSHA proposal fails to comply with those limitations and criteria.

A. The Inclusion Of Laboratory, Construction And Maritime Workplaces Makes The Proposed Regulation Unreasonably Broad

OSHA proposes to treat laboratory workplaces, both research and other types, and construction and maritime workplaces, in precisely the same manner as other industrial workplaces. OSHA offered no evidence concerning the application of these regulations to the construction industry, maritime industry or agriculture. AIHC believes, and we believe the record shows, that there is a need to exempt these kinds of workplaces from this regulation and deal with these workplaces in appropriate separate regulations.

Laboratories. Industrial and academic quality control and research laboratories, unlike most industrial workplaces, typically handle many substances in very small quantities for short periods of time. It is these conditions which make the Proposed Regulation inappropriate for laboratories.[1/]

1/ For a discussion of the laboratory problem, see the comments filed by the University of Rochester, University of Minnesota, the California Institute of Technology, Johns Hopkins University, Mayo Clinic, Association of American Cancer Institute and Johns Hopkins University School of Medicine.

See also NIOSH Answer to OSHA Question 8; AIHC Tr. 3836-3839. Further, the persons working in laboratories are usually well-educated scientists who appreciate the hazard with which they are working. See, e.g., UpJohn Tr. 4233-4239, 4265-4273; Uniroyal Tr. 8260-8261.

If the Proposed Regulation is adopted without modification of its scope, laboratories, which typically handle many of the substances that might be subject to this regulation, apparently would be required to monitor each time a carcinogen (typically in a very small quantity) is introduced into the laboratory workplace; they would be required to keep innumerable records and to file innumerable notices of use with OSHA; they would be required to have separate vacuums for each substance used in the laboratory; and further, they would be required to clutter the laboratory with dozens of signs.[1/] It is requirements such as these which independent, university and other laboratory representatives stated would significantly impede their research efforts; including, ironically, in some instances cancer research See, e.g., American Industrial Hygiene Association Tr. 8492. Not only would these provisions reduce laboratory productivity, they would also be extremely costly. See Snell Report, Chapter VII; see also Dr. Campbell Tr. 3306-3308.

AIHC is not suggesting that laboratory workplaces are not in need of regulation. We are, however, suggesting that what is appropriate for a large chemical plant may not be appropriate for an academic or industrial research or quality control laboratory. Representatives from labor also acknowledged

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1/ Many of the provisions of the standards are inappropriate for most laboratory situations, such as the provisions requiring a compliance program for each substance even though it may be used infrequently and in very small quantities.

that it might be more appropriate to set vertical standards for laboratories rather than proceed in the manner suggested by OSHA. (Tr. 5765.) Dr. Squire also favored separate regulations for laboratories which do not regularly use a particular chemical. (S. 31-32.)

In this connection it is significant that the Committee to Coordinate Toxicology and Related Programs of the Department of Health, Education and Welfare ("DHEW") has just released a document entitled "Guidelines for the Laboratory Use of Chemical Substances Posing a Potential Occupational Carcinogenic Risk." (AIHC P.H.) An open meeting for comment was held on September 25, 1978 and written comments have been invited. It is clear that the special problems of laboratories are being addressed by DHEW. Certainly OSHA should await the results of the work of that committee before adopting any regulation for laboratories.

OSHA offered no evidence to show that this inflexible generic standard is appropriate for control of exposure in laboratories. Those organizations which operate laboratories presented facts showing that the Proposed Regulation was unreasonable in its application to laboratories. See also AIHC P.H. (Dr. Campbell's submission). The special problems of laboratories are being addressed by DHEW. Upon this record, it is unreasonable to apply the Proposed Regulation to laboratories. OSHA should publish a new proposed regulation for laboratories and provide a reasonable opportunity for comment.

Construction and Maritime. The National Constructors Association, the Asbestos Information Association of North America and the West Gulf Maritime Association presented evidence demonstrating that construction and maritime workplace characteristics differ markedly from typical industrial workplaces. Construction workplaces and workforces are often temporary and transitory. Turnover rates may be as high as 600% per year for large industrial contractors and even higher for smaller construction contractors. Workplace conditions also vary considerably depending on the precise nature of the project and the particular task in question. (Nat'l Constructors Ass'n Tr. 7123-7124; Asbestos Info. Ass'n Tr. 7696-7714; West Gulf Maritime Ass'n Tr. 7171-7172.)

Among the many provisions which seem out of place are those which require employee notification and recordkeeping, without regard to the transitory nature of the workforce. (Asbestos Info. Ass'n Tr. 7709-7710.) In addition, for construction workplaces, particularly remote ones, the kinds of hygienic facilities demanded by the model standards are simply often not realistically available. Certainly it is not possible to maintain, as the regulations would require, construction surfaces free of accumulations. Further, it seems to make little sense to require, as the regulations would, a separate compliance report reviewing engineering controls for each substance in such workplaces.

OSHA has in previous standards recognized the need

for special consideration for construction and other workplaces. Indeed, OSHA has appointed a separate Advisory Committee on Construction Safety and Health to address the peculiarities of this industry. We would urge that similar consideration be given here. 1/

Agriculture. The record is virtually barren of evidence by OSHA concerning the need for, or the reasonableness of, the Proposed Regulation as it applies in agriculture. There is no discussion of agricultural workplaces in the Preamble nor are the special problems of agriculture addressed. If in a separate proceeding OSHA presents facts showing the need for, and reasonableness of, a generic regulation applicable to the agricultural workplace, a generic regulation may be authorized. No such showing has been made here.

B. OSHA's Sweeping And Inflexible Proposed Regulation Is Unauthorized Under The Statute

As its authority for promulgating the Proposed Regulation, OSHA has cited Sections 6(b), 8(c), and 8(g) of the Act, 29 U.S.C. §§ 655(b), 657(c) and (g). 42 Fed. Reg. 54148. None of these sections (except to the extent that Section 8(c) permits OSHA to promulgate general rules on recordkeeping and notices) speaks to OSHA's authority finally to decide in one massive proceeding the many technical, scientific, procedural and legal

1/ OSHA has dealt with exposure to asbestos in the maritime and construction industries. 29 C.F.R. § 1910.1001. Regulation of exposure to other specific substances may be appropriate prior to the issuance of a generic standard for these industries.

issues underlying the Proposed Regulation. To the contrary, Section 6(b) requires that OSHA proceed, as it has consistently in the past, to resolve these issues in the context of the promulgation of occupational safety and health standards for specific toxic substances. While there is room, as we shall discuss infra, at 51, for OSHA to issue limited generic regulations, any such regulations must be based on the statutory plan embodied in Section 6(b), under which issues as to the regulation of specific substances will be resolved in the context of the promulgation of standards for each of those substances. OSHA cannot depart from the statutorily mandated procedure under which it must consider each standard in the light of feasibility and on the basis of the "latest available scientific data" with respect to the particular substance. Moreover, by excluding evidence on generically determined issues in subsequent Section 6(b) rulemakings for the issuance or modification of standards, OSHA will deny affected parties their legal right to comment upon, or offer evidence on, these issues as they relate to specific toxic substances.

In view of the diversity of the underlying subject matter, OSHA does not have authority, under the Act or otherwise, to adopt a generic regulation of the type that it has proposed, in which inflexible standards are set for all substances meeting predetermined criteria.[1/] The Proposed Regu-

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1/ The present rulemaking differs fundamentally from situations in which agencies have promulgated rules of

(Footnote continued on p. 43)

lation fails to comply with the provisions of Section 6(b)(5) of the Act, 29 U.S.C. § 655(b)(5), regarding the promulgation of standards for toxic materials, which require specific consideration of "the latest available scientific data in the field, the feasibility of the standards, and experience gained under [the Act] and other health and safety laws."

In the Preamble to the Proposed Regulation, OSHA cites three cases as authority for its departure from the statutory procedure set forth in Section 6(b). 42 Fed. Reg. 54154. These are United States v. Storer Broadcasting Co., 351 U.S. 192 (1956), Federal Power Commission v. Texaco, Inc., 377 U.S. 33 (1964), and Airline Pilots Association v. Quesada, 276 F.2d 892 (2d Cir. 1960). These cases, however, deal with situations fundamentally different from the present rulemaking.

Each of these cases cited by OSHA involved an agency to which Congress had delegated broad powers of control over an area of economic acitivity to which access was made subject to agency authorization by license or permit. The reviewing courts found the broad rulemaking authority exercised by the agencies to be within Congress' intent. In contrast, nothing in the Act or in its legislative history suggests that Congress

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(Footnote continued from p. 42)

general application to cover a variety of items or situations that are essentially uniform in the features affected by the rule. Whether OSHA has authority to make inflexible rules for a particular category of substances where true uniformity in fact exists would depend on the facts in the particular case.

intended to delegate sweeping and unrestricted authority to OSHA to regulate by an inflexible generic scheme all industrial and business activity without adherence to the carefully delimited procedures and criteria set forth in Section 6(b) of the Act.

In each of the cases cited by OSHA, the administrative agency, after affording opportunities for interested parties to comment, issued a regulation relating to a single specific act: ownership of a sixth television station (Storer), inclusion of certain price escalation clauses in contracts for sale of natural gas (Texaco), and piloting a commercial airliner after age sixty (Quesada). The situations covered by the regulation in each case, while not totally identical, are both simple and uniform. The interested parties could easily determine the effect of the regulation upon their businesses or profession and frame their comments accordingly. Thus, each of the regulations in question was adopted after the agency received as complete a picture as possible concerning its effect on the regulated parties, who were easily identified. The reviewing courts found the parties' hearing rights satisfied because they could be identified and hence had an opportunity to effectively comment upon the proposed regulation as it would apply to them. The present case stands in stark contrast. Rather than a single specific prohibition, OSHA has proposed a complex regulation which effectively would decide in an inflexible manner a myriad of scientific, technical, procedural and legal issues to be

automatically applied in the subsequent promulgation of occupational safety and health standards for specific substances which are in no fashion uniform, or even similar. It is therefore virtually impossible for interested parties in these circumstances to anticipate fully the potential effect of the Proposed Regulation on their business.

OSHA has compounded the difficulties faced by interested persons wishing to meaningfully comment upon the Proposed Regulation by failing to identify clearly the many principles and concepts which OSHA intends to generically resolve in the proceeding. OSHA's stating that its forthcoming regulatory analysis "will demonstrate what issues are intended in the generic approach to be foreclosed from further rulemakings" is a clear admission by OSHA of its failure to date to provide such information to the public. (Memorandum from Messrs. Morris and Wrenn to Ms. Bingham and Mr. Wellford, dated August 3, 1978 (AIHC P.H.).) Thus, the public has been forced to comment upon the broad-ranging Proposed Regulation in a general manner, without any real notice as to the specific issues OSHA intends to resolve generically in this proceeding.

The fact that OSHA failed to make a regulatory analysis of the significant issues involved in the Proposed Regulation, as required by Executive Order 12044, also denied members of the public the benefit of OSHA's discussion of the particular issues and alternatives which OSHA considered. The fact that OSHA has agreed after the hearings were closed to make an

analysis of the regulatory issues and "realistic alternatives" (see supra, at 6-7) underlines the inadequacy of the notice which the public received and their inability to participate meaningfully in a hearing on generic issues. In its proposed review, OSHA will also "look at alternative criteria for the classification of substances within the generic standard." There was no way that participants could meaningfully participate in these hearings without this information.

C. The Provisions In The Proposed Regulation For Waiver Or Amendment Are Inadequate

In both Storer and Texaco, supra, the Supreme Court found that the parties' statutory hearing rights also were satisfied, in part, by the agencies' providing procedures by which parties could seek waivers or amendments to the respective regulations. United States v. Storer Broadcasting Co., supra, at 201, 205; Federal Power Commission v. Texaco, Inc., supra, at 40-41. OSHA has made no comparable provision in the Proposed Regulation. It is difficult to conceive how OSHA could entertain such requests in view of its expressed intention to foreclose future discussion of the many issues being generically addressed in this proceeding. It is equally difficult to conceive how a fair waiver procedure could be created in the face of the vast range of carcinogenicity issues, the great diversity of physical properties exhibited by substances, and the wide variations among workplaces (including farms, ships, factories, laboratories and

and construction sites) in which the Proposed Regulation would be applied.

OSHA has stated in a footnote in the Preamble to the Proposed Regulation that it "will encourage petitions for amendments to these regulations, including the model standards, as conditions so warrant." 42 Fed. Reg. 54149 n.2. OSHA has issued no guidelines indicating how it will handle amendments. More importantly, however, Mr. Wrenn's testimony clearly demonstrates that OSHA has no intention of considering requests for waivers or amendments in the context of a rulemaking proceeding for a specific substance. Rather, such requests would be considered in a separate rulemaking proceeding convened for consideration of the requested waiver or amendment. (Wrenn Tr. 148-149, 151.) By definition the classification system would apply to a particular substance unless there was an amendment to the Proposed Regulation. While the standard setting proceedings on the substance and the proceedings to amend the Proposed Regulation could be parallel, the person involved in the standard setting proceeding could not seek an amendment to the Proposed Regulation which his facts justify in the proceeding on the individual substance. The proposed procedure is legally improper under the Storer and Texaco decisions since the affected parties would be denied the right to seek an amendment or variance as to a particular substance, an essential element of a valid generic regulation.

D. The Proposed Regulation Violates The Due Process Clause

The conclusion that the Proposed Regulation is unlawful is reinforced by the decisions of the Supreme Court holding that a regulation based on irrebuttable presumptions of fact which do not give parties adversely affected an opportunity to demonstrate the incorrectness of the presumption is a violation of the Due Process Clause of the Constitution. Stanley v. Illinois, 405 U.S. 645 (1974); Vlandis v. Kline, 412 U.S. 441 (1973); Cleveland Board of Education v. La Fleur, 414 U.S. 632 (1974). The Vlandis case involved an irrebuttable presumption of non-residence for a student who initially matriculated as a non-resident, thus charging the student at the higher non-resident tuition rate. Rejecting this presumption which barred the student from showing he had become a resident, the Court said:

> "[I]t is foribdden by the Due Process Clause to deny an individual the resident rates on the basis of a permanent and irrebuttable presumption of non-residence, when that presumption is not necessarily or universally true in fact, and when the State has reasonable alternative means of making the crucial determination." 412 U.S. at 452.

Many of the generic administrative policy decisions proposed by OSHA are irrebuttable presumptions of fact under the Proposed Regulation. Thus the policy determination that a safe level or threshold cannot be determined for a carcinogen is a presumption of fact which is not necessarily universally true. But the policy determination will prevent presentation

of evidence that as a matter of fact there is a threshold for a particular substance until the generic policy has been amended. Thus Grover Wrenn testified that a scientific breakthrough, such as "strong evidence" of a threshold for a particular substance, would be rejected in a rulemaking on that substance; the data would be considered only after the generic regulation had been amended. (Tr. 148-149, 151.) OSHA's position on this amendment procedure effectively prevents presentation of evidence of a threshold, even if the regulatory action on the particular substance and the petition to amend are conducted simultaneously. There is no realistic possibility of an amendment to the generic regulation within the mandatory six-month time frame for regulation of particular substances under the proposal. The generic determinations therefore become irrebuttable presumptions of fact which violate the Due Process Clause. Moreover, as the Supreme Court recently held, administrative convenience is not a valid basis for disregard of Constitutional rights. Marshall v. Barlows, Inc., ___U.S. ___, 44 L.W. 4483 (decided May 23, 1978). In addition, the Benzene decision confirms that the use of a generic standard to exclude data contrary to the generic policy determinations violates the Act.

Apart from the constitutional issues raised by the irrebuttable presumptions of fact incorporated into the Proposed Regulation, the classification procedure inherently results in the denial of due process to affected persons. Under that procedure, classification of substances will occur based

on generically resolved and woodenly applied criteria prior to a scientific evaluation of the evidence of carcinogenicity. Considerable adverse publicity and a substantial drop in business may occur for any substance labeled a carcinogen, yet OSHA demonstrates an intent to apply such labels before an appropriate scientific review is undertaken. The AIHC Alternative avoids this violation of due process rights by providing for review of the evidence of carcinogenicity by the Data Evaluation and Classification Panel prior to any provisional classification.

The putative classification of substances in the NIOSH "Suspect Carcinogens" list by Clement issued July 14, 1978 (Ex. 132) well demonstrates the violation of due process rights which is inherent in the classification procedure in the Proposed Regulation. Persons now producing or using the substances found on that list face great uncertainty regarding the future production and distribution of their products. The use of these substances, many of which serve valuable functions, could be effectively restricted or banned as industry and the public reacts to the listing of these substances as carcinogenic. Errors in the Clement list may eventually be demonstrated but significant, irreparable harm to industry and to the public may have been done in the interim. In short, the Clement list is likely to operate as a carcinogen "blacklist". Similarly, proceedings on individual substances will "blacklist" those substances for the months between provisional classification and the operation of the artificial rebuttal process where an appropriate scienti-

fic review will first be undertaken.

E. The AIHC Alternative Satisfies The Criteria For A Valid Generic Regulation

The AIHC Alternative, while it has the same objective as OSHA's proposal -- regulation of workplace exposure to carcinogens -- differs from the OSHA proposal in significant ways relevant here.

First, the AIHC proposal would apply only to industrial workplaces. Until OSHA proposes valid generic standards, regulation of workplace exposure in agricultural, transportation, and construction industries and in laboratories would be on an individual substance basis under Section 6(b).

Second, in contrast to the Proposed Regulation, the AIHC Alternative sets forth a system for identifying and regulating suspected carcinogens in the industrial workplace which would operate expeditiously while maintaining sufficient flexibility to regulate substances in light of their different properties. The Alternative would not attempt to freeze science nor exclude relevant facts from consideration in a rulemaking proceeding. The criteria for categorizing substances set forth in the Alternative would require the proposed Data Evaluation and Classification Panel to exercise scientific judgment on the basis of all the relevant evidence, rather than by applying rigid, overly simplistic criteria which are proposed for their supposed ease of administration.

Nor does categorization under the AIHC Alternative dictate an automatic regulatory response. Instead, sufficient flexibility is maintained by calling for risk/hazard/benefit analyses, providing for mixtures and action levels, and not mandating the control of exposure to the "lowest feasible level" regardless of the factual showing as to the danger of exposure.

Finally, the Alternative specifically authorizes the Panel to propose revisions of the catgorization scheme or the criteria in light of scientific advancements, additional information, or experience with the categorization scheme. Reasonable notice of intended changes and an opportunity to comment are to be afforded the public, in accordance with the Administrative Procedure Act. Thus a reasonable method of providing for variances and amendments is provided as required by Storer and Texaco.

III

SINCE OSHA INTENDS TO ENLARGE THE PROPOSED REGULATION IN UNDISCLOSED BUT SIGNIFICANT WAYS, A HEARING ON THE INCOMPLETE REGULATION IS WITHOUT MEANING AND DENIES DUE PROCESS

In his opening statement Mr. Wrenn stated that "OSHA's proposed classification scheme involves the development of criteria for conducting and ultimately evaluating animal and human studies." (Wrenn S. 4.) During his testimony Mr. Wrenn expressed the hope that ambiguous terms would be clarified and criteria be more firmly set after the hearing. He agreed that to the extent criteria for well conducted tests can be identified, it would be desirable to set forth such criteria in the regulations. (Tr. 227.) However, Mr. Wrenn was unable to identify the criteria being considered or to indicate how the impact of the criteria could be examined in the course of the hearing. None of OSHA's witnesses was able to describe or identify these criteria. 1/

It is apparent from Exhibit 34 2/ that the criteria

1/ With respect to risk assessment procedures, Dr. Albert stated that he had reviewed a first draft being considered by the Interagency Regulatory Liaison Group on risk assessment, but was unwilling to describe the draft because it was being changed significantly and a second draft was being circulated. (Tr. 2319.) See discussion of risk assessment infra, at 56.

2/ Exhibit 34 consists of the prepared statements of Douglas M. Costle, Administrator, Environmental Protection Agency, Eula Bingham, Assistant Secretary of Labor for Occupational Safety and Health Administration, John Byington, Chairman, Consumer Product Safety Commission, and Donald Kennedy,

(Footnote continued on p. 54)

which are being considered by OSHA are in fact of great significance and could have a major impact on the operation of the Proposed Regulation. On August 2, 1977, OSHA, the Environmental Protection Agency ("EPA"), the Food and Drug Administration ("FDA") and the Consumer Product Safety Commission ("CPSC") entered into an agreement to form an Interagency Regulatory Liaison Group ("IRLG") to coordinate the activities of the four agencies.[1/] In the written agreement dated September 26, 1977, the four agencies agreed to endeavor to develop, inter alia, "common, consistent, or compatible":

> "1. Testing protocols, criteria for interpretation, quality assurance procedures, and other policies relating to the testing of toxic and hazardous substances;
>
> 2. Epidemiological practices and procedures;
>
> 3. Approaches to the assessment of risk presented by a toxic or hazardous substance and to the estimation of benefits associated with a substance."

(Footnote continued from p. 53)

Commissioner, Food and Drug Administration before the Subcommittee on Environment and Atmosphere, House Committee on Science and Technology, April 25, 1978. Attached to the prepared statements are materials furnished by the witnesses as supporting materials consisting of the Interagency Agreement, President Carter's letter to the IRLG, the IRLG work plans set out in the Federal Register for February 17, 1978 (43 Fed. Reg. 7174), a memorandum entitled "Examples of IRLG Accomplishments," and press clippings and news releases.

1/ The agreement is included as supporting materials in Exhibit 34.

Thus two months before the Proposed Regulation was published, OSHA, as part of the IRLG, was participating in an inter-agency program to develop outside this regulatory proceeding criteria and standards essential to the operation of the Proposed Regulation. The progress of the IRLG toward these objectives is apparent from the IRLG work plan published February 17, 1978.[1/] In that Work Plan, the IRLG disclosed the formation of eight working groups and detailed the functions of each group.

Mr. Costle described the objectives of the IRLG at the hearing on April 25, 1978:

> "Based on their investigation and discussions, the IRLG presented us with a report suggesting seven possible initiatives which they felt would contribute to the goals we had set ourselves. They included an attempt to evolve common, consistent, or compatible approaches to testing criteria and policies, risk assessment, information acquisition and exchange, research and development policies (possibly including methods of sharing costs and facilities), joint regulation and regulatory development activities, compliance and enforcement procedures and policies, and public communication and education. We added an eighth, the coordination of epidemiological practices and procedures. We decided to implement them all." (Ex. 34, Costle S. 3.)

A. IRLG Work Group Activities Closely Parallel And Involve Subjects Which Are Under Consideration In This Proceeding

The objectives of three IRLG work groups are of

1/ The Work Plan as published in the Federal Register on February 17, 1978 (43 Fed. Reg. 7174), is attached as supporting material in Exhibit 34.

particular interest here: Epidemiology, Risk Assessment, and Testing Standards and Guidelines.

Epidemiology. The objectives of this work group are described in the IRLG Work Plan as follows:

> "While it is not intended that a standard model would be developed against which epidemiologists would mold their research, we believe it is necessary to develop minimum criteria by which submitted studies can be objectively evaluated." (Ex. 34, 43 Fed. Reg. 7186.)

Mr. Costle advised Congress that the IRLG hopes to have the epidemiology criteria complete by late 1978. (Ex. 34, Costle S. 8.)

Risk Assessment. In the Preamble to its Proposed Regulation OSHA invites comments on the question whether a risk assessment should be employed by OSHA. 42 Fed. Reg. 54167. There has been extensive testimony in the record on risk assessment and the methods and procedures to be used. See the discussion of risk assessment beginning infra, at 197.

In the meantime the IRLG Risk Assessment Group under the chairmanship of Assistant Secretary Bingham is pursuing the following objective:

> "The Risk Assessment Work Group will develop procedures and criteria that can be uniformly applied by the four agencies for purposes of characterizing and quantifying human health risks associated with certain chemicals." (Ex. 34, 43 Fed. Reg. 7195.)

The task of the Work Group was described as follows:

"5. Task of the Work Group - An objective of the Work Group might be the development of systems to insure that the agencies routinely work together to conduct risk assessments on specific substances of mutual interest. However, the Work Group holds that such an objective is far less important than the broader one of developing and selecting general procedures and criteria for risk assessment that can be uniformly applied to all chemicals regulated by the agencies, including those substances for which only one agency is responsible.

Until the rules for risk assessment are clearly laid out and agreed upon, efforts to reach a consensus of the type and degree of risk associated with specific substances of mutual concern will in many instances be thwarted. Furthermore, in the absence of uniform criteria and procedures, the risks associated with chemicals that are the responsibility of only one agency will continue to be estimated in a different manner than those associated with chemicals regulated only by a second agency. This undesirable situation will not be remedied if the task of the Work Group is limited to the joint conduct of risk assessments on substances of mutual interest." Id.

This work group is addressing specific subjects being considered in this hearing.

"R.A.1.3 - Procedures for Quantifying Carcinogenic Risk.

Output: Procedures for treating available dose-response relationships to estimate risk at expected or known levels of human exposure.

Task - The subgroup will survey the risk estimation procedures currently in use by the agencies. Reasons for the use of specific procedures, including relevant legal matters, will be detailed.

An updated review and discussion of all current mathematical models will be undertaken, including consideration of time-to-tumor analyses as a preface to the final selection of a model(s). The final document will include procedures for combining data from

several experiments, use of human data, and modifications based on metabolic and kinetic data." (Ex. 34, 43 Fed. Reg. 7197.)

In her testimony before the House Committee Dr. Bingham said:

> "This Work Group is now developing a carcinogenesis risk assessment guideline that is to be reviewed by the IRLG member agencies next month. The guideline will then be published in the Federal Register for public comment. We expect the final document to be ready by October. The carcinogenesis guideline is a general educational device to alert the public to the dangers of chemical carcinogens as well as a manual for Federal agency scientists. This guideline will contain specific criteria for judging the likelihood that a chemical is a human carcinogen, procedures for treating available data to estimate human exposure to suspect chemicals, and procedures for attempting to quantify carcinogenic risk." (Ex. 34, Bingham S. 3 (emphasis added).)

The progress made by the group is set out in the memorandum entitled "Examples of IRLG Accomplishments."[1/] In that memorandum the carcinogenic risk assessment was described as follows:[2/]

> "The carcinogenesis document contains three parts:
>
> (1) criteria for judging the likelihood that a chemical is a human carcinogen, including a review of the significance of various types of data;
>
> (2) procedures for treating available data to estimate type, level, and extent of human exposure to suspect chemicals, including a survey of approaches used by the four agencies; and

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1/ Attached as supporting materials to Exhibit 34.

2/ Id. at 5.

(3) procedures for quantifying carcinogenic risk, i.e., procedures for treating available dose-response relationships to estimate risk at expected or known levels of human exposure."

In a joint letter dated June 8, 1978 to Mr. W. Bowman Cutter, Executive Associate Director for Budget, Office of Management and Budget, the heads of the four IRLG agencies described the objective of the Risk Assessment Group:

> "As mentioned previously, procedures and criteria for identifying carcinogens are being developed by the IRLG Risk Assessment Work Group; a draft document will be circulated to the agencies this summer and to the public in early fall. The document will define the criteria for the use of scientific evidence in determining carcinogenic risk as a basis for establishing regulatory policies. It will deal with at least the following issues:
>
> 1. The extent to which, and the circumstances under which, mammalian animal studies will be relied upon in identiifying potential carcinogenic substances and in evaluating their impact upon human health.
>
> 2. Appropriate species of animals for carcinogenic testing.
>
> 3. Whether threshold or safe levels of exposure to carcinogens can be established.
>
> 4. The types of tumors and other lesions that indicate a carcinogenic effect or potential.
>
> 5. The appropriate routes of administration used in animal testing and the circumstances under which the route of administration affects the extrapolation of data from animals to humans.
>
> 6. The circumstances under which the use of high doses in animal tests is appropriate and valid.
>
> 7. The implications of similarities in chemical structure.

8. The relative weights that should be given to different types of evidence (e.g., epidemiological and animal studies) where the results reinforce or contradict each other.

9. The extent to which results from various in vitro tests can be applied to the assessment of risk." (AIHC P.H.)

Testing Standards and Guidelines. The Work Group on Testing Standards and Guidelines has the following objectives:

> "The Work Group has agreed that the following tenets will be applied as it proceeds with the task to develop testing guidelines, criteria for interpretations, quality assurance procedures, and other policies relating to the testing of toxic and hazardous substances." (Ex. 34, 43 Fed. Reg. 7197.)

The work of this group is supplemented by the Risk Assessment Group:

> "As a first task, the subgroup will address the significance of various types of data including those from epidemiologic studies, animal bioassay studies, short term, in vitro tests, chemical structure, metabolic data, etc. Statistical procedures for treating animal data to establish significance will also be detailed.
>
> The subcommittee will identify those problems attendant to the evaluation of data as evidence that an agent poses a carcinogenic risk and, where guidance is not available, will make recommendations for resolving difficult issues. A particularly troublesome issue to be treated is that of deciding the extent of testing required before a chemical can be classified as posing no carcinogenic threat. This matter is important for substances (e.g., food additives) requiring premarket clearance." (Ex. 34, 43 Fed. Reg. 7196.)

B. Key Issues Being Decided In Another Forum Will Be Unlawfully Applied Here

It is perfectly plain from this brief summary of the

work of the IRLG that the criteria, methods and procedures of risk assessment and quantification being developed by the IRLG go to the heart of the Proposed Regulation.

In a speech entitled "Goals of the Risk Assessment Work Group of the Interagency Regulatory Liaison Group," Dr. Rodericks (Special Assistant to the Bureau Director for Science Policy, Food and Drug Administration, Bureau of Drugs) stated:

> "We intend to provide detailed guidance on the evaluation of the various types of scientific data. Several such guidelines are available, but they do not supply the specificity needed to ensure a high degree of uniformity in the evaluation of test data. For example, some guidelines state that animal bioassays can be profitably evaluated only if they have been 'adequately designed and conducted.' We have no disagreement with such a guideline, but, if it is the only guidance available, it is almost certain that different scientists will have different notions of the term 'adequately'. Uniform evaluation of bioassays cannot be achieved without development of guidelines with greater specificity. We are attempting to add the necessary specificity and a large part of our guideline will be devoted to fairly detailed discussions of the dozen or so important bioassay variables and how they are each to be evaluated in reaching conclusions about the evidential value of a bioassay." (Ex. 147 at 6-7 (emphasis added).)

Until it is possible to examine these criteria and standards, there is no way to assess the Proposed Regulation.

The hearing therefore is being held in a vacuum. While witnesses are addressing the questions, the key issues are being decided in another forum. No adequate or valid hearing can be held until the parties know what criteria and standards essential to the operation of the Proposed Regulation are being considered and adopted in the IRLG.

Nor can the participants be afforded due process by being provided with an opportunity to comment on the work product of the IRLG at some later date. There will be no opportunity in such a hearing to demonstrate that the Proposed Regulation should, upon consideration of the new criteria and risk assessment procedures, be amended. Thus, for example, while risk assessment, as OSHA recognizes, is relevant to the level of control for a particular substance (42 Fed. Reg. 54167), comment on the use of risk assessment for that purpose would be frustrated by the policy determination that control shall uniformly be imposed to achieve lowest feasible exposure. 42 Fed. Reg. 54166. Similarly, comment on the criteria for carcinogenicity adopted by the IRLG would have no meaning if OSHA has already adopted the criteria for its categories.

IV

THE PROPOSED REGULATION IS AN OPEN-ENDED ASSERTION OF REGULATORY AUTHORITY LACKING IN THE NECESSARY CONSTRAINING CRITERIA AND GUIDELINES WHICH MIGHT LIMIT ARBITRARY AGENCY ACTION

The foregoing section discussing the work of the IRLG makes clear that the Proposed Regulation is skeletal and incomplete. No standards or criteria are set forth for judging the validity of animal tests or human epidemiological studies. The need for such criteria is underscored by the provisions in §§ 1990.110(b) and 1990.120(b) which permit categorization of a substance on an open-ended basis of "evidence sufficient to convince" the Secretary that the substance should be classified in Category I or II. This open-ended unrestricted basis for classification finds no support in law or in the record.

The need for criteria for the conduct of tests and for identification and evaluation of data is made clear by the IRLG Work Plan discussed supra, at 55.[1/] Nor does OSHA lack the resources to set out relevant criteria. In July 1977, three months before the Proposed Regulation was published, OSHA entered into a contract with Clement Associates to screen the NIOSH list of suspect carcinogens and to evaluate, prioritize and categorize

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1/ In a post-hearing statement Dr. Heston listed environmental factors which influence the incidence of tumors in inbred mice: age, hormonal status, diet, temperature, parasites, etc. (Ex. 224-G.) He stressed the importance of performance standards in relation to validity of the test results.

suspect workplace carcinogens. (Ex. 12.) The Agreement dated July 13, 1977 provides:

> "Within six (6) months from the approval of the initial plan, the contractor shall have initially screened the substances to determine the preliminary OSHA Categories I, II, and III. In the interest of orderly regulation, those that exhibit extreme and/or confirmed carcinogenic effects should naturally take primary importance, but those with weak effects should also be thoroughly screened to reduce uncertainty. Scientific expertise and judgment will play a great part in this step of the process. . . .
>
> (1) Contractor's experts in chemical carcinogenesis shall establish criteria for categorization, with the realization that this material does not lend itself to rapid systemization. Again, expert judgment will largely determine these criteria.
>
> (2) The scientists will then critically analyze and review all carcinogenicity and other data. These data will be systematically screened and evaluated on the following points:
>
> * the appropriateness of the method and route of exposure to test animals for indicated occupational exposure risk in humans and the suitability of the experimental animal species used
>
> * the adequacy of test protocols for determining carcinogenicity, particularly with regard to:
>
> -- the experimental design and its conformity to accepted protocols
>
> -- sample size
>
> -- the quality of the pathology review
>
> -- statistical significance of positive results
>
> -- adequacy of reporting results
>
> * for epidemiological studies in humans:
>
> -- adequacy of medical records and diagnoses

-- statistical significance of positive results

-- reliability of data on degree of exposure to the suspected carcinogen and to any other material which could affect results

* the degree to which animal results can be extrapolated to human risk from occupational exposure, and where appropriate, review of of comparative metabolism

The contractor will attempt to deveop a semi-quantitative scale, upon which each chemical will be ranked according to several independent, relevant factors. The weighted sum of the rankings may then establish an order of chemicals. The factors to be ranked may include, but may not necessarily be limited to, the following:

* qualitative and quantitative presence (when available) of the toxic material in the workplace, data to be drawn from several sources mentioned in contractor's proposal

* degree of confidence to be placed in results of studies, e.g. has the study been duplicated?"

Thus OSHA has instructed its contractor to develop the very criteria which are necessary to evaluation of the scientific data: potency, risk quantification, criteria for evaluating tests and human studies, priorities, etc.[1/]

As a member of IRLG, OSHA is working on the preparation of criteria which would have a major impact on the substance and operation of the Proposed Regulation. Some clue to the type of criteria for the conduct and evaluation of animal data being considered by the IRLG is provided by the rule proposed by EPA

1/ Recommended procedures for chronic animal tests are set out in the National Cancer Institute's "Guidelines for Carcinogen Bioassay in Small Rodents," NCI Carcinogenesis Technical Report Series No. 1 (February 1976).

to establish guidelines and criteria for this purpose in connection with the Federal Insecticide, Fungicide and Rodenticide Act. 43 Fed. Reg. 37336 (August 22, 1978) (AIHC P.H.).[1/] These criteria govern acute, subchronic and chronic testing, including oncogenic, teratogenic and mutagenic testing. These same test criteria were made applicable "for the most part" to the Premanufacture Notification under Section 5 of the Toxic Substances Control Act, 15 U.S.C. § 2005. (Appendix I to Premanufacture Notification Draft Guidelines, September 1978, BNA Chemical Regulation Reporter, at 1118-1119 (September 22, 1978).)

The Work Plan of the IRLG and the Clement contract demonstrate that OSHA recognizes the need to establish criteria and standards as part of the Proposed Regulation. Until that is accomplished, the Proposed Regulation is an open-ended assertion of regulatory authority with none of the required criteria or standards to govern that authority so as to avoid unpredictable and inconsistent action by the agency.

AIHC clearly recognized this deficiency in the Proposed Regulation, and the AIHC Alternative sets out criteria for the conduct and evaluation of animal experiments and human studies and for the identification and evaluation of those data.[2/] The

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1/ Drafts of the EPA proposed guidelines were published on June 25, 1975 (40 Fed. Reg. 76802), Ex. 150.

2/ See also the discussion of criteria in "The Design Criteria and Application of Dose Response Relationships to Interpretation of Carcinogenic Bioassay," Morris F. Cranmer, Ph.D. (1978) (Ex. 37).

lack of such criteria in the Proposed Regulation renders it unreasonable and invalid.

V

THE PROPOSED REGULATION MANDATING A STANDARD OF NO EXPOSURE IF THERE ARE "SUITABLE SUBSTITUTES" IS INVALID, AND SHOULD BE ABANDONED BY OSHA

Section 1990.112(b) of the Proposed Regulation provides in part:

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

A. The Terms Used In The Proposed Regulation Are Impermissibly Vague

Nowhere in the Proposed Regulation or in the Preamble are there any criteria for determining what constitutes a "substitute," nor are there any criteria for measuring "suitability" of a substance as a substitute. OSHA has not consulted NIOSH regarding the criteria for determining a "suitable substitute". (Tr. 3056-3057.) Mr. Wrenn candidly admitted that OSHA had not moved beyond the conceptual stage in developing factors for determining what is a "suitable substitute". (Tr. 117-118.) Nor was Mr. Wrenn able to identify a witness other than himself who would testify directly regarding the issues of substitution and suitability. (Tr. 49-50.) A request for OSHA to produce such a witness was made during the course of the hearing (Tr. 3056-3059), however, no such witness appeared in the proceedings.

A number of witnesses addressed the complexity of the decision to substitute products. As AIHC witnesses pointed out, "[s]ubstitution . . . would be dramatically costly and disruptive if forced where no technological alternative now exists." (Tr. 3823.) The Shell Oil Company commissioned Charles H. Kline to assess the economic impact of both a price increase as a result of controls imposed on an industry and the consequences of a ban by a no exposure standard upon a finding that a "suitable substitute" exists[1/] with respect to three basic petro-chemicals: ethylene oxide, benzene, and vinyl chloride. The huge irreversible shifts in the economy from such a price change or ban underline the great economic significance of this issue. (Tr. 5547-5550.)

Foster D. Snell, in its economic analysis of the impact of the Proposed Regulation on the producer and user industries prepared at the request of AIHC, studied the effect of substitution with respect to certain uses of two substances: ethylene oxide and perchlorethylene. As the perchlorethylene instance illustrates, the complexity and cost are great.[2/] The ethylene oxide case raises issues as to the suitability of the substitute, with the added complexity of proprietary control over the tech-

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1/ Charles H. Kline & Co., Inc., "An Assessment of the Economic Impact of OSHA's Proposal For the Identification, Classification and Regulation of Toxic Substances Posing a Potential Carcinogenic Risk to Ethylene Oxide, Benzene and Vinyl Chloride" (April 11, 1978).

2/ See also id. at 215-230.

nology for use of a substitute for one use (ethylene glycol).[1/]

A major factor in the competitive process is commercial pressure to find new and better materials. The substitutes for existing substances used in the manufacturing process have already been examined and the most useful and cost effective substances selected. (Tr. 4020-4021.) Substitution by OSHA mandate will require use of less desirable materials. (Tr. 7045-7049, 7751, 7756-7757, 7842, 7847, 7913-7915, 8348-8349, 8381-8383, 8405.) OSHA has provided no clue as to how it proposes to measure substitutability in terms of the efficiency of the substitute process or in terms of equivalency of product.

On the record we are left completely in the dark regarding how economic factors figure in the decision. What if the proposed substitute costs two, three, fifteen or twenty times more? At what level is it economically suitable? What role do energy requirements play in the determination? What expenditure for process modification will be considered reasonable? What steps does OSHA propose to take if the substitute product or process is proprietary? Does OSHA believe it has authority to require compulsory licensing of proprietary or patented products or processes?

Similarly, the record is blank as to the criteria

1/ AIHC Economics Panel Tr. 4024; Snell Report at 260. See also Kline Report at 23-24 cited supra, at 69 n. 1. See Statements of Dry Cleaning Industry Council, International Fabricare Institute, Neighborhood Cleaner's Association Association and Cleaning and Laundry Association Executives.

for technological substitutability, although that is what OSHA "primarily had in mind." (Tr. 38-39.) What if a whole process must be scrapped to use the substitute? Is a substance technologically suitable if the product produced using the substitute lacks important qualities of the original product? How will OSHA weigh the impact on users of the product by reason of the new and different qualities? If the product is an intermediate for downstream users, how will OSHA weight the impact of the changes in the product on downstream users?

If the substance is manufactured from different raw materials, what analysis will OSHA make of the raw material supply and availability? How will OSHA assess the environmental impact of increased production of the raw materials? What will be the conclusion if the raw materials are in whole or in principal part imported, thus creating a reliance on foreign sources?

Similarly, OSHA has provided no clue as to the method or criteria it will use to determine that the substitute is less hazardous than the original substance. What form of risk analysis does OSHA propose to use in such a determination? What are the elements which will demonstrate the less hazardous character of the substitute? What difference in hazard is significant? Will OSHA assess the hazard associated with the original substance subject to controls with the hazard from use of the substitute, or will the assessment be made on the assumption that the original material is unregulated? What if the substitute requires controls; how will the comparative cost of

controls be assessed?

We believe it is clear that the terms used in the Proposed Regulation are impermissibly vague and OSHA's failure to define the terms or to offer any witness who could define the terms or the criteria to be applied leaves the proposal without any support in the record. See EPA Intra-agency Memorandum from Walter Barber to Andrew Breidenbach, dated November 29, 1977 (API P.H.).

Moreover, the "no exposure" limit, which is required automatically when a "suitable substitute" exists, also fails to give due consideration to economic feasibility. The failure of the Proposed Regulation to provide for specific consideration of the economic costs in determining whether there is a suitable substitute is likely to affect not only the enterprise in whose workplace the substitution would be required, but also customers and suppliers of that enterprise. It is not only possible, but even probable, that the "suitable substitute" requirement will lead to unreasonable results. For example, even an extremely weak carcinogen can automatically fall in Category I if the definitional criteria are met. Such a substance may well have a substitute that is technically and economically adequate within the context of the industry manufacturing that substance and which is marginally less carcinogenic. Under the Proposed Regulation these facts apparently would automatically trigger the imposition of a "no exposure" limit, even if the marginal benefits to be attained were at the cost of devastating another industry which

supplied the substance in question.

B. The Proposed Requirement Of "No Exposure" If A "Suitable Substitute" Exists Or In Other Circumstances Is Tantamount To Banning A Substance And Is Beyond OSHA's Authority

The term "no exposure" is undefined. Does OSHA intend "no exposure" as measured by today's standard industry monitoring equipment or does OSHA intend to use the most sensitive testing devices to determine no exposure? Moreover, "no exposure" is a moving target. (Koppers Co. Tr. 7780-7781.) In the recent past measuring to one part in a million was difficult. Today measurements to parts per billion are feasible and OSHA has imposed a standard of parts per billion (DBCP). Tomorrow we may be able routinely to measure parts per trillion or parts per quadrillion. If a plant is engineered and achieves control at parts per billion, a test sensitive to a part per million would register "no exposure". That plant, however, is faced with violation of the standard as a sufficiently sensitive test is devised. As a practical matter therefore, a "no exposure" limit is in effect a ban on the product. Indeed, Dr. Holaday stated that it is not possible to eliminate all exposure even in a completely enclosed system. (Tr. 2626.)

OSHA proposes to use the no exposure limit when it finds that there is a "suitable substitute". In addition, Mr. Wrenn said the Proposed Regulation did not preclude the imposition of a "no exposure" limit even when there are no suitable substitutes. (Tr. 114.) Mr. Wrenn acknowledged that OSHA has

prepared no criteria as to when the no exposure limit would be imposed when there are no substitutes. (Tr. 114.)

Thus OSHA is proposing a regulation which purports to grant to it broad and undefined authority to ban substances on a finding that a suitable substitute exists or when OSHA makes the judgment on the basis of undisclosed and undefined criteria that a substance should be banned even if there are no substitutes. OSHA has no authority under the Act to impose such a ban.

OSHA's powers to prevent worker exposure to a substance by closing down a plant are carefully defined in Sections 9 and 13 of the Act, 29 U.S.C. §§ 658, 662. Section 9 provides for citations for violation of a standard, rule or order. Section 13 establishes a carefully defined procedure under which the Secretary may seek an injunction against imminent dangers "which could reasonably be expected to cause death or serious physical harm. . . ." The injunction may

> "prohibit the employment or presence of any individual in locations or under conditions where such imminent danger exists, except individuals whose presence is necessary to avoid, correct, or remove such imminent danger or to maintain the capacity of a continuous process operation to resume normal operations without a complete cessation of operations, or where a cessation of operations is necessary, to permit such to be accomplished in a safe and orderly manner." 29 U.S.C. § 662(a).

No authority to issue a "no exposure" ban on a substance can be found in these provisions. The legislative history confirms that these provisions were adopted to define

the limits of OSHA's authority to ban exposure to a substance. One of the major issues considered during the debates on the bill was the extent of authority, if any, the Secretary should have as an administrative matter to order a plant closing. The Conference Report rejected a grant of administrative authority to ban exposure by ordering a shutdown.[1/] Thus the provisions of Sections 9 and 13 are the only authority under the Act to ban exposure to a substance. Usery v. Whirlpool Corp., 416 F. Supp. 30, 34 (N.D. Ohio 1976).

A ban on a substance by a "no exposure" standard is clearly not a "feasible" means of implementing the Act. Congress' intent in passing the Act was to protect employees, but not by putting their employers out of business or completely eliminating hazardous occupations. AFL-CIO v. Brennan, 530 F.2d 109, 120-121 (3d Cir. 1975); AFL-CIO v. Hodges, 499 F.2d 467, 477-478 (D.C. Cir. 1974).

Similarly, Section 3(8) of the Act, 29 U.S.C. § 652(8), requires that any standard or provision of a standard must be "reasonably necessary or appropriate" to provide a safe workplace. There is nothing in the record to support a conclusion that OSHA's attempt to assert authority to ban a substance is

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1/ The difference between the House bill, which insisted on judicial proceedings to ban exposure, and the Senate bill, which favored a grant of administrative authority, was resolved in Conference in favor of the House position. H.R. REP. No. 1765, 91st Cong., 2d Sess. 401 (1970) in Legislative History of the Occupational Safety and Health Act of 1970 [hereinafter cited as "Legislative History"].

"reasonably necessary or appropriate." The Benzene decision clearly sets out the meaning of reasonable necessity in the Act. Affirming the construction given the same term, "reasonably necessary", found in the Consumer Product Safety Act (see Aqua Slide 'N' Dive Corp. v. Consumer Product Safety Commission, 569 F.2d 831 (5th Cir. 1978); D.D. Bean & Sons Co. v. Consumer Product Safety Commission, 574 F.2d 643 (1st Cir. 1978)), the Court stated:

> "Before it regulates, the agency must show that a hazard exists and that its regulation will reduce the risk from the hazard, for 'no [occupational safety and health] standard would be expected to impose added costs or inconvenience . . . unless there is reasonable assurance that the frequency or severity of injuries or illnesses will be reduced.' 569 F.2d at 839. More importantly for today's case, Aqua Slide also requires the agency to assess the expected benefits in light of the burdens to be imposed by the standard. Although the agency does not have to conduct an elaborate cost-benefit analysis, 569 F.2d at 840, it does have to determine whether the benefits expected from the standard bear a reasonable relationship to the costs imposed by the standard. 569 F.2d at 842." ___F.2d 90-91.

OSHA has conspicuously failed to make any cost assessment justifying the "suitable substitute" provision and indeed has not indicated that cost would be a factor. To the extent that OSHA's conceptual thinking has been revealed, OSHA was thinking solely of technological substitutability. (Wrenn Tr. 38-39.) For this additional reason the "suitable substitute" provisions are unauthorized under the statute.

In the absence of an explicit grant of authority to ban substances, such a power cannot be created in OSHA by implication. Statutes allegedly authorizing administrative agencies to utilize the drastic remedy of banning substances must be strictly construed, and there is no freedom to add to the language of the statute as written by Congress. 62 Cases of Jam v. United States, 340 U.S. 593 (1951); United States v. Lexington Mill & Elevator Co., 232 U.S. 399 (1914). The Act is a detailed piece of legislation, and the presumption should be that Congress defined the limits of OSHA's authority in the express terms of the statute. 1/

This rule of strict construction is clearly demonstrated in 62 Cases of Jam v. U.S., supra, where the Supreme Court ruled that the Federal Food, Drug and Costmetic Act, 21 U.S.C. § 301 et seq., did not "implicitly prohibit" the marketing of a product labelled as "imitation jam", as the government had contended when it seized the product. The Court stated that its

> "problem is to construe what Congress has written. It is for us to ascertain -- neither to delete nor to distort. . . . In our anxiety

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1/ The Report of the Comptroller General to Congress dated June 16, 1976, entitled "Federal Efforts to Protect the Public from Cancer-Causing Chemicals are Not Very Effective", concluded

> "OSHA sets and enforces occupational safety and health standards, which pertain to a wide variety of areas, such as farm vehicles and a chemical worker's exposure to a carcinogen. OSHA cannot ban production or use of a hazardous chemical but can protect a worker from exposure to them." Ch. 2, at 8.

> to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop." Id. at 596, 599-600.

Similarly, in United States v. Lexington Mill & Elevator Co., supra, the Court ruled that the government lacked the power to condemn sacks of flour admittedly containing poisonous substances, since it had not been proved, as required by statute, that these substances rendered the flour "injurious to health". The Court stated that

> "where a law is expressed in plain and unambiguous terms, whether those terms are general or limited, the legislature should be intended to mean what they have plainly expressed, and consequently no room is left for construction. . . . [I]f Congress had intended to enact the statute in [a particular] form, it would have done so by choice of apt words to express that intent." Id. at 410.

Similarly, if Congress had intended that OSHA have the authority to ban substances, it would have said so expressly in the statute. Where Congress intended to vest in an administrative agency the authority to ban substances, it has indicated and effectuated that intention by explictly granting the power to do so. See, e.g., the Toxic Substances Control Act, 15 U.S.C. § 2601 et seq.; the Federal Hazardous Substances Act, 15 U.S.C. § 1261 et seq.; the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. § 135 et seq.; the Consumer Product Safety Act, 15 U.S.C. § 2051 et seq.; and the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. It is thus clear that where Congress intended to grant the authority to ban substances, it knew

how to do so using explicit terms. No such explicit grant is contained in the Occupational Safety and Health Act.

Comparison with the recently enacted Toxic Substances Control Act is particularly instructive. That statute expressly grants the Environmental Protection Agency the authority to ban toxic substances upon a finding, following a carefully specified administrative procedure, that the substance poses an unreasonable risk of injury to the health or environment. The legislative history of that statute indicates that Congress assumed OSHA had no such authority. See H.R. Rep. No. 94-1341, 94th Cong., 2d Sess. 2, 6, 32-40 (1976); 122 Cong. Rec. E 5585 (October 1, 1976).

C. The Toxic Substances Control Act Makes The OSHA Substitute Provision Unworkable

As Mr. Dominguez stated "the whole question of substitution is now an entirely different issue than it was historically" due to passage of the Toxic Substances Control Act. (Tr. 4063.) When the inventory of existing substances is published later this year pursuant to that Act, significant new substances and significant new uses of existing substances will be subject to pre-market notification and screening under Section 5 of the Act, 15 U.S.C. § 2605. Thus before a manufacturer could use a substitute, the substitute substance could be subject to the constraints of Section 5 pre-market notification. Review of the pre-market notification will require 90 to 180 days. Thus it will be virtually impossible to determine within the six-

month period OSHA has allowed for the rulemaking whether the substitute OSHA has identified can in fact be used.

To identify and appraise the economics, technology, comparative risk and environmental impact of using a substitute is a time consuming processs. If, in addition, the substitute must be subject to pilot tests, and downstream users are allotted time to appraise the product, the process is certain to take longer than the six months allotted for setting individual standards under this proposal. See, e.g., Refractories Tr. 6399-6400. The substitute provisions are therefore unrealistic and the process of nominating substitutes so foreshortened as to be arbitrary on its face.

D. A Grant Of Authority To Ban Without Guiding Standards Would Be An Unconstitutional Delegation Of Legislative Authority

Even if it were assumed arguendo that OSHA does have the authority to ban substances under the Act, the manner in which such authority has been granted to the agency by Congress would constitute an unconstitutional delegation of legislative policy-making functions. A delegation of legislative authority is unconstitutional in the absence of standards to guide the delegatee's actions, Yakus v. U.S., 321 U.S. 414, 425-26 (1944), and in no circumstances is Congress permitted to abdicate the task of determining the policy of the law. See id. at 424; Panama Refining Co. v. Ryan, 293 U.S. 388, 421 (1935); Alexander v. Thompson, 313 F. Supp. 1389, 1395 (C.D. Cal. 1970). The Proposed Regulation allows OSHA, rather than Congress, to formu-

late difficult policy choices by authorizing the banning of substances without reference to whether the benefits of the ban are outweighed by the costs and the detriment that will be done to the economy. As such, the power to ban in these circumstances constitutes an unconstitutional delegation of legislative authority to OSHA. Cf., Stearns Electric Paste Co. v. EPA, 461 F.2d 293, 308-309 (7th Cir. 1972).

Conclusion

The AIHC Alternative would avoid all of these legal difficulties. Unlike the OSHA proposal, the AIHC Alternative would not call for OSHA to decide whether substitutes are available for a chemical being regulated as a carcinogen. (Tr. 3614-3615.) Nor would the Alternative impose a zero-exposure limit (tantamount to a ban of the substance) where substitutes are thought to be available. The AIHC Alternative would rely upon the incentives to industry of cost efficiency and health factors to provide replacements for materials discovered to be carcinogenic. See AIHC Alternative at 43-45. As Dr. Selikoff eloquently urged, the matter of substitutes should be left to the market place. (Tr. 1739-1740.)

VI

OSHA HAS FAILED TO COMPLY WITH THE NATIONAL ENVIRONMENTAL POLICY ACT

Introduction

OSHA has violated the provisions of Section 102(2)(C) of the National Environmental Policy Act ("NEPA"), 42 U.S.C. § 4321 et seq., by failing to prepare and circulate for comment a detailed and comprehensive draft environmental impact statement ("EIS"), by failing to publish and circulate such a draft prior to the first significant point of agency decision, and by making irretrievable commitments of resources to the Proposed Regulation prior to issuance of an adequate draft or final EIS.

Pending full and adequate compliance with its NEPA obligations, OSHA should not promulgate its final regulations. OSHA's failure to comply with NEPA has deprived interested parties and other Federal agencies of the opportunity to submit the critical commentary and objective data which OSHA is required to consider prior to taking any action.

Section 102(2)(C) of NEPA requires OSHA to issue not only a final but also a draft statement assessing in detail the environmental consequences of its proposed action. See Cedar-Riverside Environmental Defense Fund v. Mills, 422 F. Supp. 294, 323 (D. Minn. 1976). Full and adequate compliance with NEPA at the draft stage is a prerequisite to an agency's implementation of the NEPA mandate at the final stage, since adequate

weight cannot be given to environmental factors when data appear in the final EIS without being subject to the critical evaluation that occurs through public scrutiny at the draft stage. Appalachian Mountain Club v. Brinegar, 394 F. Supp. 105, 121-122 (D. N.H. 1975); see Realty Income Trust v. Eckerd, 564 F.2d 447, 453-454 (D.C. Cir. 1977); Jones v. District of Columbia Redevelopment Land Agency, 499 F.2d 502, 511 (D.C. Cir. 1974), cert. denied, 423 U.S. 937; Atchison, Topeka & Santa Fe Railroad Co. v. Callaway, 431 F. Supp. 722, 728 (D. D.C. 1977); Maine Central Railroad Co. v. ICC, 410 F. Supp. 653, 656 (D. D.C. 1975).

In purported compliance with its obligation to issue a detailed draft EIS, OSHA has included in the Preamble to its Proposed Regulation a two-page discussion entitled "Environmental and Economic Impact Assessment." 42 Fed. Reg. at 54180-54182. The agency styles this discussion, along with the rest of the proposal, as its draft EIS. This draft purports to set out the agency's complete thinking on the environmental impact of a regulation which will directly impact, by the agency's own admission, several hundred substances. This draft, however, does not contain the detailed comprehensive and objective analysis of environmental factors required by Section 102(2)(C) of NEPA, OSHA's own regulations, and the CEQ Guidelines.

OSHA's recent release of Clement's tentative categorization of substances on the NIOSH List of Suspect Carcinogens underscores the need for a comprehensive EIS. This new infor-

mation which OSHA should have had in its posssession at a very early point in its decision-making process should assist OSHA considerably in more precisely quantifying the environmental impact of its proposal which it has heretofore stated was so difficult to quantify.

The same reasons which lead OSHA to change its original position that a regulatory analysis of the Proposed Regulation under Executive Order 12044 was not required (see supra, at 6-7) demonstrate that OSHA's decision to prepare an Environmental Impact Statement only in individual substance rulemaking is invalid. In the letter to ORC giving the reasons why a regulatory analysis was required, OMB stated:

> "As Dr. Bingham has noted, it is difficult to conduct meaningful analyses for a generic standard when specific definitions have not been published. However, when generic standards will, upon promulgation preempt later regulatory decisions, then the economic effect of significant regulatory alternatives may never be analyzed." (AIHC P.H.)

In the memo to the Assistant Secretary, Messrs. Morris and Wrenn stated that the regulatory analysis being prepared would examine "realistic alternative approaches." Thus unless a comprehensive EIS is prepared now, the Agency will never consider, and the public will never have an opportunity to comment on the environmental impact under NEPA in later regulatory decisions on issues which are preempted by the generic standard, nor on the "realistic alternative approaches" to be discussed in the forthcoming regulatory analysis.

A. OSHA Has Failed To Prepare A Detailed And Comprehensive Statement

OSHA has totally failed to measure up to the rigorous standards of Section 102(2)(C) of NEPA. Its draft EIS is couched in conclusory language and its vague generalizations are often unsupported by objective data. In no sense can the draft be considered a "detailed" inquiry into the analysis of the environmental impact of the Proposed Regulation, and OSHA has therefore violated its duty to comply with NEPA "to the fullest extent possible."

The provisions of Section 102(2)(C) establish "a strict standard of compliance." Calvert Cliffs' Coordinating Committee, Inc. v. U.S. Atomic Energy Comm'n, 449 F.2d 1109, 1112 (D.C. Cir. 1971). Nothing less than a comprehensive and objective treatment of environmental issues by the responsible agency will suffice. Environmental Defense Fund, Inc. v. Corps. of Engineers, 348 F. Supp. 916, 927 (N.D. Miss. 1972), aff'd, 492 F.2d 1123 (5th Cir. 1974). A detailed statement serves three important purposes: (1) It permits a court to ascertain whether the agency has made a good faith effort to take into account the values NEPA seeks to safeguard, and to that end the EIS must explicate fully its course of inquiry, its analysis, and its reasoning; (2) It serves as an environmental full disclosure law; and (3) Perhaps most crucial, it "helps insure the integrity of the process of decision by precluding stubborn problems or serious criticisms from being swept under the rug." Sierra Club v. Morton, 510 F.2d 813, 820 (5th Cir. 1975); State of Alabama ex rel. Baxley v. Corps. of

Engineers, 411 F. Supp. 1261, 1267 (N.D. Ala. 1976).

The draft EIS issued by OSHA is neither a comprehensive nor an objective treatment of the environmental consequences of its Proposed Regulation. Rather, OSHA's EIS contains just the sort of superficial consideration of environmental factors that NEPA was meant to preclude. It fails to serve the three important purposes which the courts have interpreted NEPA as demanding.

OSHA's failure to comply with its obligation to file a "detailed" draft EIS mainifests itself in a number of areas. The statement omits a description of the present baseline workplace environment, fails to substantiate the alleged beneficial environmental impact of the Proposed Regulation on that workplace environment, and inadequately discusses the secondary environmental consequences of the proposed action. The interrelationships and cumulative environmental impacts of the Proposed Regulation and other related Federal projects are not adequately analyzed, nor is the relationship between local short term uses of the environment and the maintenance and enhancement of long term productivity. Moreover, OSHA's discussion of alternatives to its proposed action is woefully deficient. Some of these points are discussed in greater detail below.

Scope. In July 1977, OSHA entered into a contract with Clement to screen and categorize the substances in the NIOSH suspect carcinogen subfile. The draft EIS, however, fails to mention or list the suspect chemicals being evaluated by OSHA and its

contractor for regulation under the proposal. It fails to discuss the alternative chemicals which are or may be used to substitute for the chemicals foreclosed from use by the regulations, or the environmental consequences of using these alternative chemicals.

Baseline. OSHA's draft EIS contains no description of the baseline workplace environment. There are no data or analyses, for example, of the number of employees exposed to the substances to be regulated, or of current conditions and practices in workplaces which might be covered by the regulation. Without an analysis of existing conditions such as these, there is no basis for evaluating the alleged beneficial environmental impact of the proposed generic standards.

Environmental Impacts and Benefits. OSHA's analysis of the potential environmental impact of its proposal and the potential benefits falls far short of NEPA's requirements.

The draft EIS is replete with examples of OSHA's incertainty as to its ability to substantiate the beneficial environmental impact of its proposed generic standard. The primary impact of the Proposed Regulation is "expected to impact on the workplace by reducing worker exposure to Category I and Category II toxic substances." 42 Fed. Reg. 54182 (emphasis added). OSHA declares that "[t]he specifics of potential impacts, expected as a result of the promulgation of [the Proposed Regulation] cannot . . . be foreseen and is somewhat speculative." 42 Fed. Reg. 54182. The best that OSHA can offer is an "overview" giving "a

general idea of some of the types of impacts which may result." Id. The requirement that an EIS be detailed places a heavy burden on the responsible agency to gather and include in the EIS enough information to show that compliance has been genuine, not perfunctory. Brooks v. Volpe, 350 F. Supp. 268, 276 (W.D. Wash. 1972), aff'd, 487 F.2d 1344 (1973). OSHA's reliance on conclusions and assumptions without reference to supporting objective data prevents it from meeting that burden.

Adverse Impacts and Irretrievable Commitments. OSHA's failure to discuss in detail the adverse environmental consequences of its proposal, including irreversible and irretrievable commitments made, is another serious deficiency in the EIS. Among the significant adverse impacts of the proposal on the physical environment which have not been adequately examined are the following:

> (a) unnecessary use or depletion of energy resources by OSHA's (1) requirement to reduce workplace exposure limits to the lowest level feasible without regard to what is an adequate level and without regard to the cost of such controls and (2) mandated preference for energy-intensive engineering controls as the method for complying with permissible workplace exposure limits even though less energy intensive personal protection and administrative controls may accomplish the same end result; and
>
> (b) air, water, solid waste and land use impacts likely as a result of the proposal's provisions (1) to ban substances where there are "suitable" less hazardous alternative substances and (2) to require reduction of exposures to the lowest level feasible without regard to economic cost or effects on international trade.

OSHA does purport to address the issue of possible energy resources depletion. Its conclusions, however, are not only vague, conclusory, and unsupported by objective data, but also contradictory. OSHA states in the draft EIS that its proposal "might result in an insignificant increase in energy consumption." 42 Fed. Reg. 54182. It does not provide any support for this assertion. Later in the draft, however, OSHA admits that potential impacts upon energy "cannot readily be quantified." Id.

The treatment in the draft EIS of the potential adverse impact on air, water, solid waste, and land use is also inadequate and unilluminating. OSHA admits that various engineering and hygienic controls "may result in increased contamination of water and increased sludge production, representing a potential negative impact on both water quality and the amount of solid waste." Dust collection methods, for example, "could impact water quality, solid waste and land use categories." 42 Fed. Reg. 54182. OSHA also admits, however, that it has little data which quantify these potential impacts." Id. Without such data, the balancing of beneficial and adverse environmental effects which NEPA demands prior to agency decision cannot take place.

Secondary Impacts. The indequacy of the draft is further reflected in OSHA's failure to discuss in detail the secondary environmental consequences of its proposal. Among the matters which should have been considered in detail was the possibility of plant redundancies and dislocations caused by a ban or very

restrictive limits on a chemical, especially in circumstances where no alternatives are practically available, with attendant secondary environmental impacts in local communities. OSHA states only that the potential impact of its Proposed Regulation upon "human resources . . . cannot readily be quantified." 42 Fed. Reg. 54182. Besides these possible domestic unemployment effects, the draft EIS should certainly have discussed the probable impairment of the international balance of payments position due to the standards. There is no indication that this factor was considered at all. OSHA should also have addressed more adequately the impact of its Proposed Regulation upon medical research and on care and industrial hygiene resources. The draft EIS confines its discussion of this issue to the conclusory assertion that "[t]he exposure levels and compliance methods chosen should have no effect on the amount of monitoring and medical surveillance required." Id.

Alternatives. OSHA has said that its forthcoming regulatory analysis will "examine realistic alternative approaches for regulating these hazards" as well as "alternative criteria for the categorization of substances within the generic standard." The draft EIS contains only the most cursory discussion of possible alternatives to the proposed regulatory action and the environmental impacts of such alternatives. OSHA, however, is required to consider these matters as thoroughly at the draft as at the final stage. Natural Resources Defense Council, Inc. v. Nuclear Regulatory Commission, 539 F.2d 824, 842 (2d Cir. 1976); Natural Resources Defense Council, Inc. v. Hughes, 437 F. Supp. 981

(D. D.C. 1977). This requirement has not been satisfied. OSHA's statement omits altogether discussion of such crucial alternatives as the "no action" alternative, without which no EIS can be considered complete. Monroe County Conservation Council, Inc. v. Volpe, 472 F.2d 693, 698 (2d Cir. 1972). Even the discussion of those alternatives which are included is largely vague and uninformative, indicative of OSHA's failure to comply with the obligations of Section 102(2)(C) "to the fullest extent possible." OSHA states, for example, that the choice of alternative levels of exposure compliance is expected "to have impact in some way" on every category of the external environment. Such statements are neither supported by scientific data nor adequately explained. In no sense is OSHA's discussion of alternatives an adequate compliance with NEPA's requirement of a thorough consideration of alternative regulatory approaches and their environmental impacts.

Interrelationships With Other Federal Agency Actions. OSHA's failure to adequately discuss the interrelationships and cumulative environmental impacts of the Proposed Regulation and other Federal activities is also violative of NEPA.

As was made clear by Messrs. Wrenn, Byington, Kennedy, and Jellinek, OSHA and other Federal agencies have embarked on a coordinated program to deal with toxic substances, including carcinogenic substances. The forums for these programs have been principally the IRLG and the Toxic Substances Strategy Committee where there is little or no opportunity for public participation. The deliberations of these bodies are intimately in-

tertwined with the OSHA regulatory program and accordingly merit full discussion in the EIS. AIHC believes it is incumbent on the IRLG to prepare an EIS before agreeing on the criteria, standards, etc. to be developed under the IRLG work plans. In any event, OSHA should prepare such an EIS with reference to this Proposed Regulation and those decisions being made in the IRLG context.

B. OSHA Has Violated NEPA's Mandate For Early Consideration Of Environmental Issues

OSHA's failure to publish and circulate an adequate draft EIS for comment prior to the first significant point of decision is also violative of NEPA. Contrary to the requirements of NEPA and the CEQ Guidelines, 40 C.F.R. § 1500.7(a), OSHA waited until a number of significant decisions had already been made before publishing its draft EIS. An EIS is meant "to serve as the means of assessing the environmental impact of proposed agency actions, rather than as a justification for decisions already made." Id. OSHA had begun work on the generic proposal in January 1976. (Tr. 164.) In January 1977, OSHA publicly circulated and made available to NACOSH for comment a proposal essentially identical to that published in the Federal Register. The purported EIS was not, however, released until October 1977. The course of action taken by OSHA undermines the intent of NEPA because it deprives government agencies and the public of a meaningful opportunity to comment and lends an irreversible momentum to the Proposed Regultion before an analy-

sis of environmental factors is ever undertaken. See Jones v. District of Columbia Redevelopment Land Agency, 499 F.2d 502, 511 (D.C. Cir. 1974), cert. denied, 423 U.S. 937 (1975); Natural Resources Defense Council, Inc. v. Hughes, 437 F. Supp. 981, 991 (D. D.C. 1977); Atchison, Topeka & Santa Fe Railroad Co. v. Callaway, 431 F. Supp. 722, 728 (D. D.C. 1977).

C. OSHA Has Failed To Assess Adequately The Generic Issues

Since this rulemaking purports to resolve certain critical issues and to foreclose their later consideration, it takes on added significance. To imply as OSHA does that it is "unable" (Wrenn S. 6) to make such an analysis now because the potential impact is difficult to analyze and to suggest therefore that it is better to wait until subsequent rulemakings on individual substances to make such analyses is akin to closing the barn door after the animals have fled, a fact which OSHA has acknowledged in its post-hearing agreement to prepare a regulatory analysis under Executive Order 12044.

There is a long line of judicial precedent which supports the need for a thorough NEPA analysis at the outset of a generic or programatic government action which will result in a series of environmental impacts. See, e.g., Scientists Institute for Public Information v. AEC, 481 F.2d 1079, 1088 (D.C. Cir. 1973); Jones v. Lynn, 477 F.2d 995 (1st Cir. 1973); see also Natural Resources Defense Council Inc. v. Nuclear Regulatory Committee, 539 F.2d 824, 839 (2d Cir. 1976).

D. OSHA Has Made And Continues To Make Irretrievable Commitments To The Proposed Regulation

OSHA has also violated and is continuing to violate NEPA by making irretrievable commitments of resources to the Proposed Regulation prior to the issuance of an adequate final EIS. The agency has, for example, already begun implementing the Proposed Regulation by relying upon it in the formulation of standards for particular substances. The economic feasibility studies for acrylonitrile and DBCP were prepared by OSHA contractors under instructions from OSHA to treat the generic standards as applicable. This course of action is clearly impermissible, for it prevents an EIS from serving as an input to the decision-making process before the final decision has been made by the agency.[1/] A full environmental impact analysis must occur prior to an agency's commitment to a project. Inman Park Restoration, Inc. v. Urban Mass Transportation, 414 F. Supp. 99, 119 (N.D. Ga. 1975). Reliance by OSHA upon the Proposed Regulation prior to issuance of an adequate final EIS is improper because such activity involves irretrievable commitments of resources which serve to tip the balance away from environmental concerns and to prejudice the final agency decision. Subsequent broad-scale assessment of alternatives is also foreclosed. See Natural

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1/ In addition, OSHA seems to be moving forward on record-keeping rules in a separate proceeding without consideration of evidence developed in these proceedings and, of course, without NEPA compliance. See 43 Fed. Reg. 31329, 31371 (July 21, 1978).

Resources Defense Council, Inc. v. U.S. Nuclear Regulatory Commission, 539 F.2d 824, 843-844 (2d Cir. 1976); Realty Income Trust v. Eckerd, 564 F.2d 447, 455 (D.C. Cir. 1977).

Conclusion

Section 102(2)(C) of NEPA requires that prior to the implementation of the Proposed Regulation in any manner, a full, comprehensive and adequate consideration of the probable environmental consequences of agency action be made and set forth in a detailed draft and final EIS. To date, OSHA has failed to undertake such a comprehensive analysis. A two-page analysis of a proposal of this importance on its face violates NEPA.

In order to insure that the interest in informed decision-making is preserved and that the agency's NEPA obligations have been fully complied with, OSHA should not issue final regulations and should prevent further commitment of resources thereto until an adequate NEPA analysis has been made.

VII

OSHA HAS FAILED TO MEET ITS LEGAL OBLIGATIONS TO ASSESS THE POTENTIAL ECONOMIC IMPACT OF THE PROPOSED REGULATION AND ALTERNATIVES THERETO

Introduction

OSHA has a legally-binding obligation to consider the economic impact of all aspects of this regulation and alternatives thereto. This obligation is triggered in this rulemaking, not, as OSHA suggests, in subsequent rulemakings on individual substances when the important issues will already have been decided. If economic analysis is to be a useful decision-making tool, as mandated by the Congress and the President, it must be utilized in this rulemaking. Studies submitted by Foster D. Snell and others demonstrate that such studies are possible and can meaningfully be done. Indeed, Appendix A to the Snell Report sets out a methodology which OSHA might utilize for such a study. Further, these studies demonstrate that the costs associated with the proposal are likely to be very substantial.

AIHC and others have urged OSHA to prepare an economic analysis of the Proposed Regulation since its first public release in January 1977. Only now, nearly three years after OSHA began working on the proposal and long after the hearing has closed, has OSHA agreed to undertake an economic analysis.

In response to a letter from Organization Resource Counselors ("ORC") dated June 14, 1978, requesting the Office of Management and Budget ("OMB"), the agency responsible for imple-

mentation of the President's Regulatory Analysis Program, to use its good offices to require OSHA to prepare a regulatory analysis of its proposal, OMB, in a letter dated July 25, 1978, advised that OSHA has "agreed that a regulatory analysis will be done for the generic standards and that [OMB] will continue to work with [OSHA] on the design of the analysis." (AIHC P.H.) In its letter OMB recognized, as AIHC and others have, that "when generic standards, will, upon promulgation, preempt later regulatory decisions, then the economic effects of significant regulatory alternatives may never be analyzed" if they are not analyzed in the generic proceedings.

OSHA has not released an outline or detailed description of the analysis being undertaken. In the memorandum which Messrs. Morris and Wrenn sent to the Adminstrator, there is some indication of the kind of analysis OSHA is making. (AIHC P.H.) As part of its analysis of "realistic alternative approaches," OSHA plans to use quantitative data from economic impact analyses of substances already regulated by OSHA. In the analysis OSHA will also "set forth for review the parameters which are included in a determination of feasibility." The review was to have been completed by October 1, 1978, but has not yet been made public.

AIHC welcomes OSHA's agreement to undertake a regulatory analysis. It is our hope that the analysis will have the objectives and content outlined by the President's Regulatory Analysis Review Group ("RARG"). In the analysis of the proposed acrylonitrile standard, the RARG described the analysis in

these terms:

> "But simply knowing that the lower the permissible exposure level (PEL), the lower the risk of cancer, is not information enough upon which to base a standard unless it is intended to eliminate immediately all risks regardless of the consequences. Although as a long range goal this may describe the intent of the OSH Act, as an operational procedure it is empty, since in order to eliminate all risks forthwith, industry would have to shut down. Just as there is no absolute 'safe' level, there is no absolute 'feasible' level.
>
> Thus decisions must be made by regulators as to how far it makes sense to us as a society to go and how fast. To use the criterion that we should reduce risk to the point just before the industry would be forced to shut down is illogical since the goal of the OSH Act is to protect workers, not industries. The proper procedure should be to promulgate regulations that provide greater gains to society than burdens." (AIHC P.H.)

We urge that a thorough airing of all of the economic aspects of this proposal and alternatives thereto with sufficient, meaningful opportunity for public notice and comment be had prior to final agency action.

A. The Legal Basis For Economic Analysis Is Clear

There are several independent legal bases upon which required analysis of economic impact rests. Each emphasizes the need for the use of such analyses as a tool at an early stage in the decision-making process.

1. The Occupational Safety and Health Act

The principal statutory bases for the Proposed Regulation are Sections 3(8), 6(b)(5) and 6(b)(7) of the Act. 42 Fed.

Reg. 54153-54154, 54183. These sections require OSHA to promulgate "reasonably necessary", "feasible", and "appropriate" standards or regulations. An integral element embodied in these concepts, as recognized by OSHA, the courts, and Congress, is an economic impact analysis. See Tr. 3796; American Iron & Steel Institute v. OSHA, 6 OSHC 1451 (3rd Cir.); Turner Co. v. Secretary of Labor, 561 F.2d 82 (7th Cir. 1977); AFL-CIO v. Brennan, 530 F.2d 109 (3rd Cir. 1975); Industrial Union Department, AFL-CIO v. Hodgson, 499 F.2d 467 (D.C. Cir. 1974); Florida Peach Growers Ass'n v. Department of Labor, 485 F.2d 120 (5th Cir. 1974); Aqua Slide 'N' Dive Corporation v. Consumer Product Safety Commission, 569 F.2d 831, 840, 845 (5th Cir. 1978); D.D. Bean & Co. v. Consumer Product Safety Commission, 574 F.2d 643 (1st Cir. 1978); Legislative History at 147, 148, 197, 464, 471-472.

The Court in Turner, adopting a decision of the Occupational Safety and Health Review Commission, underlined the importance of economic considerations in determining feasibility and emphasized that in determining economic feasibility both costs and benefits must be weighed. The Court held:

> "It was, therefore, after thorough consideration of the relevant legislative history that the Commission formulated the standard which we presently adopt:
>
> '* * * we conclude that the standard should be interpreted to require those engineering and administrative controls which are economically as well as technically feasible. Controls may be economically feasible even though they are expensive and increase production costs. See Arkansas-Best Freight Systems, Inc., 529 F.2d 649, 653 [3 OSHC 1910](8th Cir. Jan. 29,

1976); Industrial Union Department, AFL-CIO v. Hodgson, supra [162 U.S.App.D.C. 311,] 499 F.2d [467] at 477. But they will not be required without regard to the costs which must be incurred and the benefits they will achieve. In determining whether controls are economically feasible, all the relevant cost and benefit factors must be weighed.' (Id.)" 561 F.2d at 85.

The Benzene decision demonstrates the basic importance of OSHA's determination of both costs and benefits in reaching the conclusion that a regulation is "reasonaably necessary". OSHA must be able to show both costs and benefits, for without these findings OSHA cannot demonstrate the reasonableness of the cost in relation to the benefits. The court underlined the importance of both determinations when it said:

> "OSHA's failure to provide an estimate of expected benefits for reducing the permissible exposure limit, supported by substantial evidence, makes it impossible to assess the reasonableness of the relationship between expected costs and benefits. This failure means that the required support is lacking to show reasonable necessity for the standard promulgated." __ F.2d at 93.

2. The National Environmental Policy Act

As discussed in the preceding section of this brief, NEPA and implementing CEQ guidelines and OSHA regulations require that a detailed environmental impact statement be prepared for major federal actions significantly affecting the quality of the human environment. Such statements must examine costs and benefits and consider economic impacts of contemplated government action. See, e.g., Chelsea Neighborhood Ass'n v. Postal Service,

516 F.2d 378, 386-387 (2d Cir. 1975); Sierra Club v. Morton, 510 F.2d 813, 827 (5th Cir. 1975); Calvert Cliffs' Coordinating Comm. v. AEC, 449 F.2d 1109, 113 (D.C. Cir. 1971); Texas Comm. on Natural Resources v. Bergland, 433 F. Supp. 1235, 1252 (D. Tex. 1977); Citizens Against Toxic Sprays, Inc. v. Bergland, 428 F. Supp. 903, 934-935 (D. Or. 1977).

CEQ's most recently proposed NEPA implementation regulations summarize NEPA's requirements as follows:

> "When an environmental impact statement is prepared and economic or social and natural or physical environmental effects are interrelated, then the environmental impact statement will discuss all of these effects on the human environment." 43 Fed. Reg. 25229, 25245 (June 9, 1978).

3. Executive Order No. 11821 (Inflationary or Economic Impact Statements)

Executive Order No. 11821, 39 Fed. Reg. 41501 (November 20, 1974), as amended by Executive Order No. 11949, 42 Fed. Reg. 1017 (January 5, 1977), and as implemented by OMB (Circular No. A-107) and agency directives, including a directive of the Secretary of Labor, Secretarial Order No. 15-75, 40 Fed. Reg. 54484 (November 24, 1975), required "Inflationary" or "Economic" Impact Statements for "major" proposed regulatory actions.[1/]

1/ The Executive Order, as implemented, defined "major" actions as those which would result in (1) a net increase in costs to consumers, businesses, federal, state or local governments of $100 million or more; or $10 million or more for any industry or level of government (certain specified productivity parameters were required to be considered in making such cost analyses); (2) energy demand increases of

(Footnote continued on p. 102)

Executive Order No. 11821 was in effect at the time the OSHA proposal was first published.

4. Executive Order No. 12044 (Regulatory Analysis)

Executive Order No. 12044 (43 Fed. Reg. 12660 (March 24, 1978)) requires "Regulatory Analyses" for significant proposed regulatory activities.[1/] To be included within the scope of this order are all pending regulatory proceedings for which inflationary or economic impact statements have not been issued pursuant to Executive Order No. 11821 as amended. Section 3, 43 Fed. Reg. at 12663. "Closely related sets of regulations" are required by the Executive Order "to be considered together." Section 6, 43 Fed. Reg. at 12664. The Executive Order has recently been implemented by proposed Department of Labor regulations.[2/] 43 Fed. Reg. 22915 (May 26, 1978).

(Footnote continued from p. 101)

25,000 barrels of oil per day or its equivalent; (3) reduction of the national supply of critical materials by 3 percent or more; (4) reduction of labor demand by 0.2 percent at the national level or 10,000 workers at the industry, state or local level; or (5) substantial (a) limitations on market entry, (b) market concentrations, or (c) potential for monopoly in a line of commerce.

1/ Pursuant to this Executive Order, a proposed action is to be considered "significant" where the action will result in an annual effect on the economy of $100 million or more or a major increase in costs or prices for individual industries, levels of government or geographic regions. Section 3(a)(1), 43 Fed. Reg. at 12663.

2/ The proposed regulations require an analysis where the regulation is likely to result in: (1) an increased cost of $100 million or more in any one year for the

(Footnote continued on p. 103)

We quoted earlier from the comments filed by the President's Regulatory Analysis Review Group on the proposed acrylonitrile standard. More recently on September 5, 1978 the Council on Wage and Price Stability ("CWPS") in comments on EPA's proposed drinking water standard described the reason for, and the contents of, a regulatory analysis under Executive Order 12044 in words directly applicable here:

> "Because the resources available for health-related programs are limited, it is important that those resources be allocated in a way that maximizes the benefits (in terms of lives saved or cases of illness or injury avoided). This in turn requires that the incremental cost per case avoided be at least approximately equated for different regulations or different adopted standards. To ignore this fact is to allow more deaths than necessary for a given expenditure on health-related programs. It is therefore incumbent upon EPA to suport its proposed regulations with careful risk-assessment and cost-benefit analyses, employing the best estimates available regarding uncertain variables, parameters, and relationships.
>
> There is a considerable amount of uncertainty about both the costs and the benefits of these alternatives, but it makes little sense to act on uncertain evidence by imposing costly regulations on local communities while, at the same time, eschewing cost/benefit analyses because of this uncertainty." (At 1-2, AIHC P.H. (emphasis in original).)

(Footnote continued from p. 102)

nation, (2) a $50 million or more increase in costs or total revenues in any one year for a specific segment of the economy, (3) a direct dislocation of 10,000 jobs, or (4) a substantial limitation on competition, marketing, market information or an increase in concentration in a market doing $100 million of business a year or more. 43 Fed. Reg. at 22918.

B. An Economic Analysis Will Be Meaningful And Is Feasible

While it may be difficult to cost or precisely quantify all aspects of the Proposed Regulation, the preliminary economic analysis of the generic proposal made by Foster D. Snell, Inc., a division of Booz, Allen & Hamilton, Inc., for AIHC demonstrates that a meaningful analysis can be made. While the Snell Report was principally a "scoping" effort prepared under severe time contraints, it points the way for a full analysis. Appendix A to the Snell Report sets out a suggested methodology OSHA might use for a comprehensive analysis which Snell believes is both feasible and meaningful.

Moreover, the tentative categorization of substances on the NIOSH List of Suspect Carcinogens by OSHA's contractor, Clement Associates, released July 14, 1978, should greatly facilitate such analysis by removing some of the uncertainty associated with which substances will fall into which categories. The release of this document makes even clearer the need for an economic analysis.

While the application of the Proposed Regulation, as any regulation, will obviously be uncertain, this should not be an excuse to avoid an economic analysis. The use of alternate regulatory scenarios and case studies, standard economic analysis tools frequently utilized by OSHA itself, can overcome much of the uncertainty. Only through such analyses can optimal cost-effective regulation be assured. Such analysis will permit better understanding of how various aspects of the pro-

posal and alternatives thereto might impact costs. The CWPS in its comments on EPA's drinking water standard quoted above underlines the mistake of an agency's acting on uncertain evidence by imposing a costly regulation and at the same time failing to make a cost/benefit analysis because of the uncertainty. OSHA should not make the same mistake here.

C. The Potential Economic Impact Of The Proposed Regulation Is Significant

Studies by Snell and other participants in these proceedings demonstrate the substantial potential impact of the OSHA proposal, particularly when viewed in the context of the broader costs of compliance with a wide variety of government regulations of this sort. These substantial costs which are, in effect, costs to the entire nation (AIHC Economic Panel Tr. 3802-3803, 3825-3835), impose an obligation on OSHA to take a very close look at the economic costs of the Proposed Regulation and the alternatives thereto.

1. The Snell Report

The Snell Report is an effort, within the limited time[1/] and resources available, to roughly estimate some of the potential compliance and other costs associated with the OSHA pro-

1/ The Proposed Regulation was published October 4, 1977. AIHC was formed and Snell retained by the end of October. Written comments were originally due by December 8, 1977. Although two extensions of time were thereafter granted by OSHA, those extensions were not granted in a way which allowed sufficient time to substantively change the scope or direction of the Snell Report. (Tr. 3810.)

posal.[1/] The Report was not commissioned with a view toward balancing lives against dollars or assessing risks against benefits, but rather toward examining how best to use society's limited resources, how best to render a "meticulous accounting". (Dr. Zeckhauser Tr. 4352, 4410).

It was, and is, AIHC's view that the Snell Report is useful in pointing out that the costs associated with the OSHA proposal are substantial, that certain aspects of the proposal might be particularly costly and that there may be ways to achieve similar goals more economically. The main conclusion of the Snell Report lies not in the costs developed themselves, but rather the inescapable fact that the costs are likely to be substantial and the Proposed Regulation and alternatives thereto therefore merit careful economic analysis by OSHA.

Snell examined the costs of compliance for three regulatory scenarios with alternate mandated control levels. The direct compliance costs, estimated by Snell were as follows:

Direct Compliance Costs ($ Billion, 1977)

Scenario	Capital Cost 10 ppm to 1 ppm	Annual Cost 10 ppm to 1 ppm
Low scenario (38 high volume substances)	9-23	6-11
Medium scenario (1,870 substances)	17-47	10-20
High scenario (2,415 substances)	30-88	18-36

(Snell Report at 3.)

1/ Exhibit 66 briefly summarizes Snell's methodology and conclusions.

Snell found that smaller businesses and user industries were those most likely to bear the brunt of the economic burden. Snell Report at 494-495. This view was shared by numerous other participants in the hearing. See, e.g., Chamber of Commerce Tr. 8345-8349; PMA Tr. 7041-7051. Snell also concluded that certain features of the Proposed Regulation were particularly costly. These included monitoring, medical surveillance, OSHA's mandated preference for engineering controls, the absence of an exemption for mixtures or of an action level and the substitution requirements. (Tr. 3795, 3804.)

In addition to the compliance costs noted above, Snell also concluded that there would be other potential macroeconomic effects, including reduced labor and capital productivity, increased operating costs making U.S. firms less competitive with their foreign counterparts[1/] and increased market concentrations with particularly adverse effects for small businesses. Snell estimated that the Proposed Regulation has the potential to add in excess of one percent to the annual rate of inflation.

2. Other Studies

Hearing participants other than AIHC also offered evidence supporting the view that the OSHA proposal could have substantial economic impact.

In a study prepared for the Shell Oil Company, Charles H. Kline & Co., concluded that there could very well be significant

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1/ See also Dr. Zeckhauser's comments on these points. (Tr. 4326.)

economic impact associated with a price increase as a result of OSHA-imposed controls or a ban by a requirement of "no exposure" due to a finding that "suitable substitutes" were available. (Tr. 5549-5550.)

In a study done for the Refractories Institute, Arthur D. Little, Inc. concluded that a regulation for crystalline silica similar to the one proposed by OSHA for a Category I substance could have a far-reaching impact on the refractories industry. (Tr. 6433-6435.) See also comments of other hearing participants, e.g., Chamber of Commerce Tr. 8345-8349; National Association of Chemical Distributors Tr. 8421-8424; Crane Packing Company Tr. 7559-7561; National Manufacturers Association Tr. 7661-7668, 7674-7676; Society of American Wood Preservers, Inc. Tr. 7750-7757; Sun Chemical Company Tr. 7840-7841; Muskegon Chemical Company Tr. 7312-7313; Mallinckrodt, Inc. Tr. 7419-7421, 7433-7438.

3. The Broader Picture

The broader cumulative economic impact of the Proposed Regulation and similar proposals by other federal agencies make the need for a thorough analysis of this proposal even clearer.

Glenn Schweitzer of Cornell University and formerly Director of EPA's Office of Toxic Substances expressed serious reservations about, and submitted a report on, the cumulative impact of OSHA and other agency proposals on the growth of our economy and on innovation and technological advances. (Tr. 7108-7109, 7116-7119; Ex. 124.)

Studies by Edward Denison of the Brookings Institution

(Ex. 64) and Robert DeFina of Washington University (Ex. 65) also review the dramatic impact federal regulatory programs, including OSHA programs, have had on the economy. Denison concludes that by 1975 the output per unit input was 1.8 percent smaller than it would have been if business had operated under 1967 conditions. DeFina conservatively estimates the cost to the nation for job safety and health to be $4.5 billion annually. (Ramey Tr. 8400-8402.)

In a recent memorandum dated June 26, 1978, to the President's Economic Policy Group, the Director of the CWPS states that regulations pending before OSHA and the Department of Transportation alone would require a total $35 billion in capital costs. The Director cautions, however, that the economic costs may even be greater "because in several areas these decisions will set guidelines for future detailed regulations . . . [in such areas as] carcinogens, toxic substances, noise, air and water quality." The Director observes that "the estimated cost of proposed [OSHA] regulations suggests a cost impact in the future that approaches that for environmental improvement," the inflationary impact of which he notes EPA estimates at 0.4 to 0.8 percent annually. According to the Director, based on information from available studies, regulations by OSHA and other agencies "have contributed to about a 25 percent reduction in the rate of productivity growth within the private nonfarm economy."

These kinds of broader considerations add considerable urgency to the need for a thorough airing of the cost of the

Proposed Regulation and alternatives thereto.

D. Criticism Of The Snell Report Is Without Support

The Snell Report was criticized on several grounds, principally by OSHA's consultant, Southwest Econometrics, and by the AFL-CIO's consultant, Ruth Ruttenberg. A detailed commentary on these criticisms prepared by Foster D. Snell was filed as part of the AIHC post-hearing filing. The response by Snell to the post-hearing comments filed by Econometrics is being filed concurrently with this brief.

The first major criticism was that the underlying raw data were not made available. As pointed out by AIHC, it was not possible within the limited time available for submissions to the hearing record to collect meaningful data without a guarantee of confidentiality. (Tr. 3811.) Further, as noted by Snell, provisions for confidentiality are not unusual in studies of this kind. (Tr. 3811.) Indeed, the Bureau of the Census and the International Trade Commission follow similar confidentiality procedures in gathering their data. OSHA's solicitor argued that Wirtz v. Baldor Electric Co., 337 F.2d 518 (D.C. Cir. 1964), precluded OSHA reliance on studies for which the underlying data were not available. Whatever merit this decision may have in another context, it certainly is inappropriate here, for AIHC does not argue that the Snell estimates are hard numbers upon which regulatory decisions should be made, but rather that they are indicators of the need to take

a closer look.

The second principal objection to the Snell Report is that it fails to examine several other impacts of the Proposed Regulation, including the benefits of reduced medical care, expenses associated with reduced disease incidence and the differential economic impact of the AIHC Alternative.[1/] (Tr. 5737.)

As pointed out by the AIHC Economics Panel, the Snell Report was only intended to be a "first step". AIHC and Snell both acknowledged the need to consider many of the additional factors suggested by its critics. Indeed, Appendix A to the Snell Report, which George Taylor of AFL-CIO said was an appropriate methodology for economic assessment (Tr. 5748-5759), set out a methodology for a complete study considering all the suggested factors. (Tr. 5747-5748.)

The third principal criticism directed at the Snell Report was that it was just industry "crying wolf". Vinyl chloride was again cited as the example of a regulation which industry, in a report prepared for it by Arthur D. Little, Inc.

1/ Snell and AIHC were also criticized for failing to analyze the potential cost impact of the AIHC Alternative. As was pointed out at the hearing, in addition to the problem of AIHC's own finite resources, it was not possible to examine the Alternative within the deadlines for filing in this proceeding since the Alternative was being developed in parallel with the Snell effort. In addition, as AIHC understands the law, it is OSHA's obligation, not AIHC's, to examine the impact of its Proposed Regulation and all reasonable alternatives thereto, including the AIHC Alternative. We might add in passing that almost three years have passed since work on the Proposed Regulation began without economic analysis of any sort by OSHA.

("ADL") (Ex. 69), said it could not live with and in fact did live with, according to some, very comfortably. Those who relied on the vinyl chloride "story", principally Ms. Ruttenberg and Dr. Epstein, however, obviously did not understand the assumptions built into the ADL analysis. (Tr. 5799-5800; 1250-53.) ADL surveyed the potential economic impact of a vinyl chloride regulation requiring no detectable exposure, which would shut down the industry. (Tr. 5800.) The regulation adopted by OSHA imposed a much more lenient permissible exposure limit of 1 ppm with a 5 ppm ceiling, not a no-detectable exposure limit. In fact, under questioning, Ms. Ruttenberg acknowledged she had not even read the ADL study upon which she so heavily relied. (Tr. 5799-5780.) It was obvious that she was confusing a study of the regulation prepared by Snell for OSHA (Snell's client) with the ADL study. Id.

Another example of "crying wolf" cited by Dr. Epstein was industry's compliance estimates for the Toxic Substances Control Act ("TSCA"). In his testimony, Dr. Epstein, however, mistakenly quotes Snell as estimating costs of $12 billion. In fact, Snell estimated costs would range from $360 million to $1.3 billion depending on various assumptions and scenarios. Further, Dr. Epstein confuses EPA's budget for TSCA with the cost of TSCA compliance to the nation. (Epstein S. 72.) While on the issue of "track" records, it may be useful to examine EPA's own record on this issue. EPA originally estimated the costs of TSCA to the economy to be $40 million which was

raised to $45 million; EPA later raised the estimate to $80 million, and then to $140 million. In 1975 EPA estimated an TSCA annual operations budget of $10 million. EPA now is discussing an annual TSCA budget of $50 million.

To further put the allegations of industry overestimates and "crying wolf" into perspective, it may be helpful to examine the Snell data more closely. Snell estimated a compliance cost of $1.1 billion for regulating the manufacture (as distinguished from downstream use) of 1,870 subtances to 1 ppm. The MIT retrospective vinyl chloride study upon which Ms. Ruttenberg so heavily relied (Ex. 70) estimated the cost of compliance with vinyl chloride alone at $350 million. This on its face certainly does not seem to be a case of industry crying wolf.

Finally, a number of methodological flaws were cited in the Snell Report which purportedly undermined it. Putting aside the fact that the stated significance of the Snell Report was not in the particular numbers set out therein but rather in illustrating the need to take a hard look at the OSHA proposal, it is clear that those criticizing the methodology did not adequately understand or take the time to understand the Report. For example, Ms. Ruttenberg criticized Snell for failing to take into account technological advances in the chemical industry which might result in cost savings. In fact, Snell had done so by relying heavily upon the data derived from its vinyl chloride case study, a substance for which significant technological control advances resulted in considerable economies.

Ms. Ruttenberg also criticized Snell for using an annual 10% employee turnover rate in its study. Ms. Ruttenberg argued, based on Department of Labor statistics, that the rate should have been only 1.8% annually. As pointed out in questioning, Ms. Ruttenberg mistakenly assumed her 1.8% figure was an annual one, when in fact it was a monthly figure. (Tr. 5801-5802.) Further, Ms. Ruttenberg criticized Snell for failing to take into account the purported cost savings of substitution. In fact, Snell did consider substitution cost savings and used substitition costs where applicable. See Snell Supplemental Statement at 12 (AIHC P.H.). Again in questioning, Ms. Ruttenberg's failure to study and understand this aspect of the Report was evident. (Tr. 5802-5806.)

Despite the criticisms of the Snell Report, one fact remains unalterably correct: the OSHA proposal will have significant economic impacts, a fact which Southwest Econometrics, Inc. acknowledged. For this reason alone, the Proposed Regulation and alternatives thereto should be carefully analyzed from an economic perspective. Only through such analyses can societal resources be maximized.

Conclusion

Prior to publishing a final regulation in this rulemaking, OSHA has an obligation to conduct a thorough economic analysis of the proposal and allow meaningful public comment on its analysis.

PART TWO

VIII

THE METHOD OF CLASSIFICATION AND THE CRITERIA FOR OSHA'S CATEGORY I ARE IMPERMISSIBLY VAGUE AND ARBITRARY

"Science deals in probabilities, and carcinogenesis bioassays give results that may fall anywhere on a continuous spectrum of probabilities, extending from 2 or 3% at the lowest to nearly 100% at the highest. Division of this spectrum into discrete categories may be necessary for regulatory processes, but is necessarily arbitrary from a scientific point of view. Thus the recommendations of a scientist would be to make the criteria for categorization flexible, and to apply as much scientific judgment to each case as is compatible with legal and regulatory requirements." (Dr. Rall S. 14.)

"The complexity of the problem dictates that the evaluation of the potential human hazards of a given agent must be individualized in terms of the chemical and metabolic aspect of that agent, its intended use(s), and data available at the time the decision must be made, and other factors pertinent to the case under consideration. Each case must be considered on its own and the criteria appropriate to one agent may not necessarily apply to another."1/

"The judgment of carcinogenicity needs to be made by competent, experienced and objective professionals after analysis of all the relevant evidence. It goes without saying that this judgment should be objective and immune from conflicts of interest." (Dr. Saffiotti S. 7.)

"We believe that some flexibility is important to OSHA's categorization scheme both to avoid

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1/ "General Criteria for Assessing the Evidence for Carcinogenicity of Chemical Substances; Report of the Subcommittee on Environmental Carcinogenesis, National Cancer Advisory Board," 58 J. Natl. Cancer Inst. 461 (Preamble Ex. 71) [hereinafter referred to as NCAB General Criteria].

unreasonable results and to separate clearly scientific from regulatory judgments. The greater the degree to which regulatory judgments flow from scientific judgments, the greater is the possibility that the scientific judgments could become biased. Conversely the more discretion the policy maker has to determine what regulatory action to take, the less likely is it that policy judgments will enter into scientific opinions." (EPA S. 4.)

"As a check on the reliability of the experiment and for the quantification of carcinogenicity, a positive test is generally not considered adequate unless the frequency of cancers is found to be dose dependent." 1/

Introduction

The regulation of carcinogens in the workplace involves two separate decisions. First, whether or not the substance is a carcinogenic risk to man. Second, whether or not regulatory action should be taken. These are separate and distinct decisions as a number of the OSHA and other witnesses recognized when they clearly separated their comments on scientific issues from matters of regulatory authority or policy. See, e.g., Upton Tr. 276-277, 297; Rall S. 2; Griesemer Tr. 894, 922; Lave Tr. 7013; EPA S. 4, quoted at the beginning of this section; and Meselson Tr. 1488. In this section of the brief, AIHC will address the issues relating to the determination that a substance presents a human cancer risk. In subsequent sections of the brief we will address the issues that relate to regulatory action.

1/ The National Academy of Sciences Report, "Contemporary Pest Control Practices and Prospects" NAS (1975), at 65 (attached to Dr. Kennedy's statement).

A. There Should Be An Independent Scientific Evaluation Of The Data

The scientific evaluation process for both epidemiological studies and animal tests involves evaluation of the soundness of the design and conduct of the study and a determination as to whether the conclusions of the study are justified by the data. There are, of course, major differences in the evaluation of animal and human studies; a basic difference being that an animal study requires extrapolation across species to man while an epidemiological study does not.

AIHC believes that it is fair to say that OSHA witnesses agreed that the evaluation of human risk calls for exercise of scientific judgment by experts in several disciplines. Dr. Upton said "many experiments raise specific problems of interpretation. The resolution of these problems requires evaluation by experienced professionals in several disciplines and cannot be reduced to a formula." (Upton S. 12; see also Tr. 276-277, 292-293, 329-332.) Similarly, Dr. Rall said the evaluation process was one which demanded scientific judgment. (Tr. 358, 362.) In his prepared statement, Dr. Saffiotti (one of whose statements is quoted at the beginning of this section) referred to "judgment" fifteen times. (Saffiotti S. 6, 7, 13, 15, 16, 25, 27, 37, 38, 39, 41; see also Tr. 854, 896, 900; and see Dr. Griesemer Tr. 961, 971-974.) Most witnesses also agreed that the scientists making the judgment wanted all available facts. See, e.g., Schneiderman Tr. 818-819; AISI 4669, 4671; Rall Tr.

380, 417; NIOSH Tr. 2981-2982, 3075; see also Dr. Golberg Tr. 6488; Dr. First Tr. 6885; Dr. Kessler Tr. 6920; and Dr. Lave Tr. 6935. The weight to be given the data would be determined by the exercise of informed scientific judgment, not by any pre-judgment or prior administrative policy decision.

We addressed earlier in this brief (see supra, at 41-51) the legal question whether OSHA's "freezing" of science by its proposed policy determinations on scientific issues is valid under Section 6(b)(5) of the statute, 29 U.S.C. § 655(b)(5), which requires OSHA to consider the "best available evidence," including the "latest scientific data in the field," and whether OSHA's proposed process of amendment of the generic standard to accommodate new scientific information is valid or whether it denies due process. In this portion of the brief we are addressing the question whether foreclosing consideration of data bearing on the scientific evaluation of a substance is scientific.

1. The AIHC proposal for an Independent Scientific Data Evaluation and Classification Panel

OSHA's error stems in part from the intermixture of the scientific evaluation of the data on a substance with the separate issue as to what regulatory action should be taken. Each question is separate and distinct and the former should precede the latter.

The AIHC proposal for the creation of an independent, unbiased scientific Panel to evaluate the data and its relevance to man is a clear recognition of the fact that evaluation

of the data involves scientific rather than regulatory judgments.[1/] AIHC proposes that the determination by the scientific Panel be final and binding on the regulator for three reasons: to bring the scientific evaluation to a speedy conclusion, to avoid intermixture of that evaluation with the regulatory determination, and at the same time to provide a basis for judicial review.

The second step in the process is a determination by the regulator of the nature of the hazard -- number of workers exposed and level of exposure -- and a determination as to what action, if any, is warranted based on the hazard evaluation.

AIHC agrees with EPA and Dr. Saffiotti in the statements quoted at the beginning of this section of the brief, that the scientific evaluation should be objective, unbiased and immune from conflicts of interest. For this reason, the selection process for membership in the independent scientific Data Evaluation and Classification Panel proposed by AIHC involves nomination by scientific institutes and associations, with selection of members of the Panel by the National Academy of Science. To assure objectivity, no member of the Panel would be employed by any other executive agency or independent regulatory agency during his term on the Panel, except in an academic, teaching or research capacity. The National Academy

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1/ A description of the function and operation of the proposed scientific panel, together with a memorandum regarding authority to establish a panel is set out in Exhibit 62 (a copy of which is attached as Appendix C).

would be instructed to screen very carefully for conflicts of interest persons nominated for membership on the Panel who are employed by private industry. A proposed plan for the establishment and operation of the Panel is set out in Appendix C.

The idea of an independent panel is not new. The National Cancer Institute Ad Hoc Committee on Testing for Environmental Carcinogens in its report dated August 31, 1973, recommended the formation of a scientific panel to ensure reasonable standards for evaluation of tests and test results,

> "in order to insure, insofar as possible, the validity of the experimental data and the interpretations placed upon them." (Ex. 14 at 4.)

Dr. Epstein also recommended an independent scientific panel, with functions considerably larger than those proposed by AIHC. (Epstein S. 103-105; see also NIOSH S. 7.)

AIHC believes its proposal is better suited to the function of scientific evaluation in this context than the proposals mentioned above. The AIHC proposal will assure consistent application of the best scientific judgment in the identification and evaluation of substances which pose a human carcinogenic risk from exposure in the workplace. 1/

1/ AIHC has suggested that an independent scientific panel of the stature and quality envisaged might also serve the other regulatory agencies: EPA, CPSC and FDA -- thus, assuring uniformity of scientific evaluation of the data for regulatory purposes. The establishment in the IRLG of a Toxic Substances Data Committee to identify and share data needed by the four regulatory agencies underscores the need for an agency such as the scientific Panel advocated by AIHC to serve as a source of reliable, uniform, scientific information and evaluation to the regulatory agencies. See Ex. 34, 43 Fed. Reg. 7186; Tr. 1418.

2. OSHA's intermixture of scientific and regulatory functions

OSHA's proposal to pre-determine scientific issues by policy decisions is based on a failure to recognize that scientific evaluation of data should be separate from societal decisions which are part of the regulatory process. 1/ The intertwining of the two functions in one regulator creates problems of the kind recognized by EPA in its statement quoted at the beginning of this section. When the two separate processes are combined, the scientists are constrained and the regulator does not have the essential freedom to make the regulatory judgment on the basis of a separate unbiased scientific evaluation. (EPA Intra-Agency Memorandum from Roy Albert, Chairman, Carcinogen Assessment Group, to Andrew Breidenbach, dated November 25, 1977 (API P.H.).)

OSHA's confusion of the regulatory and scientific functions led OSHA to construct its Proposed Regulation on an artificial presumption/rebuttal process which is inconsistent with the process of scientific evaluation. As Dr. Griesemer said "[r]ebut is not a word in our vocabulary." (Tr. 941.)

Under the OSHA conception, positive results in animal tests create the presumption and the scientific evaluation follows as a rebuttal process. Dr. Rall's description of the scientific

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1/ The IRLG Risk Assessment Work Plan carefully distinguishes the scientific problem on risk assessment from the policy decision as to the level of acceptable risk. See Ex. 34, 43 Fed. Reg. 7195.

evaluation process makes clear that a presumption/rebuttal model does not fit:

> "The scientific decision as to whether a chemical has been shown to be carcinogenic in an animal species requires consideration of all aspects of the experiment, including not only the statistics of the number of tumors but also the pathological diagnoses, exposure regimens, health and nutrition of the animals, and many other factors. Once a chemical is established as a carcinogen in an animal species, there follows a presumption of risk to exposed humans, but the precise degree of risk depends on consideration of other factors, including routes of exposure, metabolic pathways, structure-activity relationships, etc. It is difficult to reduce these manifold considerations to a formula." (Dr. Rall S. 13.)

Positive results in animal studies before evaluation establish only that a potential for human risk exists. As both Dr. Upton and Dr. Rall made clear, it is only after the full scientific evaluation is made that a determination as to probable risk to man can be made.[1/] In his testimony, Dr. Upton also referred to some of the factors which must be considered before

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1/ The Subcommittee of the National Cancer Advisory Board described the scientific evaluation as follows:

> "Quantitative extrapolation from animal studies for the purposes of evaluating human risks entails large uncertainties at the present time. Each case must be individually evaluated, taking into consideration such factors as adequacy of experimental design, statistical significance of the data, dose-response relations, duration of exposure, route of administration, metabolism (including species variations), host susceptibility, co-factors and other modifying factors, and the amount of the material to which humans will be exposed. The criteria for extrapolation may vary depending on the agent in question." NCAB General Criteria at 463.

a conclusion can be reached as to the risk to man:

> Dose response
> Ability of humans to detoxify, metabolize or excrete the substance
> Mechanism of action and the way the substance is handled in human tissue
> Adequacy of pathology
> Route of exposure
> Validity of test procedures (Tr. 322-325.)

See also Dr. Griesemer Tr. 936; Dr. Gross Tr. 8320.

OSHA's presumption/rebuttal procedure has turned the whole evaluation process upside down. Until the evaluation has shown that there is a human risk there is no basis for classification for regulatory purposes. OSHA's misunderstanding of the evaluation/extrapolation process is shown by its reluctance to add the fifth "rebuttal criteria": that for some scientific reason the results in animals "are not scientifically relevant to man." 42 Fed. Reg. 54171. When asked whether such evidence should be considered, Dr. Rall gave the unequivocal answer "always". (Tr. 364.) Dr. Saffiotti concurred. (Saffiotti S. 41.) See also NIOSH Tr. 3075; EPA Tr. 2366; and Dr. Gross Tr. 8315-8319.

The Proposed Regulation needs to be re-oriented. Evaluation must take place at the outset, not as an afterthought. Further, the relevant issue is human risk. Until such risk is established after scientific evaluation of all the evidence, there is no basis for regulatory action and categorization of substances. Only when the human risk is scientifically evaluated and presented to the regulator can the regulator assess hazard and reach the

appropriate regulatory conclusion.[1/]

It is precisely for this reason that AIHC proposed the creation of the Scientific Data and Evaluation Panel. A substance would not be categorized under the AIHC proposal until the evaluation is complete.

B. The Criteria For OSHA Category I Are In Many Instances Arbitrary, Inflexible And Unwarranted

Both OSHA (Category I) and AIHC (AIHC Categories I and II) agree that a substance may be determined to present a carcinogenic risk to man on the basis of human epidemiology or mammalian animal data. There is agreement further that a substance which is a confirmed oncogen in two mammalian species should be subject to regulation as a probable human carcinogen. AIHC also agrees with OSHA that injection site sarcomas and chemical structure do not provide a basis for classifying a chemical.

These are major areas of agreement. There are, however, major areas of disagreement and, as we shall show, the record supports the AIHC Alternative as being the more scientifically sound. We shall discuss each of the areas of disagreement.

1. Human epidemiology

AIHC agrees with OSHA that positive epidemiology is

1/ If evaluation follows categorization, a great disservice is done. Not only is the product and the manufacture subject to increased burdens but the public may be unnecessarily alarmed. A serious due process issue arises if materials are categorized and stigmatized as a carcinogen before a reasonable opportunity to present evidence is afforded. (See discussion supra, at 48-51.)

the best evidence that a substance is a human carcinogen; indeed human experience is the only evidence that a material is a human carcinogen. (Dr. Van Raalte S. 12-22.) To underline the significance of this identification in man, AIHC proposed a separate category (AIHC Category I) which includes those substances identified by positive epidemiology as human carcinogens.

There are major differences, however, between OSHA and AIHC concerning the weight or importance of negative epidemiological studies.[1/] In the Preamble OSHA details the difficulties associated with the design and conduct of epidemiological studies (42 Fed. Reg. 54155-156) and concludes that, as a "practical rather than a theoretical matter, positive animal data should supersede negative human data, in general, because of the inherent defects in such human studies, as pointed out above." Id. at 54161.

The record shows that OSHA for "practical" reasons is disregarding evidence which should be evaluated as a scientific matter with respect to any substance. Perhaps the clearest statement of the role of negative epidemiology is in the Report of the Subcommittee of the National Cancer Advisory Board entitled "General Criteria for Assessing the Evidence for Carcinogenicity of Chemical Substances." In this very careful report subject to

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1/ On September 11, 1978, as part of its post-hearing filing AIHC furnished to OSHA a copy of "Guidelines for Evaluation and Use of Occupational Epidemiologic Cancer Studies" prepared by AIHC. A copy of the guidelines is attached as Appendix D.

extensive peer review, the Committee concluded:

> "Negative epidemiological data may not establish the safety of suspected materials. Negative data in a given agent obtained from extensive epidemiologic studies of sufficient duration are useful for indicating upper limits for the rate at which a specific type of exposure to that agent could affect the incidence and/or mortality of specific human cancers." NCAB General Criteria at 462.

Dr. Rall agreed with the NCAB as to the appropriate role for epidemiology. (Tr. 366.) Dr. Hoover and Dr. Bates also agreed that a valid negative study could identify the upper boundary of a potential hazard. (Tr. 794; Bates S. 11.) Dr. Berg urged OSHA not to reject a valid negative study. (Tr. 1679.) Dr. Epstein testified that negative studies should be weighed in the regulatory process. (Tr. 1462.) NIOSH testified flatly that "[a] negative epidemiological study should receive the same weight as a positive one but, in either case, this weight is a function of the scientific quality of the research. . . . It is obvious that if well designed and executed negative epidemiological studies are given little weight in scientific decision making, then no industry will conduct them." (NIOSH supplemental answer to OSHA question 5(3); see also Tr. 2954; Dr. Upton Tr. 317-318; AISI Tr. 4662; Dr. Gehring Tr. 4152; and Dr. Gross Tr. 8322; Dr. Robert Morgan written statement at 11 (AIHC P.H.).)

Dr. Morgan testified to a methodology for weighing negative and positive studies. (Tr. 3619-3622.) His statistical methods are set out in his paper. (AIHC P.H.) Thus OSHA has

available statistical methods for weighing positive and negative studies. Other witnesses set out alternative methods of evaluation of positive and negative studies. See, e.g., Hooker Chemical Tr. 4116-4140.

There are physiological and metabolic differences between rodents and man and substances which may be carcinogenic to animals may not be carcinogenic to man. There is evidence in the record that epidemiology can identify substances shown to be carcinogenic in animal tests which do not present a carcinogenic risk to man at the levels to which man is exposed. Dr. Clemmesen and Dr. McLean referred to phenobarbitol (Tr. 3553-3556; 4804-4805). DDT[1/] and saccharin were cited by Dr. Olson (Tr. 3226). Dr. Golberg referred to dinitrotoluene (Tr. 6511-6513), and DDT and aldrin/dieldrin were cited by Dr. Van Raalte (Tr. 3556-3558, Ex. 53) and Dr. Astolfi (S. at 3-5). Dr. Murray also referred to his extensive practical experience with a number of substances (S. 4).

Negative epidemiology can also serve to correct risk estimates based on positive animal data. Perhaps the best example in this record is ethylene dibromide where on the basis of an epidemiological study of 158 exposed workers, EPA was led to modify its risk assessment from exposure to that compound based on positive animal data. (Ex. 43, Tr. 2336; "Risk

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1/ The NCI announced that its bioassay of DDT in Osborne-Mendel rats and B6C3F1 mice found no evidence of carcinogenicity. 43 Fed. Reg. 46585 (October 10, 1978).

Assessment for Ethylene Dibromide (EDB)," API P.H.) EPA also testified that negative epidemiological data are particularly useful where a positive animal study involves a route of exposure different from human exposure. (Tr. 2383.)

Another example in the record of the use of human epidemiology to adjust or correct a risk assessment based on animal data is the FDA risk assessment of aflatoxin in peanut butter. (Ex. 38.) The FDA relied on epidemiological data in reaching the conclusion that humans are biologically closer to aflatoxin resistent mice than the more aflatoxin susceptible rats. Id. at 3-4. The data were also used to calculate the potential health benefits from an additional reduction in aflatoxin level. Id.

The record does not support OSHA's administrative rejection of negative human studies. On the contrary, the record makes clear that such studies can have significant value.

2. Animal data -- an overview

Perhaps the most concise and clear statement regarding animal data was made by Dr. Rall. He testified:

> "I believe that most scientists will be happy to see the introduction of something like Category II, recognizing that some experiments give inconclusive results and allowing us to escape from the dilemma of having to assign all chemicals into 'Yes' or 'No' categories. On the other hand, scientists always feel unhappy about the application of rigid criteria to complex questions. The scientific decision as to whether a chemical has been shown to be carcinogenic in an animal species requires consideration of all aspects of the experiment, including not only the statistics of the number of tumors but also the pathological diagnoses, exposure regimens, health and nutrition of the animals, and many other factors. Once a chemical is established as a carcinogen

in an animal species, there follows a presumption of risk to exposed humans, but the precise degree of risk depends on consideration of other factors, including routes of exposure, metabolic pathways, structure-activity relationships, etc. It is difficult to reduce these manifold considerations to a formula.

On the one hand, there are cases where a single well-conducted experiment giving clearly positive results should suffice to establish a chemical as a carcinogen and to justify stringent measures to reduce occupational exposure. On the other hand, there are cases where two or even three less conclusive positive results would still leave some doubt. The fact is that scientific experiments never give results that are 100% positive, nor 100% negative. Science deals in probabilities, and carcinogenesis bioassays give results that may fall anywhere on a continuous spectrum of probabilities, extending from 2 or 3% at the lowest to nearly 100% at the highest. Division of this spectrum into discrete categories may be necessary for regulatory purposes, but it is necessarily arbitrary from a scientific point of view. Thus the recommendation of a scientist would be to make the criteria for categorization flexible, and to apply as much scientific judgment to each case as is compatible with legal and regulatory requirements." (Rall S. 13-14.)

In addition, OSHA "recognizes that the results of a single study in a single species can be in error." 42 Fed. Reg. 54170. This is an acknowledgement of the more general principle cited by the National Academy of Science in the study "Drinking Water and Health"[1/] [hereinafter referred to as "NAS Drinking Water Study"] where it noted:

> "Any series of experiments will yield false-positive and false-negative results." NAS Drinking Water Study at 27.

1/ (NAS 1977). Appendix I to the prepared statement of Dr. Rall.

Dr. Furst discussed at length the problem arising because many tests performed in the past are invalid. Thus early positive tests on a number of substances are not reliable bases for regulatory decisions. (Tr. 6924-6926.)

Dr. Peto explained the statistical possibility that an erroneous positive result can be a matter of chance. (Tr. 2547-2550.) If the confidence level is 95% then there will be one positive study as a matter of chance in twenty studies of the same substance. (Peto S. 5.) See discussion infra, at 143, 163-164. Professor Zeckhauser made a similar explanation. (Tr. 4334.) See also Dr. Robert Morgan's written statement at 5 (AIHC P.H.). Dr. Greisemer did a calculation as to the probabilities of a false positive under conditions of the NCI bioassay, a calculation which has to be made for each study based on the conditions of that study. (Greisemer S. 8-10.)

Thus, the issue at the outset is the degree of certainty that a substance is an animal oncogen. The second question is the degree of certainty that the animal data may be validly extrapolated to man. Unfortunately, OSHA has not disclosed the criteria which it and the IRLG are considering for evaluating animal tests and thus a number of issues remain open and in doubt; they cannot be usefully commented on in this proceeding. It is clear, however, that OSHA should supplement or modify its criteria for Category I with respect to the following:

-- maximum tolerated dose studies

-- pharmacokinetics, metabolism and DNA repair

-- statistical significance

-- tumor prone species

-- mouse data

-- factors affecting test results

-- positive/negative results

-- single species or two species

-- replication

-- short term tests

-- route of exposure

3. Maximum tolerated dose studies

The Proposed Regulation speaks of positive results in animal studies without any distinction between studies conducted at maximum tolerated dose ("MTD") or at levels more nearly similar to those to which humans are exposed.[1/] This is a misuse of these animal data for regulatory purposes.

It is important to understand the very limited conclusion which NCI believes can be drawn from an MTD test. Dr.

1/ The NCI Guidelines for Carcinogen Bioassay in Small Rodents defines MTD as follows:

> "The MTD should be the highest dose that causes no more than 10% weight decrement, as compared to the appropriate control groups, and does not produce mortality, clinical signs of toxicity, or pathological lesions (other than those that may be related to a neoplastic response) that would be predicted to shorten the animal's natural life span." (NCI Guidelines for Carcinogen Bioassay in Small Rodents, at 14-15, quoted in Dr. Saffiotti S. 9-10.)

The Guidelines limit the amount of a substance in a feeding trial to 5% of the diet. Id. at 18.

Upton explained that the NCI bioassay based on MTD is intended as a screening procedure to identify a substance with the potential to cause cancer, not as a test to measure the frequency of induced cancer at a particular level of exposure.[1] (Upton S. 11 Tr. 322; see also Bates Tr. 642-644.) Dr. Greisemer described the results of the program in the same way.[2] See also Tr. 4295-4296; Dr. Lijinsky S. 29. NCI's Clearinghouse has itself recognized that the "studies are a screen to provide a yes/no indication of carcinogenicity in animals."[3]

Dr. Upton and Dr. Rall both made clear that in order

1/ In earlier testimony, Dr. Upton described the NCI bioassay program to the House Interstate and Foreign Commerce Committee as follows:

> "The NCI animal bioassay efforts from chemical carcinogens can merely detect the chemical's potential for causing cancer in humans. Its results cannot tell us whether a particular chemical will cause human cancer, but they may alert us to the presumptive risk, and thus serve as a basis for further studies of the chemical in question." (Tr. 322.)

2/ "The results of animal experiments conducted with the highest possible doses should not be used for quantitative risk assessments. By themselves, they provide little information about dose response and none that can be directly extrapolated to man. Such experiments, however, do provide a starting point for exploring dose response relationships in the experimental animals." (Dr. Griesemer S. 6; see also Tr. 958-959.)

3/ Report of the Clearinghouse on Environmental Carcinogens on the Review of the Bioassay Backlog and Data at 21 (May 1978) (emphasis added) [hereinafter referred to as "Report of the Clearinghouse"] (AIHC P.H.).

to evaluate the human risk additional data are needed.[1/] (Tr. at 322-325, 487-488.) The NCI multidisciplinary evaluation process, which includes an independent review by the National Clearinghouse for Environmental Carcinogens, was described in detail by Dr. Griesemer. (Tr. 971-977). NIOSH similarly has a full multidisciplinary review of test data before reaching conclusions as to animal carcinogenicity and extrapolation to man. (Tr. 2884-2893, 2895-2898.)

Other witnesses indicated the particular weaknesses of the MTD test as an indication of human risk. Dr. Van Duuren expressed concern that only weight loss was considered by the NCI as a limiting parameter of MTD. He said

> "an acceptable and more agreeable maximum tolerated dose is when the animals grow normally and healthy and gain weight normally unless they come down with a tumor." (Tr. 1808; see also Tr. 1814.)

1/ In an article by Dr. Rall entitled "Species Differences in Carcinogenic Testing," attached as Appendix E to Dr. Rall's testimony, Dr. Rall set out in tabular form the factors to be assessed as follows:

Table 1
Assessment of Environmental Chemicals for Carcinogenicity
Differences between Test Animals and Man

I. Sensitivity of laboratory animals as compared to man
   - A. pharmacological differences
   - B. receptor differences
   - C. temporal differences
   - D. size differences

II. Population differences
   - A. size
   - B. heterogeneity
   - C. selected nature of test population

III. Environmental differences
   - A. nutritional
   - B. physical
   - C. chemical

He urged that a MTD be selected which did not damage organs or result in metabolic overloading. Dr. Gehring stressed the importance of the fact that repair mechanisms are overwhelmed at high doses. (Tr. 5034-5036, 5131-5132.) Similarly, Dr. McLean testified that large doses can alter metabolic pathways and injure tissues making it difficult to extrapolate from MTD doses. (Tr. 4845-5846.) Dr. Olson also emphasized that MTD can incapacitate or injure organ systems leading, for example, to renal damage as well as neoplastic lesions. (Tr. 3238.) Dr. Olson referred specifically to the MTD bioassay on trichloroethylene where there was evidence of renal and cardiac damage. (Tr. 3244.) Exhibit 83 is a statement by Dr. Bernard Oser, presented to the National Academy of Science committee evaluating saccharin, in which he refers to the organ damage which raised questions about the results of the experiments on saccharin. Similarly, Dr. Furst discussed the consequences of physical damage from an excessive dose. (Furst S. 7-9, Tr. 6931-6932, 6947-6948.)

Dr. Kotin stated that using high dose as an equivalent or substitute for large numbers of animals is "subject to very serious question," since the use of high doses may result in a series of chemical pathways resulting in the formation of end-products with contrasting biological effects. (Tr. 8615, 8716.) High doses, he added, interfere with DNA repair mechanisms as well as change metabolic pathways. (Tr. 8722-8723; see also Dr. Skalsky Tr. 7589-7590.)

Dr. Golberg testified in detail regarding the complexi-

ties of MTD testing. (Golberg S. 3-6, Tr. 6484-6491.) He pointed out the difficulties of choosing the correct MTD -- not too toxic or too low. Id. He called attention to the criteria of the Food Safety Council for selection of MTD:

> "1. Induces no overt toxicity, i.e., appreciable death of cells or organ dysfunction as determined by appropriate clinical, pathological, or biochemical methods.
>
> 2. Induces no toxic manifestations which are predicted to shorten the lifespan of the animals except as the result of neoplastic development.
>
> 3. In two generation studies, is not detrimental to conception rates, fetal or neonatal survival, or postnatal development.
>
> 4. Does not retard weight gain during the subchronic test by greater than 10% as compared to control animals.
>
> 5. Takes into consideration metabolic and pharmacokinetic data, and if dose-dependent qualitative or quantitative differences occur, at least one test dose should be set above the metabolic shift (provided the level(s) does not exceed the criteria listed above 1 through 4)."
> (Golberg S. 3-4.)

Thus, Dr. Golberg testifed, if the MTD is not selected properly, massive nonspecific tissue damage can result. Id. at 4. This can lead to carcinogenic results by a "secondary mechanism" -- tissue damage. (Golberg S. 4-6, Tr. 6484-6491.) The questionable relevance of a positive result from secondary carcinogenesis was recognized, Dr. Golberg said, by the Food and Drug Administration in the case of selenium and by investigators in the case of antithyroid action of substances in rats which have no counterpart in man. (Golberg S. 5-6.)

The IRLG Risk Assessment Group also recognizes the phenomenon of secondary carcinogenesis as a result of stresses to physiological systems of the test animals to the point that the altered physiology itself leads to cancer. (Ex. 147.)

Despite these limitations on data from MTD experiments, the OSHA proposed categorization does not distinguish between MTD and lower dose experiments. This omission is not cured by the "rebuttal" criteria of Section 1910.111(a). If the route of exposure in the animal experiment was different from the route of exposure to man, it must be shown to be "grossly inappropriate", Section 1990.111(a)(2), a term undefined in the regulations. There is no definition of "suggestive" in Section 1910.111(a)(3) nor is there any indication as to how one could demonstrate the data are "totally inadequate" to establish conclusions under Section 1990.111(a)(4). Similarly, "some other reason" is not defined in subsection 5, Section 1990.111(a)(5).

To eliminate this ambiguity with respect to the MTD data, AIHC set out to establish criteria to identify these data and give them the meaning consistent with the NCI description. Thus experiments conducted at excessive doses are placed in Category III in the AIHC Alternative as substances for further testing which may be regulated in the meantime for acute or chronic toxicity other than carcinogenicity. This is substantially the same treatment as for substances OSHA classified in OSHA's Category II.

Criteria to identify excessive dose experiments have

been proposed by the American Conference of Government and Industrial Hygienists before this proceeding began. Since these were independently derived criteria, AIHC adopted them as guidelines for its Alternative. AIHC recognizes that such criteria can be refined to serve the purpose of identifying the MTD bioassay results so that on the basis of such tests substances would be classified in OSHA Category II and AIHC Category III.

4. Pharmacokinetics, Metabolism and DNA repair

The validity of animal tests as a basis for extrapolation to man depends on the similarity between the metabolism of man and the test species with respect to a particular substance. Despite similarities between mammalian species with respect to metabolic processes, there are also differences. (Dr. Hart Tr. 3491-3492, 3499-3501; Dr. Kotin Tr. 4890-4891, 4908-4909, 8653-8654; Dr. Golberg Tr. 6498, 6511-6514; Dr. Yang Tr. 6799-6827; Dr. Rousch Tr. 4978-4979; Dr. Olson Tr. 3242-3241; Gross Tr. 8320).[1/] As we have pointed out supra, at 121-123 and 128-131, many witnesses, including Dr. Rall and Dr. Upton, testified that a scientific evaluation of animal data to determine risk to man includes an appraisal of differences in metabolism and pharmacokinetics of the test animal and man. Dr. Albert

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1/ A recent example of an instance in which an expert body took into account metabolic differences between species in assessing carcinogenicity is a 1978 report of a joint FAO/WHO committee on pesticide residues in food. (Ex. 53.) The committee concluded that aldrin and dieldrin were not carcinogens for man despite certain mouse data to the contrary. The committee discounted the mouse data on the basis of a thorough review of metabolic data. Id. at 11-12.

testified that EPA would evaluate metabolic data. (Tr. 2369.)

Much of the criticism of the relevance of metabolic differences between man and test animals turned on two points:

1) little is known about metabolism of substances, and uncertainties are great;

2) any delay to secure metabolic data would delay the regulatory processes unreasonably.

There is little doubt that the study of comparative metabolism is a science which has not yet developed to a level which allows careful interspecies analysis. On the other hand, experimenters like Dr. Hart and Dr. Yang make clear that the science of comparative metabolism has made great strides. (Dr. Hart Tr. 3481-3483; Dr. Yang Tr. 6799-6827.) Comparative metabolism provides results which are not only useful now when the data are available, but also holds enormous promise for the future if OSHA and other regulatory agencies recognize its value and encourage development of the data.

A number of witnesses addressed the subject of DNA repair, which is barely referred to by OSHA in the Preamble to the Proposed Regulation. DNA repair can be regarded as a phenomenon having a bearing on thresholds since DNA repair systematically and effectively can overcome deleterious effects of exposure to chemicals. (Dr. Hart S. 14-28, Tr. 3459-3462, 3477-3484; Dr. Skalsky Tr. 7584-7592.) Further, species differences in DNA repair capacity provide a number of insights as to man's ability to repair carcinogenic insults and acti-

vate compounds to their carcinogenic state.[1/] Dr. Kotin referred to DNA repair as one of the areas in which the most important discoveries of recent years have been made. (Tr. 8752-8753.) In the present context, DNA repair is being discussed in the context of metabolic differences and similarities between animals and man.

Dr. Hart discussed and referred to the literature on the newly developing science of comparative studies of species differences in DNA repair. (Dr. Hart S. 14-28, Tr. 3459-3462, 3477-3482.) This work, like that of Dr. Yang, opens the door to the possibility of identifying the species whose metabolism is closest to man. The experimenter could use these data to select the species whose test results would be more relevant to man and the scientist could use the data in the risk evaluation with confidence. Indeed, Dr. Hart held out the prospect that test systems developed by this emerging science may enable scientists to identify, monitor and indeed quantify exposure of individuals to suspect sustances. (Tr. 3473-3476, 3495-3496.)

AIHC joins with Dr. Hart in urging that OSHA encourage the development of data on metabolism and DNA repair. While these data serve a purpose now, their promise for the future is

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1/ Dr. Hart noted that there was some emerging evidence to support the view that longer-lived species such as man are less able to electrophilically activate substances to their carcinogenic state and better able to repair carcinogenic insults than shorter-lived rodents. (Dr. Hart S. 28.)

great. Any refusal by OSHA, under the guise of administrative determination of scientific issues, which cuts off use of these data in individual substance proceedings can only be described as tragic.

There is an additional aspect of metabolism analysis which should also be noted. As we have pointed out supra, at 133-137, MTD testing may lead to metabolic overloading and organ damage. This in turn can lead to what Dr. Golberg and Dr. Skalsky referred to as "secondary" carcinogenesis. Thus, metabolic analysis can offer new interpretive tools which will enable the scientists to distinguish the "secondary" results whose relevance to human risk may be slight. See Dr. Gehring Tr. 5034-5035, 5186-5191.

Several witnesses have testified that the science of metabolic differences and pharmacokinetics have reached the stage in development where it is reasonable to include the data in mathematical extrapolation models. (Dr. Hoel Tr. 2145-2148; Dr. Peto Tr. 2538-2540; see also Dr. Skalsky Tr. 7590-7591, 7597-7599.)

AIHC does not suggest that OSHA require that metabolic data be available before a risk assessment is made based on animal data. However, in view of the developments in the science of comparative metabolism and the development of tests which promise relatively speedy metabolic comparisons (Dr. Hart Tr. 3473-3476, 3495-3496; Dr. Yang Tr. 6802-6807, 6811-6812; and Dr. Skalsky Tr. 7591-7602), OSHA should encourage the development and use of metabolic data

(1) to select the test animals whose metabolism of a particular substance is extrapolatable to that in man;

(2) to evaluate test results obtained when comparative metabolism data was not examined before selecting the test species or strains;

(3) to evaluate test results for "secondary" carcinogenesis;

(4) in the qualitative and quantitative risk assessment and in determining the permissible exposure limit.

Certainly it would be unreasonable for OSHA to exclude such comparative metabolic data from evaluation when such data are available.

5. Statistical significance

OSHA recognizes in the definition of "toxic substance" in Section 1990.102 that statistical significance is an important ingredient in the evaluation of animal and human data. However, that recognition is ambiguous in two respects and should be clarified.

In the Preamble to the Proposed Regulation, OSHA comments:

> "5. Statistical significance. For an adequate demonstration of carcinogenicity of a substance in test animals, it is generally necessary that the increased incidence of neoplasms in one or more of the experimental groups should be evaluated statistically for significance (NCAB Report, p. 5; MRAK Commission Report, p. 465)." 42 Fed. Reg. 54162.

However, in the Proposed Regulation OSHA refers to statistical significance only with reference to decreased latency, and does not refer to statistical significance in connection with induc-

tion of tumors except by implication. The definition of "suggestive" in Section 1990.102 refers to results which are not statistically significant, thus implying that statistical significance is required for Category I purposes.

Moreover, as Dr. Saffiotti points out, the reference to statistical significance is ambiguous in that if fails to specify the value of the statistical significance required. (Saffiotti S. 25.) Dr. Saffiotti would solve the problem of this ambiguity by dropping rather than defining the term "statistically significant" and would rely on the much vaguer word "cause" as implying "adequate criteria". (Saffiotti S. 25-26, Tr. 908.) Rather than clarifying the meaning of the regulation, Dr. Saffiotti's proposal would introduce greater uncertainty and vagueness.

We believe it is clear from the record that "statistical significance" is an essential element in the evaluation of any animal or human study. Indeed one of the criteria of a valid study is that the results are statistically significant. See NCAB General Criteria at 463; Dr. Rogers Tr. 8565-8566. Thus, to leave out the evaluation criterion of statistical significance is "unscientific" in the sense that an essential part of the evaluation process is ignored.[1/]

1/ Statistical significance is discussed in a memorandum from John Gart to Albert Kolbye dated July 11, 1978. (AIHC P.H.) See particularly the discussion therein of the Bonferroni correction factor. See also articles following the referenced memorandum in the AIHC post-hearing filing.

AIHC urges OSHA on the basis of this record to include statistical significance in its proposed criteria for the conduct and evaluation of animal and human studies. Whether or not a single common level of confidence should be selected in advance for all studies is controversial. Thus, NIOSH recommends that "statistically significant" be defined as "at the 95% confidence level" without any distinction as to the use to be made of an evaluation at that level of confidence. (NIOSH S. 5.) Dr. Peto, on the other hand, testified that significance levels of .05 (95% confidence level) should not be taken as strong evidence of carcinogenicity. (Tr. 2517.)

It is AIHC's view that it is not only important to retain the concept of statistical significance; it is also important to recognize that the level of statistical significance selected for a particular evaluation depends on the use to be made of the data. If the 95% level such as NIOSH recommended were to be selected by OSHA, OSHA should recognize three points relevant to that selection:

(i) Since 1/20 of the tests may be random false positives under this confidence criterion (Dr. Peto Tr. 2548), confirmatory evidence becomes a matter of prime importance.

(ii) There will be circumstances where a much higher level of confidence is required, as is discussed in a succeeding section of this brief. See infra, at 163-164.

(iii) Different levels of statistical significance may be relevant in evaluating an experiment which produces rare tumors as distinguished from one which induces an increase in the tumors to which a tumor prone species is subject.

Dr. Upton made clear that statistical significance is not solely reliance on a bare arithmetic concept. We need to know also, he said, whether the controls behaved in accordance wtih the characteristics of the strain (Tr. 284); and the test results must be significant in light of the overall scientific evaluation of the test. Id. As Dr. Shimkin notes "[s]tatistics must make biological sense first and not be a mathematical exercise." (Report of the NCI Clearinghouse at 74, AIHC P.H.)

6. Tumor prone species

The record makes clear that one of the significant developments in cancer research has been the development of inbred strains of rodents. As several witnesses testified, these strains have been created to make the rodents more "sensitive" and hence better detectors of carcinogens. However, there have been consequences of this development which are not reflected in the Proposed Regulation.

The inbreeding has resulted in a varying but high degree of spontaneous tumor incidence. Dr. Jandl referred to the catalogues which enable the experimenter to select animals with particular spontaneous tumor rates. (Jandl Corrected S. 26-30.) He pointed out that inbred strains are not only less resistant to carcinogenesis (e.g., defects of DNA repair mechanisms, detoxifying mechanism, etc.) but, in addition, may be defective in their ability to excrete, to metabolize and may have other nonspecific defects which increase their susceptibility to potentially injurious agents. Id. at 34-36. Dr. Van Duuren testi-

fied that he preferred random-bred animals with a low incidence of spontaneous tumors because results of inbred species, particularly the mouse, are difficult to interpret. (Tr. 1814-1815.)

We have pointed out above the need for OSHA to clarify what is meant by the term "statistical significance". With respect to the tumor prone strains, this becomes a matter of prime importance. Dr. Griesemer's testimony as to the statistical probabilities of a false positive in an NCI bioassay underlines the need for a separate calculation where conditions of the experiment are different from the NCI bioassay. Dr. Olson referred to the unexpected changes in the basal spontaneous tumor rate in the mouse, thus making a mouse experiment in such a strain difficult to interpret. (Tr. 3239; see also Dr. Crampton S. 5.) Nor can there be assurance that randomization will cure the defect. Since the qualities which lead to the change in the basal rate are not known, it is difficult to randomize for such a change. (Dr. Olson Tr. 3241-3245.) Dr. Furst testified that if the controls develop more spontaneous tumors than is "normal" for the particular strain, the experiment should be regarded as invalid.[1/] (S. 22-23.)

1/ Thomas R. Fears, Robert E. Tarone, and Kenneth C. Chu, "False-Positive and False-Negative Rates for Carcinogenicity Screens" 37 Cancer Research, 1941-1945, 1941 (1977) (Attachment to Statement of Dr. Griesemer):

> "The implementation of a number of chemical carcinogen screening programs has been accompanied

(Footnote continued on p. 146)

One of OSHA's witnesses, Dr. Robert Squire, gave consideration to the significance for classification purposes of whether the tumors induced were rare (i.e., tumors with spontaneous rates in controls of no more than 5%) or were an increase in spontaneous tumors. (Squire S. 27-28.) Dr. Squire concluded:

> "The categories, as they are currently defined, are too restrictive and do not allow for consideration of all pertinent evidence. The determination of potential carcinogenicity must allow for some degree of judgment -- both in determining what data is relevant and in objectively evaluating that data. I fear that otherwise we may on occasion regulate on the basis of false positives and false negatives. I propose therefore that the categories be redefined to allow a greater role for scientific judgment in assessing the evidence." Id. at 27.

Based on these comments, Dr. Squire made suggestions for modification of the OSHA Category I criteria which would take into account the difference (in evaluation terms) of induction of rare

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(Footnote continued from p. 145)

by the observation that some screens might have high false-positive error rates. With designs presently used at the National Cancer Institute and historical spontaneous tumor rates based upon control animals in previous experiments, we compute upper bounds on the false-positive error rates for several screening strategies. False-positive results are much less likely to occur at tissue sites with low spontaneous tumor rates; hence the site at which a significant tumor increase occurs is important. There is danger in relying solely upon the finding of statistical significance without incorporating biological knowledge and corroborative evidence such as the presence of a dose-response relationship or experimentally consistent results in different species or sexes. A report by the National Cancer Institute Carcinogenesis Program demonstrates these concepts." (Emphasis added.)

tumors as compared to an increase in spontaneous tumors. Id. at 27-28.

Dr. Dubin stated he would not use a strain with a 25% spontaneous tumor incidence. (Tr. 1188.)[1/]

Nowhere in its classification system does OSHA take into account the consequences of the physical and genetic defects of the inbred strains of rodents.[2/] If a scientific evaluation panel of the kind proposed by AIHC were adopted, these factors could be evaluated in the appropriate scientific atmosphere.

7. Mouse data

In addition to the problems presented by tests conducted on tumor prone species discussed above, there are special problems with reference to the mouse which deserve discussion.

Dr. Crampton and Dr. Grasso testified as to the extensive analysis they have made of published mouse data under the auspices of the British Industrial Biological Research Association. See Tr. 6557-6568, and publications listed in Ex. 138. Drs. Crampton and Grasso concluded that the mouse is a satisfac-

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1/ For an interesting analysis of spontaneous tumor incidence in NCI bioassay animals, see letter from Thomas Cameron to Eric Schwartz dated September 13, 1978 and Report of the Clearinghouse at 84 (AIHC P.H.). Of particular interest is the comparatively high incidence of spontaneous tumors in mice at the lung (11.0) and the liver (19.7) and the comparative increase over time for these two sites. See also analysis of mammary pituitary and testes tumors for certain rat strains.

2/ The influence of environmental factors on incidence of tumors in inbred mice is discussed by Dr. Heston in a post-hearing statement. (Ex. 224-G.)

tory test animal if actual malignancy is induced by exposure to a chemical. Id. However, they have raised doubts as to the validity for extrapolation to man of four types of mouse tumors:

(i) Lymphomas which are associated with a virus which is activated in a manner not found in man;

(ii) Hepatomas to which the mouse is particularly prone and which can be induced by dietary changes and stress;

(iii) Pulmonary adenomas which develop spontaneously because of genetic factors; and

(iv) Mammary tumors which are associated with a virus not found in man. Id.

Similar objections as to mouse data were raised by Dr. Butler (Tr. 5384-5386, 5400-5401) and Dr. Vesselinovitch (Tr. 5391-5397). Dr. Butler offered as support for his views a monograph edited by himself and Dr. Paul Newberne of MIT on an international workshop called to address the problem of mouse heppatic neoplasia. Dr. Vesselinovitch offered into evidence a recent NAS analysis of data relating to the pesticides heptachlor and chlordane which validated a number of the views expressed by Dr. Crampton and Dr. Grasso with respect to the mouse. (Dr. Vesselinovitch Tr. 5390-5392.)

Two international peer groups meeting under the auspices of the International Agency for Research on Cancer ("IARC") have also recently had occasion to evaluate certain mouse data.

A reprint of an article which appeared in Cancer Research, April, 1978, entitled "Evaluation of the Carcinogenicity of Chemicals: A Review of the Monograph Program of the

International Agency for Research on Cancer (1971-1977)" by Dr. Tomatis and others was attached as an appendix to the statement of Dr. Tomatis filed in this proceeding. In that article Dr. Tomatis notes that the IARC Monograph program had been criticized for failing to assess human risk of exposure to carcinogens (id. at lines 350-362), and as a consequence an ad hoc working group was convened jointly by IARC and the World Health Organization in October 1977 "to update and revise the criteria on which carcinogenicity of chemicals to humans and/or experimental animals is assessed and on which the evaluation of the possible carcinogenic risks that they may represent for humans is made." Id. at lines 363-369. As a result of the deliberations of the committee, the changes made in the Preamble were described as follows:

> "While it was recognized that no adequate criteria are presently available to interpret experimental data on carcinogenicity directly in terms of their carcinogenic potential to humans, it was also noted that extrapolation to a possible human risk can be reasonably approximated by utilizing data from appropriate animal tests. These data, however, may represent different degrees of evidence, this drawback being mainly due to our present insufficient knowledge of the mechanisms of carcinogenesis. Thus it was tentatively agreed that the carcinogenicity data may represent strong evidence of carcinogenicity when they indicate the unquestionable production of malignant neoplasms or 'weak evidence' when they solely indicate the appearance of neoplastic lesions such as lung adenomas or hepatomas in mice. In the presence of appropriate experimental carcinogenicity data and in the absence of adequate human data, it is reasonable to regard chemicals for which there is strong evidence of carcinogenicity as if they were carcinogenic to humans. Chemicals for which there is weak

evidence of carcinogenicity in experimental animals will, in general, require more experimental and epidemiological investigation." Id. at lines 381-402 (emphasis added).

A second ad hoc group was convened by the IARC earlier this year to review the work of the first ad hoc group. (Dr. Griesemer Tr. 926-927.) The revised criteria as they are to be published in IARC Monograph 17 appear in Exhibit 135. In this second peer review in a scientific rather than adversarial atmosphere, the criteria were discussed as follows:

> "The term 'carcinogenic risk' in this IARC MONOGRAPH series is taken to mean the probability that exposure to the chemical will lead to cancer in humans.
>
> Many chemicals induce both benign and malignant tumors; few instances are recorded in which only benign neoplasms are induced by chemicals that have been studied extensively. Benign tumors may represent a stage in the evolution of a malignant neoplasm or they may be 'end-points' which do not readily undergo transition to malignant neoplasms. If a substance is found to induce only benign neoplasms in experimental animals, the chemical should be suspected of being a carcinogen and requires further investigations.
>
> * * *
>
> In general, the evidence that a chemical produces tumors in experimental animals is of two degrees: (1) sufficient evidence of carcinogenicity is indicated by the production of malignant tumors; and (2) limited evidence of carcinogenicity reflects the qualitative and/or quantitative limitations of the experimental results.
>
> * * *
>
> In the present state of knowledge, it would be difficult to define a predictable relationship between the dose (mg/kg bw/day) of a parti-

cular chemical required to produce cancer in test animals and the dose which would produce a similar incidence of cancer in humans. The available data suggest, however, that such a relationship may exist, at least for certain classes of carcinogenic chemicals. Data that provide sufficient evidence of carcinogenicity in test animals may therefore be used in an approximate quantitative evaluation of the human risk at some given exposure level, provided that the nature of the chemical concerned and the physiological, pharmacological and toxicological differences between the test animals and humans are taken into account. However, no acceptable methods are currently available for quantifying the possible errors in such a procedure, whether it is used to generalize between species or to extrapolate from high to low doses. The methodology for such quantitative extrapolation to humans requires further development. (Ex. 135 at 15.)

* * *

Evidence for the carcinogenicity of some chemicals in experimental animals may be limited for two reasons. Firstly, experimental data may be restricted to such a point that it is not possible to determine a causal relationship between administration of a chemical and the development of a particular lesion in the animals. Secondly, there are certain neoplasms, including lung tumors and hepatomas in mice, which have been considered of lesser significance than neoplasms occurring at other sites for the purpose of evaluating the carcinogenic risk of chemicals to humans. Such tumors occur spontaneously in high incidence in these animals, and their malignancy is often difficult to establish. An evaluation of the significance of these tumors following administration of a chemical is the responsibility of the particular Working Group preparing the individual monograph, and it has not been possible to set down rigid guidelines; the relevance of these tumors must be determined by considerations which include experimental design and completeness of reporting.

Some chemicals for which there is limited evidence of carcinogenicity in animals have

> also been studied in humans with, in general, inconclusive results. While such chemicals may indeed be carcinogenic to humans, more experimental and epidemiological investigation is required.
>
> Hence, 'sufficient evidence' of carcinogenicity and 'limited evidence' of carcinogenicity do not indicate categories of chemicals; the inherent definitions of those terms indicate varying degrees of experimental evidence, which may change if and when new data on the chemicals become available. The main drawback to any rigid classification of chemicals with regard to their carcinogenic capacity is the as yet incomplete knowledge of the mechanism(s) of carcinogenesis." Id. at 21 (all footnotes omitted)(italics in original, double emphasis added).

Thus, two separate international peer review committees of the IARC have identified specifically as "weak" or "limited" evidence of carcinogenicity two of the mouse lesions whose weight and relevance Dr. Crampton and Dr. Grasso questioned. Both peer groups concluded that such lesions in the mouse were merely an indication that further investigation was required and not sufficient evidence for classification of a substance as a human carcinogen.[1/]

We urge that on this record the Proposed Regulation should be amended to make clear that certain mouse data do not satisfy the criteria of OSHA Category I. Evaluation of these

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1/ Another recent report raising questions about the relevance of mouse liver data is the report of the December 1977 meeting of a joint FAO/WHO expert committee. The committee concluded that, for the compound in question, "[c]ompared to other animal species, [the mouse] reacts rather anomalously and the mouse, therefore, may not be an appropriate model for man in this case." (Ex. 53 at 12.)

data is strictly a scientific matter. No policy decisions with respect to these data are warranted.

8. Factors affecting animal test results

In addition to the problems presented by tumor prone species, there are a number of other factors which can have a bearing on the outcome of an experiment. Dr. Furst testified that animal tests can be manipulated to give positive results. (Tr. 6932-6933, Furst S. 25; see also Dr. Roe S. 67, 74.) Dr. Furst spoke of inattention to diet and dietary deficiencies, to contamination of the test agent or diet,[1/] to variations in the test agent, and hormonal stress, as factors which could influence the outcome of the study. Id; see also Dr. Kotin Tr. 4893-4894,

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1/ The question of nitrosamine contamination in diet fed animals in NCI's bioassay program recently received considerable attention at an American Chemical Society (ACS) meeting. See W. Leary, "Nitrosamine, in Animal Feed May Affect Tests for Cancer", Washington Post September 13, 1978 (AIHC P.H.) The paper presented at that meeting concludes as follows:

> "The highest NDMA level found was 52 ppb in the new National Institutes of Health open formula rat and mouse ration.
>
> * * *
>
> The presence of appreciable levels of so toxic an animal carcinogen as NDMA in the diets of laboratory animals which are being used for long-term carcinogenesis studies represents an awkward problem, particularly when possible cancer causing compounds are being tested at low levels. We recommend that the N-nitrosamine level of the control diet be reported in future carcinogenesis studies."

(Footnote continued on p. 154)

4911-4912. The bias may not be intentional but rather simply the result of error in design or conduct of the experiment.

Dr. Golberg testified that because of the complexities of selecting an MTD which does not produce tissue toxicity (other than carcinogenesis), tests are sometimes run with fluctuating dose levels. (Golberg S. 3, Tr. 6494-6495.) He cautions that evaluation of such test results should be examined with great care and preferably be redone with a valid protocol. Id.

Dr. Squire discussed the particular problems of hormone carcinogenesis and the possibility of experimental manipulation:

> "Hormone carcinogenesis will be an issue of major concern under these proposed regulations. Hormones represent an unusual class of carcinogens and they require special regulatory attention. Hormones may not be carcinogens in the classical sense of being initiators; rather, they may act as promoters with dose-dependent, reversible cellular effects. Furthermore, in some cases, because of the fundamental differences between species in endocrine and reproductive physiology, test animal results may not be relevant to the human situation. The FDA Toxicology Advisory Committee on the Carcinogenic Risk of Antipsychotic Drugs (FDA 1977) concluded a discussion on the findings of mammary carcinogenesis in test animals with the following comments:
>
> > A. By using the rats and mice and manipulating variables associated with ovarian function and prolactin production, it is

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(Footnote continued from p. 153)

D.H. Fine et al., "N-nitroso Compound Impurities in Consumer and Commercial Products", presented at the American Chemical Society Meeting September 11, 1978, at 2, 3 (AIHC P.H. (Supplemental 9/25/78)).

possible to design experiments that would demonstrate either a positive or negative carcinogenic effect or a protective effect against mammary tumor induction.

B. It is, therefore, inappropriate to consider the studies under review according to their design or whether mammary cancer was or was not induced.

C. There is, at present, insufficient evidence to extrapolate from mice and rats to humans with respect to the role of prolactin in human mammary carcinogenesis.

D. The rodent studies are not relevant to determination of the magnitude of human risk from mammary carcer.

E. The relevance to humans of rodents or other models requires additional pharmacological and physiological studies.

The present classifications require estrogenic substances to be Category I. I question whether estrogens used in drug formulations should be categorized and regulated in the same way as vinyl chloride, bis(chloromethyl)ether, and other confirmed occupational carcinogens." (Dr. Squire S. 30-31.)

Dr. Roe and Dr. Olson discussed in some detail the impact of caloric intake on the cancer incidence in rodents. (Dr. Roe S. 31-41; Dr. Olson S. 16-19.) Differences in caloric intake significantly affected the incidence of tumors, with restrictions on caloric intake markedly reducing the tumors. Id. Dr. Roe referred particularly to a pathogen-free colony of random-bred Swiss mice established by Imperial Chemical Industries, Ltd. ("ICI") in England. The colony established in 1960 had a natural tumor incidence of 10%. Ten years later on the same diet and under the same conditions the spontaneous tumor incidence had risen to 80%. When an experiment was performed

in which the diet was reduced slightly in one group of test animals from 5.8 grams (ad libitum) to 5 grams per day, there was an 8 fold reduction in tumor incidence before the animals were 18 months of age in the animals on the restricted diet. (Dr. Roe S. 33-34.)

A subsequent life time experiment by ICI on both mice and rats indicated that dietary restriction extended the average life span of the animals. In addition, despite the fact that most of the difference in survival occurred after 18 months -- the period when tumors are most likely to arise -- the overall incidence of tumors in the animals on a restricted diet was significantly less. (Dr. Roe S. 35-39.)

Dr. Roe cautions against assuming that caloric intake alone was responsible. An animal on a restricted diet tends to consume its food quickly and be without food until the next ration. Ad libitum fed animals nibble throughout the day. As a result, the bacterial flora in the gut of the animals differ. In addition, the strain of looking at an empty food basket can induce a stress in the animals on restricted diet. (Dr. Roe S. 34.) Thus, unless close attention is paid to caloric intake by the experimenter, the results could be misleading.

Dr. Roe also points out that laboratory animals are left in an environment which results in unnatural hormonal status. (Dr. Roe S. 42.) Temperature, number of animals per cage, and lack of exercise have been shown to have an influence on the induction of tumors. Id.

Finally, we noted supra, at 148 that rodents are sensitive to viruses which are not oncogenic to man. Dr. Roe discusses at some length the prevalence of these tumor viruses in rodents. (Dr. Roe S. 62-65.)

Thus, depending on the level of confidence, the tumors induced in the treated animals as compared to the controls could be a matter of chance or diet. It could also be due to activation of a virus [1/] or to hormonal imbalance or other mechanisms not relevant to man.

Since OSHA has not disclosed the criteria it is considering with respect to the conduct and evaluation of animal tests, it is not possible to know whether OSHA will take into account the factors referred to above in evaluation of the test results. AIHC submits that any sound evaluation must take into account these factors which influence the outcome of animal studies. As Dr. Kennedy pointed out, no conclusions should be drawn from a poorly designed test. (Tr. 521-522.) For the same reasons it is imprudent to act on the basis of a single animal study without adequate confirmatory evidence. See discussion infra, at 162-166.

9. Positive/negative results

In the Preamble to the Proposed Regulation, OSHA discusses the relevance of negative and positive results in animal species. 42 Fed. Reg. 54161. OSHA concludes that positive

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1/ See V. Riley et al, "The LDH virus: An Interferring Biological Contaminant," Science (AIHC P.H.).

results should generally supersede negative results because of the insensitivity of the animal studies. OSHA should re-examine this proposed administrative determination in light of the testimony in the record.

OSHA's statement as to positive and negative results is stated in terms of tests of equal soundness from an experimental point of view. Id. There is, however, a general recognition that tests are of varying quality and, as many witnesses pointed out (e.g., Dr. Griesemer Tr. 930; Dr. Furst Tr. 6924-6926, 7159-7160), the tests in the literature are recognized to be of very uneven quality. See discussion supra, at 128-131. Thus, OSHA's administratiave determination is based on an assumption as to validity which is essentially unrealistic.

Indeed, as Dr. Golberg pointed out in his testimony, analysis of the results of tests under the NCI Bioassay program point to a wide variety in quality; even though these tests are more uniform than most, many are defective for a variety of reasons. (Ex. 113 at 3-5, Table II; Tr. 6487-6492.) He concluded:

> "I know that changes have been made in an effort to correct some of these deficiencies. Nevertheless, the heritage of just this one program has provided a record of hundreds of tests whose results cannot be taken at their face value for automatic decisions on carcinogenic potential. For purposes of assessment of risk to man, the full data forthcoming from each test will need careful evaluation by appropriate experts who will consider them in the context of all the available information on the compound in question, not solely on the basis of

the test results forthcoming from the carcinogenesis bioassays." (Golberg S. 3.)

Thus, negative studies may raise questions as to the validity of positive results. (Kimbrough Tr. 1795-1796.) A careful analysis of negative and positive results may show that the studies are not inconsistent. (Dr. Hoel Tr. 2159-2160.) However, it is also possible that the positive result was random depending on the level of confidence required in the statistical analysis of the results (see supra, at 143), or that such a result may be an artifact of the design or conduct of the test (see supra, at 153-157). None of the witnesses were willing to exclude examination of negative data to provide administrative convenience. Indeed, Dr. Furst took the position that if a substance is positive in one species but negative in others, much less stringent regulation is warranted. (Tr. 6929-6930 S. 20; see also Dr. Roe S. 68.) In a paper filed as an exhibit to his written statement, Dr. Morgan discussed in detail the statistical analysis which can be used to determine the probability of carcinogenesis when there are numerous tests, some positive and some negative. (AIHC P.H.) See also "Guidelines for Evaluation and Use of Occupational Epidemiologic Cancer Studies" (AIHC P.H.), Appendix D hereto.

While as an administrative matter it may be convenient to reject negative results in the face of a positive test, the record demonstrates that any such conclusion is inconsistent with the scientific evaluation process.

10. Single species or two species

Generally it is AIHC's position that in a regulation

of this kind where interspecies extrapolation is made, it is sound to have as basic criteria for OSHA Category I and AIHC Category II the requirement that the substance be shown to be carcinogenic in two mammalian species. The basic uncertainties in animal data discussed in the preceding sections of this brief point to the conclusion that it would be unwise as a general matter to rely on a single test in a single species for a generic classification scheme.

There is an additional compelling reason for requiring tests in two species. As Dr. Saffiotti said, one cannot exclude the possibility that a carcinogenic response is species specific. (Tr. 857-858; see also Dr. Lamm Tr. 4598; Dr. Kotin Tr. 8679-8680.) Dr. Rall pointed out that a substance may affect one species but not another. (Tr. 486.) While such an event may be rare, there are numerous instances cited in the record where a substance is oncogenic to one species or strain, but not to another. The differences go both ways. Arsenic may be carcinogenic in man, but not in rodents. The reverse situation also has been shown. There has been no demonstration that DDT, aldrin/dieldrin or phenobarbitol cause excess cancer in man. See discussion of negative epidemiology, supra, at 127.

Indeed, the possibilities of species differences are sufficiently real that the NCI bioassay calls for the screening test to be conducted in two species to reduce chances of a false negative. The same reasoning leads to the possibility that rodent data in one species gives a false signal of human risk

because of metabolic or other differences between man and the rodent. (Dr. Rall Tr. 391, 487-488; Dr. Meselson Tr. 1542; see supra, at 127, 137-141.) These differences between man and animal are not taken into account when testing to determine whether a substance is an animal carcinogen. (Dr. Griesemer Tr. 935.)

Differences between man and the rodent are particularly apparent when man is compared to the tumor prone rodent species, especially the mouse. A test with a sick, genetically defective animal subject to the unusual stresses of the test conditions raises particularly difficult problems of evaluation. Moreover, substances may be activating viruses in animals which are not oncogenic in man. See discussion, supra, at 148.

Finally, there are differences in sensitivity to substances between species and strains in a single species. (Dr. Peto Tr. 2674-2565; Dr. Kotin Tr. 8679-8680.) Both in extrapolating to man and particularly in quantifying the risk, a more reliable and accurate evaluation can be made if data from two species are available.

Since a regulatory decision in most cases is a $100 million plus decision (Benzene $500 million, Vinyl Chloride $200 million plus), it is important that the agency act on the best information for making such a decision. The fact that a substance is not carcinogenic in one of two species is a signal that other differences in response may be found. Man may respond the way the animal in the negative test reacted.

AIHC is not suggesting that OSHA do nothing during the

period while a second test is being conducted, nor does AIHC suggest that OSHA await a comparative metabolic analysis before taking regulatory action when there are positive results in a single species. To the contrary, under AIHC Category III the agency might take action to lower exposure pending the development of more complete data.

The single test exception. During the hearings a number of witnesses suggested that OSHA was too conservative and should be willing to regulate a substance on the basis of a single positive animal test. Such statements usually referred to a "well conducted" or a "well designed and conducted" test and commonly the test was described as "clearly positive". E.g., Dr. Rall Tr. 386-387, 448; Dr. Bates Tr. 631. NIOSH testified that there may be an "exception" to the requirement that a test result be replicated when "highly significant results are obtained in an adequately conducted and biologically appropriate test." (Tr. 3030.)

Discussion of this proposed reliance on a single positive test can be assisted by reference to the statement of Dr. Rall:

> "The fact is that scientific experiments never give results that are 100% positive, nor 100% negative. Science deals in probabilities, and carcinogenesis bioassays give results that may fall anywhere on a continuous spectrum of probabilities, extending from 2 or 3% at the lowest to nearly 100% at the highest. Division of this spectrum into discrete categories may be necessary for regulatory purposes, but it is necessarily arbitrary from a scientific point of view. Thus the recommendation of a scientist

> would be to make the criteria for categorization flexible, and to apply as much scientific judgment to each case as is comparable with legal and regulatory requirements." (Dr. Rall S. 13-14.)

He also said:

> "On the one hand, there are cases where a single, well-conducted experiment giving clearly positive results should suffice to establish a chemical as a carcinogen and to justify stringent measures to reduce occupational exposure. On the other hand, there are cases where two or even three conclusive positive results would still leave some doubt." Id.

Dr. Peto has probably the most complete comment on the problem of reliance on a single test. (Dr. Peto S. 13; Tr. 2548-2551.) He pointed out that in most experiments the separate incidence of tumors at different sites is independently documented and some of the many significance levels will be less than p. 0.05 by chance. In his testimony he elaborated on the random chance of a positive result when the confidence level is 0.05. In his statement he concluded:

> ". . . for a single animal experiment to be convincing without such support, a P-value of well under 0.01 (perhaps even 0.001) should usually be required. Unless this policy of requiring rather extreme P-values is adopted, an unacceptably large number of misleading results will emerge by chance alone." (Dr. Peto S. 13) (emphasis added).

Thus, the reliance on a single positive test is highly qualified by those witnesses who addressed the subject.

Amplifying somewhat on Dr. Peto's argument, one might naively assume that a statistical finding of significance at the 5% level indicates that there is only one chance in 20 that the

data is "false positive". If, however, 10 or more criteria are applied to the same set of data, the probability that at least one criterion will appear to be statistically significant is no less certain than the toss of a coin. Should 20 criteria be applied, there is a high probability that at least one will be found statistically positive. The blind application of multiple criteria to the same set of data without recognition of this mathematical truth is bound to place OSHA in an untenable position. Using OSHA's own criterion of relying on a single positive test without reference to the total body of scientific knowledge of a given material, one can demonstrate that any substance is carcinogenic merely by repeating the same test frequently enough.

In addition to the statistical criterion suggested by Dr. Peto, AIHC believes that OSHA should press for comparative metabolic data when it is proposed that regulation be undertaken on the basis of a single animal study. See discussion supra, at 137-141. The AFL-CIO acknowledges the importance of these comparative metabolic data when it proposes that a substance be regulated upon a showing that it is metabolized in man into a metabolite which has been shown to be carcinogenic. (AFL-CIO S. 6.) The same reasoning leads to the conclusion that a showing of metabolic differences between man and the test animal are equally relevant and should be evaluated when such data are available. The fact that such data are being developed experimentally should encourage OSHA to press for such data, particularly when regulation on the basis of a single test is being considered.

However, AIHC believes that the issue of regulation on the basis of a single test may be largely an academic one. It is very unlikely that information other than a bare test result will not be available regarding the substance in question and that OSHA would have to decide whether to act on the basis of this test result alone. It is for this reason that AIHC has proposed that any regulatory action based on a single test should be outside the classification scheme and be handled as a regular administrative proceeding under Section 6 of the Act. OSHA would not be precluded from using an ETS in such a proceeding if there were a basis for the statutory findings. To include this probably highly unusual situation in the classification scheme would require separate treatment and separate criteria which would add complexities of interpretation.

It is AIHC's suggestion that the Proposed Regulation should not refer to the single test exception nor foreclose OSHA's beginning a regular administrative proceeding to establish standards in reliance on the results of a single animal study meeting the extraordinary criteria described above.

By definition, animal studies which do not meet the single test exception criteria discussed above have a lower confidence level and the results give a lower probability of risk to man.[1/] In Dr. Rall's scale of probabilities, these tests

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1/ The NCAB Subcommittee on Environmental Carcinogens states:

> "The extrapolation of experimental carcinogenicity data to the human situation is strengthened by obtaining results in more than one species." NCAB General Criteria at 463.

fall in a range that does not approach the 100% level and range down to the 2-3% level. AIHC believes that it is both prudent policy and consistent with the scientific evidence in the record to require confirmation of such tests. AIHC urges adoption by OSHA of a positive test in a second species as the sounder basis for confirmation.

11. Replication

Section 1990.110(a)(3) of the Proposed Regulation provides that a substance shall be classified in Category I on the basis of a positive test in a single species "if those results have been replicated in another experiment." We have addressed in the previous section the reasons why we believe it is important for OSHA, except in rare cases, to require positive results in two species before classifying a substance in Category I. It is unsatisfactory to attempt to argue away the need for a two-species test by confirming "replication" of a positive test in a single species. Should OSHA, despite the soundness of the view to the contrary, decide to rely on a single species, OSHA should require at a minimum the confirmation of "replication". (NIOSH S. 5.)

However, a number of problems remain. As NIOSH points out, the meaning of replication as used in the regulation is not clear. Id. at 5-6. Does OSHA mean replication by the same researcher; with the same strain; at the same dose levels; in the same laboratory; with separate controls? NIOSH proposed:

> "We would hope that where researchers have the option, such confirming experiments would be

> performed in a different laboratory, perhaps using a different sex or strain of test animal, additional dose levels, or a different route of administration to provide for a more comprehensive and accurate measurement of the substance." Id. at 6.

Dr. Weinstein and Dr. Furst made similar recommendations (Tr. 2249-2250, 6928), as did Dr. Squire (Dr. Squire S. 29).

Dr. Squire stated:

> "OSHA should make explicit what it means by the replication of a finding in a second experiment. I suggest that the second experiment be defined as one conducted at a different laboratory by a different investigator, or one conducted at a different time." (Squire S. 29.)

As NIOSH points out, "simple replication using the exact same study design may not be particularly definitive." (NIOSH S. 5-6; see also Dr. Crampton S. 8.) It is imperative that if OSHA decides, incorrectly AIHC believes, to rely on replication of a test as confirmatory evidence, OSHA should clarify the ambiguous term "replication". The protocol or study design should be clearly defined. AIHC urges that OSHA adopt the NIOSH recommendations and require replication in a separate laboratory with separate controls. AIHC also recommends that a different strain and additional dose levels be required. If the route of administration is not the same as the route of exposure of humans, the replication should use the same route of exposure as humans:

> "To properly evaluate carcinogenicity the suspect agent should be administered to animals by the same route as humans are exposed, namely, via the lungs, gastrointestinal tract, dermally and in some cases intramuscularly, intradermally and subcutaneously." (NIOSH response to Q. 31.)

12. Short term tests

Section 1990.110(a)(4) of the Proposed Regulation provides that a substance will be classified in Category I on the basis of positive results in a single mammalian species "if those results are supported by short term tests." The term "short term tests" is defined in Section 1990.112 as follows:

> "'Short-term tests' includes, but is not limited to, positive results in more than one of the following assays for: (1) the induction of DNA damage and repair ; (2) mutagenesis in bacteria, yeast, or Drosophila melanogaster; (3) mutagenesis in mammalian somatic cells; (4) mutagenesis in mammalian germinal cells; or (5) positive results in tests for neoplastic transformation of mammalian cells in culture."

Not adequate confirmatory evidence. The end result of most short term tests is mutagenicity, not carcinogenicity. Mutagenesis and carcinogenesis are not biological equivalents. (NIOSH Answer to Q. 28; Dr. Kotin Tr. 8703.) Dr. Griesemer pointed out that the end point of long term animal experiments is the induction of cancer and that cancer is discovered by methods used by a pathologist. (Tr. 981.) Thus, any use of short term tests in connection with the Proposed Regulation must depend on a relationship between the different end points achieved and the difference between carcinogenicity and mutagenicity.

In August 1977, the Chemical Industry Institute of Toxicology ("CIIT") conducted a workshop on "Strategies for Short-Term Testing for Mutagens/Carcinogens" at which more than 50 ex-

perts from academia, government and industry met to assess the status and usefulness of the principal short term tests and to produce a set of practical guidelines for dealing with the results of those assays. (Golberg Tr. 6527-6528; Golberg, Transcript of Proceedings.)

The meeting produced agreement on several points. Dr. Golberg described the results of the workshop as follows:

> "Our own efforts to date, coupled with familiarity with the work of others in this field, lead to the conclusion that short-term tests have potential value but require a great deal of further investigation and validation before they can be considered reliable indicators of carcinogenic or mutagenic potential. Moreover, it is fundamental that no single test of this sort can yet be relied upon exclusively to reach a conclusion regarding carcinogenesis/mutagenesis. A battery of tests should be used, but there is no general consensus of the components of the battery, nor are all the necessary, currently available tests adequately developed and validated for inclusion in such a battery." (Golberg S. 2.)

Dr. Golberg in summarizing the conclusions of the workshop, cautioned against such statements as: "The results of the test correlate 90 per cent with animal carcinogenicity studies." Such statements are misleading because the measure of correlation can be manipulated by judicious selection of the chemicals tested. (Tr. 6533-6534.)[1/] The workshop cautioned

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1/ Dr. Marvin Legator (University of Texas), a participant in the CIIT workshop, criticized generalized statements that a system was "validated":

> "Legator: In the literature, although we often refer to the 90% figure, in terms of correlation

(Footnote continued on p. 170)

against commonly accepted deviations from defined procedures in the conduct of the tests. Id. Only one test, the Ames test, has published criteria for the conduct and evaluation of the test. (Tr. 1521-1522.) However, in the course of the CIIT workshop, Dr. Marvin Legator of the University of Texas outlined "some serious limitations" to the Ames test because of questions about the S9 (activator) portion of the test:

> "(1) Inability to standardize in vitro activation systems.
>
> (a) Insufficient understanding of the relationship of enzymes to mutagenicity.
>
> (b) Variability with the amount of S9 fraction used.
>
> (c) Variability with chemical inducer of liver microsomal enzymes, administered beforehand to the animal.
>
> (2) Inability of in vitro systems to detect promutagens activated by means other than by liver microsomes."

(Footnote continued from p. 169)

between the Salmonella system, and known carcinogens, the truth of the matter is that one can find in the literature correlations ranging from 44% to 90+%. In our own analysis of these studies, we can, in part, attribute the variation in correlation either to the number of classes or number of compounds studied. The high correlations reported in the literature are probably not valid for one or more of the following reasons: (1) Failure to establish uniform and meaningful criteria for what is a carcinogen, (2) Failure to establish meaningful criteria for the response in the Salmonella system, (3) Failure to code samples, and (4) Using literature studies to derive correlations." (Proceedings II 27.)

In the same workshop, there was a report of the NCI validation process by Dr. Virginia Dunkel who is in charge of of the NCI validation program (Dr. Golberg Tr. 6531)):

> "b. Status of NCI validation studies. While it is anticipated that many of the proposed assays will become useful short-term tests, it must be remembered that substantial work remains to define systems and correlate results for most of the assays. Dr. Dunkel described the correlation studies that are in progress by the NCI:
>
> Dunkel: The in vitro carcinogenesis program is currently both developing and validating a series of microbial and mammalian cell systems. The microbial assays include (1) mutagenesis in Salmonella typhimurium strains and E. coli WP2; and (2) DNA repair in E. Coli and pol A+ and pol A- strains. The mammalian cell assays include mutagenesis in the L5178Y mouse lymphoma cell line at the thymidine dinase locus; (2) DNA repair in primary rat liver hepatocytes; and (3) transformation in systems using BALB/c 3T3 mouse cells, early passage Fischer rat embryo cells, Fischer rat embryo cells infected with Rauscher leukemia virus, hamster embryo cells either treated directly in cell culture or exposed to the chemical transplacentally and then placed in culture and liver and skin epithelial cells. As now structured approximately 90 compounds will be tested blind in all assays.
>
> Cline: How long will it be before we know the results of the study?
>
> Dunkel: It may be two years before we know the results of the blind studies." (Proceedings II-27-28.)

Dr. Ray discussed the standardization and validation process:

> "c. The standardization and validation process. Dr. Ray expressed the concern of many that some tests could be brought to regulatory status before they were sufficiently characterized.
>
> Ray: I'd like to make a few comments on the standardization and validation process. Currently, a

number of mutagenicity assays have been proposed for use in safety evaluation studies to evaluate chemicals already marketed, or being made ready for introduction into man's environment. However, many of these assays have not been validated to the extent where their sensitivity and reproducibility have been established. Further, even the most thoroughly studied procedures, such as the Ames test, have not been analyzed to the extent that positive and negative compounds can be identified routinely by rigorous tests of statistical significance. Also, there are many forms of these assays, depending upon the laboratory involved. Clearly, the time has come to establish procedural standards in the performance of each assay. Especially so, since regulatory agencies are now considering guidelines which may impose requirements for these tests. Criteria must be established which define the validation process itself, and statistical methods adopted which permit all test substances to be evaluated by the same set of rules. Unfortunately, some tests are being made ready for adoption before a critical analysis has been performed on the available literature data. Correlative studies are being quoted in which one or more components lack standards of performance. Because short-term mutagenic tests hold considerable promise for identifying both the mutagenic and carcinogenic potential of chemicals, it is mandatory that they be developed in a rigorous scientific manner. The good which can come from the application of these assays will be hampered considerably if the standardized validation process is not adopted soon. This process not only validates individual assays, but must involve inter-test results and a comparison to relevant human experience when available. When one considers the cost of programs which are being proposed for implementation using these assays, surely the critical analysis suggested here will, in the long run, save millions of dollars and prevent many useless debates over test utility and reliability. A program which includes critical analysis of existing data, establishment of standard procedures, identification of proper statistical models and which requires examination of a minimal number of chemicals of diverse chemical classes for validation purposes, should be implemented, I believe, at the international level. This program

should be so constructed as to engender participation and support from industrial, government and academic organizations, and have a broad base of information exchange." (Proceedings II 28-30 (emphasis added).)

In response to OSHA question 28 calling for a full scientific discussion of short term tests, NIOSH stated:

"For scientific purposes, justification of the use of short-term tests for the purpose of screening thousands of chemicals for their suspected carcinogenic activity and for the purpose of prioritizing these chemicals for long-term animal bioassay, appears to be adequate. However, the original intent for utilization of these tests was only for these two objectives and not for use of a confirmation test for long-term animal bioassay.

It is inappropriate at this time to attempt to substitute a short-term test for a long-term animal bioassay for at least two reasons:

(1) Validation procedures are not complete and correlations between the test systems have not been adequately performed; and

(2) The outcome of the short-term tests as compared to the long-term bioassay are not biological equivalents. In one case the end point is mutagenesis, in the other case, carcinogenesis. However, one (mutagenesis) may often cause the other (carcinogenesis)."

The Clearinghouse on Environmental Carcinogens adopted a resolution on October 31, 1977 describing the role of short term tests as follows:

"Notwithstanding the limitations imposed by the current state-of-the-art, there still appears to be an immediate, practical application for short-term assays. At present, microbial mutagenicity assays offer a rapid and inexpensive approach to acquire information useful in selecting and ranking chemicals for long-term carcinogen bioassay. The concomitant or sequential use of

> DNA repair and mammalian cell transformation systems should enhance the selection process. Results from these short-term assays should eventually provide important information that may be useful in assisting in the evaluation of marginal data on carcinogenicity.
>
> It is recognized that short-term assays are still in the process of evaluation. Further, it is acknowledged that short-term assay data, by themselves, are inadequate to define the carcinogenicity or lack of carcinogenicity of a given chemical. Still, it is the sense of the Clearinghouse on Environmental Carcinogens that short-term assays are sufficiently developed to provide information useful in the selection of chemicals for carcinogen bioassay and in their later evaluation. It, therefore, is recommended that the Carcinogenesis Testing Program take the necessary measures to integrate short-term assays into the chemical selection and experimental design processes in a manner consistent with the tone and tenor of this resolution." Clearinghouse Resolution at 2.

There was also general agreement that short term tests alone are not a sufficient basis at the present time for regulatory of a substance as a carcinogen. (Dr. Upton Tr. 289-290; Dr. Griesemer Tr. 946; Dr. Epstein Tr. 1412; Dr. Fishbein Tr. 1868; Dr. Brusick S. 16, Tr. 5011-5012; Dr. Lijinsky S. 25; Dr. Revson Tr. 4220; Dr. Skalsky Tr. 7592-7593; Dr. Lawrence Tr. 778-7779; Mr. Gibbons Tr. 7389-7390; Dr. Gottesman Tr. 7487.) EPA in its Interim Cancer Policy treats mutagenicity and in vitro cell transformation as only "suggestive evidence" of carcinogenicity. 41 Fed. Reg. 21404 (May 25, 1976). Similarly, the Subcommittee of the National Cancer Advisory Board concluded:

> "At present none of the short term tests can be used to establish whether a compound will or will not be carcinogenic in humans or experimental animals. Positive results obtained in

> these systems suggest extensive testing of the agency in long-term animal bioassays, especially if there are other reasons for testing." NCAB General Criteria at 463.

The same reasons which lead to the conclusion that short term tests alone are not a satisfactory basis for regulatory action, point to the conclusion that the tests should not be used as confirmatory evidence in the regulatory process. The tests are in various states of development with agreed criteria for conduct and evaluation of the tests only in the case of the Ames test. (Dr. Meselson Tr. 1471; Dr. McCann Tr. 1551-1552.) However, Dr. Golberg testified that the workshop last year concluded that even the Ames test was not sufficiently standardized. (Tr. 6550.) All of the tests are currently being validated. (Dr. Upton Tr. 289-290; Dr. Rall Tr. 369; IARC Ex. 135 at 26-27.)[1/] The in vitro tests produce false positives and false negatives. (Dr. Bates Tr. 6455.) The mechanism of mutagenesis is believed

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1/ Dr. Valcovic of NIEHS described the state of validation of such assays in an article entitled "Mutagenesis Testing Program", 20 Environmental Health Perspectives 253 (1977)(AIHC P.H.) as follows:

> "Until recently, mutagenicity testing was done on preselected compounds in a manner in which the testing laboratories know the identity of the substances under test and the 'expected' results, i.e., positive for compounds selected because of their carcinogenicity and negative for food additives. There is no completed study in which substances were tested blind using a standardized protocol. Also, little attention has been placed on reproducibility and variability within and between laboratories. These aspects are currently under investigation in microbial systems by NCI but the results will not be available for 1-2 years."

to be related to the mechanism of carcinogenesis in the cases where the substance (or metabolite) bind to the DNA. However, there is still great uncertainty about the mechanism even when DNA damage is involved and about whether the same mechanism is involved in mutagenesis and carcinogenesis.

Dr. Greisemer concluded:

> "I think it is premature to attempt to utilize short term data as a very large component of the decision making process. At present I do not find short term tests very useful." (Tr. 946.)

Dr. Epstein concluded that the Ames test should not be used for regulatory purposes. (Tr. 1412.)

The Commissioner of the Food and Drug Administration summarized in the decision banning chloroform the reasons why short term tests are not an appropriate basis for regulatory action:

> "Regarding the reported findings of Uehleke in the 'Ames study,' which used a bacterial system, the Commissioner recognizes that rapid progress is being made in the development of mutagenicity test sytems. He is aware of a number of reports indicating a mutagenicity-carcinogenicity correlation using these test systems. However, a number of 'false positives' as well as 'false negatives' have been observed in these test systems. Such tests using non-mammalian systems have not been validated for establishing correlations and are not considered an appropriate basis for regulatory action." 41 Fed. Reg. 26842, 26843 (June 29, 1976).

The conclusions of the International Agency for Research on Cancer are similar. (Ex. 135 at 26, 27.)

Criteria and need for battery. If in the future short term tests are sufficiently validated and a correlation between the test results and carcinogenesis is established, criteria should be set out and a full battery of tests should be required.

Dr. McCann recommended that a full battery of tests should be used. (Tr. 1562.) Dr. Fishbein recommended that substances should produce positive results in two types of tests before reliance can be placed on them: microbial and mammalian cell tests. (Tr. 1888.) Dr. Brusick also recommended that a battery of at least four tests would be necessary to reach a conclusion regarding genetic activity. (Dr. Brusick S. 15, Tr. 5014.) The CIIT workshop also recommended a battery of tests. (Workshop Proceedings II 3-4.) Dr. Furst testified that a single positive test was not enough. (Tr. 6932.) Dr. Squire recommended that at a minimum a battery of tests be used. (Dr. Squire S. 9.)

Dr. Rall urged OSHA to adopt criteria and guidelines for short term tests and recommended the "Guidelines" produced by the DHEW Committee to Coordinate Toxicology and Related Programs[1/] as a source for those criteria and guidelines. (Tr. 368 369, 457-462; see also Dr. Saffiotti Tr. 943-945.) The evaluation criteria used by Litton Bionetics are set out in the contract forms for the various tests. (Ex. 136.)

1/ DHEW Committee to Coordinate Toxicology and Related Programs, "Guidelines for the Laboratory Use of Chemical Substances Posing a Potential Occupational Carcinogenic Risk" (August 1978) (AIHC P.H.).

Both Dr. Peto (Tr. 2593) and Dr. Brusick (S. 15, Tr. 5014) urged that, if OSHA is going to use results of short term tests, criteria of mutagenicity should be established. Otherwise experimenters will reach different conclusions from the same data and consistent results cannot be achieved. Criteria to evaluate inconsistent results in in vitro tests also need to be established. The Environmental Defense Fund also favored establishment of guidelines as criteria for short term tests. (Tr. 7348.)

The IARC similarly recommended a battery of tests and criteria for their use:

> "The present state of knowledge does not permit the selection of a specific test(s) as the most appropriate for identifying potential carcinogenicity. Before the results of a particular test can be considered to be fully acceptable for predicting potential carcinogenicity, certain criteria should be met: (1) the test should have been validated with respect to known animal carcinogens and found to have a high capacity for discriminating between carcinogens and noncarcinogens, and (2) when possible, a structurally related carcinogen(s) and noncarcinogen(s) should have been tested simultaneously with the chemical in question. The results should have been reproduced in different laboratories, and a prediction of carcinogenicity should have been confirmed in additional test systems. Confidence in positive results is increased if a mechanism of action can be deduced and if appropriate dose-response data are available. For optimum usefulness, data on purity must be given.
>
> * * *
>
> An adequate assessment of the genetic activity of a chemical depends on data from a wide range of test systems. The monographs include, therefore, data not only from those already

> mentioned, but also on the induction of point mutations in other systems, of structural and numerical chromosome aberrations, including dominant lethal effects, of mitotic recombination in fungi and of sister chromatid exchanges." (Ex. 135, at 27 (footnotes omitted).)

The CIIT workshop discused supra, at 168 similarly recommended a battery of tests and urged that criteria be established for those tests.

As noted in the earlier section, we believe short term tests should be used only as screens for further testing and prioritization of future testing. When short term tests have been validated and shown to be accurate predictors of carcinogenesis:

1. The tests which can be used should be identified and supporting validation supplied.
2. The battery to be used should be specified.
3. Criteria for the tests and for evaluation of results should be established.
4. Replication of the tests should be required.
5. Before relying on short term test results, an evaluation by geneticists and toxicologists with experience in short term tests should be performed.

13. Route of exposure

The record is clear that route of exposure is an essential element to be considered in the extrapolation of human risk from animal data. (Dr. Upton Tr. 324-325; Dr. Rall Tr. 485; Dr. Kennedy Tr. 579-580; Dr. Griesemer S. 8, Tr. 957-958; Dr. Claus S. 40; Dr. Gross Tr. 8315-8317, 8323.) Perhaps the most complete statement regarding the significance of the

route of exposure in the evaluation of animal data and the extrapolation to human risk was by NIOSH:

> "Another consideration in evaluating a predictive model for human carcinogens is the route of administration. Although the route of administration might not be important in determining whether or not an agent is carcinogenic for research purposes, it is important from a preventive health standpoint. To properly evaluate carcinogenicity, the suspect agents should be administered to animals by the same routes as humans are exposed, namely, via the lungs, gastrointestinal tract, dermally and subcutaneously. The latter conditions would apply, for example, to those agents such as metal fragments that might become embedded in skin or muscles. In industrial exposures to particulates, oral exposures are frequently as important as pulmonary exposures in as much as the particulates that are trapped in the upper respiratory tract are usually swallowed." (NIOSH first answer to Q. 31; see also answer to Q. 1(a).)

Many witnesses (Dr. Rall Tr. 485; Dr. Van Duuren S. 5; Dr. Claus S. 40) expressed serious reservations concerning the use of animal data except for qualitative purposes where the route of exposure of man is different from that in an animal experiment.[1/] The importance of the same route of exposure for humans and in animal experiments was emphasized by the NAS:

> "Before extrapolation is attempted, considerable attention must be given to the appropriateness of the experimental data. Bioassay procedures must be of high quality in order to avoid

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1/ NIOSH points out the difficulties when the route of exposure used in an animal experiment is different from that by which man is exposed in the workplace. However, such a test may yield valid qualitative data. In evaluating human risk from a different method of exposure each case would have to be evaluated individually. (NIOSH first answer to Q. 6 and second answer to Q. 6(b)).

misleading risk estimates. Also oral administration of the carcinogen is necessary because we are concerned with estimating the risks associated with drinking water consumption." Id. at 48-49 (emphasis added).

The scientific reservations as to the risk assessment for man when the human route of exposure is different from that in animal experiments means that OSHA should be reluctant to regulate where the animal data are not relevant to the human route of exposure until there is, as Dr. Rall proposed, a risk assessment defining as precisely as possible the magnitude of the risks and defining the uncertainties in the estimate. (Tr. 456-457.)

C. OSHA Is Correct In Rejecting Structure Similarity And Physical Induction Such As Injection Site Sarcomas As Bases For Regulatory Action

1. Molecular structure or similarity

In the Preamble to the Proposed Regulation, OSHA sets out the reasons for concluding that structure similarity between known carcinogens and an untested substance does not provide a basis for regulating the untested substance as a carcinogen. 42 Fed. Reg. 54168. OSHA's conclusion is supported by the record. 1/

While two witnesses thought that investigators with years of experience and research could arrive at a conclusion

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1/ The issue is not whether structure similarity would be considered along with other data in evaluating a particular substance. Numerous witnesses listed structure as one factor to be included in the evaluation. The issue discussed here is whether structure similarity is a valid basis for classification.

that on the basis of structural similarity a compound is likely to be carcinogenic (Drs. Van Duuren and Fishbein Tr. 1825-1828), [1/] a number of witnesses testified that structure similarity is not a valid basis for classifying a substance as a carcinogen. E.g., Dr. Lijinsky Tr. 1048; Dr. Meselson Tr. 1526-1528; Dr. Weinstein S. 9; NIOSH answer to Q. 29; Dr. Hart Tr. 3467-3468; Dr. Furst S. 27-29, Tr. 6932, 6943; Dr. Holmberg S. 4.

In EPA's Interim Cancer Policy chemical structure is included in the risk assessment among "ancillary reasons which bear on judgments about carcinogenic potential." 41 Fed. Reg. 21404 (May 25, 1976). Others described structure similarity as useful for prioritization for further testing. (Dr. Rall Tr. 446; Dr. Weinstein Tr. 2273-2275; NIOSH answer to Q. 29.)

2. Injection site sarcomas and other instances where induction due to physical causes, e.g., implants, stones or calculi

In the Preamble, OSHA discusses the reasons why particular routes of exposure should not be considered applicable to man: injection site sarcomas and other instances where there is reason to believe the tumors that occurred may not be due to a specific effect of the compound, e.g., bladder implant. 42 Fed. Reg. 54164. We believe the record supports the conclusion that tumors induced by the physical damage at injection site or the physical action from an implant do not provide an adequate

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1/ According to Dr. Fishbein "hundreds" of chemicals could be identified as probable carcinogens on the basis of structure similarity. (Tr. 1829.)

basis for extrapolating the risk to man. (NIOSH answer to Q. 6 (b); Dr. Rall Tr. 484; Dr. Furst Tr. 6925.) The same reasons should apply to other instances where the induction is from physical causes such as stones or calculi. (Dr. Rall Tr. 455; Dr. Roe S. 68; Dr. Grasso S. 3.) The same principles should lead to rejection of test results where the lesion is due to "secondary carcinogens" and organ damage, supra at 133-137.

Conclusion

It is apparent from this discussion that the scientific knowledge of carcinogenesis is far from complete; it is also apparent that significant advances in knowledge are being made almost daily. It behooves OSHA, therefore, to structure a regulation so that it acts always on the basis of the "latest available scientific data in the field." 29 U.S.C. § 655(b)(5).

It is apparent, moreover, that carcinogenesis is a complex area and that no simple or simplistic statement can serve as a satisfactory summary for regulatory purposes. Prior to the issuance of its Interim Cancer Policy, EPA published first 9, later 16, and later 17 "principles" of carcinogenesis drafted by Dr. Saffiotti. These "principles" were widely criticized and on November 10, 1975, the NCAB subcommittee discussed these "principles" which Dr. Saffiotti described as "a sort of personal and somewhat informal summary of state of the art of points that

had been previously debated and discussed in great detail."[1/]

The NCAB subcommittee, after discussion, concluded that the "principles" were not "an adequate definition of a carcinogen for use by a regulatory agency for regulatory purposes."[2/]

The 17 principles rejected by the NCAB subcommittee bear a striking resemblance to the "Policy Determinations" and "Concepts" on which OSHA relies in the Preamble. Appendix E of this brief is a tabular comparison of the "principles" and

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1/ Proceedings National Cancer Advisory Board Subcommittee, November 10, 1975, at 23. (These proceedings were filed with NACOSH at the time the draft of this Proposed Regulation was being considered by NACOSH.)

2/ A motion was made by Dr. Weinstein with references to the "principles" as follows:

"DR. WEINSTEIN: Is a motion in order?

DR. SHUBIK: Yes.

DR. WEINSTEIN: I would move that the draft by Dr. [Umberto] Saffiotti, titled 'Statements on Principles of Chemical Carcinogenesis in Relation to the Evaluation of Carcinogenic Hazards,' be considered as a useful background for discussions on the definition of a carcinogen, but that we do not feel that it is an adequate definition of a carcinogen for use by regulatory agencies for legislative purposes. This Committee should, therefore, consider de novo the problem of deriving a definition of carcinogen and that if necessary a subcommittee of this group, recruiting additional expertise, be appointed for this purpose.

DR. SHUBIK: Thank you. Do we have a second to that?

DR. NELSON: I second it.

DR. SHUBIK: All in favor?

(There was a chorus of "Ayes".) (Proceedings at 28.)

the "determinations" and "concepts". Two examples illustrate the similarity.

Principle	Policy Determination or Concept
12. "Since many benign tumors can develop into cancers, for the purposes of carcinogenicity testing there is no valid distinction between the induction of benign or malignant tumors and they should be considered synonymous."	OSHA "proposes to place as much weight on an experiment in which only benign tumors are observed, as upon experiments in which both malignant and benign tumors are induced." (42 Fed. Reg. at 54163-54164)
15. "There is no scientific basis for the existence of a "no effect" level for carcinogens. In principle no dose of a chemical carcinogen is too small to induce tumors in susceptible individuals."	"[A] no-effect or threshold level may theoretically exist for any specific carcinogen. As yet, however, there is no satisfactory scientific basis for determining such levels for any given population. Thus, as has been proposed any human exposure to a carcinogen . . . would be considered by OSHA to present a potential cancer risk as a policy matter." (42 Fed. Reg. at 54174)

Elizabeth Anderson, Executive Director of EPA's Carcinogen Assessment Group, in a recent speech traced the history of EPA's 17 principles. She explained that the agency had decided to establish a Cancer Review Group with a two-step approach to regulation, rejecting the 17 principles because "[s]uch a simplified approach received broad and general criticism by the scientific community, a substantial part of the private sector and the Congress."[1/]

1/ E. Anderson, "Risk Assessments and Regulatory Approaches to Carcinogens", presented at the Symposium on Risk/ Benefit Decisions and the Public Health Third FDA Office of Science Symposium, at 2 (February 15, 1978).

The reasons which lead to the rejection of the EPA principles as a basis for regulatory action are equally applicable to the "Policy Determinations" and "Concepts", which bear a striking similarity to the rejected "principles".[1/]

AIHC submits that its Alternative minimizes the errors outlined above and offers a reasonable, workable basis for regulatory action based on the "latest available scientific data in the field."

1/ For the same reasons the "principles" proposed by NRDC (NRDC S. 18-19) which were patterned on the EPA principles do not provide an adequate basis for regulatory action.

IX

THE PROPOSED REGULATION WOULD IMPERMISSIBLY "FREEZE" THE PRESENT STATE OF RELEVANT SCIENCE BY FORECLOSING RECONSIDERATION OF THE VALIDITY OF THE CLASSIFICATION SYSTEM AND OTHER POLICY ISSUES IN RULEMAKINGS ON INDIVIDUAL SUBSTANCES, AND BY ERECTING UNREASONABLE BARRIERS TO OSHA'S OWN CONSIDERATION OF RELEVANT NEW SCIENTIFIC DEVELOPMENTS

> "I feel that the criteria proposed by OSHA for classifying chemicals into Categories I, II and III are somewhat too rigid, and that the preamble introducing them does not adequately reflect the complexity of the processes involved in chemical carcinogenesis. . . . If regulations are to be rational, they should be firmly based on up-to-date scientific knowledge." (Dr. Farber S. 1-2.)

Section 6(b)(5) of the Act requires that OSHA formulate standards dealing with toxic materials or harmful physical agents "on the basis of the best available evidence," including "the latest available scientific data in the field." 29 U.S.C. § 655(b)(5). Despite this statutory mandate, OSHA proposes, once its generic standard is promulgated, to foreclose consideration of scientific and other evidence by preventing the introduction in subsequent individual rulemakings of evidence concerning the "validity of this classification system and most other policy determinations made in this proposal, including the procedural structure intended to be followed." 42 Fed. Reg. 54154. Such a "freezing" of scientific and other evidence as of the date of the promulgation of the generic standard is clearly improper and a violation of the Act.

Moreover, by foreclosing discussion of the underlying issues in subsequent Section 6(b) rulemakings, OSHA will deny to

affected parties their legal right under both the Administrative Procedure Act and the due process clause of the U.S. Constitution to comment upon these issues as they relate to specific toxic substances. This issue is discussed more fully in the portion of this brief dealing with OSHA's lack of authority to establish generic rules where an inflexible set of regulatory consequences automatically flow from the classification. See discussion supra, at 44-51.

It is particularly inappropriate to preclude consideration of newly available evidence or data in a field which is undergoing as rapid an evolutionary change as the study of the causes and mechanisms of cancer. The testimony of a number of witnesses explored the ongoing or expected development of major advances in carcinogenesis reasearch and theory. 1/ See, e.g., Dr. Hart Tr. 3457-3458, 3468-3469; Dr. Snyder Tr. 4696-4697, 4734-4735; Dr. Yang Tr. 6799-6827; Dr. Rogers Tr. 8585; Dr. Kotin Tr. 8751-8753. Many of these witnesses testified that it would be improper, unwise, and indeed, arbitrary and capricious, for OSHA to ignore these developments by foreclosing consideration of the factual premises and policy grounds on which its generic standard is based; premises and policies

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1/ In addition to those areas of research discussed earlier in the brief, one such area is immunotherapy research. See J. Kuahenbul and J. Remington, "Belligerent Blood Cell: Immunotherapy and Cancer," Human Nature 52 (January 1978) and W. Stockton, "A New Clue in the Cancer Mystery," The U.S. Times Magazine 18 (April 17, 1978) (AIHC P.H.).

which even if valid today could become obsolete in the very near future. See, e.g., Mr. Gideon Tr. 3050-3051; Mr. Dominguez Tr. 3924-3925; Mr. Janous Tr. 4114-4115; Mr. Woolrich Tr. 4231, 4296-4298; Dr. Synder Tr. 4683-4684. The need for consideration of all relevant evidence in the development of a rational approach to the regulation of carcinogens was constantly stressed during the course of the hearings, as was the need for providing a means by which the regulatory scheme can be modified to include new information as it becomes available. See, e.g., Dr. Hart Tr. 3469, 3484; Dr. Thorpe Tr. 4582; Dr. Swanson Tr. 4597-4598; Dr. Synder Tr. 4696-4698.) Glen Schweitzer admonished OSHA (Tr. 7112) to heed the words of caution issued by the court in Ethyl Corp. v. EPA, 541 F.2d 1 (D.C. Cir. 1976):

> "By its nature, scientific evidence is cumulative: the more supporting . . . evidence available, the more likely the accuracy of the conclusion." 541 F. 2d at 38.

However, OSHA proposes not only to foreclose consideration of newly available evidence presented by employers subject to regulation in the individual rulemakings conducted pursuant to Section 6(b) of the Act; it also intends to erect formidable barriers to its own ability to take advantage of improvements or developments in relevant learning by preventing modification in proceedings on individual substances of the scientific principles administratively adopted in this generic rulemaking proceeding. Mr. Wrenn testified that the objective of the Proposed Regulation is to identify and establish generic policy

determinations. (See Wrenn S. 8, 9, 12 for examples of "generic" policy determinations.) When the policy considerations of a "generic" nature are made, no evidence contradicting those administrative conclusions would be admissible in individual substance rulemaking. Thus, for example, in a subsequent rulemaking strong evidence of a threshold would not be considered; the policy determination that there is no safe level would prevail. (Mr. Wrenn Tr. 148-149, 151.) EPA, on the other hand, testified that "we believe that opportunity should always be available for presentation of substantial genuine new evidence." (EPA S. 9, Tr. 2361.) In contrast, under the OSHA proposal such new evidence would only form the basis for a petition to amend the generic regulation, but until that amendment was made, the evidence would not be receivable despite its strength or validity. (Wrenn Tr. 148-151.)

This time-consuming and ponderous mechanism for incorporating into the regulatory standards newly available evidence or data concerning heretofore unresolved issues surely does not satisfy OSHA's obligation to premise its standards on "the best available" and "latest available" evidence in the field.

The AIHC proposal, on the other hand,

> "proceeds on the basis that if a categorical approach is desirable and necessary to enable OSHA to deal effectively with potential carcinogens, there is still no statutory authority--or need--to preclude interested parties from presenting evidence, with respect to any particular chemical, to counter any conclusion of carcinogenic risk that might otherwise be

> drawn on the basis of the general principles on which the OSHA proposal intends to rely." AIHC Alternative at 29.

AIHC's Alternative, unlike the Proposed Regulation, provides a mechanism by which all relevant evidence of new scientific developments will be considered in determining appropriate categorization and regulatory responses to particular substances. The Data Evaluation and Classification Panel recommended by AIHC could, from time to time, propose revisions of the categorization scheme or its criteria, in light of the latest scientific advancements, newly available information, or knowledge derived from experience with the categorization scheme. In addition, reasonable public notice of intent to make such changes would be provided, in accordance with the Administrative Procedure Act, as well as an opportunity for interested persons to comment on such changes. See AIHC Alternative at 60-61. Further, the AIHC Alternative would permit any interested party to petition the Panel for reclassification of a chemical on the basis of significant data or scientific learning not considered at the time of prior classification. See AIHC Alternative at 69-70. The absence of provisions such as these in OSHA's proposal will prevent the agency from complying with its statutory obligation to consider the "best available" and "latest available" scientific evidence.

X

CATEGORY IV SHOULD BE ELIMINATED BECAUSE OSHA LACKS STATUTORY AUTHORITY TO CREATE IT AND BECAUSE IT IS OTHERWISE UNWISE AND INAPPROPRIATE

The Proposed Regulation would require OSHA to publish a Category IV list of substances which meet its definition of toxic substance but which are "not found in the American workplace."

It is our view that OSHA lacks statutory authority to create such a list and that it would serve no useful purpose within the context of this rulemaking. Furthermore, the arbitrary inclusion of substances on such a list could unnecessarily inhibit technical innovation, cause unwarranted damage to foreign industry, establish a new non-tariff barrier to chemical trade and potentially affect adversely our relations with foreign countries.

This view was expressed by numerous participants in these proceedings (e.g., AIHC International Committee comments) including NIOSH, which stated in its written submission:

> "We do not recommend a Category IV in this classification system since U.S. workers would not have the potential for exposure to these agents and hence they would fall beyond the regulatory responsibility of OSHA as we understand it. Should these substances enter the U.S. workplace, they would automatically become eligible for classification into Categories I, II or III." (NIOSH S. 3.)

See also Environmental Defense Fund S. 10 recommending that Category IV be eliminated.

A. OSHA Lacks Statutory Authority To Establish Category IV

OSHA lacks any authority to classify or to regulate toxic substances which are not currently found in and may never enter American workplaces. The Act grants to OSHA the authority to assure safe and healthy working conditions only in the domestic workplace.

In enacting the Act, Congress declared its purpose to be "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions." 29 U.S.C. § 651(b) (emphasis added). Section 4 of the Act states that it applies only with respect to employment performed in a State, the District of Columbia, and various U.S. territories and possessions. This statutory grant of authority does not extend to substances which have not yet entered the American workplace. Where Congress intended to vest an agency with such authority, it has expressed that intent in clear statutory language. Such is the case, for example, with the Toxic Substances Control Act ("TSCA"). 15 U.S.C. §§ 2601 et. seq. Absent explicit authorization in the Act to classify toxic substances which are not currently found in any American workplace, such authority cannot be implied in OSHA.

B. OSHA's Resources Could Be More Effectively Channeled

OSHA suggests that the listed foreign toxic substances may become subject to future regulation if they are introduced into American workplaces, and notes that OSHA intends to enter

into an agreement with EPA with respect to implementation of the TSCA so that if such substances are introduced into the American workplace OSHA will be able to develop an appropriate standard. 42 Fed. Reg. at 54169.

OSHA therefore apparently recognizes that TSCA is the appropriate vehicle for monitoring the introduction of potentially toxic substances into the American workplace. The provisions of Section 5 of TSCA, 15 U.S.C. § 2604, regarding premanufacturing and preimportation screening for new chemicals are adequate to enable EPA to monitor and obtain information concerning toxic substances before they are introduced into American workplaces. There is certainly no demonstrated need for OSHA to blacklist such substances before they have been subjected to the screening mechanism which Congress has established for that purpose.

To follow the course of action suggested by OSHA would be a poor allocation of precious resources that could better be channeled to regulate substances already found in the domestic workplace. To the extent that the purported purpose of this generic rulemaking is to make the regulatory process more efficient, the proposed Category IV provision does the opposite.

C. There Is A Strong Possibility That The Decision To Classify A Substance In Category IV Could Be Arbitrary And Without Due Process

OSHA states with regard to the listing of foreign toxic substances that "OSHA does not intend to review the evi-

dence concerning carcinogenicity at [the] time [of listing]." 42 Fed. Reg. 54169. OSHA thus proposes to add substances to this list simply on the basis of unevaluated studies, whether or not they are scientifically sound. Witness after witness at the hearing has cautioned that studies are often of very uneven quality ranging from worthless to exceptional. To use unevaluated studies for the intended purposes can lead to inumerable problems.

This is further complicated by the fact that the procedures OSHA contemplates utilizing will be "without the formality of rulemaking, per se." 42 Fed. Reg. 54173. Because the allegedly toxic substance will not be used in the United States at the time of classification, all of the regulatory activity could unfold without any substantive review of the evidence concerning carcinogenicity. As a result, there is a strong possibility that the decision to classify a substance in Category IV could be wholly arbitrary and without due process.

D. Listing A Substance In Category IV May Create Misconceptions With Many Unintended Adverse Effects

Blacklisting a substance may create misconceptions among the public and press which, even if mistaken, are difficult to correct. The public and press misunderstanding of the NIOSH List of Suspect Carcinogens is an example of how lists such as these can create problems. Condemnation of a chemical product by listing it will certainly adversely affect the U.S. market for that product and will deter both domestic and foreign

companies from engaging in further development of that product, often without justification for such actions. Such a classification will also discourage a foreign company from exporting the substance to the United States. Category IV classifications have the clear potential to cause considerable problems with foreign industry and governments. The likely foreign view would be that a U.S. government agency has seen fit to blacklist products not found in the United States, over which that agency has no jurisdiction or statutory mandate, without making a careful review of the evidence. Indeed, this may be viewed by some as a non-tariff trade barrier to exclude potentially competitive products from the American market.

Conclusion

Rather than create a Category IV list, the authority for which is non-existent, and the wisdom of which is doubtful, OSHA should enter into an agreement with EPA whereby EPA will inform OSHA of the introduction of substances which might meet its definition of toxic substances into the American workplace. When and if such a substance is introduced into the U.S. workplace, OSHA can take appropriate action.

PART THREE

XI

QUANTITATIVE RISK ASSESSMENT IS ESSENTIAL TO A DETERMINATION OF THE REASONABLE NECESSITY OF A REGULATION

"It [OSHA] contends the standard promises appreciable benefits at a cost which industry can absorb. This justification is deficient in one crucial way: substantial evidence does not support OSHA's conclusion that benefits are likely to be appreciable. Without an estimate of benefits supported by substantial evidence, OSHA is unable to justify a finding that the benefits to be realized from the standard bear a reasonable relationship to its one-half billion dollar price tag." 1/

"There is needed some simple measure of cost and benefit that would make widely different risk situations comparable so as to attempt to maintain, in different areas, roughly similar standards for spending government and industrial funds to save lives. Without such a standard, as economists will sense immediately, cancer-avoiding expenditures cannot be spent efficiently. And, in addition, the public will have the greatest difficulty distinguishing minimal risks from large ones." 2/

"The societal need must be balanced against the estimated risks to society, for this is the only way any rational decision may be made. With the plethora of synthetic organic chemicals in use today, it will be a major task to develop the data base to allow risk estimations. But it must be done, for how can society intelligently

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1/ The Benzene decision, ___ F.2d at 91.

2/ Federation of American Scientists, "Public Interest Report," at 7, May 1976.

regulate chemicals which pose human benefits and human risks without having an estimate of the risk?" 1/ (Emphasis supplied.)

"We believe that a risk assessment using the best data and techniques available, is needed as part of an adequate regulatory analysis." 2/

In the Preamble to the Proposed Regulation OSHA discussed briefly the matter of quantification of risk. 42 Fed. Reg. 54167. In that discussion OSHA proposes that quantification of risk be applied, if at all, only at the point of determining the feasibility of the regulatory provision of a particular standard, not to risk as determined by the classification system. 3/ Id. OSHA concluded its brief discussion with a request for comments on the question of whether quantitative risk estimate should be made and, if so, the methods to be employed in the standard set-

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1/ Dr. David P. Rall, "The Role of Laboratory Animal Studies in Estimating Carcinogenic Risks for Man," at 12, November 30, 1977. Appendix B to Dr. Rall's statement.

2/ Regulatory Analysis Review Group, Council on Wage and Price Stability, Report on OSHA Proposed Permanent Standard on Acrylonitrile, at 4, May 22, 1978 (Ex. 45).

3/ It is important to note that the term "risk" is used in the Preamble with two different meanings: qualitative human risk and quantitative human risk. A full scientific evaluation of human and animal data must address a determination not only of qualitative but the methodology of quantitative risk assessment to man.

Under the OSHA proposal a substance will be classified in OSHA Category I prior to the scientific evaluation of the data, particularly animal data, to determine its relevance to human risk. Thus metabolic, physiological and other differences between man and the test animal is considered after classification. Under the AIHC Alternative, the qualitative risk and quantitative risk to man is assessed by the Data Evaluation and Classification Panel as part of the classification process.

ting process on a particular substance. Id.

A. Risk Assessment And Quantification Are Necessary Components Of Regulatory Decisions

The Benzene decision provides a clear answer to the question OSHA posed. OSHA must provide a reasonable estimate supported by evidence to demonstrate that "measureable benefits will result." ___ F.2d at 91. The court specifically rejected OSHA's speculation that the benefits "may be appreciable" based on the assumption that exposure to benzene was unsafe at any level and that lower levels would be safer than higher levels. The court recognized the logic of OSHA's speculation but held that

> "[T]his finding and deduction, however does not yield the conclusion that measureable benefits will result. . . Aqua Slide requires OSHA to estimate the extent of expected benefits in order to determine whether these benefits bear a reasonable relationship to the Standard's demonstrably high cost." ___ F.2d at 91-92.

Without a risk assessment there can be no determination of the measureable benefits, the indispensible predicate for regulatory action.

The record also provides a clear answer to the question OSHA posed: [1/] identification of the techniques for quantification

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1/ We shall discuss in another section of the brief what factors other than risk estimations OSHA should take into account in determining the level of control (see infra,

(Footnote continued on p. 200)

of the risk is an essential element of the scientific evaluation and risk quantification should be used by OSHA in the hazard analysis and in the regulatory determination of the degree of control appropriate to a particular substance. 1/ Dr. Upton, Dr. Rall, Dr. Kennedy, the witnesses for EPA and numerous other witnesses urged OSHA to make a quantitative risk assessment. Dr. Van Duuren testified that there are scientific bases for making a risk assessment and agreed that such an assessment should be made by OSHA. (Tr. 1879-1880.) Dr. Albert has expressed the view that the failure to provide for risk quantification in the Proposed Regulation is a defect which "could in the long run seriously jeopardize the Federal regulatory effort against carcinogens." (EPA Intra-Agency Memo from Dr. Roy Albert to Andrew Breidenbach, dated November 25, 1977, (API P.H.).) The methodology of an assessment of relative risks was discussed by Dr. Wilson, Professor Zeckhauser and Professor Lave.

EPA and FDA routinely make risk assessments and examples of these quantitative risk assessments are in the record. (Ex. 38, API P.H.) Other exhibits discuss the principles of, and examples of, risk assessment. (Exs. 13, 43, 45, 78, 85). The

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(Footnote continued from p. 199)

at 215); in this section of the brief we are addressing the issue of risk assessment and the elements and methods involved in such an assessment.

1/ A risk quantification is implied in the OSHA proposal to identify suitable substitutes; unless a comparative risk analysis were made, OSHA would have no way of knowing whether it was increasing or decreasing the risk from use of the substitute.

quantitative risk assessment methods used by the NAS/NRC are set out in considerable detail in the chapter entitled "Chemical Contaminants, Safety and Risk Assessment" in the NAS Drinking Water Study. See Dr. Rall S. Appendix I.

We believe it would be difficult to state more succinctly or persuasively the need, despite the uncertainties, for such quantitative risk assessment and hazard evaluation than was set forth in the Work Plan of the Risk Assessment Group of the IRLG of which Dr. Bingham is a member:

> "1. Introduction - A common objective of the four agencies is the assessment of human health risks associated with chemicals, devices, consumer goods, etc. to which the population of the United States is exposed in a variety of ways. In general the goals of risk assessment are to characterize the types of health hazards that may result from such exposures and to quantify the expected risks. For the present, the Work Group intends only to treat the problems associated with health risks due to chemicals. It is in this area that the greatest commonality of purpose exists among the agencies. Moreover, it is the area in which the greatest confusion now exists, not only among the public, but also within the regulated industry. It is also the subject presenting one of the greatest opportunities for success-achievement of the broad objectives of the IRLG.
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> 2. The Scientific Problem. - Characterizing and quantifying health risks are scientific tasks. The data necessary to accomplish such tasks derive from toxicity testing and/or epidemiological studies.
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> * * *
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> Because of serious gaps in scientific knowledge, there are often alternative and conflicting views of the risks associated with chemicals to which people can be exposed. The Risk Assessment Work Group will examine the available scientific tools used in such assessments and select for use by the four agencies those currently having the strongest

experimental and theoretical support. Unless selections of these types can be made and agreed upon, conflicting views of risk will continue to cloud regulatory decision-making.

3. Role of the Policy-Maker - Whether a particular type or level of risk may have to be accepted in certain circumstances is a policy decision, but this issue should not become entangled with the scientific problem of risk measurement.

* * *

4. Need for Uniform Procedures and Criteria - The public and the regulated industry are ill-served when the agencies assess risk in different ways. Policy decisions made by the four agencies on the degree of acceptable risk in different circumstances create substantial confusion (in part brought about by differences in legal mandate and interpretation) and this confusion should not be compounded by differences in approach to the scientific assessment of risk.

5. Task of the Work Group - An objective of the Work Group might be the development of systems to insure that the agencies routinely work together to conduct risk assessments on specific substances of mutual interest. However, the Work Group holds that such an objective is far less important than the broader one of developing and selecting general procedures and criteria for risk assessment that can be uniformly applied to all chemicals regulated by the agencies, including those substances for which only one agency is responsible.

Until the rules for risk assessment are clearly laid out and agreed upon, efforts to reach a consensus on the type and degree of risk associated with specific substances of mutual concern will in many instances be thwarted. Furthermore, in the absence of uniform criteria and procedures, the risks associated with chemicals that are the responsibility of only one agency will continue to be estimated in a different manner than those associated with chemicals regulated only by a second agency. This undesirable situation will not be remedied if the task of the Work Group is limited to the joint conduct of risk assessments on substances of mutual interest.

6. Output of the Work Group - Several projects are envisioned (Section IV). Out of each will come a document detailing a set of procedures and criteria that can be adopted by each agency as acceptable for assessing risk. After appropriate internal review, these documents will be jointly published in some form and will become part of the scientific operations of agencies.

* * *

Of the several types of health risk projects that could be undertaken by the Work Group, a project on cancer risk assessment presents the highest probability for relatively short-term, successful accomplishment. A good portion of the necessary background documentation and study has been done, and the remaining tasks of bringing together the necessary information and making selections among the available approaches to carcinogenesis risk assessment should prove relatively straightforward.

* * *

RA 1.3 - Procedures for Quantifying Carcinogenic Risk

Output: Procedures for treating available dose-response relationships to estimate risk at expected or known levels of human exposure.

Task - The subgroup will survey the risk estimation procedures currently in use by the agencies. Reasons for the use of specific procedures, including relevant legal matters, will be detailed.

An updated review and discussion of all current mathematical models will be undertaken, including consideration of time-to-tumor analyses as a preface to the final selection of a model(s). The final document will include procedures for combining data from several experiments, use of human data, and modifications based on metabolic and kinetic data." 43 Fed. Reg. 7195-7197 (February 17, 1978).

B. The Prevalence of Uncertainties Underlines The Need For Risk Quantification So Far As Possible

There can be no doubt that there are uncertainties associated with risk assessment, as virtually all witnesses

pointed out, but the record shows that the existence of uncertainties should not lead to the nihilistic conclusion that no risk assessment should be attempted. There are uncertainties associated with all scientific matters; as Dr. Rall emphasized, scientists are dealing in probabilities, not certainties. (Dr. Rall S. 14.) Dr. Wilson and Professor Lave urged that the existence of the uncertainties makes a risk quantification and hazard evaluation more urgent and necessary. (Dr. Wilson Tr. 3364-3372; Dr. Lave Tr. 7002.) To the extent that any elements in the risk assessment can be quantified, the elements which must be evaluated by judgment can be identified and the decision made easier. Id.

Underscoring these points, Dr. Lave emphasized strongly that a careful quantification of risk and benefits is the only rational way to speed up the administrative process. (Tr. 7000-7003.) It is only by this process that the issues can be sharply defined so that testimony at the hearings will be directed at the areas of uncertainty, thus speeding up the administrative determination. Id.

Sheldon Samuels (AFL-CIO) testified that risk analysis is improving in accuracy and indeed proposed a permit system for the most "virulent" carcinogens in OSHA Category I. (Tr. 7256-7257, 7270-7274, 7290, 7300.) Any such distinction between carcinogens must of necessity be based on a risk analysis, as Mr. Samuels recognized. (Tr. 7300.)

C. Animal Data May Be Used For Quantitative Risk Assessment

AIHC believes that the record shows that animal test results, properly done and evaluated can provide a valid basis on which to assess the risk to man. As Dr. Kennedy said:

> "Animal tests may be used to predict within confidence limits human risks. The hypothesis is tested by going through the exercise of making some human risk predictions and then turning to human data and assessing whether the predictions are accurate." (Tr. 505.)

Dr. Rall discussed this problem and expressed the view:

> "There is very good general correlation between the carcinogenic activity of chemicals in animals and that in humans." (Dr. Rall S. 8.) 1/

After reviewing several studies in which comparisons were made between the response of animals and the response of humans to particular substances, including an NAS study entitled "Contemporary Pest Control Practices and Prospects," 2/ (Dr. Rall S. 8-11), Dr. Rall concludes:

> "Weighing all this evidence, it appears that carcinogenic responses of animals can be used both qualitatively and quantitatively to predict carcinogenic risks in humans." (Dr. Rall S. 10.)

Similarly, Dr. Upton described the information necessary in assessing the risk as including the relative potency of the

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1/ In addition to the studies referred to by Dr. Rall, Dr. Meselson described his efforts to find correlation among in vitro results and the reaction of animals and man. (Tr. 1492-1497.)

2/ Appendix H to Dr. Rall's testimony.

carcinogen and the mechanism of action of the carcinogen. (Tr. 267-268.) [1/] While there are uncertainties, he concluded - and recommended - that a quantitative risk assessment should be part of the regulatory decision on the level of control. (Tr. 268-269, 296-297; see also IARC Ex. 135, at 20.)

D. Interchangeability Of Carcinogens Has Not Been Demonstrated

Several witnesses raised objections to a risk assessment, arguing that carcinogens are interchangeable and all exposures are additive. Dr. Hoel and Dr. Peto acknowledged that the supposed interchangeability of carcinogens was merely an assumption. (Dr. Hoel Tr. 2133; Dr. Peto Tr. 2513, 2512.) The record clearly establishes that there are no experimental or human data supporting a general assumption that exposure to submanifestational doses of several carcinogens either simultaneously or sequentially is additive.[2/] (Dr. Stewart Tr. 620-621; Dr. Saffiotti Tr. 928-929; Dr. Greisemer Tr. 928-929.)

The record does demonstrate that both in animals and in human experience (smoking and asbestos and smoking and radon) there are instances of additive or synergistic action between carcinogens or between a carcinogen and a potentially carcinogenic substance. However, this is far from a demonstration that

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1/ Dr. Bates said that quantification of risk included consideration of potency. (Tr. 608-610.)

2/ See also the discussion by Dr. Mantel on the lack of evidence for the interchangeability of carcinogens set out in a letter attached to the statement of Dr. Gross.

cancer is a "multifactorial disease", in the sense that some use the term, and that exposure in the workplace is additive to the cancer burden from exposure to environmental carcinogens from diet, lifestyle, etc. On the contrary, the record shows that in many instances subtances are inhibitory and indeed that some carcinogenic substances inhibit other carcinogenic substances. (Dr. Kaufman S. 21; Dr. McLean Tr. 4824, 4825; Dr. Kotin Tr. 8691.) This inhibitory action of one carcinogen on another is the basis of many drugs used in chemotherapy. Exhibit 42 contains a discussion of inhibitors of carcinogens. Several witnesses testified to the inhibiting effects of Vitamin A and Vitamin C. E.g., Dr. Kaufman S. 20; Dr. Upton, Ex. 82 at 3.

Dr. Kennedy, describing the work of the Research Planning Work Group of the IRLG in testimony before Congress, said:

> "The inadequacy of scientific information to support regulatory decisions, and the lack of enough capability to produce more, present major problems for FDA and other agencies that share in the regulation of toxic substances." (Ex. 34, Kennedy S. 1.)

He identified areas where little or no research was being supplied by the four agencies, including "methods to measure total exposure and body burdens of chemicals." Id. at 3. Attached as Appendix A to Dr. Kennedy's statement is a list of High Priority Research areas including

> "2. Interaction of hazardous substances - develop and validate for regulatory use, rapid, effective tests to predict interactive effects between two or more hazardous chemical substances.

* * *

4. Methods to measure total exposure and body burden on chemicals. Develop and validate for regulatory use a systematic approach to the determination of total exposure and body burden for chemical substances." (Kennedy S., Appendix A at 1.)

Dr. Saffiotti said that NCI is beginning some experiments with the objective of demonstrating whether exposure to submanifestational doses of several carcinogens either simultaneously or sequentially is additive. (Tr. 928-929.) The NIOSH statement on this subject demonstrates that a supposed interchangeability of carcinogens cannot be the basis for regulatory decision. NIOSH stated:

> "Present knowledge does not permit development of a consistent and rational basis for decisions on additive and synergistic effects. Complicating this problem is the question of promoting agents and co-carcinogens, widely and variously used terms without the same meanings to everyone.
>
> Additive effects should be assumed when two agents cause cancer at the same site, especially when the two agents also have chemical similarities, such as PN's or aromatic amines. Synergistic effects should be assumed only when there are data or principles suggesting in the specific case that potentiation is likely. Similarly, co-carcinogenicity and promotion should not be assumed except in a specific case where there are data or principles that apply." (NIOSH first answer to Q. 10.)

The argument that risk assessment is undermined by a supposed interchangeability of carcinogens is without support in the record.

E. Epidemiology Can Greatly Assist In Making Risk Assessments

The value of epidemiology in identifying and quantifying

risk has been discussed supra and that discussion will not be repeated here. Epidemiology can be used to identify the human risk. Negative epidemiology is useful to indicate "upper limits for the rate at which a specific type of exposure to that agent affect the incidence and/or mortality of specific human cancers."[1/] As NIOSH points out, by using epidemiological studies and animal data in a coordinated way, the "benefits of each can be maintained and many of the individual methodological weaknesses can be overcome." (NIOSH first answer to Q. 5(c).)

F. Methods Are Available For Extrapolating To Low Doses

A basic problem in risk assessment arises from the fact that animal studies are normally conducted at doses significantly higher than those to which man is exposed and it is necessary to extrapolate resultant animal data to quantify human risk at low levels of exposure. Chapter II of the NAS Drinking Water study contains a discussion of various mathematical models used for extrapolating risk at low doses. Dr. Hoel and Dr. Peto discussed the mathematical models and attached to their written statements articles discussing various models. Dr. Gross discussed the Mantel Bryan model and attached a statement by Dr. Cornfield discussing that model.

The record points to the conclusion that the methods of extrapolation are in a period of development. It would be

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1/ NCAB General Criteria at 462.

inappropriate therefore to select a single method now; to the contrary, the scientists working on the extrapolation should be alert to use improvements and new developments as they occur. The complexities which seem to be presented in selecting the method with the best data fit and most appropriate for the mechanism of action of a particular substance underlines the importance of the Agency's calling for development of data at multiple dose levels and for the development of metabolic and pharmacokinetic data to facilitate the selection of, and the refinement of, extrapolation techniques. Both Dr. Hoel and Dr. Peto suggested that pharmacokinetic data should be incorporated into extrapolation models. (Dr. Hoel Tr. 2145-2148; Dr. Peto Tr. 2538-2540; see also Dr. Skalsky Tr. 7590-7591, 7597-7599.)

In the interim, it seems wise to use more than one model, as does EPA. (Tr. 2289-2290.) However, this puts the responsibility for identifying the best model or the best technique on the scientists, an additional reason in support of the Scientific Panel proposed by AIHC. This will help to avoid the tendency of a regulator to choose the most conservative model, however inappropriate scientists may believe such a model may be for a particular human exposure.

These extrapolation techniques must be designed to be used by the Agency in its hazard evaluation. Properly done, the scientific risk analysis is an integral part of the appraisal of regulatory alternatives which the agency must consider as part of its decision to regulate and to what level. Thus,

selection of the appropriate method of extrapolation is one of the most important parts of a quantitative risk assessment, a fact which underlines the importance of the creation of the Scientific Panel proposed by AIHC.

G. Time-To-Tumor Concepts Should Be Used In Making Risk Assessments

The definition of toxic substances in Section 1990.102 of the Proposed Regulation (42 Fed. Reg. 54184) includes substances exposure to which

> "(2) in a statistically significant manner decreases the latency period between exposure and the onset of neoplasms in (i) humans or (ii) in one or more experimental species."

This is a recognition by OSHA that the latency period for a particular substance is a function of both time and dose. As Dr. Jones pointed out, with a sufficiently small dose the time to first tumor will exceed man's lifetime, thus producing an effective carcinogenic threshold. (Dr. Jones S. 2-3; see also McArdle Laboratory for Cancer Research Comment at 2). The extension of time-to-tumor if the dose is lowered is shown by the draft report of the NCTR "megamouse" study. (Ex. 36.) Figure 9 of that report shows that a 24 months exposure at three levels (150 ppm, 100 ppm, and 75 ppm) had induced bladder neoplasms; however, exposure at four lower levels (60 ppm, 45 ppm, 35 ppm, and 30 ppm) had produced no tumors. See also Kaufman S. 5; Ex. 46.

Dr. Hoel discussed this question and while he agreed that on a statistical basis the time to first tumor will increase with

decreasing dose in the multistage model, he argued that some risk will still exist. (Dr. Hoel S. 7.) However, this conclusion is the result of the use of linear through zero extrapolation, which Dr. Peto frankly acknowledges is based on an "assumption" that some "asymptotic effectiveness" exists so that there is risk at any dose. (Dr. Peto S. Part I.)

In light of these analyses it seems appropriate to approach the matter of time-to-tumor as an important part of the risk assessment. Dr. Hoel also acknowledges this point when he says that "the choice of time-to-tumor model can greatly change any estimated low dose effects." (Dr. Hoel S. 7.)

Further refinement of the data may demonstrate that Dr. Jones is correct: there is an effective threshold at the dose level when time-to-first-tumor exceeds man's lifetime.[1/] It is important that the Proposed Regulation does not prevent presentation of such data when appropriately developed. In

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1/ Zapp, J.A., "An Acceptable Level of Exposure," 38 Am. Ind. Hyg. Assoc. J., at 425-421, 430 (1977) (AIHC Bibliography):

> "We know that there is a dose: disease effect for carcinogens, as there is a dose: effect relationship for other toxic manifestations. We see it in the laboratory. As the dose of carcinogen is increased, the proportion which does not get tumors is decreased. As we lower the dose, the proportion of the animals which get tumors is decreased. In the laboratory one can find a dose which does not produce any excess of tumors within the lifetime of the animals under test."

(Footnote continued on p. 213)

the interval, there is no doubt that evaluation of these data are an important part of the risk assessment. The risk may be overstated because of the "assumptions" made in the particular extrapolation method, but if the regulator recognizes the consequences of the assumption, a risk analysis which includes these data can make an important contribution in the administrative process.

Conclusion

The record strongly supports the need for a risk quantification by OSHA as an integral part of the regulatory process. The work of the IRLG in developing methods of risk assessment is a step in the right direction, but it is impossible to comment on these efforts since no public information is available.

Risk assessment is indispensible to a determination of the measureable benefits which various possible regulatory measures offer. It affords a reasonable basis for determining goals

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(Footnote continued from p. 212)

Roe, F.J.C., "The Principles of Cancer Prevention," 19 Gazetta Sanitaria, at 51-62, 53, (1970)(AIHC Bibliography):

> "In animal experiments the risk of cancer development increases with dose. With increase of dose the average induction time tends to approach a minimal, seemingly obligatory, period. When this point has been reached, further increase in dose is without effect on induction time. At the other end of the scale, however, reduction in exposure dose is associated with prolongation of the induction time until within the limits of a particular experiment, none of the exposed animals develop cancers before they die from other causes . . . We have demonstrated these dose response relationships in mice exposed just once at birth, to a potent chemical carcinogen."

for risk reduction by assessing the degree of risk presented in the workplace as contrasted with the degree of risk that we all face from chemicals (natural or man-made) in our everyday lives.

The big problem for risk assessment arises from selection of an appropriate model for extrapolating animal dose/response data to man. The most conservative approach is a strictly linear extrapolation, which some have asserted to be scientifically supportable in a limited number of cases but which frequently leads to totally impractical and inappropriate exposure levels for occupational, environmental, or personal care considerations. Broadly applied, this would place an unjustified and excessive inflationary burden on the American public through loss of or increased cost of products.

In many cases a linear model is not the best fit to experimental data and should therefore not be used for extrapolation purposes.[1/] AIHC believes that other methods may be more applicable in many cases. In no event should an agency foreclose the use of the best tool available in this period of rapid scientific advances.

1/ See J. Totter, "Discussion of the Use Of Thresholds in Regulatory Processes" (AIHC P.H.).

XII

UNDER THE STATUTE OSHA MUST DETERMINE NOT ONLY THE FEASIBILITY OF A STANDARD BUT WHETHER BENEFITS COMPARED TO COSTS DEMONSTRATE THE STANDARD IS REASONABLY NECESSARY

> "Because resources are limited, eschewing explicit cost/benefit analyses can result in more deaths and or cases of disease or injury; the costs imposed by a certain regulation might save more lives or prevent more cases if spent in other ways." 1/

Introduction

One of the most important and controversial provisions of the Proposed Regulation is that which requires the lowest feasible levels of exposure to be achieved for all Category I substances. Section 1990.112(b), 42 Fed. Reg. 54173. This provision embodies a proposed policy determination which "will not be permitted to be changed in the subsequent substance-by-substance rulemakings." 42 Fed. Reg. 54173.

There are two bases for objection to the single lowest feasible criterion. First, OSHA has never clarified what it means by "feasible" but has promised to do so in the forthcoming Regulatory Analysis. More important, the Benzene decision demonstrates that OSHA has disregarded the criteria of Section 3(8) which require that standards be "reasonably necessary and appropriate." 29 U.S.C. § 652(8).

1/ Evaluation of EPA's new drinking water regulations by the Council on Wage and Price Stability: Ivy Broder, "Analysis of EPA Proposed Drinking Water Regulations," at 9-10, September 5, 1978 (AIHC P.H.).

We will not repeat here the discussion of the Benzene decision which establishes that OSHA must quantify the benefits as an essential part of the regulatory determination that the costs involved are "reasonably necessary". See supra, at 7. We will discuss in this section OSHA's failure to define feasibility in a manner compatable with the Act.

A. The Definition of Feasibility

Unfortunately OSHA has not released its Regulatory Analysis so that participants in this proceeding could comment on whatever definitions or criteria of feasibility OSHA derives. Indeed it is not possible in this brief to do more than point to the considerations which the courts and other agencies have indicated are an essential part of determining feasibility.

The President's Regulatory Analysis Review Group in its comments on the proposed acrylonitrile standard pointed out that "[j]ust as there is no absolute 'safe' level, there is no absolute 'feasible' level." (Ex. 45 at 5.) The process of determining what is the "feasible" level in a particular situation was described by the CWPS in its comments on EPA's proposed drinking water standard:

> "Regulatory agencies, within their legal constraints, may exercise much flexibility in the choice of specific activities or substances to be regulated and the type of standards to employ. Many alternatives, which produce varying health-related and economic impacts, are possible. That is, there are different costs and benefits to be derived from different regulatory alternatives.

> In order to ensure that the regulatory process is efficient, an agency needs to perform cost-benefit analyses for proposed regulations. The benefits to be derived from many social regulations can be stated in terms of lives saved or cases of a disease avoided. Many regulators are reluctant to translate those benefits into dollar terms. However, the efficiency of the regulatory process cannot be improved upon without putting a 'dollar value on life.'
>
> One can, through a risk-assessment procedure, calculate the number of lives saved or cases of a disease avoided by various regulatory alternatives. In particular, calculating the cost per life saved for the least stringent alternative and for more stringent regulatory levels yields estimates of the incremental costs of imposing increasingly stringent standards. Efficiency requires that these incremental costs be equated across regulatory actions that save lives and/or prevent cases of disease or injury. Although the 'lumpiness' of design standards and other factors make it impossible to arrive at exact equality of these costs per case avoided, it is sensible to avoid letting these values be unreasonably disparate. Because resources are limited, eschewing explicit cost/benefit analyses can result in more deaths and/or cases of disease or injury; the costs imposed by a certain regulation might save more lives or prevent more cases if spent in other ways." (CWPS Comments supra, at 9-10, AIHC P.H.)

We believe the record clearly shows and the statute requires that the factors and methods outlined by the OMB should be considered in determining feasibility. Alternate methods of control should be analyzed from a technical and economic point of view. The incremental health benefits can be examined in the manner suggested by CWPS and a realistic determination made of feasibility in light of costs and benefits.

AIHC hopes that in its Regulatory Analysis OSHA will

realistically deal with those factors to be considered in determining feasibility. Since we cannot comment on OSHA's proposed definition or listing of factors, we shall in this section of the brief discuss briefly those elements which we believe should enter into a determination of an appropriate exposure level.

B. The Proposed Regulation Should Be Amended To Provide For Consideration of Economic Feasibility

Section 6(b) of the Act requires the Secretary of Labor to consider feasibility in promulgating standards pursuant to the Act. Mr. Wrenn in his prepared statement and in his testimony recognized that feasibility involves consideration of both technology and economics. (Wrenn S. 6, 11, Tr. 34.) In addition, Mr. Wrenn stated that the agency makes decisions on the basis of judgments as to cost effectiveness. (Tr. 35.) In the preamble to the acrylonitrile standard OSHA acknowledged the need to evaluate economic as well as technological feasibility. 43 Fed. Reg. 45762, at 45779-45789 (October 3, 1978).

Both the courts and the Occupational Safety and Health Review Commission have construed the feasibility criterion as requiring a balancing of costs and benefits. See discussion supra, at 98-100. Dr. Rall as well as other witnesses urged OSHA that in selecting a "feasible" level, health risks, resources costs, economic costs and benefits should be taken into account. (Tr. 364.)

It is significant in this connection that the AFL-CIO recognized that economic analysis plays a significant role in

the regulatory process. (Tr. 5816-5826.) Indeed the AFL-CIO recommended that OSHA's economic capability be enlarged to analyze costs in the regulatory context and urged the development of a "respected methodology for cost benefit analysis" by OSHA. (Ruttenberg S. 5-9.) Mr. George Taylor endorsed the utility of a cost/benefit analysis. (Tr. 5748-5749, 5832.) Speaking for the Steelworkers, Mr. Wright said that if there are to be economic studies the Steelworkers wanted them done "right". (Tr. 5822.)

Despite this background, the Preamble and the Proposed Regulation itself are silent as to how costs are to be weighed in the light of benefits. Given complete freedom an engineer can always spend more to decrease exposures further. But the incremental gains drop significantly and costs rise exponentially as lower and lower levels are fixed. It is precisely this relationship between incremental gains and incremental costs which the Regulatory Analysis Review Group established by President Carter pursuant to Executive Order 12044 concluded was part of an "adequate regulatory analysis". (Ex. 45 at 4.)

Yet nowhere in the Preamble nor in the Proposed Regulation does OSHA indicate how economic considerations will be taken into account in setting standards. Until AIHC can review the Regulatory Analysis being prepared by OSHA it cannot know whether OSHA will clarify its position on this point. AIHC agrees with EPA in urging OSHA to set forth clearly in the Proposed Regulation how feasibility will be determined and what role cost and benefits will play in reaching that decision.

(EPA S. 5, 27-30.)

The Proposed Regulation would foreclose consideration in future standard-setting procedures of the most cost and health effective combination of engineering controls, work practices, personal protective devices and administrative controls. The inflexibility of OSHA's position is particularly obvious in the construction industry. The most effective combination of engineering controls, administrative controls and personal protective systems requires consideration of the special problems of the construction industry -- the transitory nature of the work, the high labor turnover, and the complexity of using engineering controls. See the discussion supra, at 40.

The same principles apply in protecting workers in a plant. It is for this reason that AIHC urged that OSHA set performance standards, and require each plant to prepare a plan detailing the reasons why each part of the plan was adopted. Attached as Appendix F are pages from the AIHC Alternative describing the nature of the plan and guidelines for the plan. The existence of the plan in no way excuses the plant from failure to meet the PEL. But it does permit a plant owner to take into account the special problems of his plant without requiring an inflexible approach to the method of control, thus giving real meaning to the term "feasible".

The OSHA policy decision that mandates engineering controls even if they will not achieve the desired level is not consistent with the requirement that OSHA take economic

feasibility into account.[1/] While AIHC recognizes that engineering controls are the preferable means of control, to mandate such an inflexible policy for all future standard-setting procedures conflicts with the requirement that economic feasibility be considered in each area.

This conclusion is reinforced by consideration of Section 3(8) of the Act. A standard must be demonstrated to be not only feasible but "reasonably necessary." 29 U.S.C. § 652. The Benzene decision makes clear that if OSHA mandates control of exposure to the lowest feasible level without a careful balancing of benefits and economic considerations, OSHA is failing to make the determination of "reasonable cost" required by the Act in order to show that a standard is "reasonably necessary".

C. The Record Supports The Conclusion That Exposure Levels Should Be Established On The Basis Of Acceptable Risk

Much of the testimony in the record has been aimed at OSHA's rejection as a policy matter of the concept of "threshold"

1/ The AFL-CIO suggested that the model standard for Category I substances requires control of exposures in particular plants to lower than the specified PEL -- i.e., lowest possible limit -- when such control is possible. (AFL-CIO S. 13, Tr. 5710-5711.) The AFL-CIO recognized that a requirement for "all feasible engineering controls" even where the PEL is not exceeded presents a statutory problem. (Tr. 5710.) This may be a matter for collective bargaining, it is not a basis for regulatory action.

or "no-effect" levels for carcinogens.[1/] Dr. Claus and Dr. Olson testified that a "threshold" can be demonstrated on the basis of the biomolecular phenomenon of the number of molecules of a substance necessary to interact with cells of the target organ. (Dr. Claus S. 22-39, Tr. 3508-3511; Dr. Olson S. 31-34.) Many others testified on the basis of the principles of biology and toxicology that "threshold" is a universal concept in nature and there is no reason to conclude that a threshold does not exist for carcinogens. See, e.g., Dr. Skalsky Tr. 7588-7589, 7630; Dr. Goldwater S. 4-8; Dr. Lu S. 9-10. Dr. Upton testified that the possibility of a threshold cannot be excluded. (Tr. 347.) Dr. Kotin stated that a no-effect level can be predicted quantitatively in a variety of animal models for a variety of organ or organ system targets. (Tr. 8646.) Others testified that while a "threshold" has not been experimentally demonstrated, should such a demonstration be made, it should be considered by the agency in evaluating the human risk from exposure to a substance and in fixing levels of control. E.g., Dr. Upton Tr. 272; NIOSH Tr. 3075; see also EPA S. 9. Indeed failure to consider such evidence would be contrary to the requirement in Section 6(b)(5) that OSHA consider the latest scientific data available.

1/ A number of OSHA witnesses recommended the lowest feasible level of exposure on the ground that carcinogens are interchangeable and that exposure to a carcinogen in the workplace is added to the existing "burden" and may put an individual over the threshold. As we have shown supra, at 206-208, this concept of interchangeability is an assumption for which there is no data.

The fact that scientific debate continues on this subject does not alter in any way the fact that the record shows that OSHA should reconsider the policy decision upon which the unvarying low-as-feasible determination was made. That chemical substances which will be classified in Category I will vary widely in potency is a conclusion which OSHA itself recognized (42 Fed. Reg. 54165) and which the record amply supports. Indeed, it is this wide variation which makes quantitative risk assessment an essential part of the regulatory process. See the discussion supra, at 197-203.

There is no way to achieve zero risk in the workplace short of banning substances, unless a threshold is recognized and not exceeded. Even assuming that OSHA cannot identify a threshold for exposure to a carcinogen, it can assess the risks involved and take that risk into account in determining what is a permissible level of exposure, recognizing that some level of risk may be associated with the exposure. But it makes no sense in advance of such a risk evaluation to mandate lowest feasible for all future individual substance rulemakings. 1/

It requires no scientific evaluation to conclude that risks from exposure are different when a worker is exposed to

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1/ Dr. Rall endorsed generally the principle set out in the NAS Drinking Water Study, attached as Appendix I to Dr. Rall's statement:

> "4. Material should be assessed in terms of human risk rather than as 'safe' or 'unsafe'." (S. 8.)

aflatoxin or bischloromethyl ether on the one hand or to nickel dust on the other when, for example, a cashier handles coins in making change. It is equally clear that the level of control of exposure should be different in light of the differences in risk. E.g., Dr. Jellinek S. 5-6; see also Mr. Samuels Tr. 7259-7271, 7272; Dr. Rall Tr. 385-386.

The fact that such extremes exist suggests that a careful evaluation of level of control can utilize a risk assessment in determining an acceptable level of risk for different substances. This will be possible when a systematic method of risk assessment such as that recommended by EPA and FDA, and which hopefully the IRLG is in process of formulating, is made part of the regulatory process.

D. Costs And Benefits Must Be Considered In Regulatory Decision Making

Risk and hazard constitute half of the essential evaluation which should be made in the regulatory process. The Benzene decision makes clear the other essential considerations are cost and benefits. Nowhere in the Proposed Regulation does OSHA indicate how costs will be taken into account or what factors are part of a cost consideration.

There was resistance on the part of some witnesses to consider benefits at all. Others shied away from the analysis of benefits because of the complexities and difficulties of quantification. AIHC believes these objections are based on a mis-

conception of the evaluation which should be made.

Costs in this context mean health and resources flowing to or from different groups - workers, taxpayers, consumers and industry. (Zeckhauser Tr. 4321-4322; Dr. Lave Tr. 7003-7005.) What one may view as a benefit, the other views as a cost. It is for this reason that Dr. Ashford recommended that a risk/benefit analysis be made to identify what he called "trade-offs". (Tr. 2429.) Dr. Zeckhauser called this "a meticulous accounting". (Tr. 4352, 4410.)

The position of the AFL-CIO is instructive. In their testimony they urged that OSHA's economic capability be increased and that where economic analysis is called for under the regulations, the analysis should be done "right". (Tr. 5822.) George Taylor stated that a cost/benefit analysis of the kind outlined by Snell was an appropriate part of the regulatory process on particular substances. (Tr. 5748-5749, 5745, 5751.) Sheldon Samuels testified that cost/benefit analysis was at an early stage of development; while many items in the analysis could not be quantified, he agreed that the items which could be quantified should be quantified to assist the regulator. (Tr. 7283-7285.) As an alternative to cost/benefit analyses, Mr. Samuels discussed "necessary" and "unnecessary" risks, unnecessary risks being those encountered in producing socially unnecessary products. (Tr. 7286-7287.) However, Mr. Samuels recognized this was in effect a different name for a cost/benefit analysis. (Tr. 7287-7289.)

While OSHA can and should never lose sight of the fact that the objective of regulation is to protect worker health, it cannot escape consideration of the effects which its regulations have on the worker's job and on workers in other industries. Thus, as Dr. Wilson pointed out, if compliance with a regulation requires construction, OSHA should not lose sight of the historical fact that one worker loses his life for every $36 million in construction. (Dr. Wilson S. 47-49, Tr. 3372.)

Dr. Rall made the same point in a different way when he said:

> "Ultimately, however, the selection of a 'feasible' level depends on a judgment as to when the costs of control (which may include health risks and resource costs as well as economic costs) are justified by the magnitude of the carcinogenic risks posed by unregulated exposure."
> (Dr. Rall S. 1-2.)

The fact that OSHA does not make such an overt analysis should not conceal the fact that OSHA is making the societal judgments without acknowledging that it is doing so. (Dr. Lave Tr. 7003-7004, 7011-7013.) If a cost/benefit evaluation is made, regulatory judgment would be made on the basis of the best facts available; on the other hand, if OSHA does not make such an analysis, the judgment is being made by OSHA in ignorance and without consideration of the societal costs and benefits.

The fact that such an analysis is difficult should not stand in the way of attempting the assessment. FDA makes such

analyses as a regular part of its regulatory function. Many of the analyses involve drugs where the same person is both the person at risk and the one who receives the benefits. But FDA also makes analyses of risks and benefits where the costs, risks and benefits involve different groups. A good example is the analysis which FDA recently made in regulating the amount of aflatoxin which will be permitted in peanut butter. (Ex. 38.) EPA regularly makes cost/benefit analyses at various levels of control under the Federal Insecticide Fungicide and Rodenticide Act and will make such analyses under the Toxic Substances Control Act. (Tr. 2357.)

Another example of a risk/cost assessment is that undertaken by the Nuclear Regulatory Commission. (Ex. 67.) As a part of its determination of the numerical guides for design objectives and limiting conditions for operation required to meet the criteria "as low as practicable", the Commission adopted a monetary value for reducing exposure of $1000 per total-body man-rem. 40 Fed. Reg. 19439 (May 5, 1975.)

On the basis of the interim value of $1000, the Commission has prepared evaluations of the cost/benefit analyses in support of nuclear power reactor applications. (Ex. 67.) This experience, evaluated in the light of applicable EPA environmental standards, lead the Commission to reconsider the need for further efforts to redefine the worth of reducing radiation exposure to

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1/ In December 1975, the Commission changed the terminology "as low as practicable" to "as low as is reasonably achievable" to conform to the International Commission on Radiological Protection. 40 Fed. Reg. 58845 (December 19, 1975).

the general population. Id. The Commission cancelled the proposed rulemaking to review the interim value, stating:

> "The cancellation of this rulemaking should not be interpreted as an abandonment by the Commission of the concept of a quantified cost-benefit analysis for defining as low as is reasonably achievable levels of radiation exposure. The Commission believes that the Appendix I rulemaking proceeding (Docket No. RM-50-2) and the subsequent experience with the Appendix I rule show that this concept has considerable merit and utility. In this regard, the Commission notes the opinions of the Advisory Committee on the Biological Effects of Ionizing Radiation of the National Academy of Sciences - National Research Council 6/ that:
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> Such analyses could facilitate rational and cost-effective safety and control procedures and the avoidance of health hazards and economic dislocation associated with excessive or inadequate expenditures in relation to risk. Health benefit/cost assessments, even though present data are incomplete, can provide some guidance to decision makers, direct attention to gaps in knowledge, indicate priorities for research, and stimulate the accumulation of needed data and analysis, and contribute to public understanding of the relevant issues and problems *** (page 6).
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> * * *
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> 6/ National Academy of Sciences - National Research Council Advisory Committee on the Biological Effects of Ionizing Radiation. 'Considerations of Health Cost-Benefit Analysis for Activities Involving Ionizing Radiation Exposure and Alternatives.'" Issued as EPA Report in EPA 520/4-77-03 (1977).

The reasons why the NRC found a risk/benefit analysis useful should be persuasive that a similar analysis should be

made by OSHA. Based on his experience in radiation, Dr. Upton said that the principle of "diminishing returns" is generally valid:

> "In connection with radiation, it has been suggested that beyond a certain point, the costs to society involved in further reducing the dose and hence the presumptive risk may outweigh the costs associated with that hypothetical risk. So I think the principle that one may reach a point of diminishing returns is a valid principle. And I would suppose that a regulatory decision would weigh in arriving at the concept of feasibility all of the factors that have to go into a socially acceptable judgment." (Tr. 271; see also Tr. 283.)

As Dr. Wilson and Professor Lave pointed out, to the extent it is possible to quantify even partially the complex factors in a regulatory proceeding, the proceeding is facilitated because the number of factors which must be evaluated on judgment alone will be identified and their number reduced. (Dr. Wilson Tr. 3374; Professor Lave Tr. 7001-7002.) Indeed, as Professor Lave emphasized, making such a cost/benefit analysis is the best way to speed up the administrative process. (Tr. 7000-7002.)

The CWPC's comment on uncertainty in determining costs and benefits emphasizes the urgency of making the analysis:

> "There is a considerable amount of uncertainty about both the costs and the benefits of these alternatives, but it makes little sense to act on uncertain evidence by imposing costly regulations on local communities while, at the same time, es-

chewing cost/benefit analyses because of this uncertainty." 1/

AIHC believes that the record strongly supports the conclusion that OSHA should undertake a cost/benefit analysis as part of the regulatory process to determine the level of control. This may not necessitate an elaborate formal cost/benefit analysis but it does mean that OSHA will have sufficiently identified the societal costs and benefits that it can more reasonably determine an acceptable level of risk - the reasonably necessary level - in setting particular standards. Section 3 B(1) of Executive Order 12044 requires that such an analysis be performed; it directs the agency to identify alternatives and assess their economic consequences. See discussion supra, at 102-103.

Some form of risk/benefit analysis is being developed by the IRLG. AIHC applauds this development in principle but cannot comment in greater detail because the recommendations of the IRLG are not available for comment. We do not know whether the proposals will or will not be reasonable and adequate.

E. The AIHC Alternative Provides A Reasonable Procedure For Identifying An Acceptable Level Of Risk

The AIHC Alternative spells out the procedure for determining the reasonably necessary and acceptable level of

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1/ CWPS comments on EPA's proposed drinking water standard, September 5, 1978 (AIHC P.H.).

risk.[1/] An orderly method of risk quantification is set out and the analyses of the risks and societal costs and benefits of alternative methods or levels of control is described. Under the AIHC Alternative an orderly and logical sequence for administrative determination of an acceptable level of risk for both emergency temporary and permanent standards would be established. Costs and quantified benefits are examined as the court directed in the Benzene decision.

Emergency Temporary Standards ("ETS"). Under AIHC Category I (known human carcinogens) and Category II (confirmed animal oncogens) the initial step is a determination whether the facts justify an ETS. If an ETS is issued, the level of exposure is set based upon all the data available. If sufficient data are available to quantify risks and to perform the cost/benefit analysis, the acceptable level will be identified and the method of attaining it described. If sufficient data are not available for the necessary analysis, the temporary standard will specify a permissible exposure level which can be achieved through a practical combination of readily available engineering controls and personal protective equipment. The Interagency Testing Committee established under the Toxic Substances Control

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1/ AIHC Alternative at 70-84, (Appendix G to this brief is a supplementary statement of the principles AIHC believes should be followed in a risk/benefit analysis).

Act would be notified of the desirability of further testing.[1/]

Permanent Standard. Under AIHC Categories I and II the Alternative provides that where data are available to quantify risks, the acceptable exposure level will be set after evaluating the risks, costs and the benefits in the manner provided. Where data are not sufficient to quantify risks, a five-year "interim permanent" standard would be fixed upon the basis of the best data available. If data became available in the five year period, the "interim permanent" standard will be reviewed in light of the data and a permanent acceptable level fixed. If data do not become available, the permanent standard will be fixed at the lowest level economically and technologically feasible.

We believe that AIHC's proposal satisfies the statutory standard of feasibility in Section 6(b)(5), read in the light of the "reasonably necessary" criteria in Section 3(8).

F. A Risk/Benefit Analysis Is Required Under The National Environmental Policy Act

Finally, the statutory requirements of the Act must be considered in light of OSHA's obligations under the National Environmental Policy Act, 42 U.S.C. § 4321 et seq. (See supra,

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1/ Both the temporary and permanent standards provide for exclusions of mixtures containing low concentrations of the substance and for an "action level". The mixture exclusion level and the action level would be determined based on the risk/cost/benefit analysis.

at 100 for a discussion of OSHA's obligations under that statute.) It is sufficient to note here that unless OSHA makes the risk/cost/benefit analysis of the kind discussed above, it will have neither the necessary basis upon which to weigh the broad environmental impact of alternative control levels in devising a particular standard, nor the data to analyze the resource commitment as required under Section 102 of NEPA, 42 U.S.C. § 4332.

Conclusion

Compliance with these statutory requirements cannot be made without a risk/cost/benefit analysis of the kind embodied in the AIHC Alternative. The fact that other agencies make such analyses demonstrates that while the analysis may have uncertainties and may indeed be complex, such analyses can be made and do contribute to rational decision making.

XIII

THE PROPOSED REGULATION UNLAWFULLY REQUIRES ISSUANCE OF EMERGENCY TEMPORARY STANDARDS WITHOUT APPRAISAL OF RISK

The Proposed Regulation would require, in every case of a Category I classification within its scheme, automatic issuance of an ETS. This requirement clearly contradicts the plain language of the statutory authorization for the issuance of an ETS, the Congressional intent behind the grant of authorization, and the court decisions construing this authorization.

Section 6(c)(1) of the Act, 29 U.S.C. § 655(c)(1), requires that prior to the issuance of an ETS the Secretary of Labor must make a determination that "employees are exposed to grave danger" from toxic and physically harmful substances, and that an ETS is "necessary to protect employees from such danger." The Proposed Regulation would not require these specific, prescribed factual findings to be made prior to the issuance of an ETS. In fact, no assessment of the degree or significance of carcinogenic risk posed by a particular substance is provided for, either in the classification process or subsequent thereto.

The proposed automatic issuance of an ETS for every Category I substance is contrary to the intent of Congress that the power to issue an ETS be used sparingly and only in unusual circumstances: "Congress considered that . . . emergency temporary standards should be considered an unusual response to exceptional circumstances."

Dry Color Manufacturers Ass'n v. Department of Labor, 486 F.2d 98, 105 n. 9a (3d Cir. 1973). In like fashion, the Court of Appeals for the Fifth Circuit has stated that "[the extraordinary powers] granted to the Secretary in Section 6(c) of the Act should be delicately exercised, and only in those emergency situations which require it." Florida Peach Growers Ass'n v. Department of Labor, 489 F.2d 120, 129-30 (5th Cir. 1974). See also Taylor Diving and Salvage Co. v. Department of Labor, 537 F.2d 819 (5th Cir. 1976).

OSHA's purported justification for the wholesale issuance of ETS is that any substance which has been shown to cause cancer in animals, ipso facto, presents a grave danger to humans. The courts, however, have not supported this contention when offered by OSHA in the past.

In Dry Color Manufacturers Ass'n, Inc. v. Department of Labor, supra, the United States Court of Appeals for the Third Circuit stated that, "[a]lthough the danger of cancer is surely 'grave,' Subsection 6(c)(1) of the Act requires a grave danger of exposure to substances 'determined to be toxic or physically harmful.'" Id. at 104. For a valid ETS to issue, there must be a showing of "more than some possibility that a substance may cause cancer in man." Id. The court then stated that the record before it failed to show "more than some possibility that DCB [3,3' Dichlorobenzidine] and EI [Ethyleneimine] may cause cancer in man," and that the "most that can be said is that DCB and EI pose a 'potential' cancer hazard to man," indicating that the record did not

support issuance of an ETS. Id. at 105 (emphasis added);[1/] see also Florida Peach Growers Ass'n v. Department of Labor, supra, at 131. The evidence then before the court included the reports of laboratory rodent experiments on DCB and EI which OSHA and NIOSH regarded as constituting clear evidence of carcinogenicity in two species, far more evidence than the OSHA proposal would require for an ETS.

In interpreting the requirements for issuance of an ETS, the court stressed the value Congress had intended that the normal rulemaking procedure would have, noting that it was clear that Congress

> "considered that the ordinary process of rulemaking would be that provided in subsection 6(b), dealing with permanent standards; emergency temporary standards should be considered an unusual response to exceptional circumstances. The courts should not permit temporary emergency standards to be used as a technique for avoiding the procedural safeguards of public comment and hearings required by subsection 6(b). Especially where the effects of a substance [on man] are in sharp dispute, the promulgation of standards under subsection 6(b) is preferable since the procedure for permanent standards is specifically designed to bring out the relevant facts." Dry Color Manufacturers Ass'n Inc. v. Department of Labor, supra, at 104 n. 9a.

Consistent with the statutory language, Congressional intent, and relevant court decisions, the AIHC Alternative would not require automatic issuance of an ETS. Instead, it calls for

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1/ Having clearly indicated its views that an ETS would not generally be warranted on the basis of animal data alone the court set aside the ETS on another ground. Dry Color Manufacturers Ass'n Inc. v. Department of Labor, supra, at 104-105.

the exercise of informed judgment and discretion exercised on the basis of an evaluation of all the evidence of potential carcinogenic risks (e.g., carcinogenic potency as indicated by the epidemiologic data, animal experimental data, where available, such as dose-response relationships, metabolism, duration and amount of exposure, route of exposure) and an evaluation of actual hazards, (e.g., physical and chemical properties, degree of occupational exposure, likelihood of a carcinogenic event.)

In short, the AIHC Alternative fully complies with the statutory requirements. The Secretary will not only appraise the facts to determine if there is "grave danger," but also to determine, as the Act requires, whether an ETS "is necessary to protect employees from such danger." 29 U.S.C. § 655(c)(1). The Benzene decision underlines the need for specific findings of benefits before an ETS can be shown to be "necessary".

XIV

OSHA HAS A LEGAL AND MORAL OBLIGATION TO SET REGULATORY PRIORITIES

> "The more we spend on safety, the less we have with which to fight poverty and disease or to spend on those goods and services which make life worth living, for ourselves and others. Whatever money we make available for safety we should spend in such a way that it produces the maximum benefit. There is nothing humanitarian in spending lavishly to reduce a particular hazard which has been brought to our attention and ignoring the others." 1/

In the Preamble to the Proposed Regulation OSHA discusses various procedures by which it can systematically classify and regulate the substances in the NIOSH list of "Suspected Carcinogens". 42 Fed. Reg. 54169. Several proposals are discussed, including the possibility that the substances be taken in alphabetical order. This discussion must be considered in the perspective of Section 1990.103(a) of the Proposed Regulation, which would require the Secretary to initiate the regulatory process whenever information is presented by a public petition.

The issue of priorities was brought into sharp focus during the hearings on July 14, 1978. On that date OSHA released a preliminary list of chemicals classified according to the system in the Proposed Regulation. (Ex. 132.) The lists were pre-

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1/ Kletz, T. A., "The Application of Hazard Analysis to Risks to the Public at Large," at 1. Presented at World Congress of Chemical Engineering, Amsterdam, July 1, 1976. AIHC Bibliography.

pared by Clement pursuant to contract. The NIOSH list was screened by Clement to identify commercial products on the NIOSH list. Two computer comparisons were made: one with the EPA tentative inventory of existing chemicals under the Toxic Substances Control Act; and the second with the International Trade Commission data on commercial organic chemicals. The chemicals on the NIOSH list identified as commercial were then screened by review of articles cited in the NIOSH list; review of the U.S. Public Health Service survey of chemicals tested for carcinogenesis; a check of the National Library of Medicine's Cancer Line data base; and review of the IARC monographs.

As a result of the screening process the chemicals were presumptively assigned to the OSHA categories as shown in the following table:

	List I (Based on EPA TSCA Candidate List)	List II (Based on USITC Data Base)
Category I	269	116
Category II	218	72
Category III	396	181

In a memorandum accompanying the press release, and in the press release itself, participants in the hearing were asked to propose a system of priorities for regulation of those substances and to explain the criteria they would use.

AIHC has responded to this request in a separate communication. (Appendix H to this brief.) In this section of

the brief, we address the more general question of priorities under a generic regulation such as that proposed by OSHA.

A. The Statute Requires OSHA To Establish Priorities

Section 6(g) of the Act directs the Secretary to establish priorities. 29 U.S.C. § 655(g). That section provides:

> "(g) Priority for establishment of standards. In determining the priority for establishing standards under this section, the Secretary shall give due regard to the urgency of the need for mandatory safety and health standards for particular industries, trades, crafts, occupations, businesses, workplaces or work environments. The Secretary shall also give due regard to the recommendations of the Secretary of Health, Education and Welfare regarding the need for mandatory standards in determining the priority for establishing such standards."

Congress has specifically directed that OSHA "shall give due regard to the urgency of the need for mandatory safety and health standards for particular industries, trades, crafts, occupations, businesses, workplaces or work environments" in determining the priority for establishing standards. 29 U.S.C. § 655(g). Clearly, Congress intended that OSHA first address those health problems presenting the greatest hazard to workers. A decision by OSHA to regulate substances in the random fashion suggested would constitute a flagrant denial of this intent.

Perhaps of greater practical significance, a failure to prioritize substances for regulation on the basis of the potential risk for human carcinogenicity and the degree and extent of employee exposure to the substances, could result in a serious

waste of OSHA's and industry's manpower and resources. Surely the state of scientific knowledge allows for this rational approach to regulation, as recognized by the FDA, EPA, and CPSC.

Donald Kennedy, U.S. Commissioner of Food and Drug, Food and Drug Administration, testified at the hearing that hazard assessment should be employed for setting agency regulatory priorities. Commissioner Kennedy described the factors considered in such an assessment as the relative carcinogenic potency of the substance, the number of workers exposed and the dosage of exposure. (Tr. 493-497, 514.)

EPA utilizes a similar system for setting regulatory priorities. The Assistant Administrator for Toxic Substances for the EPA, Steven Jellinek, testified that the agency prioritizes substances for regulation on the basis of an analysis of relative potencies and the number of persons exposed. (Tr. 2359, Jellinek S. 2.)

Finally, both the testimony of Chairman Byington in this hearing and the recently published Interim Statement of Policy and Procedure for Classifying, Evaluating, and Regulating Carcinogens in Consumer Products, 43 Fed. Reg. 25657 (June 13, 1978), demonstrates that the CPSC will utilize quantitative hazard assessment in establishing regulatory priorities, with the extent of exposure being a major consideration. (Tr. 2095, 2088-2089). The Interim Statement of Policy and Procedure specifically states that:

> "In determining the order in which products containing classified substances will be evaluated by the staff, the Commission recognizes that it may need to set priorities among substances. Generally, priority will be based on the relative certainty of the evidence concerning the substance (i.e., the category to which it is assigned), the apparent potency of the substance, the extent of consumer exposure to products containing the substance, including the approximate number of products and the amount of the substance contained in each, and the potential for human uptake. This may lead in some cases to the allocation of resources to the investigation and possible regulation of high priority Category B or C substances rather than low priority Category A substances." 16 C.F.R. § 1040.31 (published at 43 Fed. Reg. 25664).

The past actions of OSHA demonstrate its concurrence in the approach of the FDA, EPA and CPSC. As discussed supra, at 65, in their contract OSHA has instructed Clement to develop criteria for, inter alia, potency and risk quantification for the purpose of "ranking" substances:

> "The contractor will attempt to develop a semi-quantitative scale, upon which each chemical will be ranked according to several independent, relevant factors. The weighted sum of the rankings may then establish an order of chemicals."

Presumably, this ranking is to serve as the basis for prioritization of substances for regulation.

In addition, the affidavit executed by Grover Wrenn in Textile Workers Union of America v. Usery, Civil Action No. 75-2157 (D.D.C., filed March 1976) demonstrates that historically NIOSH has prepared criteria documents on a priority basis and that OSHA has set regulatory priorities "based on severity of

the hazard and extent of employee exposure . . . ." (Wrenn Affidavit at 2, 4). In fact, the Wrenn affidavit flatly states that it is a function of Mr. Wrenn's job to determine priorities. The affidavit specifies the factors involved in past prioritization:

> "One major function of my job is determining priorities for health standards development. In making such determinations I consider among other things the type of hazard involved, its extent and severity, whether it is seasonal or continuous, whether it is already meaningfully regulated in whole or part, and the number of employees exposed. These factors must also be balanced against my manpower capabilities and those of the Solicitor's Office, since no employee will be protected if we undertake so many proceedings we cannot effectively complete any." Wrenn Affidavit at 10 (emphasis added).

Materials that are known or seriously alleged to be human carcinogens or highly potent animal carcinogens surely present a much more manageable number of substances for regulatory and compliance purposes than the "universe" described by the NIOSH subfile, and are very likely to account for the great majority of the potential occupational hazards being encountered in domestic workplaces. Regulating these substances first would enable greater benefits to be achieved, and ensure greater acceptance by those being regulated, in view of its manifest reasonableness.

B. OSHA Should Not Allow Persons Outside The Agency To Dictate Its Priorities

At any rate, OSHA should retain the flexibility to exercise informed judgment and to consider regulating first the

most potent human carcinogens to which the greatest number of employees are exposed. Regulating substances not currently on the NIOSH subfile of "suspect carcinogens" in the order that information is received by OSHA from any source would deprive OSHA of the ability to exercise judgment in establishing priorities for rulemaking. For example, under the OSHA proposal, the filing of a "citizen petition" could force OSHA to give equal priority to such seemingly unequal problems as selenium, an essential human nutrient, asphalt, and carbon tetrachloride, compared to bischloromethyl ether and aflatoxin. In addition to being irresponsible, allowing citizen petitions to force automatic regulatory responses would be a clear abdication by OSHA of its duty to set priorities in accordance with the guideines set by Congress in Section 6(g) of the Act, 29 U.S.C. § 655(g).

EPA has testified that OSHA would lose control of its processes unless it established priorities and reserved discretion to decide not to regulate a particular substance. (Jellinek S. 6; EPA S. 20-22.) The CPSC Interim Statement of Policy and Procedures does not provide for "citizen petitions" which would trigger automatically the regulatory procedure, despite the close adherence of the Statement to OSHA's Proposed Regulation. In short, other federal agencies have recognized the inadvisability of placing their regulatory responsibilities in outside persons. We believe OSHA should do so also on both policy and statutory grounds.

C. OSHA Should Heed The Advice Of The Interagency Task Force On Priorities

The Interagency Task Force on Workplace Safety and Health has recommended that OSHA better utilize its limited standard-setting and enforcement resources and maximize worker protection by issuing criteria for determining which hazards will become the subject of proposals and of final standards:

> "The new Administration has taken significant steps to make OSHA enforcement more rational, remove unnecessary paperwork and compliance burdens, and provide workers neglected health protection. The more the agency gears up to issue health standards, however, the more it will need a system for determining priorities to insure that maximum worker protection is obtained and that standards begun are completed in time. The universe of job safety hazards is relatively finite; chemical threats to health expand by hundreds of substances each year and are unlikely to be completely covered even through rulemaking aimed at generic chemicals or processes rather than single substances. The need to carefully select areas for which regulation will produce the greatest health and safety gains at the least cost to the government is clear. Lack of such a priority system leaves the agency vulnerable to pressures against as well as for particular standards. It has in the past delayed standards completion and demoralized both standard-setting and enforcement staff, who have found themselves flung from one project to the next on a crash-and-wait basis. It has in the past put the agency on the defensive with respect to NIOSH, which has a formal priority system and pursues it with some rigor, generating dozens of criteria documents to which OSHA has been forced to respond ad hoc. Perhaps more importantly, it hampers the long-range standards planning a priority system will provide.
>
> This recommendation proposes that OSHA establish formal criteria for determining when particular hazards should trigger full-scale rulemaking, including:

- number of workers exposed
- extent of their exposure
- potential severity of resulting injuries and illnesses
- alternative means of controlling the hazard
- practical aspects of enforcing the standard
- costs to the government of developing and enforcing the standard.

The recommendation also proposes that based on these criteria, OSHA should develop a weighted numerical index for ranking hazards being considered for protective rulemaking; that it should publish an annual list of such candidates for public comment; that it should disclose the reasons for deciding which hazards to regulate; and that it should set up a separate office, building on current plans for an Office of Carcinogen Classification, to set, monitor, and revise resulting priorities.

Because of present deficiencies in available data, it is the systematic consideration of the listed criteria, rather than the numbers emerging from that consideration, which will probably prove most productive over the short run. It should also be emphasized that this recommendation will afford OSHA continued flexibility by enabling it more productively to select not only topics for rulemaking at the initial stage, but aspects of proposed standards to press to completion after rulemaking has begun. Finally, it should be noted that this recommendation merely proposes to systematize factors which OSHA has long used to make similar decisions on a more ad hoc basis. Making those criteria explicit offers a significant opportunity to better manage standards setting and efficiently comply with the President's recent order on improving government regulations." ("First Recommendation Report" August 1, 1978, at IV-24 - IV-25 (AIHC P.H.).)

PART FOUR

XV

THE PROPOSED REGULATION SHOULD PROVIDE THAT IN SETTING STANDARDS IN SUBSEQUENT RULEMAKINGS AN EXCLUSION FOR MIXTURES CONTAINING SMALL QUANTITIES OF A CARCINOGEN WILL BE MADE AND AN ACTION LEVEL WILL BE ESTABLISHED

The Proposed Regulation does not contain provisions on two subjects which would have a material impact on the cost of compliance with particular standards and yet would not impair worker health protection:

(a) exclusion of mixtures which contain a small quantity of a carcinogen as a constituent or contaminant;

(b) establishment of an action level below which a number of the requirements of the standards, particularly monitoring and medical surveillance, are significantly reduced.

The Proposed Regulation should be amended to provide that in setting individual substance standards an appropriate exclusion will be made for mixtures and an action level established.

A. A Mixture Exclusion And An Action Level Should Be Incorporated Into The Standards

Any conceptual difficulty which OSHA may have with a mixture exclusion and an action level stems from two administrative policy determinations which, as we have shown, should on the basis of the record be modified. These policy determinations are:

(i) There is no safe exposure level and any exposure is associated with risk.

(ii) Therefore, lowest feasible exposure is mandated in all cases.

When the concepts of risk analysis, and an evaluation of the reasonable necessity of controls following a risk/cost/benefit analysis of the kind described above replace the two inflexible policy determinations proposed by OSHA, the conceptual difficulties vanish.

An acceptable level of "contamination" of mixtures by a carcinogen can be established in the same way that an acceptable risk level of exposure is determined. The level will vary with the substance and the risks associated with the level of contamination. The same reasons that a mixture cut-off was set in the proceedings involving the fourteen carcinogens, and more recently in the standards for benzene and acrylonitrile, point to the conclusion that the Proposed Regulation should authorize such a mixture "cut-off" in individual substance standards.

There is no conceptual difficulty with an action level if the standard is set at a feasible, reasonably necessary level. When controls are engineered, they are generally engineered to achieve a level below the PEL. Otherwise the normal operation of a plant would lead to continued violations or changes in control methods as production and control efficiencies changed. Thus an action level is in reality a recognition of this engineering "fact".

B. A Mixture Exclusion And An Action Level Could Materially Reduce Cost And The Number Of Establishments Regulated

Since the proposed model standard provides that it is

applicable whenever a substance is "introduced" or is "present" in the workplace, (Section 1910.000(d)), the workplaces subject to the standard will include every workplace where a mixture containing any amount of the substance is opened or used. By fixing a mixture cut-off, the number of regulated workplaces will drop dramatically without in any way endangering employee health.

Similarly, the use of an action level makes it possible to reduce dramatically the cost of compliance since monitoring and medical surveillance, which make up a large part of the cost of compliance, will be reduced.

Snell testified that the mixture exclusion would have a material effect on costs of compliance and costs of enforcement. (Tr. 3837-3838, 3890; Snell Report at 520-521.) An action level would not adversely affect worker health since the worker exposure would be below the PEL. Without such exclusions for mixtures and an action level Snell estimated that the entire workforce of the United States could be covered by standards promulgated pursuant to the Proposed Regulation with costs of compliance "significantly higher" than those estimated in the Report. (Snell Report at 5, 520-521.) Further, it would eliminate from the standards requirements many persons with infrequent and minimal exposure who might otherwise be unintentionally and needlessly covered, such as delivery men, telephone repairmen and safety inspectors. See Air Products S. App. 9-10.

Conclusion

AIHC, SPI and a number of witnesses recommended that OSHA include the action level concept and mixture exclusion in the Proposed Regulation. See, e.g., NIOSH Tr. 3133-3136; Dr. Harris Tr. 3170-3171; Dr. Billings Tr. 2866-2867; Mr. Holaday Tr. 2321-2324. The AFL-CIO did not oppose the principle of an action level and indeed made proposals as to the level of an action level and as to monitoring. (AFL-CIO S. 17-18.) Absent such provisions all of the requirements of the standards arguably would apply even where only a single molecule is present. Indeed, amounts which are at the part per trillion level would be deemed "present" by Mr. Wrenn for purposes of the model standards. (Tr. 67-68.) The Proposed Regulation should be amended to provide that an appropriate mixture exclusion and action level may be set in rulemaking on individual substances.

XVI

THREE MATTERS SHOULD NOT FOR PRACTICAL AND LEGAL REASONS BE PART OF THE PROPOSED REGULATION: (1) RATE RETENTION, (2) A PERMIT SYSTEM OR (3) LIMITATIONS ON THE USE OF COMPANY DOCTORS IN MEDICAL SURVEILLANCE

Three matters have been addressed by union representatives which should not be included in the Proposed Regulation: (1) rate retention; (2) the proposal first made by Mr. Samuels on July 18 that OSHA adopt a permit system for potent carcinogens; and (3) the suggestion first made by union representatives on July 14 that severe limitations be imposed on the use of company doctors in the medical surveillance programs.

(1) Mr. Wrenn said at the opening of the hearings that rate retention would be considered for this Proposed Regulation in a subsequent hearing after OSHA has evaluated the earnings retention hearings held last fall in the context of the proposed lead standard. (Tr. 9698; see 42 Fed. Reg. 46547 (September 16, 1977).)

(2) At the hearing on July 18, 1978 for the first time Mr. Samuels presented a permit program for "particularly virulent carcinogens". (Tr. 7256-7258, 7270-7273, 7290, 7300-7301.) This was a revival of a proposal made in 1973 in the proceedings involving the 14 carcinogens (Ex. 131.) and rejected by OSHA at that time. Mr. Samuels' proposal was in fact a modification of the earlier proposal but without details as to the modification.

(3) In their prepared statement the AFL-CIO urged that physical examinations be given by a doctor of the worker's choice.

(Notice No. 71, attachment at 15.) On July 14 and 15, union representatives greatly enlarged this proposal by the surprise suggestion that severe limitations be imposed on the use of company doctors in the medical surveillance programs. (UAW Tr. 5723-5724, 5778-5781, 5791-5795; Steelworkers Tr. 5993-5995, 6032, 6050; Teamsters Tr. 5842-5843.)

On practical and legal grounds, none of these proposals should be part of the Proposed Regulation.

A. Rate Retention Provisions Should Not Be Incorporated Into The Proposed Regulation

It has been suggested in these proceedings that OSHA adopt a provision which would require an employer to ensure no loss of employee wages, seniority or other benefits where that employer removes an employee because of a medical determination which indicates that further exposure to the subtance in question would seriously increase the employee's health risk.

AIHC believes such a provision to be unwise and without legal foundation. We support Mr. Wrenn's suggestion that this issue be addressed in a subsequent rulemaking after OSHA has had an opportunity to consider its record on this matter in the earnings protection hearings held last fall in the context of the proposed lead standards. (Tr. 96-98; see 42 Fed. Reg. 46547 (September 16, 1977).)

Without belaboring the point, we should point out that the problem of rate retention is a complex one, varying from situation to situation and not readily amenable to uniform nationwide

solution. Further, we believe there is no sound evidence to support the proposition that there is a serious problem which requires such drastic measures.

Finally, and perhaps most importantly, we do not believe the Congress intended that OSHA venture into the area of economic protection but rather intended the agency to focus its efforts on providing a safe workplace. The explicit provisions of the Act, its legislative history, and other legislative efforts all clearly indicate that economic protection is an area beyond OSHA's statutory authority.

Section 27 of the Act, 29 U.S.C. § 676, recognizes the problems associated with employee economic security. However, rather than authorizing OSHA to deal with the inadequacies of available economic assistance, the Congress decided in that section that a national commission should be established to review and report on the adequacy of worker's compensation laws. The commission's report, published in 1972, has, in fact, led to many legislative amendments at both the state and federal levels. (See OSH Rep. (BNA - Cur. Dev.) 1448 [1976]; and Director, Office of Workmen's Compensation v. Boughman, 545 F.2d 210, 215 n.15 (D.C. Cir. 1976). See also Section 4(b)(4) of the Act, 29 U.S.C. § 653(b)(4).

In addition, the Congress has considered and continues to consider legislative matters pertaining to economic compensation for work-related injuries and diseases. See, e.g., OSHA Rep. (BNA - Cur. Dev. -- Workmen's Comp.): H.R. 8689, 95th Cong., 1st Sess. (1977) (asbestos) and H.R. 3480, 95th Cong., 1st Sess.

(1977) (cotton dust); BNA, supra, August 3, July 7 and March 17, 1977 at 313, 178-179 and 1311-12; H.R. 3630, 95th Cong. (hearings were held September 1978). Such matters are perceived by the Congress to be and are appropriately within the domain of the legislature, not OSHA.

The legislative history of the Act further demonstrates that Congress did not intend that OSHA become involved in economic protection. Indeed, an earlier bill approved by the House Committee on Education and Labor would have permitted a form of earnings protection. The bill as passed by both the House and Senate, however, contained no such provision. See Legislative History at 416, 842, 860, 985-86, 1008-1009 and 1089.

Where the Congress has intended that an agency step into the area of economic protection, it has clearly spoken out. For example, the Coal Mine Health & Safety Act, enacted a year prior to the Act, explicitly provides a federal directive on economic compensation for individual workers. See 30 U.S.C. § 901. Further, the Clean Air Act Amendments of 1977 explicitly include authorization for worker protection. See 42 U.S.C. § 7410(a)(6). The fact that no such provisions are contained in the OSH Act is highly significant.

B. The Permit System Has Been Insufficiently Considered In This Hearing And Is Not Authorized By Law

The suggestion was made in the course of these proceedings that OSHA should include in its Proposed Regulation

a system whereby an employer would be required to seek a use permit prior to any use in his workplace of a regulated carcinogen. Such a permit system would require the employer to be inspected and licensed by OSHA before employees are allowed to work in the area of exposure. Shutdown orders would be issued by OSHA to employers operating without a permit or to permit holders who fail inspection. In addition, permit applicants would have the burden of proving the absence of a safe or technologically feasible alternative to the regulated substance. (AFL-CIO Tr. 7256-7258; see also Dr. Wolfe Tr. 6353-6354).

AIHC strongly believes that the establishment of a use permit system is not only unwise, but is beyond the scope of OSHA's legal authority.

The primary rationale voiced in favor of a use permit system is that such a system is "the only way to ensure that zero level exposures will be implemented." (Dr. Wolfe Tr. 6353.) Indeed, pre-approval inspection as a means of ensuring that no exposure will result from the activity inherently raises the concept of zero tolerance. However, AIHC believes that it would be improper for OSHA to set uniformly a lowest feasible level of exposure, no less a zero exposure level. Imposition of any such single level of exposure would disregard the potency and risk of exposure to a particular substance. Therefore, AIHC supports, and the record demonstrates the propriety of the establishment of exposure levels on the basis of acceptable risk, after the risk/cost/benefit assessment, which must be an indispensable

part of OSHA's regulatory decisions, has been made.

Moreover, the establishment of a use permit system would clearly exceed OSHA's statutory authority. Nowhere in the statute is OSHA explicitly granted the power to impose a permit system on employers. OSHA's authority is limited under Section 6 of the Act, 29 U.S.C. § 655, to the promulgation of occupational safety and health standards, to be uniformly applied to places of employment as a means of protecting the safety and health of affected employees. Where such standards could not be met, Congress provided the Secretary with authority to grant variances from standards issued under the Act under specified circumstances. 29 U.S.C. §§ 655(b)(6) and (d).

It must be recognized that the authority to impose a permit system is equivalent to the authority to prevent a business from getting started, to close down an existing operation, or, at the very least, to ban production of a particular substance from an operation, simply by denying a permit or refusing to renew a permit. However, both the Act and its legislative history demonstrate that OSHA does not have and was never intended to have such authority. The section of this brief dealing with the "suitable substitute" provisions demonstrates OSHA's lack of authority to completely ban the production of substances. Similarly, the agency cannot order a particular plant to cease its operations. Rather, the statute contemplates that an employer shall conduct his business in accordance with duly promulgated standards in order to provide safe and healthful working condi-

tions for his employees. If, after an investigation (pursuant to Section 8 of the Act, 29 U.S.C. § 657), the Secretary determines that the employer is in violation of a standard, a citation may be issued (pursuant to Section 9, 29 U.S.C. § 658). The employer is provided with a "reasonable time" to correct the violation or fifteen days to contest the citation. 29 U.S.C. §§ 658, 659. The Act does not, however, provide for the cessation of operations during the time in which the employer seeks to correct the violation or contest the citation.

In fact, the legislative history of the Act indicates that when it was proposed that the Secretary be vested with the power to shut down an operation for up to 72 hours if he found that an "immiment danger" existed, such a suggestion was rejected. See 116 Cong. Rec. 38,379 (1970), U.S. Code Cong. & Admin. News, 91st Cong., 2d Sess., at 5236 (1970). Under Section 13 of the Act, the Secretary may seek a cessation of operations in the case of an "imminent danger", but such an order can only be issued by a United States District Court. See 29 U.S.C. § 662. OSHA itself has no direct authority to order a shutdown. Thus,

> "[i]t is obvious that Congress considered the shut-down of an operation such a serious matter that nothing short of the judicial process with its full complement of due process protections was acceptable as a means of accomplishing it." Usery v. Whirlpool Corp., 416 F. Supp. 30, 34 (N.D. Ohio 1976).

A use permit system such as that proposed during these proceedings would vest in OSHA the very authority which Congress intended to be exercised, if at all, by the courts, and not by the agency.

Had Congress intended that OSHA have the power to issue permits ordering a cessation of operations (or a ban on production) it would have granted such authority expressly in the statute. In a number of other statutes, Congress has explicitly granted administrative agencies the authority to issue permits or licenses. These statutes include: the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq.; the Federal Water Pollution Control Act, 33 U.S.C. § 1151 et seq.; and the Communications Act of 1934, 47 U.S.C. § 151 et seq. Absent such explicit authorization in the Act, the power to establish a use permit system cannot be implied in OSHA. The Supreme Court has clearly stated that "[w]hen Congress passes an Act empowering administrative agencies to carry on government activities, the power of those agencies is circumscribed by the authority granted." Stark v. Wickard, 321 U.S. 288, 309 (1944).

Finally, it should be noted that this issue was not raised in the OSHA proposal nor has it been adequately discussed in the proceedings to date. To move forward as suggested, presents, in addition to all the other problems outlined, serious questions of procedural due process.

C. The Proposal To Restrict Use Of Company Doctors In Medical Surveillance Programs Is Unsound For Practical And Legal Reasons And Without Support In The Record

In its prepared statement, the AFL-CIO proposed that physical exams be given by a doctor of the worker's choice. (AFL-CIO Notice No. 71, attachment at 15.) At the hearing,

however, union representatives proposed a surprising new and sweeping limitation on the use of company doctors in medical surveillance. (Tr. 5723-5724, 5778-5781, 5791-5795, 5842-5843, 5993-5995, 6032, 6050.) This proposal by the unions late in the hearings presents serious practical and legal problems.

A major underlying purpose of the medical surveillance program is to enable the company and the government to do prospective epidemiology. There is no way that this objective can be achieved unless full information regarding workers' health and exposure can be appropriately recorded. Indeed, this procedure may be the only effective way to identify susceptible individuals whose exposure would present significant problems. Thus, for example, if smoking increases the risk of lung cancer by orders of magnitude when the worker is exposed to asbestos, knowledge of smoking habits is the only way to protect the worker. See Dr. Lamm S. 4-5 (AIHC P.H.).

Some of the union representatives complained about the incompetence of company doctors. E.g., Tr. 5991-5993. This is not, however, a matter for general regulation. The reasonable way to deal with incompetence, if indeed it exists, is to enlist the State medical authorities and the medical societies and to make the medical program a matter of collective bargaining. Under some circumstances, moreover, incompetence in performing medical surveillance could be a basis for an OSHA enforcement proceeding. To use the isolated instances cited by the unions as a ground for sweeping condemnation of company medical sur-

veillance programs is totally unjustified.

Post-hearing filings by Dr. Alan A. McLean, President of the American Occupational Medical Association (Ex. 209), Dr. Harold R. Imbus, Medical Director of Burlington Industries, Dr. M. A. Johnson, Administrator Environmental Health Projects of the B. F. Goodrich Company, Dr. K. D. McMurrain, Medical Director of the Procter & Gamble Company, and Edward C. Dalglish, General Manager of Hughson Chemicals, provide cogent reasons why the union's belated proposal to restrict company doctors is unsound.

First, the very high worker participation in voluntary medical examination programs demonstrates that workers do not distrust or have concern about the position of company doctors.

Second, the quality of the medical surveillance would suffer because the majority of physicians lack training in occupational medicine. When there is an examination of workers at regular intervals by a trained company doctor, earlier detection of industrially caused disease is enhanced. When the examinations are done by one physician or several physicians in close communication, it is possible to arrive at useful conclusions which would not occur if examinations were not standard and records scattered. Thus, the observation that vinyl chloride is a human carcinogen was made by a doctor who noticed three cases of an unusual tumor. Had separate doctors seen the workers it is unlikely that the connection would have been made.

Third, unless medical records are assembled centrally,

it will be much more difficult to conduct the epidemiological studies which are an essential objective of medical surveillance programs.

These post-hearing filings also demonstrate the significant efforts that are being made to upgrade the standards of occupational medicine and the high level of ethics observed by company doctors. It would do workers a disservice were OSHA to take steps which would set back occupational medicine by promoting the dispersal of medical surveillance among untrained general physicians.

Finally, despite the post-hearing filings discussed above, there is a serious question of notice and due process. This proposal was made long after the hearing began and at a time when many company witnesses had already testified and had no opportunity to respond. Others had no notice of the union demand and thus no reasonable opportunity to comment.

Conclusion

For the foregoing practical and legal reasons, there should be no provision in the final regulation requiring rate retention, establishing a permit system or restricting company medical surveillance.

XVII

KEY WORDS IN THE PROPOSED REGULATION ARE IMPERMISSIBLY VAGUE

The Proposed Regulation is impermissibly vague in its failure to define a number of key terms. For example, OSHA's proposal provides no definition of the term "suitable substitutes" (Section 1990.112) or of the phrases "as low as feasible" (Section 1990.112) and "lowest feasible level" (Section 1990.160(c)). Other impermissibly vague aspects of the regulations include the lack of definition of "suggestive" (Section 1990.102), the "any other evidence" criterion (Section 1990.110), whether a substance has "unique" properties or uses (Section 1990.113(d)), and the rebuttal criteria of Section 1990.111(a), including the terms "grossly inappropriate" (Sections 1990.111(a)(2) and 1990.121(a)(2)), and "totally inadequate" (Sections 1990.111(a)(4) and 1990.121(a)(4)). The vagueness of these terms effectively deprives the public of a meaningful opportunity to comment on the Proposed Regulation. Moreover, the vagueness of these terms would render he Proposed Regulation invalid as a denial of due process.

A. Critical Terms In The Proposed Regulation Are Vague And Inadequately Defined

A number of critical terms in the Proposed Regulation have either been inadequately defined or not defined at all. For example, the regulations provide in Section 1990.112(b) that, upon a finding by the Secretary of Labor that there are "suitable

substitutes" for certain uses or classes of uses that are less hazardous to humans, no occupational exposure shall be permitted for such uses or classes of uses. However, nowhere in the Proposed Regulation or in the Preamble thereto are there any criteria for determining what constitutes a "substitute", nor are there criteria for measuring "suitability" of a substance as a substitute. Mr. Wrenn, candidly admitted that OSHA had not moved beyond the conceptual stage in developing factors for determining what is a "suitable substitute". (Tr. 121-122.)

Similarly, the other key terms in the Proposed Regulation referred to above suffer the same defect of vagueness and inadequate definition. The AIHC, on the other hand, provides a full and precise explanation for each of the critical terms and concepts included in its Alternative. For example, in place of the vaguely defined concept of "lowest feasible level", the AIHC recommends the determination of an "acceptable risk level" for each Category I and II substance, to be determined by a process of risk and benefit assessment fully described in the AIHC Alternative. See AIHC Alternative at 33-34, 78-84. This is the procedure approved by the Benzene decision.

B. Critical Terms In The Proposed Regulation Are So Vague As To Preclude Effective Public Comment On The Proposed Regulation

Section 4 of the Administrative Procedure Act, 5 U.S.C. § 553(b)(3), requires that prior to the promulgation of a final

rule, the agency must publish either the terms or the substance of the proposed rule or a description of the subject and issues involved. The courts have ruled that an agency's notice of proposed rulemaking must describe sufficiently the subject matter of the rulemaking so that informed comment and criticism can be offered by interested parties. See Portland Cement Association v. Ruckelshaus, 486 F.2d 375, 392-394 (D.C. Cir. 1973), cert. denied, 417 U.S. 921 (1974); Mobil Oil Corp. v. FPC, 483 F.2d 1238, 1249-1251 (D.C. Cir. 1973). The courts have not hesitated to invalidate final regulations where the agency did not give adequate notice of the subjects and issues involved and thereby deprived the public of an opportunity to submit effective and meaningful comments. See, e.g., Wagner Electric Corp. v. Volpe, 466 F.2d 1013, 1019-1020 (3d Cir. 1972); Natural Resources Defense Council v. SEC, 389 F. Supp. 689, 698-700 (D. D.C. 1974).

Without more detailed knowledge of the criteria which OSHA proposes to apply in determining what constitutes a "suitable substitute", "lowest feasible exposure" or "other evidence" convincing to the Secretary, or how the presumption that a substance should be classified as a Category I substance can be rebutted, it is impossible for manufacturers or users of potentially affected substances to offer meaningful comment on the impact of OSHA's proposed method of controlling Category I toxic substances. If, for example, the public were advised whether and how OSHA proposes to take into account such factors

as differences in cost and availability of supply in determining adequacy of substitutes, manufacturers and users could submit detailed factual and legal arguments and appropriate scientific and economic data for OSHA's consideration. Use of vague and insufficiently detailed criteria thus defeats the purpose of Section 4 of the Administrative Procedure Act, to provide for informed public participation in the rulemaking proces and to enable the agency promulgating the rule "to educate itself before establishing rules and procedures which have a substantial impact on those regulated." Texaco v. FPC, 412 F.2d 740, 744 (3d Cir. 1969); see also Natural Resources Defense Council v. SEC, supra, at 699.

If the Proposed Regulation was adopted as a final regulation, manufacturers and users could be precluded from challenging the validity of the consequences of classification of a substance as a Category I toxic substance, including a ban on production if a "suitable substitute" exists. While the definition of "suitable substitute" and other vaguely-defined terms may be fleshed out on an ad hoc basis in a series of individual rulemakings, such rulemakings cannot afford industry in general an adequate opportunity for comment and hearing on OSHA's definition of these critical terms. The issues in these individual rulemakings will be limited to the principal question whether the substance was correctly classified as a Category I toxic substance and, secondarily, to various ancillary issues viewed in the context of the particular substance. Thus, there will be

little or no opportunity to comment on the more detailed criteria which OSHA will presumably adopt to give meaning to these vague and insufficient terms. Moreover, it is unlikely that parties not directly concerned with the substance at issue will be able to participate effectively, even though their interests may be vitally affected by the implicit or explicit development of precedent as to the meaning of key terms.

The courts have rejected agency attempts to circumvent the notice requirement of Section 4 of the Administrative Procedure Act where the agency has adopted ambiguous rules and evaded proper rulemaking procedures when the ambiguous rule later was clarified. In Saint Francis Memorial Hospital v. Weinberger, 413 F. Supp. 323 (N.D. Cal. 1976), the Department of Health, Education and Welfare ("HEW") adopted unclear rules on accounting for interest paid on certain construction loans and subsequently sought to "clarify" its rules, both retroactively and prospectively, without conducting a rulemaking. The court followed Pharmaceutical Manufacturers Ass'n v. Finch, 307 F. Supp. 858 (D. Del. 1970), in holding that a rulemaking was required because the clarification was not interpretative. The court observed in St. Francis that a rule is substantive and not interpretative where "there is such genuine ground for difference of opinion on the wisdom of the policy embodied in the rule as to make the hearing process a meaningful and important requirement." Saint Francis Memorial Hospital v. Weinberger, supra, at 329. The court rejected HEW's argument that its

"clarification" was not a substantive rule because, prior to its issuance, HEW's regulations were ambiguous:

> "In essence, defendants' argument seems to be that because the Secretary created an ambiguity in the regulations he need not adhere to the proper rulemaking procedure when he clears up that ambiguity. Without reaching the issue of whether there was any ambiguity in the regulations as they existed at the time section 206 was promulgated, the court rejects this argument as fundamentally inconsistent with the purposes of the rule-making requirements of the Administrative Procedure Act. The Medicare Act conferred on the Secretary the authority and duty to promulgate regulations governing reimbursement of providers of medical services. He could not fulfill that duty by enacting ambiguous regulations through the proper procedure and then 'clarifying' them behind closed doors thereafter." Id. at 330.

Similarly, OSHA may not properly seek to insulate its proposed standards for regulation of Category I toxic substances from a rulemaking which provides for public comment on the merits of the proposed standards by subsequently adopting criteria which define "suitable substitute", and "lowest feasible occupational exposure", and other critical terms without effective opportunity for public participation.

C. If Adopted In The Form Proposed, These Vague Provisions Of The Proposed Regulation Would Deprive Affected Parties Of Due Process Of Law

By reason of the defects referred to above, the Proposed Regulation is so vague and indefinite as to allow the agency virtually unlimited discretion in severely limiting or even banning the manufacture and use of Category I toxic substances. The breadth of this discretion violates the constitutional require-

ment that administrative action be guided by regulations setting out standards which are sufficiently definite to confine agency discretion within predetermined bounds.[1/] Without such standards, affected parties are deprived of due process of law, and meaningful judicial review of agency action is impossible.

In Environmental Defense Fund v. Ruckelshaus, 439 F.2d 584 (D.C. Cir. 1971), the court reviewed EPA's refusal to suspend the registration of DDT as a pesticide. The court noted that it had neither an evidentiary record, nor scientific expertise to aid its review of the agency's actions, but that it had "an obligation to ensure that the administrative standards conform to the legislative purpose, and that they are uniformly applied in individual cases." Id. at 596. The court remanded to EPA for an explanation and formulation of standards to guide agency discretion:

> "Judicial review must operate to ensure that the administrative process itself will confine and control the exercise of discretion. Courts should require administrative officers to articulate the standards and principles that govern their discretionary decisions in as much detail as possible." Id. at 598.

See also Holmes v. New York City Housing Authority, 398 F.2d 262, 265 (2d Cir. 1968).

These decisions were followed in City of Santa Clara v. Kleppe, 418 F. Supp. 1243 (N.D. Cal. 1976), a case in which

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1/ See generally Papachristou v. City of Jacksonville, 405 U.S. 156, 170 (1972); Kenneth Culp Davis, Administrative Law of the Seventies, supplementing Administrative Law Treatise, § 2.00 - § 2.04 (1976); Amalgamated Meat Cutters v. Connally, 337 F. Supp. 737, 758-759 (D. D.C. 1971).

the Bureau of Reclamation's decision withdrawing low-cost federal hydroelectric power from the City of Santa Clara was remanded for failure to provide procedural due process:

> "Procedural due process has a function beyond that of encouraging enlightened, informed administrative decisions. Courts have with increasing frequency recognized that due process means that administrators must do what they can to structure and confine their discretionary powers through safeguards, standards, principles and rules . . . It is all the more imperative that courts require administrators to articulate the standards that guide their discretion where, in cases such as the one at bar, the court lacks the scientific expertise that would permit meaningful review." Id. at 1260-1261.

Similarly, regulation of carcinogens involves complex and highly technical determinations. If the Proposed Regulation is adopted in the form proposed, OSHA's vague and indefinite standards for controlling Category I toxic substances would encourage arbitrary and inconsistent determinations by OSHA. By the same token, the lack of content of many key terms in the Proposed Regulation would effectively prevent meaningful judicial review both of the Proposed Regulation itself and of subsequent regulatory actions taken pursuant thereto.

PART FIVE

XVIII

OSHA'S MODEL STANDARDS ARE UNLAWFUL AND INAPPROPRIATE

A. The Act Prohibits The Kind Of Inflexible Model Standards OSHA Has Proposed

In describing health standards that OSHA must promulgate, among the benchmarks used by the Congress were that standards be "appropriate", "reasonably necessary or appropriate", "feasible", and based on the "best available evidence". See 29 U.S.C. §§ 652 (8), 655(b)(5) and 655(b)(7). To establish rigid, inflexible model standards in this rulemaking without regard to their need or adequacy in the context of particular substances and workplaces flies in the face of OSHA's statutory mandate.

Any model standards should be in the nature of guidelines and should be sufficiently flexible to accommodate disparate properties, hazards and workplaces. There is a great danger in deciding these matters, a priori, in this rulemaking for all subsequent rulemakings. OSHA's professed need for expedition should be no bar to a considered analysis in subsequent rulemakings of language appropriate to the matter then at hand. Certainly OSHA can, as it has in the past, and as it has in the proposed model standards, draw heavily (and expeditiously) from language used in past standards. There is no need to lock the agency in, at this time or in the foreseeable future, to specific language in a model standard.

OSHA urges that there is sufficient flexibility in the model standards because it will consider in subsequent rulemakings the "unique properties or uses" of substances to determine whether the standards are "inappropriate" or "infeasible". (Section 1990.113(d), 43 Fed. Reg. 54173.) This position is not persuasive, however, for several reasons. First, none of these critical terms is defined so there is no way of knowing how OSHA will implement this provision. Second, in looking for exceptions to what should be required rather than looking to what should be required, OSHA is turning the statute on its head and proceeding in a most unscientific manner. In addition, while there may be an opportunity in a subsequent rulemaking to argue that a model standard is "inappropriate" or "infeasible" because of the "unique" properties of the substance, this, in practice, will put a very heavy burden on the proponent of such a proposition. Moreover, while there may be some opportunity to argue the merits of permanent model standards in subsequent rulemakings, this opportunity will be considerably more limited with respect to the model emergency temporary standard which will go into effect promptly after categorization. (Hygiene Panel Tr. 2693-2694.)

Thus, while OSHA argues that there is sufficient flexibility to accommodate future concerns, we do not agree. Even if the model standards are to be used only as guidelines, there is need for significant revisions.

Because AIHC believes a "fill-in-the-blank" approach is inappropriate, it has recommended in its Alternative to the

OSHA proposal that the basic principles applicable to model standards be elucidated in this rulemaking which would then be addressed in the context of particular risk/hazard combinations in subsequent rulemakings. AIHC Alternative at 50-52. See Appendix F to this brief.

NIOSH and others have also expressed concern about the inflexibility of the standards. In particular NIOSH recommended that OSHA seriously consider an approach to the model standards which would set out several alternate options within each subsection of the standard tailored to particular characteristics and properties of the substances to be regulated. See letter from Edward J. Baier to Docket Officer dated June 7, 1978. For example, there might be three alternate sections on personal protection from which OSHA could select the best-suited provision for a particular substance. This, as NIOSH notes, is an approach that OSHA and NIOSH have used in their joint Standards Completion Project. Unfortunately, the proposed model standards seem to proceed on the assumption that the substances to be regulated present similar hazards and risks and therefore require similar monitoring, medical surveillance and housekeeping. In fact, as discussed earlier, this is clearly not the case. Indeed as API very ably points out in its post-hearing comments, OSHA's previous standards for carcinogens have frequently varied from the rigid requirements embodied in the proposed model standard.

B. Because The Model Standards Will Be Applicable In Enforcement Actions, Their Meaning Must Be Clear

Because the model standards proposed in this rule-making may be the subject of compliance action by OSHA's field enforcement staff, the standards must, to the extent possible, be crystal clear both to the regulated and to the OSHA field staff. Any possible ambiguities, as noted by OSHA's industrial hygiene panel, should be clarified now to avoid future controversy and litigation. (Hygiene Panel Tr. 2620-2621, 2698-2699.) The purpose of many of the following comments on the model standards is to do just that.

C. The Model Standards Are In Need Of Revision

1. Scope and Application (Subsection (a))

The model standards should provide for an "action level" below which certain provisions of the standards, such as medical surveillance and monitoring, are not required and should provide a cutoff for mixtures containing small amounts of the regulated substance. In the absence of such provisions, all of the requirements of the standards arguably would apply even where only a single molecule of a regulated substance is present.

The regulations should also exempt laboratory, maritime, construction, and agricultural workplaces from its scope. These workplaces should be handled separately by OSHA. See discussion supra, at 37-41.

2. Definitions (Subsection (b))

In order to avoid ambiguity, certain terms used in the model standard are very much in need of definition. Among these are the terms "feasible", "suitable," "occupational exposure" (Wrenn Tr. 37-38, 67-68), "present" and "work area" (Hygiene Panel Tr. 2813-2815). Further, the definition of the term "emergency" is too broad. It should include only occurrences which result in massive releases. See Air Products S. App. 15-16.

3. Permissible Exposure Limit (Subsection (c))

a. General

The model standard provisions requiring lowest level feasible exposures or mandating substitution should be modified as noted earlier in this brief.

b. Dermal and Eye Exposure

As proposed, the model standards for Category I and II would require that the employer "assure that no employee is exposed to eye contact or skin contact" with the substance. Sections 1910.160(c)(2) and 1910.170(c)(2). Such a seemingly absolute prohibition is logically inconsistent with permitting finite airborne exposures in the workplace. (NIOSH Tr. 3140-3141.) Moreover, even protective clothing and equipment cannot eliminate all skin and eye contact. (Dr. Holaday S. 6-7, Tr. 2838-2839.) The provisions of the model standard are also at variance with the Preamble to the Proposed Regulation which states that the provision is directed only at "repeated" skin contact. 42 Fed. Reg. 54174.

The preferable approach to requiring what appears to be zero exposure is, as noted by NIOSH, to tailor the requirements to the hazard for eye and skin contact. Varying physical properties and hazards require varying regulatory responses. (NIOSH Tr. 2634.) Some substances may require substantial safeguards, others only minimal safeguards. (NIOSH Tr. 3138-3140; Dr. Murray S. 4-5.) The concept of the significance of the hazard presented should, according to NIOSH and Dr. Soule, be factored into this aspect of the regulation. (NIOSH Tr. 3140-3141; Soule Tr. 2813-2832.) A sensible approach suggested by NIOSH is to specify protective clothing which is designed to meet a particular goal rather than require an absolute prohibition (e.g., require protective clothing sufficient "to prevent prolonged or repeated contact"). See NIOSH submission on Standards Completion Project Decision Logic at 82.

Further, Dr. Holaday suggested OSHA's permanent standard should be clarified and explicitly state for substances to be regulated "why protective clothing is required and what exposures are sought to be avoided or reduced." (Dr. Holaday S. 6.)

c. Category II Substances

OSHA has invited comment on that aspect of its proposal which requires for Category II substances that permissible exposure limits be established or reduced where necessary to that level which protects against acute or chronic non-carcinogenic effects.

AIHC is of the view that in such situations (OSHA Category II, AIHC Category III), the substance should be referred to the Interagency Testing Committee ("ITC") for possible testing. Further, we believe OSHA should have the authority to issue a notice of proposed rulemaking to set the PEL at the present OSHA standard or establish a new or reduced PEL based on the acute or chronic non-carcinogenic effects of the substance. 1/ AIHC Alternative at 85.

4. Exposure Monitoring (Subsection (e))

a. Representative Monitoring

The model standards require representative employee monitoring. The Preamble makes clear that any form of monitoring which is "representative" is permissible. 42 Fed. Reg. 54175. This would include both biological monitoring and area sampling. It may include sampling one employee or many for several hours or for a full 8-hour shift. The model standard is, however, susceptible to a different interpretation; particularly Section 1910 .160(e)(3)(ii), which requires in the case of exposures exceeding the PEL limit that the employer repeat monitoring for "each

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1/ We do not subscribe to the AFL-CIO suggestion that a substance remain in Category II for no more than three years. We believe no arbitrary time limit should be set but rather that the ITC should determine the relative urgency and need for testing the substance in question. Given the limited testing resources available in the nation, it would not be possible to test within three years the large number of substances which might fall into Category II, a number which Clement has estimated to be as high as 218.

such employee monthly." Some have taken this to mean that biological sampling of each exposed employee is necessary, a clearly unnecessary allocation of manpower and resources.[1/] See Reynolds Metals Co. S. 2-3. The standard should make clear that that the "representative" which is used only in Section 1910.160(e)(1)(i) is intended to be applicable throughout subsection (e) and that biological monitoring and area sampling are permitted forms of monitoring. Further, it should be made clear that what is "representative" may vary considerably depending on the properties of the substance and the nature of the workplace and the exposure.

b. Initial Monitoring

Where the regulated substance is "present", the model standard requires initial monitoring. While this may be a generally sensible provision, an exception to this requirement should be made where exposure is not reasonably foreseeable as in the case of materials locked into products in such a way that their release is not likely. See, e.g., Johns-Manville S., Exhibit A at 4, on fibers locked into asbestos products. The standard should permit the use of an initial "determination" in the place of initial "monitoring" in such situations, as well as in other appropriate situations. See NIOSH/OSHA Standards

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1/ If, for example, an employer has fifty employees who perform the same job, and industrial hygiene monitoring has confirmed that in the group of employees all have approximately the same type and level of exposure, the employer should be permitted to comply with the standard by monitoring three or four employees on a monthly basis.

Completion Project, 40 Fed. Reg. 20201, 20203 (May 8, 1975).

c. Additional Monitoring

The model standards require additional monitoring whenever there has been a production, process, control or personnel change which may result in new or additional exposure. Section 1910.160(e)(4). This provision is susceptible to an overly broad interpretation requiring additional monitoring when there is any change in production, process or control, however minor. The intent of the provision would appear to be to reach only matters of significance and, accordingly, AIHC suggests that the word "significant" be added before the word "exposure".

OSHA should not lose sight of the fact that our national industrial hygiene and analytical resources are limited and that these resources should not be overburdened with unnecessary chores. (Hygiene Panel Tr. 2827-2828.)

d. Employee Notification

The Act requires that notice be given only to those employees exposed in excess of the PEL, not to those exposed below the PEL. 29 U.S.C. § 657(c)(3). The model standard should be revised accordingly.

Rather than requiring written individual employee notification in all situations, the standards should permit other reasonable means of notification, such as posting.

An unintended but, we believe, serious possible ramification of the burdensome requirement for employee notification proposed by OSHA is that employers may be discouraged from using

automatic monitoring devices because minor deviations may more frequently trigger onerous notification requirements.

5. Methods of Compliance (Subsection (g))

The OSHA proposal requires the use of engineering controls or work practices to reduce exposures to the extent feasible. Further, the proposal requires the use of engineering controls even when they will not reduce exposures below the PEL.

While AIHC subscribes to the view that in many situations engineering controls are the best means of compliance, the model standard should be flexible enough to permit other effective means of control where appropriate. For example, it may be that relatively simple and inexpensive protective clothing may as adequately serve OSHA's goals as expensive engineering equipment where the hazard is skin contact. See Dr. Murray S. 4; API Alternative Panel Tr. 4539-4541.

Further, if engineering controls will, in any event, have to be supplemented by other means of control in order to achieve compliance, it makes little sense from a health or economic perspective to require installation of expensive engineering controls which cannot do the job anyway. (API Alternative Panel Tr. 4540-4543.) In its economic study, Snell concludes that the mandated preference for engineering controls is one of the single most costly aspects of the OSHA proposal. See Snell Report at 496, 503, 519.

The President's Regulatory Analysis Review Group expressed similar reservations to OSHA's mandated preference for

engineering controls in its analysis of OSHA's acrylonitrile proposal. (Ex. 45 at 21-24). The Group urged consideration be given to wider use of non-engineering controls, where appropriate, to achieve the desired end.

Finally, if respirators and protective clothing are relegated to the subsidiary role envisioned by OSHA there will be little, if any, incentive for industry to develop better respirators and protective clothing, a most unfortunate development.

We concur in the recommendation of the Environmental Defense Fund that for OSHA Category II substances OSHA should require only a practical combination of administrative, work practice and readily available and economical engineering controls. (EDF Tr. 7328-7330.) Since Category II is essentially a transitory stage, it makes little sense to require installation of expensive engineering controls for substances which are likely to be reclassified shortly as Category I or III.

6. Respiratory protection (Subsection (h))

As noted in the preceding section, AIHC is of the view that means other than engineering controls or work practices, including respiratory protection, may be appropriate in certain limited circumstances.

While AIHC and other industry participants do not believe that regular 8-hour per day use of respirators is generally a sound approach to control (Tr. 3820, 4516), there may be situations where brief exposures occur regularly or irregularly

for which respirator usage seems appropriate but which nonetheless do not appear to fall strictly within OSHA's limited exceptions for respirator use. For example, a brief exposure of a few minutes duration, a couple of days a week, for an employee entering a production room from a quality control room where there are engineering controls would seem to be a situation in which it makes more sense to use a respirator than to install very expensive engineering controls. (Mr. Douglas Tr. 2776.)

There is a need for maintaining flexibility concerning the use of respirators. NIOSH suggested an approach for respirator use similar to that in the Standards Completion Project, which permitted respirator use for one hour per week (see, e.g., 40 Fed. Reg. 20201, 20211 (May 8, 1975)) over and above the exemptions OSHA has already suggested in this proposal. (NIOSH Tr. 3145-3146.) We believe such an approach would be a useful starting point.

7. Emergency situations (Subsection (i))

Subsection (i)(2)(i) requires the installation of alarms to alert employees to emergencies. This provision should be sufficiently flexible to permit means of alerting employees to hazards other than by sound alarms.

8. Protective clothing and equipment (Subsection (j))

OSHA's proposed model standard is susceptible to the construction that whenever eye or skin contact "may occur" protective clothing is necessary.

This provision of the model standard should be clarified to assure that such equipment is required only where there is a reasonable likelihood of significant exposure which may affect the worker's health. (NIOSH Tr. 3141, 3143.)

Dr. Holaday recommended use of protective clothing to protect against the "demonstrated risk of skin cancer, or even where the risk is subject to debate, where employees are subjected to repeated insults to the liquid form of Category I substances presenting the possibility of skin absorption." (Dr. Holaday S. 5-6.) He did not recommend protective clothing wherever any contact "may occur" with a Category I substance. Indeed, he noted some of the difficulties of extended usage of such clothing. (Dr. Holaday Tr. 2839.)

9. Housekeeping (Subsection (k))

a. Surfaces

OSHA's proposal requires that all surfaces be maintained "free of accumulations". It is, as OSHA's own witnesses recognized, of course, not possible to keep surfaces absolutely free of contaminants where finite airborne exposures are permitted. (Hygiene Panel Tr. 2626.)

Among the options the Hygiene Panel suggested should be considered were that a quantitative parameter or a "visibility" criterion be used as benchmarks where appropriate. (Hygiene Panel Tr. 2627-2629, 2633, 2695, 2809-2810.) Even OSHA's recent cotton dust and inorganic arsenic standards require only that

surfaces be maintained as free "as practicable" of accumulations. See 29 C.F.R. § 1910.1018(k)(1) and 29 C.F.R. § 1910.1046a(c)(1)(i); 43 Fed. Reg. 19583, 19627 (May 5, 1978); 43 Fed. Reg. 27349, 27434 (June 23, 1978). By requiring adequate decontamination procedures, AIHC believes OSHA should be able to obtain the same workplace objective without the attendant difficulties associated with the words "free of accumulations".

b. Vacuum

The standards appear to require separate portable vacuums for each regulated substance. This is an unnecessary burden for employers who may have many regulated substances in their workplace. The burden would be particularly heavy on laboratories and batch operations. Absent a showing of hazard associated with the use of the same vacuum for multiple substances, we see no need for such a restrictive requirement. (Nat. Constructors Ass'n., Ex. 125 at 10-11.)

c. Waste Disposal

The model standards require waste from regulated substances to be disposed of in sealed bags or closed containers. While this again is generally sensible, where such wastes, because of their characteristics, e.g., having been incorporated in another substance, are not likely to present a hazard, disposal in this manner seems unnecessary. (Johns-Manville S., Ex. A at 89.) Further, disposal of large equipment in sealed bags is an obvious impossibility. Adequate decontamination procedures should be allowed as a substitute. See Air Products S. App. 13.

10. Hygiene facilities and practices (Subsection (m))

The standards require employers to provide lunchroom facilities which have a temperature controlled, positive pressure, filtered air supply whenever food and beverages are consumed in the "workplace". The term "workplace" is not defined. If it is defined to mean anywhere in the entire place of employment, a severe hardship may occur. See Polyurethane Manuf. Ass'n S. 12. The requirement for showers should be tailored to the needs of the workplace in such a way that the showers requirement could be less onerous if one is, for example, dealing with volatile substances. See, e.g., Benzene Standard, 43 Fed. Reg. 5954 (February 10, 1978).

The model standards also require employers to "assure" that employees wash their hands and face prior to eating. Apart from providing training, education, facilities and opportunity for use of facilities, it is not reasonably possible for employers to "assure" that employees wash their hands or face. If the word "assure" means the foregoing, then it should be so defined. If it means more, we think serious questions of personal freedom and physical compulsion are raised. The use of the word "assure" in this section (and in other sections) of the model standards should be deleted and the word "require" substituted therefore with an appropriate definition to exclude compulsion. See Johns-Manville S., Ex. A at 9.

11. Medical surveillance (Subsection (n))

The need for an action level is particularly evident in

this subsection which would require medical surveillance where there is any exposure whatsoever even for guards or delivery personnel who might enter a facility only a few times a year. (Hygiene Panel Tr. 2833-2835; Johns-Manville S., Ex. A at 9-10.) Such an approach to regulation would be an extremely wasteful allocation of the limited medical resources available to our nation.

The model standards do not appear to require medical exams at specified periodic intervals. AIHC endorses the need to retain this flexibility and the need for tailoring the frequency and nature of periodic exams to the substance and workplace in question. To set an arbitrary limit makes little sense since many medical procedures themselves involve inherent risks. (Dr. Lynch S. 3.)

The standards also require that a medical exam be made available to an employee who has not had an exam within six months of the termination of his employment. Such examinations do not seem to be a useful expenditure of limited medical resources particularly where periodic exams are required. The matter should be left in the sound discretion of the employer who will take into account his medical surveillance program and the medical surveillance needs for the particular substance in question. This is not a matter which should be dealt with "across the board" in a regulation. (Johns-Manville S., Ex. A at 11.)

In addition, the standards require the employee's physician to state whether the employee has "any detected medical

condition which would place [him] at an increased risk of material impairment" from exposure to the substance. Such a requirement is an unreasonable one to place on a physician, particularly in times such as these when malpractice plays such a significant role in a physician's professional life. The standards provide no guidance whatsoever to the physician in making the Solomon-like determination as to what is an "increased risk of material impairment."

Finally, the standards prohibit physicians from disclosing to employers findings or diagnoses unrelated to occupational exposure discovered in the course of medical examinations. This provision should make clear that a physician may advise the appropriate supervisor of the employee (e.g., plant manager) of restrictions which should be placed on the employee's work activities, if any, for medical reasons without disclosing the medical reasons therefore. To do otherwise would deny the employer information essential to maintaining a safe workplace. See Reynolds Metal S. at 5.

12. Signs and labels (Subsection (p))

For reasons set forth infra, at 291, AIHC believes OSHA does not have authority to promulgate the proposed standards dealing with labeling.

The record includes no evidence to support the use of the legend which OSHA proposes for its signs and labels. When OSHA's industrial hygiene panel and the NIOSH panel were queried

on this issue, neither were able to offer any evidence in support of the OSHA position. (Hygiene Panel Tr. 2699-2715; NIOSH Tr. 3052-3053.) Indeed, they were totally unfamiliar with the extensive literature on the subject cited by counsel for the Polyurethane Manufacturers Association. (Tr. 2699-2715.) Although counsel for PMA requested that OSHA present the evidence upon which it relied on this issue, OSHA failed to do so. (Hygiene Panel Tr. 2731-2732.)

As Dr. Chapanis noted, a sign with the legend "cancer" merely creates fear in employees and does not provide those employees with any understanding of the nature of the hazard to which they are exposed. (Dr. Chapanis Tr. 7076.) Dr. Chapanis was particularly critical of OSHA's failure to provide a positive instruction about what to do in the presence of the hazard. (Dr. Chapanis Tr. 7073-7077, 7084, 7090-7091.)

13. Recordkeeping (Subsection (g))

The model standards evidence no thought with respect to what OSHA intends to do with the voluminous records it has asked to be kept and no forethought as to what purpose these records will serve. Further, there is no evidence of any effort to attempt to minimize paperwork burdens by coordinating these requirements with other federal agency requirements. Dr. Berg noted critically that the time to plan the analyses of data is before collection begins, not after masses of material are accumulated. (S. 25.) He recommended that outside expertise be used in the design

of a minimally effective system to determine which administratively desirable goals are feasible, as well as to help determine how best to achieve feasible goals. Id. at 26.[1/] We wholeheartedly endorse this concept.

The ever-increasing paperwork burden has been the subject of much discussion by the Federal Commission on Paperwork, the President in Executive Order No. 12044 (published at 43 Fed. Reg. 12660, 12668 (March 24, 1978)) and others. Johns-Manville suggested that pilot recordkeeping programs be inaugurated to insure efficient, meaningful data compilation. See Johns-Manville S., Ex. A at 13-15. Some such system would appear to be necessary to insure that the right data are being collected in the right way. NIOSH's response to a question about whether it has made any effort to study the voluminous records collected to date for carcinogens is most illuminating. In response to a question as to what kind of analysis and study has taken place to date with respect to the records accumulated by NIOSH on the 14 carcinogens, the Director stated that no studies have taken place but that they have been "looked at a couple of times." (NIOSH Tr. 3144-3145.)

Much to our consternation, at the very time this rulemaking is going forward OSHA has decided to publish yet another rule and proposed rule dealing with the question of medical and

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1/ Testimony was presented by Diamond Shamrock on an innovative system they were well on the way to developing which they had offered to share with OSHA. (Tr. 7742-7749.)

exposure recordkeeping and access thereto.[1/] It is not clear whether this newly proposed regulation "preempts" the issues on this matter so that they will be resolved in another forum. In view of the strange double method of addressing the issue of these records and access thereto, we will make only a brief comment despite the importance of the matter. Medical records contain much private information and access to them should not be given to anyone without the individual's consent. There is no doubt that these records are covered by the right to privacy. DuPont v. Finklea, CCH, OSHD, 1978 ¶ 22398 (S.D. W. Va. 1970). To protect that privacy, access should be given only to another licensed physician and confined to information supplied by the employee himself, as distinguished from third parties. If OSHA or NIOSH are to have access, it must be subject to the safeguards the court imposed in the DuPont case.

Exposure records present a different but equally important problem. These records frequently contain confidential trade material. To allow unlimited access to exposure records without restriction on disclosure, use or sale of confidential trade material raises very serious problems. While it may be reasonable to provide exposure information to an employee, that disclosure must be made under circumstances which prevent disclosure of confidential information. Similarly, there must be carefully designated regulations to prevent dis-

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1/ 43 Fed. Reg. 31329, 31371 (July 21, 1978).

closure of any such secrets which may get into the hands of OSHA or NIOSH.

In view of the unusual procedure adopted by OSHA whereby two overlapping rules are being proposed on the same subject, we believe OSHA should consolidate the records so that comments filed in Docket NO. H-112 are considered also in this proceeding. To eliminate the confusion as to which rule is being considered by OSHA and which docket should be selected for filing comments, we urge that the only reasonable course is for OSHA to consider the comments in Docket No. H-112 as applicable in this proceeding.

A decision on the scope and nature of OSHA's authority to have access to, or to grant NIOSH access to, medical records is expected soon in General Motors v. Finklea, Civil No. C-3-77-339 (S.D. Ohio). That decision should clarify the statutory issue. In the meantime, OSHA should eliminate the overlapping proceedings.

D. Several Provisions Of The Model ETS Are Not Authorized By The Statute

Several provisions of the model ETS standard are not authorized by the Act. Among these are those dealing with labels, training and extensive monitoring and medical surveillance. As API correctly points out in its post-hearing comments, the Congress did not intend for such provisions to become a part of the short-lived, limited purpose ETS envisioned by it.

XIX

THE LABELING PROVISIONS OF THE MODEL STANDARDS ARE NOT AUTHORIZED BY LAW

OSHA's proposed model standards for Category I and Category II substances require that employers affix precautionary labels to containers of such substances and of products containing such substances, and that the labels remain affixed when the substances or products containing such substances are "sold, distributed, or otherwise leave the employer's workplace." Sections 1990.150(p)(3), 1990.160(p)(3)and 1990.170(p)(3). Because the scope of OSHA's authority is limited to the issuance of standards designed to protect an employer's own employees while in the employer's own workplace, these proposed labeling provisions are beyond OSHA's jurisdiction.

The language of the Act demonstrates that OSHA's authority is limited to the regulation of workplaces, not products. Section 4(a) provides that the Act "shall apply with respect to employment performed in a workplace . . . ." 29 U.S.C. § 653(a) (emphasis added). Section 2 declares the Congressional purpose to assure "safe and healthful working conditions" by encouraging employers and employees to reduce "occupational safety and health hazards at their places of employment." 29 U.S.C. § 651(1) (emphasis added). Similarly, Section 5(a), the "general duty clause", requires that each employer

> ". . . shall furnish to each of his employees employment and a place of employment which are free from recog-

> nized hazards that are causing or are likely to cause death or serious physical harm to his employees." 29 U.S.C. § 654 (a)(1) (emphasis added).

Thus, OSHA's regulatory mandate is limited to the workplace itself, and does not extend to products once they have left the workplace.

More specifically, it is clear that Section 6(b)(7) of the Act, which sets forth OSHA's only authority to promulgate standards requiring labeling, was intended to provide for signs, notices, and other forms of warning (collectively referred to as "labels") in the workplace for the benefit of employees working with substances in that workplace. Section 6(b)(7) was not meant to confer any labeling authority upon OSHA outside of those workplaces. Where Congress intended to grant to administrative agencies such broad and general labeling authority, it has, in other statutes, explicitly granted that authority. Absent such explicit authorization in Section 6(b)(7), the power to require labeling outside the workplace cannot be implied.

Section 6(b)(7) provides that:

> "[a]ny standard promulgated under this subsection shall prescribe the use of labels or other appropriate forms of warning as are necessary to insure that employees are apprised of all hazards to which they are exposed . . . " 29 U.S.C. § 655(b)(7).

The statute does not explicitly grant to OSHA the authority to require the affixing of labels to substances once they have left the employer's workplace (i.e., the place of manufacture or use)

or to require labeling as a means of protecting anyone other than one's own employees. Rather, the reference to the protection of employees clearly indicates that OSHA's standards can require labels only in the employer's workplace for the benefit of his employees working with a substance in that workplace.

The limited scope of OSHA's labeling authority is also demonstrated by the legislative history of Section 6(b)(7). The Conference Report on the Act, after summarizing the provision of the Senate bill that had required labels for employee protection, states:

> "The House amendment similarly required the posting of labels and warnings to apprise employees of the existence of hazards and of the suggested methods of avoiding or alleviating them." Legislative History at 1188 (emphasis added).

The quoted language indicates Congress' intention that OSHA require those types of labels and warnings that could be "posted". By their very nature, such labels are limited to an employer's workplace. Similarly, other references in the legislative history indicate Congress' concern that employers apprise their employees of hazards. See, e.g., Legislative History at 431, 1004. There are no references to imposition of labeling requirements for the benefit of "other persons".

Section 6(b)(7) also authorizes OSHA to promulgate standards prescribing suitable protective equipment and control or technological procedures, appropriate requirements for the monitoring or measuring of employee exposure, and the type

and frequency of medical examinations or other tests to be made available by the employer to employees. These protective measures are clearly intended to be provided by an employer for his own employees as a safeguard against hazards in the plant of manufacture or use. Absent clear Congressional indication to the contrary, the provision authorizing OSHA to require labeling is similarly limited in scope.

That OSHA has no authority to require an employer to affix labels to substances once outside the workplace as a means of protecting employees other than his own is also indicated by the variance provisions of the Act. Section 6(b)(6)(A) provides that an employer may obtain a temporary variance from a standard only if he shows that "he is taking all available steps to safeguard his employees against the hazards covered by the standard." 29 U.S.C.A. § 655(b)(6)(A). In addition, the employer must notify "his employees" of the application, so they can petition the Secretary for a hearing. 29 U.S.C.A. § 655(b)(6)(B). Section 6(d) provides for the issuance of a permanent variance to an employer demonstrating that

> "the conditions, practices, means, methods, operations, or processes used or proposed to be used by an employer will provide employment and places of employment to <u>his employees</u> which are as safe and healthful as those which would prevail if he complied with the standard." 29 U.S.C. § 655(d) (emphasis added).

Congress would not have allowed an employer to obtain a variance by showing that his employees would be protected if it had in-

tended OSHA's standards to require employers to protect other people's employees as well.

In a number of other statutes, Congress has explicitly granted administrative agencies general labeling authority, encompassing the power to require labeling of products distributed in interstate commerce. These statutes include: Consumer Product Safety Act, 15 U.S.C. § 2051 et seq.; Toxic Substances Control Act, 15 U.S.C. § 2601 et seq.; Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq.; Federal Hazardous Substances Act, 15 U.S.C. § 1261 et seq.; Poison Prevention Packaging Act, 15 U.S.C. § 1471 et seq.; and Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. § 135 et seq. Absent such explicit authorization in the Occupational Safety and Health Act, such broad and general labeling authority cannot be implied in OSHA. As the Supreme Court stated in Stark v. Wickard, 321 U.S. 288, 309 (1944): "When Congress passes an Act empowering administrative agencies to carry on governmental activities, the power of those agencies is circumscribed by the authority granted." See also Zuber v. Allen, 396 U.S. 168 (1969); Exxon Corp. v. Train, 554 F. 2d 1310 (5th Cir. 1977); Textile and Apparel Group v. F.T.C., 410 F. 2d 1052 (D.C. Cir. 1969); State Highway Commission of Missouri v. Volpe, 479 F. 2d 1099 (8th Cir. 1973); National Association of Regulatory Utility Commissioners v. F.C.C., 533 F. 2d 601 (D.C. Cir. 1976).

The Benzene decision, relying principally on cases dealing with multi-employer construction worksite cases, con-

cluded that if OSHA can validly require the affixing of labels to benzene and benzene products, OSHA can forbid the removal of those labels from the containers which leave the workplace. This is a far cry from a finding of a general labeling authority in OSHA. Moreover, the court made clear that OSHA must make a valid finding of quantifiable benefits to the workers in the employer's workplace from a labeling requirement and relate those benefits to the costs or detriments in order to show the requirement is reasonably necessary. A second similar cost benefit analysis is necessary to determine whether OSHA can reasonably require the employer not to remove the labels when the containers leave the workplace.

Thus, under the standards of the Benzene decision, it would be unreasonable to require labels on mixtures containing small amounts of the regulated substance in the absence of the requisite finding of measureable benefits with a reasonable relation to cost. Even when it is reasonable to require labeling of containers in the workplace, it may be unreasonable to prohibit removal when the containers leave the workplace if, for example, the labels "have such deleterious effects on sales that it affects the reasonable necessity for this feature of the regulation." Benzene decision, ___ F.2d at 99.

The Benzene decision provides no basis for arguing that OSHA has general labeling authority. That case deals only with removal of labels which OSHA has validly found are reasonably necessary for the particular workplace.

Conclusion

The OSHA Proposed Regulation is substantively and procedurally defective. OSHA is just now making the Regulatory Analysis of the Proposed Regulation. AIHC believes that OSHA should also conclude that an Environmental Impact Statement should be prepared. The results of the IRLG Work Group in areas relevant to the Proposed Regulation will become available in the near future. AIHC believes that in view of these developments, OSHA should withdraw the Proposed Regulation and repropose a regulation modified to correct the deficiencies in the Proposed Regulation. The AIHC Alternative provides a reasonable guide for a reproposed regulation. At a minimum, OSHA must provide an adequate opportunity to comment on the new developments before publishing a final regulation.

Respectfully submitted,

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APPENDICES

Appendix D

AIHC

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September 11, 1978

GUIDELINES FOR EVALUATION AND USE OF OCCUPATIONAL EPIDEMIOLOGIC CANCER STUDIES

The evaluation of human data is becoming increasingly important in determining when and how to regulate exposure to suspected carcinogenic materials. As described in the AIHC Alternative proposal, epidemiologic studies are invaluable in determining the fact of human carcinogenicity and in assessing the actual risk under occupational exposure conditions.

The following guidelines are intended to describe major factors in assessing the strengths and limitations of epidemiologic studies, the use of which in turn will assure maximum and appropriate utilization of valid human data. The guidelines are not intended as a check list for accepting or rejecting a study. All data on human exposure to a substance should be considered in attempting to reach a judgment on the human health risks from occupational exposure. Although studies that satisfy all of these guidelines should receive greatest attention, studies that do not should receive attention commensurate with their strengths and weaknesses. There is no substitute for the evaluation of individual studies by highly qualified experts, such as the Data Evaluation and Classification Panel recommended in the AIHC Alternative.

These guidelines have two objectives:

1. To describe the major study design features and analytic methods necessary to allow for the evaluation

of the quality and results of an epidemiological investigation and/or report.

2. To describe appropriate use of epidemiologic studies in evaluating human risk from occupational exposure.

Part A includes the description of the major study features and analytic methods of a study. It also identifies the major factors in evaluating the results and interpretations of a specific study. It will be useful for OSHA in stimulating a dialogue with the investigators and for assuring the submission of a complete information package to the expert panel.

Part B indicates areas of concern for professional evaluations in determining the utility of a specific study in reaching a judgment on the likelihood of a significant health risk from a specific exposure. It stresses the need for examining the consistency of epidemiologic and biologic data and seeking explanations or investigations of apparent inconsistencies. The demonstration of a dose-effect relationship and the calculation of a human occupational exposure risk assessment assist judgmental determinations. Thus, OSHA can be provided with information and judgment essential to regulatory decision-making, particularly the need for and degree of control of specific substances.

PART A - Description, Analysis, and Evaluation of a Specific Study

I. Description of Study Features

An epidemiologic study needs to be adequately described so that the reviewer can understand which population was studied and with whom they were compared, what exposure was under investigation,

what health effect or outcome was evaluated, and how the study was carried out to assure validity and precision.

A. Population Characteristics

1. Study Population - The description of the study population should clearly indicate the criteria necessary for inclusion in the study cohort and the reasons for choosing those criteria. Methods used to assure that all individuals meeting those criteria are included and that only those individuals are included should be described, including demographic and other appropriate characteristics. Any deviations from these criteria should be clearly described, justified and interpreted in considering the actual conduct of the study.

2. Comparison Population - Ideally, the comparison population should differ from the study population only in that it lacks the exposure under consideration. Rarely is this the case. Internal comparison groups are generally preferable to external comparison groups. Consistent findings based on several comparison groups, including external comparison groups, usually strengthen the acceptance of the results.

3. Sampling Procedure and Sample Size - When all individuals satisfying the criteria of the study population are not included in the study, the method used to select the members who are studied should be described. The method used should assure that the group actually studied is representative of the study population. The size of the total study population and of the group actually studied should be indicated.

4. Observation Period - Dates of beginning and terminating of the observation period should be stated and should be similar for the study and comparison populations. The number of individuals observed and the person-years of observation (when appropriate) consistent with the latency period under consideration should be stated. The experience at different time periods during the period of observation (5 or 10 year periods, that are appropriate for the particular study) should be analyzed.

B. Exposure Characteristics

1. Occupational Exposure Under Study

The evidence or reason for identifying the study population as an exposed group should be clearly specified. Sufficient information on exposure characteristics should be presented to assure the reasonableness of this study population and comparison population to test the hypothesis. Environmental measurements or personal monitoring data greatly assist in defining the exposures. Methods and instruments used for measuring exposures should be described in detail. Division of the study population into groups of different levels of exposure is preferable so that analysis can examine for dose-effect relationships.

2. Confounding Variables

Each individual is exposed to more than the item being studied. Within the workplace, other exposures are present contemporarily and these other exposures may be different for the

various occupational groups. Different jobs within the same employment include different sets of exposures. Prior employment and subsequent employment often introduce other exposures. These other occupational exposures cannot always be documented but should be considered in the investigation. Every effort should be made to obtain information about them which may be verified.

Individual lifestyle habits affect one's exposures. Alcohol consumption and smoking histories, for instance, may greatly affect one's risk of developing certain types of cancers and other diseases. Analysis should consider the effects of each variable that may have an independent effect on the health outcome under consideration.

Confounding variables such as sex, age and race may be dealt with in the comparative analysis of the comparison group. Confounding variables, whether or not handled in the design or analysis, should be discussed in the interpretation.

C. Health Effect

The definition of a "case", or of an individual with the health effect under study, should be clearly indicated. It will be dependent upon the data source used. However, the same definition and data source should be used for both the study population and the comparison population. The classification of health effects should be the same for study and comparison populations. The methods used in making a diagnosis in each case in the study

and comparison groups should be described. Further investigations may determine the validity of diagnosis for each case.

D. Procedures

A full description of the procedures used in the conduct of the study will assist the judgment as to the study's validity and allow for its replication if necessary. Data sources should be identified, particularly those that are used to determine who is in the study population, the level of exposure, and the health outcome. Methods used to standardize the data collection and preparation should be determined before data collection and should be described, along with methods used to verify the data. Follow-up procedures and degree of completeness of follow-up for each subgroup should be indicated. The investigators responsible for the professional work should be identified.

E. Case Presentations

A case history should be given for each "case" in the study indicating demographic variables, exposure variables, confounding variables, and clinical variables. Sufficient details should be given to indicate both that each case satisfies the study criteria and that alternative exposures and etiologies do not explain the case's occurrence.

II. Analytic Method

The term analytic method is herein used to include all procedures and techniques by which data are handled, examined and

Appendix A - Statutes Involved

Section 3(8) (29 U.S.C. §652(8))

The term "occupational safety and health standard" means a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment.

Section 6 (29 U.S.C. §655)

Standards

Promulgation by Secretary of national consensus standards and established Federal standards; time for promulgation; conflicting standards

(a) Without regard to chapter 5 of Title 5 or to the other subsections of this section, the Secretary shall, as soon as practicable during the period beginning with the effective date of this chapter and ending two years after such date, by rule promulgate as an occupational safety or health standard any national consensus standard, and any established Federal standard, unless he determines that the promulgation of such a standard would not result in improved safety or health for specifically designated employees. In the event of conflict among any such standards, the Secretary shall promulgate the standard which assures the greatest protection of the safety or health of the affected employees.

Procedure for promulgation, modification, or revocation of standards

(b) The Secretary may by rule promulgate, modify, or revoke any occupational safety or health standard in the following manner:

(1) Whenever the Secretary, upon the basis of information submitted to him in writing by an interested person, a representative of any organization of employers or employees, a nationally recognized standards-producing organization, the Secretary of Health, Education, and Welfare, the National Institute for Occupational Safety and Health, or a State or political subdivision, or on the basis of information developed by the Secretary or otherwise available to him, determines that a rule should be promulgated in order to serve the objectives of this chapter, the

Secretary may request the recommendations of an advisory committee appointed under section 656 of this title. The Secretary shall provide such an advisory committee with any proposals of his own or of the Secretary of Health, Education, and Welfare, together with all pertinent factual information developed by the Secretary or the Secretary of Health, Education, and Welfare, or otherwise available, including the results of research, demonstrations, and experiments. An advisory committee shall submit to the Secretary its recommendations regarding the rule to be promulgated within ninety days from the date of its appointment or within such longer or shorter period as may be prescribed by the Secretary, but in no event for a period which is longer than two hundred and seventy days.

(2) The Secretary shall publish a proposed rule promulgating, modifying, or revoking an occupational safety or health standard in the Federal Register and shall afford interested persons a period of thirty days after publication to submit written data or comments. Where an advisory committee is appointed and the Secretary determines that a rule should be issued, he shall publish the proposed rule within sixty days after the submission of the advisory committee's recommendations or the expiration of the period prescribed by the Secretary for such submission.

(3) On or before the last day of the period provided for the submission of written data or comments under paragraph (2), any interested person may file with the Secretary written objections to the proposed rule, stating the grounds therefor and requesting a public hearing on such objections. Within thirty days after the last day for filing such objections, the Secretary shall publish in the Federal Register a notice specifying the occupational safety or health standard to which objections have been filed and a hearing requested, and specifying a time and place for such hearing.

(4) Within sixty days after the expiration of the period provided for the submission of written data or comments under paragraph (2), or within sixty days after the completion of any hearing held under paragraph (3), the Secretary shall issue a rule promulgating, modifying, or revoking an occupational safety or health standard or make a determination that a rule should not be issued. Such a rule may contain a provision delaying its effective date for such period (not in excess of ninety days) as the Secretary determines may be necessary to insure that affected employers and employees will be informed of the existence of the standard and of its terms and that employers affected are given an opportunity to familiarize themselves and their employees with the existence of the requirements of the standard.

(5) The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.

(6)(A) Any employer may apply to the Secretary for a temporary order granting a variance from a standard or any provision thereof promulgated under this section. Such temporary order shall be granted only if the employer files an application which meets the requirements of clause (B) and establishes that (i) he is unable to comply with a standard by its effective date because of unavailability of professional or technical personnel or of materials and equipment needed to come into compliance with the standard or because necessary construction or alteration of facilities cannot be completed by the effective date, (ii) he is taking all available steps to safeguard his employees against the hazards covered by the standard, and (iii) he has an effective program for coming into compliance with the standard as quickly as practicable. Any temporary order issued under this paragraph shall prescribe the practices, means, methods, operations, and processes which the employer must adopt and use while the order is in effect and state in detail his program for coming into compliance with the standard. Such a temporary order may be granted only after notice to employees and an opportunity for a hearing: *Provided*, That the Secretary may issue one interim order to be effective until a decision is made on the basis of the hearing. No temporary order may be in effect for longer than the period needed by the employer to achieve compliance with the standard or one year, whichever is shorter, except that such an order may be renewed not more than twice (I) so long as the requirements of this paragraph are met and (II) if an application for renewal is filed at least 90 days prior to the expiration date of the order. No interim renewal of an order may remain in effect for longer than 180 days.

(B) An application for a temporary order under this paragraph (6) shall contain:

(i) a specification of the standard or portion thereof from which the employer seeks a variance,

(ii) a representation by the employer, supported by representations from qualified persons having firsthand knowledge of the facts represented, that he is unable to comply with the standard or portion thereof and a detailed statement of the reasons therefor,

(iii) a statement of the steps he has taken and will take (with specific dates) to protect employees against the hazard covered by the standard,

(iv) a statement of when he expects to be able to comply with the standard and what steps he has taken and what steps he will take (with dates specified) to come into compliance with the standard, and

(v) a certification that he has informed his employees of the application by giving a copy thereof to their authorized representative, posting a statement giving a summary of the application and specifying where a copy may be examined at the place or places where notices to employees are normally posted, and by other appropriate means.

A description of how employees have been informed shall be contained in the certification. The information to employees shall also inform them of their right to petition the Secretary for a hearing.

(C) The Secretary is authorized to grant a variance from any standard or portion thereof whenever he determines, or the Secretary of Health, Education, and Welfare certifies, that such variance is necessary to permit an employer to participate in an experiment approved by him or the Secretary of Health, Education, and Welfare designed to demonstrate or validate new and improved techniques to safeguard the health or safety of workers.

(7) Any standard promulgated under this subsection shall prescribe the use of labels or other appropriate forms of warning as are necessary to insure that employees are apprised of all hazards to which they are exposed, relevant symptoms and appropriate emergency treatment, and proper conditions and precautions of safe use or exposure. Where appropriate, such standard shall also prescribe suitable protective equipment and control or technological procedures to be used in connection with such hazards and shall provide for monitoring or measuring employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees. In addition, where appropriate, any such standard shall pre-

scribe the type and frequency of medical examinations or other tests which shall be made available, by the employer or at his cost, to employees exposed to such hazards in order to most effectively determine whether the health of such employees is adversely affected by such exposure. In the event such medical examinations are in the nature of research, as determined by the Secretary of Health, Education, and Welfare, such examinations may be furnished at the expense of the Secretary of Health, Education, and Welfare. The results of such examinations or tests shall be furnished only to the Secretary or the Secretary of Health, Education, and Welfare, and, at the request of the employee, to his physician. The Secretary, in consultation with the Secretary of Health, Education, and Welfare, may by rule promulgated pursuant to section 553 of Title 5, make appropriate modifications in the foregoing requirements relating to the use of labels or other forms of warning, monitoring or measuring, and medical examinations, as may be warranted by experience, information, or medical or technological developments acquired subsequent to the promulgation of the relevant standard.

(8) Whenever a rule promulgated by the Secretary differs substantially from an existing national consensus standard, the Secretary shall, at the same time, publish in the Federal Register a statement of the reasons why the rule as adopted will better effectuate the purposes of this chapter than the national consensus standard.

Emergency temporary standards

(c)(1) The Secretary shall provide, without regard to the requirements of chapter 5 of Title 5, for an emergency temporary standard to take immediate effect upon publication in the Federal Register if he determines (A) that employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards, and (B) that such emergency standard is necessary to protect employees from such danger.

(2) Such standard shall be effective until superseded by a standard promulgated in accordance with the procedures prescribed in paragraph (3) of this subsection.

(3) Upon publication of such standard in the Federal Register the Secretary shall commence a proceeding in accordance with subsection (b) of this section, and the standard as published shall also serve as a proposed rule for the proceeding. The Secretary shall promulgate a standard under this paragraph no later than six months after publication of the emergency standard as provided in paragraph (2) of this subsection.

Variances from standards; procedure

(d) Any affected employer may apply to the Secretary for a rule or order for a variance from a standard promulgated under this

section. Affected employees shall be given notice of each such application and an opportunity to participate in a hearing. The Secretary shall issue such rule or order if he determines on the record, after opportunity for an inspection where appropriate and a hearing, that the proponent of the variance has demonstrated by a preponderance of the evidence that the conditions, practices, means, methods, operations, or processes used or proposed to be used by an employer will provide employment and places of employment to his employees which are as safe and healthful as those which would prevail if he complied with the standard. The rule or order so issued shall prescribe the conditions the employer must maintain, and the practices, means, methods, operations, and processes which he must adopt and utilize to the extent they differ from the standard in question. Such a rule or order may be modified or revoked upon application by an employer, employees, or by the Secretary on his own motion, in the manner prescribed for its issuance under this subsection at any time after six months from its issuance.

Statement of reasons for Secretary's determinations; publication in Federal Register

(e) Whenever the Secretary promulgates any standard, makes any rule, order, or decision, grants any exemption or extension of time, or compromises, mitigates, or settles any penalty assessed under this chapter, he shall include a statement of the reasons for such action, which shall be published in the Federal Register.

Judicial review

(f) Any person who may be adversely affected by a standard issued under this section may at any time prior to the sixtieth day after such standard is promulgated file a petition challenging the validity of such standard with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such standard. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary. The filing of such petition shall not, unless otherwise ordered by the court, operate as a stay of the standard. The determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole.

Priority for establishment of standards

(g) In determining the priority for establishing standards under this section, the Secretary shall give due regard to the urgency of the need for mandatory safety and health standards for particular industries, trades, crafts, occupations, businesses, workplaces or work environments. The Secretary shall also give due regard to the recommendations of the Secretary of Health, Education, and Welfare regarding the need for mandatory standards in determining the priority for establishing such standards.

Pub.L. 91-596, § 6, Dec. 29, 1970, 84 Stat. 1593.

Section 7 (29 U.S.C. §656)

Administration

National Advisory Committee on Occupational Safety and Health; establishment; membership; appointment; Chairman; functions; meetings; compensation; secretarial and clerical personnel

(a)(1) There is hereby established a National Advisory Committee on Occupational Safety and Health consisting of twelve members appointed by the Secretary, four of whom are to be designated by the Secretary of Health, Education, and Welfare, without regard to the provisions of Title 5 governing appointments in the competitive service, and composed of representatives of management, labor, occupational safety and occupational health professions, and of the public. The Secretary shall designate one of the public members as Chairman. The members shall be selected upon the basis of their experience and competence in the field of occupational safety and health.

(2) The Committee shall advise, consult with, and make recommendations to the Secretary and the Secretary of Health, Education, and Welfare on matters relating to the administration of this chapter. The Committee shall hold no fewer than two meetings during each calendar year. All meetings of the Committee shall be open to the public and a transcript shall be kept and made available for public inspection.

(3) The members of the Committee shall be compensated in accordance with the provisions of section 3109 of Title 5.

(4) The Secretary shall furnish to the Committee an executive secretary and such secretarial, clerical, and other services as are deemed necessary to the conduct of its business.

Advisory committees; appointment; duties; membership; compensation; reimbursement to member's employer; meetings; availability of records; conflict of interest

(b) An advisory committee may be appointed by the Secretary to assist him in his standard-setting functions under section 655 of this title. Each such committee shall consist of not more than fifteen members and shall include as a member one or more designees of the Secretary of Health, Education, and Welfare, and shall include among its members an equal number of persons qualified by experience and affiliation to present the viewpoint of the employers involved, and of persons similarly qualified to present the viewpoint of the workers involved, as well as one or more representatives of health and safety agencies of the States. An advisory committee may also include such other persons as the Secretary may appoint who are qualified by knowledge and experience to make a useful contribution to the work of such committee, including one or more representatives of professional organizations of technicians or professionals specializing in occupational safety or health, and one or more representatives of nationally recognized standards-producing organizations, but the number of persons so appointed to any

Section 7 (29 U.S.C. §656)

such advisory committee shall not exceed the number appointed to such committee as representatives of Federal and State agencies. Persons appointed to advisory committees from private life shall be compensated in the same manner as consultants or experts under section 3109 of Title 5. The Secretary shall pay to any State which is the employer of a member of such a committee who is a representative of the health or safety agency of that State, reimbursement sufficient to cover the actual cost to the State resulting from such representative's membership on such committee. Any meeting of such committee shall be open to the public and an accurate record shall be kept and made available to the public. No member of such committee (other than representatives of employers and employees) shall have an economic interest in any proposed rule.

Use of services, facilities, and personnel of Federal, State, and local agencies; reimbursement; employment of experts and consultants or organizations; renewal of contracts; compensation; travel expenses

(c) In carrying out his responsibilities under this chapter, the Secretary is authorized to—

(1) use, with the consent of any Federal agency, the services, facilities, and personnel of such agency, with or without reimbursement, and with the consent of any State or political subdivision thereof, accept and use the services, facilities, and personnel of any agency of such State or subdivision with reimbursement; and

(2) employ experts and consultants or organizations thereof as authorized by section 3109 of Title 5, except that contracts for such employment may be renewed annually; compensate individuals so employed at rates not in excess of the rate specified at the time of service for grade GS–18 under section 5332 of Title 5, including traveltime, and allow them while away from their homes or regular places of business, travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of Title 5 for persons in the Government service employed intermittently, while so employed.

Pub.L. 91–596, § 7, Dec. 29, 1970, 84 Stat. 1597.

Section 8(c) (29 U.S.C. §657(c))

Maintenance, preservation, and availability of records; issuance of regulations; scope of records; periodic inspections by employer; posting of notices by employer; notification of employee of corrective action

(c)(1) Each employer shall make, keep and preserve, and make available to the Secretary or the Secretary of Health, Education, and Welfare, such records regarding his activities relating to this chapter as the Secretary, in cooperation with the Secretary of Health, Education, and Welfare, may prescribe by regulation as necessary

Section 8(c) (29 U.S.C. §657(c))

or appropriate for the enforcement of this chapter or for developing information regarding the causes and prevention of occupational accidents and illnesses. In order to carry out the provisions of this paragraph such regulations may include provisions requiring employers to conduct periodic inspections. The Secretary shall also issue regulations requiring that employers, through posting of notices or other appropriate means, keep their employees informed of their protections and obligations under this chapter, including the provisions of applicable standards.

(2) The Secretary, in cooperation with the Secretary of Health, Education, and Welfare, shall prescribe regulations requiring employers to maintain accurate records of, and to make periodic reports on, work-related deaths, injuries and illnesses other than minor injuries requiring only first aid treatment and which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job.

(3) The Secretary, in cooperation with the Secretary of Health, Education, and Welfare, shall issue regulations requiring employers to maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under section 655 of this title. Such regulations shall provide employees or their representatives with an opportunity to observe such monitoring or measuring, and to have access to the records thereof. Such regulations shall also make appropriate provision for each employee or former employee to have access to such records as will indicate his own exposure to toxic materials or harmful physical agents. Each employer shall promptly notify any employee who has been or is being exposed to toxic materials or harmful physical agents in concentrations or at levels which exceed those prescribed by an applicable occupational safety and health standard promulgated under section 655 of this title, and shall inform any employee who is being thus exposed of the corrective action being taken.

Section 8(g) (29 U.S.C. §657(g))

Compilation, analysis, and publication of reports and information; rules and regulations

(g)(1) The Secretary and Secretary of Health, Education, and Welfare are authorized to compile, analyze, and publish, either in summary or detailed form, all reports or information obtained under this section.

Section 8(g) (29 U.S.C. §657(g))

(2) The Secretary and the Secretary of Health, Education, and Welfare shall each prescribe such rules and regulations as he may deem necessary to carry out their responsibilities under this chapter, including rules and regulations dealing with the inspection of an employer's establishment.

Pub.L. 91-596, § 8, Dec. 29, 1970, 84 Stat. 1598.

Section 9 (29 U.S.C. §658)

Citations

Authority to issue; grounds; contents; notice in lieu of citation for de minimis violations

(a) If, upon inspection or investigation, the Secretary or his authorized representative believes that an employer has violated a requirement of section 654 of this title, of any standard, rule or order promulgated pursuant to section 655 of this title, or of any regulations prescribed pursuant to this chapter, he shall with reasonable promptness issue a citation to the employer. Each citation shall be in writing and shall describe with particularity the nature of the violation, including a reference to the provision of the chapter, standard, rule, regulation, or order alleged to have been violated. In addition, the citation shall fix a reasonable time for the abatement of the violation. The Secretary may prescribe procedures for the issuance of a notice in lieu of a citation with respect to de minimis violations which have no direct or immediate relationship to safety or health.

Posting

(b) Each citation issued under this section, or a copy or copies thereof, shall be prominently posted, as prescribed in regulations issued by the Secretary, at or near each place a violation referred to in the citation occurred.

Time for issuance

(c) No citation may be issued under this section after the expiration of six months following the occurrence of any violation.

Pub.L. 91-596, § 9, Dec. 29, 1970, 84 Stat. 1601.

Section 13 (29 U.S.C. §662)

Injunction proceedings

Petition by Secretary to restrain imminent dangers; scope of order

(a) The United States district courts shall have jurisdiction, upon petition of the Secretary, to restrain any conditions or practices in any place of employment which are such that a danger exists which could reasonably be expected to cause death or serious physical harm immediately or before the imminence of such danger can be eliminated through the enforcement procedures otherwise provided by this chapter. Any order issued under this section may require such steps to be taken as may be necessary to avoid, correct, or remove such imminent danger and prohibit the employment or presence of any individual in locations or under conditions where such imminent danger exists, except individuals whose presence is necessary to avoid, correct, or remove such imminent danger or to maintain the capacity of a continuous process operation to resume normal operations without a complete cessation of operations, or where a cessation of operations is necessary, to permit such to be accomplished in a safe and orderly manner.

Appropriate injunctive relief or temporary restraining order pending outcome of enforcement proceeding; applicability of rule 65 of Federal Rules of Civil Procedure

(b) Upon the filing of any such petition the district court shall have jurisdiction to grant such injunctive relief or temporary restraining order pending the outcome of an enforcement proceeding pursuant to this chapter. The proceeding shall be as provided by Rule 65 of the Federal Rules. Civil Procedure, except that no temporary restraining order issued without notice shall be effective for a period longer than five days.

Notification of affected employees and employers by inspector of danger and of recommendation to Secretary to seek relief

(c) Whenever and as soon as an inspector concludes that conditions or practices described in subsection (a) of this section exist in any place of employment, he shall inform the affected employees and employers of the danger and that he is recommending to the Secretary that relief be sought.

Failure of Secretary to seek relief; writ of mandamus

(d) If the Secretary arbitrarily or capriciously fails to seek relief under this section, any employee who may be injured by reason of such failure, or the representative of such employees, might bring an action against the Secretary in the United States district court for the district in which the imminent danger is alleged to exist or the employer has its principal office, or for the District of Columbia, for a writ of mandamus to compel the Secretary to seek such an order and for such further relief as may be appropriate.

Pub.L. 91-596, § 13, Dec. 29, 1970, 84 Stat. 1605.

Section 20 (29 U.S.C. §669)

Research and related activities

Authority of Secretary of Health, Education, and Welfare to conduct research, experiments, and demonstrations, develop plans, establish criteria, promulgate regulations, authorize programs, and publish results and industrywide studies; consultations

(a)(1) The Secretary of Health, Education, and Welfare, after consultation with the Secretary and with other appropriate Federal departments or agencies, shall conduct (directly or by grants or contracts) research, experiments, and demonstrations relating to occupational safety and health, including studies of psychological factors involved, and relating to innovative methods, techniques, and approaches for dealing with occupational safety and health problems.

(2) The Secretary of Health, Education, and Welfare shall from time to time consult with the Secretary in order to develop specific plans for such research, demonstrations, and experiments as are necessary to produce criteria, including criteria identifying toxic substances, enabling the Secretary to meet his responsibility for the formulation of safety and health standards under this chapter; and the Secretary of Health, Education, and Welfare, on the basis of such research, demonstrations, and experiments and any other information available to him, shall develop and publish at least annually such criteria as will effectuate the purposes of this chapter.

(3) The Secretary of Health, Education, and Welfare, on the basis of such research, demonstrations, and experiments, and any other information available to him, shall develop criteria dealing with toxic materials and harmful physical agents and substances which will describe exposure levels that are safe for various periods of employment, including but not limited to the exposure levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience.

(4) The Secretary of Health, Education, and Welfare shall also conduct special research, experiments, and demonstrations relating to occupational safety and health as are necessary to explore new problems, including those created by new technology in occupational safety and health, which may require ameliorative action beyond that which is otherwise provided for in the operating provisions of this chapter. The Secretary of Health, Education, and Welfare shall also conduct research into the motivational and behavioral factors relating to the field of occupational safety and health.

(5) The Secretary of Health, Education, and Welfare, in order to comply with his responsibilities under paragraph (2), and in order to develop needed information regarding potentially toxic substances or harmful physical agents, may prescribe regulations requiring employers to measure, record, and make reports on the exposure of employees to substances or physical agents which the Secretary of Health, Education, and Welfare reasonably believes may endanger

the health or safety of employees. The Secretary of Health, Education, and Welfare also is authorized to establish such programs of medical examinations and tests as may be necessary for determining the incidence of occupational illnesses and the susceptibility of employees to such illnesses. Nothing in this or any other provision of this chapter shall be deemed to authorize or require medical examination, immunization, or treatment for those who object thereto on religious grounds, except where such is necessary for the protection of the health or safety of others. Upon the request of any employer who is required to measure and record exposure of employees to substances or physical agents as provided under this subsection, the Secretary of Health, Education, and Welfare shall furnish full financial or other assistance to such employer for the purpose of defraying any additional expense incurred by him in carrying out the measuring and recording as provided in this subsection.

(6) The Secretary of Health, Education, and Welfare shall publish within six months of December 29, 1970, and thereafter as needed but at least annually a list of all known toxic substances by generic family or other useful grouping, and the concentrations at which such toxicity is known to occur. He shall determine following a written request by any employer or authorized representative of employees, specifying with reasonable particularity the grounds on which the request is made, whether any substance normally found in the place of employment has potentially toxic effects in such concentrations as used or found; and shall submit such determination both to employers and affected employees as soon as possible. If the Secretary of Health, Education, and Welfare determines that any substance is potentially toxic at the concentrations in which it is used or found in a place of employment, and such substance is not covered by an occupational safety or health standard promulgated under section 655 of this title, the Secretary of Health, Education, and Welfare shall immediately submit such determination to the Secretary, together with all pertinent criteria.

(7) Within two years of December 29, 1970, and annually thereafter the Secretary of Health, Education, and Welfare shall conduct and publish industrywide studies of the effect of chronic or low-level exposure to industrial materials, processes, and stresses on the potential for illness, disease, or loss of functional capacity in aging adults.

Authority of Secretary of Health, Education, and Welfare to make inspections and question employers and employees

(b) The Secretary of Health, Education, and Welfare is authorized to make inspections and question employers and employees as provided in section 657 of this title in order to carry out his functions and responsibilities under this section.

Section 20 (29 U.S.C. §669)

Contracting authority of Secretary of Labor; cooperation between Secretary of Labor and Secretary of Health, Education, and Welfare

(c) The Secretary is authorized to enter into contracts, agreements, or other arrangements with appropriate public agencies or private organizations for the purpose of conducting studies relating to his responsibilities under this chapter. In carrying out his responsibilities under this subsection, the Secretary shall cooperate with the Secretary of Health, Education, and Welfare in order to avoid any duplication of efforts under this section.

Dissemination of information to interested parties

(d) Information obtained by the Secretary and the Secretary of Health, Education, and Welfare under this section shall be disseminated by the Secretary to employers and employees and organizations thereof.

Delegation of functions of Secretary of Health, Education, and Welfare to Director of National Institute for Occupational Safety and Health

(e) The functions of the Secretary of Health, Education, and Welfare under this chapter shall, to the extent feasible, be delegated to the Director of the National Institute for Occupational Safety and Health established by section 671 of this title.

Pub.L. 91-596, § 20, Dec. 29, 1970, 84 Stat. 1610.

APPENDIX B - THE BENZENE DECISION

The AMERICAN PETROLEUM INSTITUTE et al., Petitioners,

The Manufacturing Chemists Association and the Chemical Specialties Manufacturers Association, Intervenors,

v.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION et al., Respondents,

Industrial Union Department, AFL-CIO, Intervenor.

Nos. 78-1253, 78-1257, 78-1486, 78-1676, 78-1677, 78-1707 and 78-1745.

United States Court of Appeals, Fifth Circuit.

Oct. 5, 1978.

Producers of benzene filed petition for review of a new health standard promulgated by the Occupational Safety and Health Administration limiting occupational exposure to benzene. The Court of Appeals, Charles Clark, Circuit Judge, held that: (1) regulation requiring employers to assure that no employee is exposed to airborne concentration of benzene in excess of one part benzene per million parts of air averaged over an eight-hour day would be set aside, in absence of substantial evidence indicating that measurable benefits to be achieved by the reduction of permissible exposure to benzene bore a reasonable relationship to the one-half billion dollar cost of such regulation for affected industries; (2) regulation requiring employers to assure that no employee is exposed to dermal contact with liquid benzene would be set aside, since such regulation was based upon dated, inconclusive data, and unrefuted evidence revealed the existence of modern experimental methods which could provide accurate information on factual issues which were unresolved by past studies, and (3) Administration had authority to prohibit employer from removing warning labels from containers of benzene and benzene products when those containers leave his work place.

Petition for review granted.

1. Labor Relations ⇐27

In reviewing regulations promulgated by the Occupational Safety and Health Administration, substantial evidence standard is applicable with respect to factual findings subject to evidentiary development; legislative-like policy judgments, though not so susceptible to verification or refutation by record, must nevertheless be scrutinized on judicial review for consideration as to whether such judgments are consistent with statutory language and purpose and within decision-making power of Secretary of Labor within limits imposed by Congress. Occupational Safety and Health Act of 1970, § 6(f), 29 U.S.C.A. § 655(f).

2. Labor Relations ⇐27

The Occupational Safety and Health Act of 1970 imposes on the Occupational Safety and Health Administration the obligation to enact only standards that are reasonably necessary or appropriate to provide safe or healthful work places; if standard does not fit in that definition, it is not one that the Administration is authorized to enact. Occupational Safety and Health Act of 1970, § 3(8), 29 U.S.C.A. § 652(8).

3. Labor Relations ⇐27

The Occupational Safety and Health Act does not give the Occupational Safe-

ty and Health Administration unbridled discretion to adopt standards designed to create absolutely risk-free work places regardless of cost, but rather, the Act requires standards to be feasible, and contains a number of pragmatic limitations in the form of specific kinds of information the Administration must consider in enacting standards dealing with toxic materials; the conditions and other requirements imposed by standards dealing with toxic materials must be reasonably necessary or appropriate to provide safe or healthful employment and places of employment. Occupational Safety and Health Act of 1970, §§ 3(8), 6(b)(5), 29 U.S.C.A. §§ 652(8), 655(b)(5).

4. Labor Relations ⇐27

Before it regulates, the Occupational Safety and Health Administration must show that hazard exists and that its regulation will reduce the risk from the hazard, and the Administration must also assess expected benefits in light of burdens to be imposed by standard; although the Administration does not have to conduct an elaborate cost-benefit analysis, it does have to determine whether benefits expected from standard bear a reasonable relationship to costs imposed by standard. Occupational Safety and Health Act of 1970, §§ 3(8), 6(b)(5), 29 U.S.C.A. §§ 652(8), 655(b)(5).

5. Labor Relations ⇐27

Occupational Safety and Health Administration's regulation requiring employers to assure that no employee is exposed to airborne concentration of benzene in excess of one part benzene per million parts of air averaged over an eight-hour day would be set aside, in absence of substantial evidence indicating that measurable benefits to be achieved by the reduction of permissible exposure to benzene bore a reasonable relationship to the one-half billion dollar cost of such regulation for affected industries. Occupational Safety and Health Act of 1970, §§ 3(8), 6(b)(5), 29 U.S.C.A. §§ 652(8), 655(b)(5).

6. Labor Relations ⇐27

Judicial review of Occupational Safety and Health Administration regulations must be of the reasoning process of the Administration at the time it promulgated the standards based on the record before it. Occupational Safety and Health Act of 1970, § 6(f), 29 U.S.C.A. § 655(f).

7. Labor Relations ⇐27

When available evidence before Occupational Safety and Health Administration is of equivalent quality and is conflicting, a finding in accordance with one view or the other should be considered to be supported by substantial evidence. Occupational Safety and Health Act of 1970, § 6(f), 29 U.S.C.A. § 655(f).

8. Labor Relations ⇐27

Occupational Safety and Health Administration's regulation requiring employers to assure that no employee is exposed to dermal contact with liquid benzene would be set aside, since such regulation was based upon dated, inconclusive data, and unrefuted evidence revealed the existence of modern experimental methods which could provide accurate information on factual issues which were unresolved by past studies. Occupational Safety and Health Act of 1970, §§ 3(8), 6(b)(5), 29 U.S.C.A. §§ 652(8), 655(b)(5).

9. Labor Relations ⇐27

Occupational Safety and Health Administration had authority to prohibit employer from removing warning labels from containers of benzene and benzene products when those containers leave his

work place, in view of purpose of Occupational Safety and Health Act to protect every worker in nation, the express and broad statutory authorization for Administration to prescribe warning labels, and in view of fact that presence of benzene in product is often a concealed hazard; Administration's authority to require labeling of products containing benzene was not preempted by the Consumer Products Safety Commission which had promulgated regulations under the Federal Hazardous Substances Act. Occupational Safety and Health Act of 1970, §§ 4(b)(1), 6(b)(7), 29 U.S.C.A. §§ 653(b)(1), 655(b)(7); Federal Hazardous Substances Act, § 2 et seq., 15 U.S.C.A. § 1261 et seq.

On Petitions for Review of an Order of the Occupational Safety and Health Administration.

Before COLEMAN, CLARK, and TJOFLAT, Circuit Judges.

CHARLES CLARK, Circuit Judge:

This case presents consolidated petitions for review [1] of a new health standard limiting occupational exposure to benzene [2] promulgated by the Occupational Safety and Health Administration of the Department of Labor (OSHA), pursuant to the Occupational Safety and Health Act, 29 U.S.C.A. § 651 *et seq.* (1975) (the Act). The basis for the standard is OSHA's determination that benzene is a carcinogen for which there is no known safe level of exposure. Briefly, the standard requires employers to assure that no employee is exposed to an airborne concentration of benzene in excess of one part benzene per million parts of air (1 ppm) averaged over an eight-hour day; [3] it requires employers to assure that no employee is exposed to dermal contact with liquid benzene; [4] and it requires employers to assure that caution labels are affixed to all containers of products containing benzene and that the labels remain affixed when the product leaves the employer's workplace.[5] In addition, the standard impos-

1. The petitioning or intervening producers of benzene and benzene-containing products are the American Petroleum Institute on behalf of itself and member companies; the American Iron and Steel Institute on behalf of itself and member companies; the Independent Petroleum Association of America on behalf of itself and member companies; and the Manufacturing Chemists Association on behalf of itself and member companies. The petitioning or intervening users of benzene and benzene-containing products are the Rubber Manufacturers Association on behalf of itself and member companies; the Armstrong Rubber Company and Uniroyal, Inc.; E. I. du Pont de Nemours and Company; and the Chemical Specialties Manufacturers Association on behalf of itself and member companies. The grouping of the petitioners into the producer or user category was made in order to coordinate the briefing and arguing of this case, and this opinion will continue to refer to those categories.

2. The standard, to be codified at 29 C.F.R. § 1910.1028, and OSHA's statement of reasons in support of the standard are published at 43 Fed.Reg. 5918–70 (1978).

3. The ceiling limit is 5 ppm as averaged over any fifteen minute period.

4. OSHA promulgated an amended standard the day before oral argument of this case which exempted from the scope of the standard all work operations where the only exposure to liquid benzene or its vapors is from liquid mixtures containing 0.5 percent (0.1 percent after June 27, 1981) or less of benzene by volume. 43 Fed.Reg. 27,962–71 (1978). The original standard's absolute prohibition of dermal contact with any liquid containing any amount of benzene is therefore no longer in existence. The effect of this amendment on the issues in this case will be discussed *infra*.

5. Not only does the scope of the amended standard affect the labeling requirement, but

es numerous compliance requirements for "each place of employment where benzene is produced, reacted, released, packaged, repackaged, stored, transported, handled, or used," with certain exceptions. These requirements include initial and continual exposure monitoring, engineering and work practice controls to reduce and maintain exposure below the permissible level, respiratory protection to prevent excessive exposure in limited situations, protective clothing and equipment to prevent dermal contact with liquid benzene, initial and continual medical surveillance, employee training programs, and retention of records regarding exposure monitoring and medical surveillance.

The petitioning producers and users of benzene and benzene-containing products principally attack the reduction of the permissible exposure limit to 1 ppm,[6] the prohibition of dermal contact with liquids containing benzene, and the labeling requirements for such liquids. The petitioners also attack several of the ancillary provisions of the standard, including its broad scope, the monitoring and medical surveillance requirements, and the specification of mandatory engineering and work practice controls.

I.

The Act authorizes the Secretary of Labor[7] to promulgate occupational safety and health standards. 29 U.S.C.A. § 655. An "occupational safety and health standard" is defined as "a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment" 29 U.S.C.A. § 652(8). In promulgating standards dealing with toxic materials, such as benzene, the Secretary is required to

> set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.

29 U.S.C.A. § 655(b)(5). When necessary or appropriate, standards may prescribe labels or other forms of warning, protective equipment, control or technological procedures, exposure monitoring, and

the amended standard also exempts from the labeling requirement liquid mixtures containing 5.0 percent or less benzene by volume which were packaged before June 27, 1978.

6. Presently the permissible exposure limit for benzene is 10 ppm. 29 C.F.R. § 1910.1000 Table Z-2 (1977). This standard has been in existence since 1971.

7. This authority has been delegated to the Assistant Secretary of Labor for Occupational Safety and Health, the chief executive officer of OSHA. References to the Secretary and OSHA are used interchangeably in this opinion.

medical examinations. 29 U.S.C.A. § 655(b)(7).

[1] Judicial review of occupational safety and health standards is authorized by 29 U.S.C.A. § 655(f), and on review "[t]he determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole." Several courts, including this one, have pointed out the problems involved in attempting to apply the traditional substantial evidence test in assessing OSHA standards resulting from informal rulemaking. *E. g., Associated Industries of New York State, Inc. v. United States Department of Labor*, 487 F.2d 342, 347–50 (2d Cir. 1973); *Florida Peach Growers Association, Inc. v. United States Department of Labor*, 489 F.2d 120, 127–29 (5th Cir. 1974); *Industrial Union Department, AFL–CIO v. Hodgson*, 162 U.S.App.D.C. 331, 336–340, 499 F.2d 467, 472–76 (1974); *Synthetic Organic Chemical Manufacturers Association v. Brennan*, 503 F.2d 1155, 1158–60 (3d Cir. 1974). The problem centers not on how to apply the test to factual findings subject to evidentiary development, but rather on how to review legislative-like policy judgments. With respect to the former, the substantial evidence standard provided in the statute clearly is applicable. *See, e. g., Industrial Union Department, AFL–CIO v. Hodgson, supra*, 499 F.2d at 474; *American Iron & Steel Institute, et al. v. OSHA*, 577 F.2d 825, No. 76–2358 *et al.* (3d Cir., filed March 28, 1978). Policy choices, though not so susceptible to verification or refutation by the record, must be scrutinized nevertheless. *See Associated Industries of New York, Inc. v. United States Department of Labor, supra*, 487 F.2d at 348. Although the courts have differed in their articulation of the standard of review of these policy judgments, they have required the Secretary's action to be consistent with the statutory language and purpose. *Synthetic Organic Chemical Manufacturers Association v. Brennan, supra*, 503 F.2d at 1159. As this court stated in assessing an emergency temporary standard in *Florida Peach Growers*, "it seems clear that even with the required substantial evidence test, our review basically must determine whether the Secretary carried out his essentially legislative task in a manner reasonable under the state of the record before him." 489 F.2d at 129. This includes, of course, a review of whether the Secretary exercised his decisionmaking power within the limits imposed by Congress.

II.

Benzene is a ubiquitous hydrocarbon compound (C_6H_6) that is manufactured for a wide variety of industrial uses.[8] The petro-chemical and petroleum refining industries are responsible for 94 percent of the total domestic production of benzene, and the steel industry produces the remaining 6 percent primarily as a by-product of the coking process. The primary use of benzene is as a feedstock in the manufacture of other organic chemicals; it is also used in the manufacture of detergents, pesticides, solvents, and paint, and as a solvent and reactant in chemical laboratories. Industries currently using benzene include the

8. Although benzene does occur naturally in small quantities (a few parts per billion) in certain substances, including the ambient air, it is produced in substantial quantities by the petroleum and steel industries. The production of benzene is rapidly expanding, and at present only eleven other chemicals and only one other hydrocarbon are produced in greater tonnage in the United States. *See* 43 Fed.Reg. 5918.

chemical, printing, lithograph, rubber cements, rubber fabricating,[9] paint, varnish, stain removers, adhesives, and petroleum industries. Among the products that contain benzene are motor fuels such as gasoline, which contain up to 2 percent benzene.

Benzene has been recognized since 1900 as a toxic substance capable of producing acute and chronic nonmalignant effects in humans. When benzene vapors are inhaled, the benzene diffuses rapidly through the lungs and is quickly absorbed into the blood. Acute circulatory failure resulting in death within minutes often accompanies exposure to benzene concentrations as high as 20,000 ppm. Other acute effects of exposure to milder, though still high (250–500 ppm), concentrations of benzene include vertigo, nervous excitation, headache, nausea, and breathlessness. When exposure is stopped, rapid recovery from these symptoms usually occurs.

The most common nonmalignant effects of chronic exposure to low[10] benzene concentration levels are a non-functioning bone marrow and deficiencies in the formed elements of the blood.[11] The degree of severity of such disorders ranges from mild and transient episodes to severe and fatal effects. Chromosomal aberrations have also been associated with chronic benzene exposure, and dermatitis or other dermal infections can be caused by direct bodily contact with liquid benzene.

As a result of its toxicity, benzene's history has been one of regulation. In 1946, the American Conference of Governmental Industrial Hygienists recommended a threshold limit value for benzene exposure of 100 ppm. This value was reduced to 50 ppm in 1947, to 35 ppm in 1948, to 25 ppm in 1963, and to 10 ppm in 1974. The American National Standards Institute adopted a threshold limit value of 10 ppm in 1969, which OSHA adopted in 1971 without rulemaking under the authority of 29 U.S.C.A. § 655(a).[12] This standard, codified at 29 C.F.R. § 1910.1000 Table Z–2 (1977) and still in effect, was based on the nonmalignant toxic effects of benzene exposure and not on any possible leukemia hazard.

Widely scattered through the benzene literature are studies suggesting a link between benzene exposure and leukemia, a usually fatal cancer of the blood-forming organs. During the 1970's several additional studies reported a statistically significant increased risk of leukemia among workers occupationally exposed to high levels of benzene and concluded

9. According to the rubber companies, the manufacture of tires requires the use of petroleum solvents which generally contain small amounts of benzene.

10. These toxic effects were documented at exposure levels above 25–50 ppm, and a few studies showed nonmalignant blood abnormalities at levels below 25 ppm. 43 Fed.Reg. 5924–25.

11. A decline in the red blood cell count (anemia) results in a decreased capacity of the blood to carry oxygen to various parts of the body and is characterized by fatigue. A decline in the white blood cell count (leukopenia) reduces the capacity of the body to defend against disease and is characterized by recurrent infections. A decline in the platelet count (thrombocytopenia) results in an impaired clotting of the blood and is characterized by bleeding tendencies.

12. 29 U.S.C.A. § 655(a) directed the Secretary, within two years after the effective date of the Act and without rulemaking, to promulgate as an occupational safety or health standard any national consensus standard that he determined would result in improved safety or health for employees. The purpose of this power was to make the Act effective immediately, and the power expired on April 28, 1973.

benzene was a leukemogen.[13] As a result of this new evidence, OSHA began procedures which culminated with the present proposal, among other things, to reduce the permissible exposure level from 10 ppm to 1 ppm.

In January 1977 OSHA issued voluntary Guidelines for Control of Occupational Exposure to Benzene recommending exposure not to exceed an eight-hour time-weighted average of 1 ppm. An Emergency Temporary Standard for Occupational Exposure to Benzene also providing for a reduction in the permissible exposure limit to 1 ppm[14] was issued in May 1977, but this standard never went into effect because of judicial challenges. The proposed permanent benzene standard, which was based on OSHA's determination that the available scientific evidence established that employee exposure to benzene presents a leukemia hazard and that exposure therefore should be limited to the lowest feasible level, was published on May 27, 1977. This proposal provided for a reduction in the permissible exposure limit from 10 ppm to 1 ppm and established requirements relating to dermal and eye contact,[15] exposure monitoring, medical surveillance, methods of compliance, labeling, and recordkeeping. Public hearings were held July 19 through August 10, 1977, at which 95 witnesses testified. In addition, numerous exhibits and documents were submitted to OSHA as part of the rulemaking record. The resulting permanent benzene standard was promulgated on February 3 and published on February 10, 1978, with a March 13, 1978 effective date.

III.

The American Petroleum Institute on behalf of itself and member companies

13. One such study was reported in 1975 by Dr. Enrico Vigliani. In 1963, Dr. Vigliani participated in a study of workers exposed to resins, inks, varnishes, and glues containing various amounts of benzene, and found a risk of leukemia among these workers twenty times greater than that for the general population. Toluene was substituted for benzene in 1964 in one of the industries studied, and the 1975 study showed no new cases of leukemia among workers in that industry.

A second study was reported in 1972 by Dr. Muzaffer Aksoy, a hematologist who testified at the rulemaking hearing. In this study Dr. Aksoy reported four leukemia deaths among Turkish shoemakers resulting from their exposure to benzene concentrations in excess of 150 ppm for periods ranging from six to fourteen years, and at the hearing he estimated that the incidence of leukemia among the population he studied was twice what would have been expected for the population as a whole. Dr. Aksoy also noted a decline in leukemia cases after other solvents were substituted for benzene.

The study most heavily relied upon by OSHA was one reported by Dr. Peter Infante of the National Institute for Occupational Safety and Health, a body created to conduct research and recommend occupational safety and health standards. *See* 29 U.S.C.A. §§ 669–71. Dr. Infante studied workers exposed to benzene in the production of Pliofilm at Goodyear's Akron and St. Mary's plants between 1940 and 1949 and found among them a five-fold increased risk of dying of leukemia when compared to two control groups. No specific exposure level during the period covered by the study was established, but testimony at the hearing indicated that exposure was probably around 100 ppm during most of the period studied with occasional exposure levels as high as several hundred parts per million.

14. Both the Guidelines and the Emergency Temporary Standard exempted work operations where the only exposure to benzene was from liquids containing 1 percent or less of benzene by volume.

15. The proposed permanent statement also exempted work operations where the only exposure to benzene was from liquid mixtures containing 1 percent (0.1 percent after one year from the effective date of the standard) or less of benzene by volume.

filed petitions for review of the standard in this court on February 2 and February 3, 1978. The American Iron and Steel Institute, the Independent Petroleum Association of America, the Manufacturing Chemists Association, the Rubber Manufacturers Association, the Armstrong Rubber Company and Uniroyal, Inc., E. I. Du Pont de Nemours and Company, and the Chemical Specialties Manufacturers Association subsequently either intervened on behalf of the American Petroleum Institute or filed original petitions for review in other circuits that were transferred to this circuit and consolidated with the American Petroleum Institute case. In addition, the Industrial Union Department, AFL–CIO, intervened on behalf of OSHA in support of the standard.[16]

The petitioners filed motions for a stay of the standard pending review on March 10, 1978, and on March 13 a judge of this court issued a temporary stay of the standard pending a hearing before a three-judge panel. The issues concerning the stay were fully briefed by the parties on an expedited basis, and after hearing oral argument a panel of the court on April 18, 1978, ordered a stay of the standard to be continued pending disposition of the petitions for review.[17]

The principal argument of the petitioning producers of benzene and benzene-containing products is that substantial evidence and the best available evidence do not show that the reduction of the permissible exposure limit from 10 ppm to 1 ppm is reasonably necessary or appropriate to provide safe or healthful employment and places of employment. These petitioners also attack several of the ancillary provisions of the standard, including its broad scope, the monitoring and medical surveillance requirements, and the specification of mandatory primary means of compliance, as not being supported by substantial evidence that they are reasonably necessary or appropriate to provide safe or healthful employment. The attack of the petitioning users of benzene and benzene-containing products is two-fold: (i) They contend that substantial evidence and the best available evidence do not show that the dermal contact prohibition is reasonably necessary or appropriate to provide safe or healthful employment, and that the dermal contact prohibition is not feasible; and (ii) they contend that substantial evidence does not show the labeling requirement to be reasonably necessary or appropriate to provide safe or healthful employment, that the labeling requirement is not feasible, and that the labeling requirement is beyond OSHA's jurisdiction. OSHA, in addition to arguing that substantial evidence, the best available evidence, feasibility considerations, and its statutory mandate to protect workers justify the standard in its entirety, contends that Congress imposed on it no substantive requirement to promulgate only standards that are reasonably necessary or appropriate to provide safe or healthful employment and places of employment.

On June 21, 1978, the day before oral argument, OSHA promulgated an amended standard to exempt from the scope of the benzene standard work operations where the only exposure to benzene is from liquid mixtures containing

16. Although we speak generally in this opinion about the contentions of the petitioners and the contentions of OSHA, the Industrial Union Department was an active participant in this case and offered considerable support to OSHA's position.

17. The issuance of a stay pending judicial review is authorized by 29 U.S.C.A. § 655(f).

0.5 percent (0.1 percent after June 28, 1981) or less of benzene by volume, and to exempt from the labeling requirements liquid mixtures containing 5.0 percent or less benzene by volume which were packaged before June 27, 1978. 43 Fed.Reg. 27,971 (1978). Although the proposed emergency temporary standard and the proposed permanent standard had exempted work operations where exposure to benzene resulted only from liquid mixtures containing 1 percent or less of benzene by volume,[18] the permanent standard that was promulgated contained no such exemption. As a result, the permanent standard prohibited all dermal contact with liquids containing any amount of benzene and it imposed the labeling requirements on all such liquids. Several industry groups petitioned OSHA for a stay of the dermal contact prohibition and labeling requirements as they applied to liquids containing small amounts of benzene.[19] OSHA subsequently granted a stay as to work operations where the sole exposure to benzene was from mixtures containing 0.1 percent or less of benzene and instituted a new rulemaking proceeding which resulted in the June 21, 1978 amendment.

The court called for supplemental briefing to address the effect of this amendment on the issues already briefed and argued. This briefing has been completed, and it appears that the major effect of the amendment is on the arguments regarding the feasibility of the dermal contact and labeling provisions. Since the considerations associated with the feasibility of those provisions have been significantly changed by the amendments, we do not address the merits of the feasibility arguments in this opinion.

IV.

OSHA justifies the reduction of the permissible exposure limit for benzene from 10 ppm to 1 ppm by coupling two factual findings, which it contends are supported by substantial evidence in the record, with a regulatory policy which OSHA contends is required by its mandate to protect workers. The factual findings are that benzene causes leukemia and that there presently exists no known safe level for benzene exposure. The regulatory policy is to limit employee exposure to carcinogens to the lowest feasible level.

The producer petitioners, in addition to attacking the factual finding that no known safe level for benzene exposure exists,[20] contend that OSHA has failed to meet a burden which the Act imposes of determining that the reduction of the permissible exposure limit from 10 ppm to 1 ppm is "reasonably necessary" to

18. As noted above, the exemption in the proposed permanent standard fell to 0.1 percent after the first year.

19. These petitioners, who generally were among the user petitioners in this case, sought relief on the grounds that OSHA failed to provide adequate notice that the final standard might contain no exemption for work operations where the only benzene exposure was from liquid mixtures containing small amounts of benzene, that the dermal contact prohibition was not based on the best available evidence, and that the dermal contact prohibition was not feasible. With respect to feasibility, the rubber industry contended that the manufacture of tires was impossible without some dermal contact with solvents containing trace amounts of benzene.

20. This argument is based on the fact that all studies associating benzene and leukemia involve high benzene concentration levels, that a substantial body of the scientific community subscribes to the theory that safe threshold levels exist for exposure to carcinogens, and that empirical evidence shows that low-level exposure to benzene does not cause leukemia

provide a safe workplace. In support of the latter contention, these petitioners point to this circuit's recent decision in *Aqua Slide 'N' Dive Corp. v. Consumer Product Safety Commission*, 569 F.2d 831 (5th Cir. 1978), and assert that OSHA failed to assess benefits expected to be achieved by the standard in light of the expected costs of compliance. The petitioners argue that by defining an "occupational safety and health standard" as one requiring conditions "reasonably necessary" to provide safe or healthful places of employment, 29 U.S.C.A. § 652(8), Congress recognized that safety and health resources are not unlimited and required OSHA somewhere in its decisionmaking process to (1) attempt to determine the extent to which its standards will benefit workers, and (2) decide whether the projected benefits justify the costs of compliance with the standard. Only if all standards are subjected to such assessment, argue the petitioners, can OSHA assure maximum benefit from the finite amount industry can expend on safety and health and thus carry out Congress' overriding policy "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions." 29 U.S.C.A. § 651(b). Since OSHA has not made a valid determination that reducing the permissible exposure level of benzene from 10 ppm to 1 ppm is reasonably necessary to protect workers from a risk of leukemia, the producers ask us to set that part of the standard aside.[21]

OSHA denies that the "reasonably necessary" language imposes any substantive obligation on it in promulgating standards. OSHA would distinguish *Aqua Slide*, which dealt with the Consumer Product Safety Act, on the basis that the "reasonably necessary" language in that Act appeared as a part of the sections which dealt with the agency's process of setting standards, 15 U.S.C.A. §§ 2056(a), 2058(c)(2)(A), whereas the "reasonably necessary" counterpart in the act it administers appears only in the section which defines the type of standard it may promulgate.

[2] In authorizing the Consumer Product Safety Commission to promulgate safety standards, Congress provided that "[a]ny requirement of such a standard shall be reasonably necessary to prevent or reduce an unreasonable risk of injury associated with such product." 15 U.S.C.A. § 2056(a). It also required the Consumer Product Safety Commission to make a specific finding that its rules were "reasonably necessary to eliminate or reduce an unreasonable risk of injury." 15 U.S.C.A. § 2058(c)(2)(A). Rather than following this format, the Occupational Safety and Health Act defines the occupational safety and health standard it authorizes as one "which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment." 29 U.S.C.A. § 652(8). We decline to construe the precisely similar requirements of these two Acts differently or to read words out of the OSHA legislation. The Act imposes on OSHA the obligation to enact only standards that are reasonably necessary or appropriate to provide safe or healthful workplaces. If a standard does not fit in this definition, it is not one that OSHA is authorized to enact.

21. As a corollary, they ask us to set aside all other provisions designed to effectuate the 1 ppm permissible exposure limit.

OSHA next argues that even if the conditions required by occupational safety and health standards must be reasonably necessary to provide safe or healthful places of employment, the Act still imposes on OSHA no obligation to undertake a cost-benefit analysis with respect to the standards it promulgates. OSHA argues that 29 U.S.C.A. § 655(b)(5) defines when conditions imposed by a standard dealing with toxic materials are reasonably necessary. It urges that the emphasis of that section on making of a standard "which most adequately assures . . . that no employee will suffer material impairment of health . . . [from] regular exposure . . . for the period of his working life," overcomes any requirement to make a cost-benefit analysis. Nevertheless, OSHA contends that it did undertake economic analyses of both costs and benefits associated with the standard as required by *Aqua Slide*, and that after assessing those analyses it promulgated the standard.

[3] Although 29 U.S.C.A. § 655(b)(5) requires the goal of attaining the highest degree of health and safety protection for the employee, it does not give OSHA the unbridled discretion to adopt standards designed to create absolutely risk-free workplaces regardless of cost. To the contrary, that section requires standards to be feasible, and it contains a number of pragmatic limitations in the form of specific kinds of information OSHA must consider in enacting standards dealing with toxic materials. Those include "the best available evidence," "research, demonstrations, experiments, and such other information as may be appropriate," "the latest available scientific data in the field," and "experience gained under this and other health and safety laws." Moreover, in standards dealing with toxic materials, just as with all other occupational safety and health standards, the conditions and other requirements imposed by the standard must be "reasonably necessary or appropriate to provide safe or healthful employment and places of employment." 29 U.S.C.A. § 652(8).

[4] Since the purpose of the Act to protect workers from dangerous conditions of employment is parallel to the purpose of the Consumer Product Safety Act to protect consumers from dangerous products, we must be guided by *Aqua Slide* in determining whether OSHA has met its burden of showing that the benzene standard is reasonably necessary to protect workers from a leukemia hazard. There we said:

> In evaluating the "reasonable necessity" for a standard, the Commission has a duty to take a hard look, not only at the nature and severity of the risk, but also at the potential the standard has for reducing the severity or frequency of the injury, and the effect the standard would have on the utility, cost or availability of the product.

569 F.2d at 844; *see also D. D. Bean & Sons v. Consumer Product Safety Commission*, 574 F.2d 643 (1st Cir. 1978). Before it regulates, the agency must show that a hazard exists and that its regulation will reduce the risk from the hazard, for "no [occupational safety and health] standard would be expected to impose added costs or inconvenience . . . unless there is reasonable assurance that the frequency or severity of injuries or illnesses will be reduced." 569 F.2d at 839. More importantly for today's case, *Aqua Slide* also requires the agency to assess the expected benefits in light of the burdens to be imposed by the standard. Although the agency does not have to conduct an elaborate cost-benefit

analysis, 569 F.2d at 840, it does have to determine whether the benefits expected from the standard bear a reasonable relationship to the costs imposed by the standard. 569 F.2d at 842.

[5] The only way to tell whether the relationship between the benefits and costs of the benzene standard is reasonable is to estimate the extent of the expected benefits and costs. *See* 569 F.2d at 843. OSHA did this with respect to costs by engaging a consulting firm to assess the expected compliance costs and economic feasibility of the proposed standard. 43 Fed.Reg. 5934–39. Based on this study and other evidence, OSHA estimated compliance costs for all affected industries to be $187–205 million first year operating costs, $266 million engineering control costs, and $34 million recurring annual costs.[22] OSHA determined these costs to be feasible since they would not threaten the financial welfare of the affected firms or the general economy. However, OSHA disclaimed any obligation to balance these costs against expected benefits. 43 Fed. Reg. 5940–41. Rather than attempting to measure the extent to which the leukemia hazard of benzene exposure would be reduced by lowering the permissible exposure limit from 10 ppm to 1 ppm, OSHA merely assumed that benefits from the reduction "may be appreciable." It based this assumption on a finding that benzene was unsafe at any level and its conclusion that exposures to lower levels of toxic materials would be safer than exposure to higher levels.

OSHA's fall-back position attempts to justify its standard as being reasonably necessary within the meaning of *Aqua Slide*. It contends the standard promises appreciable benefits at a cost which industry can absorb. This justification is deficient in one crucial way: substantial evidence does not support OSHA's conclusion that benefits are likely to be appreciable. Without an estimate of benefits supported by substantial evidence, OSHA is unable to justify a finding that the benefits to be realized from the standard bear a reasonable relationship to its one-half billion dollar price tag.

OSHA's assumption that the standard is likely to result in benefits is not unsupported. The divided opinion in the scientific community over the existence or not of safe threshold levels of exposure to carcinogens provides substantial evidence which would support the finding that exposure to benzene at the present level of 10 ppm poses some leukemia risk. The general agreement in the scientific community that exposure to carcinogens at low levels is safer than exposure at higher levels permits the further factual deduction that reducing the permissible exposure limit from 10 ppm to 1 ppm will result in some benefit. This finding and deduction, however, does not yield the conclusion that measurable benefits will result, and OSHA is unable to point to any studies or projections supporting such a finding. As we noted in *Aqua Slide*, mere rationality is not equivalent to substantial evidence that conditions required by standards are reasonably necessary. 569 F.2d at 841. The lack of substantial evidence of discernable benefits is highlighted when one considers that OSHA is unable to point to any empirical evidence documenting a leukemia risk at 10 ppm

22. Although the petitioners do not seriously challenge OSHA's estimate of costs in this suit, they refer to the promulgation of this standard as a $1 billion decision. Neither OSHA's estimate nor the petitioners' estimate takes into account the effects of the amendment, which narrows the scope of the standard.

even though that has been the permissible exposure limit since 1971. OSHA's assertion that benefits from reducing the permissible exposure limit from 10 ppm to 1 ppm are likely to be appreciable, an assumption based only on inferences drawn from studies involving much higher exposure levels rather than on studies involving these levels or sound statistical projections from the high-level studies, does not satisfy the reasonably necessary requirement limiting OSHA's action. *Aqua Slide* requires OSHA to estimate the extent of expected benefits in order to determine whether those benefits bear a reasonable relationship to the standard's demonstrably high costs.

We are not persuaded by OSHA's argument that this standard should be upheld since the lack of knowledge concerning the effects of exposure to benzene at low levels makes an estimate of benefits expected from reducing the permissible exposure level impossible.[23] The statute requires all conditions imposed by a standard to be reasonably necessary to provide safe or healthful employment, and it requires decisions to be based on "the best available evidence," "research, demonstrations, experiments, and such other information as may be appropriate," "the latest scientific data in the field," and "experience gained under this and other health and safety laws." By requiring the consideration of such kinds of information, Congress provided that OSHA regulate on the basis of knowledge rather than on the unknown. *But see Society of Plastics Industry, Inc. v. OSHA*, 509 F.2d 1301, 1308 (2d Cir. 1975). Until OSHA can provide substantial evidence that the benefits to be achieved by reducing the permissible exposure limit from 10 ppm to 1 ppm bear a reasonable relationship to the costs imposed by the reduction, it cannot show that the standard is reasonably necessary to provide safe or healthful workplaces.

This does not mean that OSHA must wait until deaths occur as a result of exposure at levels below 10 ppm before it may validly promulgate a standard reducing the permissible exposure limit. *See Florida Peach Growers Association, Inc. v. United States Department of Labor*, 489 F.2d 120, 132 (5th Cir. 1974). Nevertheless, OSHA must have some factual basis for an estimate of expected benefits before it can determine that a one-half billion dollar standard is reasonably necessary. For example, when studies of the effects of human exposure to benzene at higher concentration levels in the past are sufficient to enable a dose-response curve[24] to be charted that can

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

24. A dose-response curve shows the relationship between different exposure levels and the risk of cancer associated with those exposure

reasonably be projected to the lower exposure levels, or when studies of the effects of animal exposure to benzene[25] are sufficient to make projections of the risks involved with exposure at low levels, then OSHA will be able to make rough but educated estimates of the extent of benefits expected from reducing the permissible exposure level from 10 ppm to 1 ppm. Until such estimates are possible, OSHA does not have sufficient information to determine that a standard such as the one under review which it can only say might protect some worker from a leukemia risk is reasonably necessary.

We will not attempt to reconcile our decision with the cases from other circuits which uphold other standards regulating exposure to carcinogens. *See Industrial Union Department, AFL–CIO v. Hodgson,* 162 U.S.App.D.C. 331, 499 F.2d 467 (1974) (asbestos dust standard); *Society of Plastics Industry, Inc. v. OSHA,* 509 F.2d 1301 (2d Cir. 1975) (vinyl chloride standard); *American Iron & Steel Institute et al. v. OSHA,* 577 F.2d 825, No. 76–2358 *et al.* (3d Cir., filed March 28, 1978) (coke oven emission standard). Those opinions did not address what Congress meant by requiring the conditions imposed by standards to be reasonably necessary to provide safe or healthful places of employment. In this circuit, under our *Aqua Slide* decision, substantial evidence must support a finding that those conditions are reasonably necessary, a showing that OSHA has not made. In addition, those cases were decided on their own records. Without critical analysis of what was established in those proceedings, we hold in today's case that Congress intended for OSHA to regulate on the basis of more knowledge and fewer assumptions than this record reflects.

OSHA's failure to provide an estimate of expected benefits for reducing the permissible exposure limit, supported by substantial evidence, makes it impossible to assess the reasonableness of the relationship between expected costs and benefits. This failure means that the required support is lacking to show reasonable necessity for the standard promulgated. Consequently, the reduction of the permissible exposure limit from 10 ppm to 1 ppm and all other parts of the standard geared to the 1 ppm level must be set aside.

V.

OSHA's prohibition of dermal contact with benzene is based on "OSHA's policy that, in dealing with a carcinogen, all potential routes of exposure (*i. e.*, inhalation, ingestion, and skin absorption) be limited to the extent feasible." 43 Fed. Reg. 5948. OSHA, while acknowledging that the record evidence on the effect of benzene on the skin is "extremely limited" and that the few studies in the area "are not definitive as to the extent of benzene that is absorbed through the intact skin or as to the comparative rate of absorption through damaged skin," 43 Fed.Reg. 5948–49, nevertheless decided to prohibit dermal contact with liquids containing benzene. In arriving at this decision OSHA relied on animal studies

levels. Generally, exposure to higher levels carries with it a higher risk, and exposure to lower levels is accompanied by a reduced risk.

25. Although there have been attempts to demonstrate the development of leukemia in animals exposed to benzene, those attempts for the most part have been unsuccessful. Those studies do not even establish that benzene exposure causes leukemia, much less the degree of risk associated with various exposure levels. *See* 43 Fed.Reg. 5930–31, 5932.

and one human study suggesting that benzene is absorbed through intact skin, on the assumption that benzene would more readily be absorbed through damaged skin than undamaged skin, and on the belief that substances containing benzene are readily absorbed through the skin and act as vehicles for absorption of benzene.

[6] OSHA now seeks in part to justify this prohibition as an adjunct to the permissible exposure limit for airborne concentrations of benzene and because of a concern for dermatitis. To the extent that the dermal contact prohibition is an adjunct of the permissible exposure limit, it would have to be set aside along with the permissible exposure limit. The concern for dermatitis, on the other hand, appears to be a post hoc rationalization for the dermal contact prohibition since it was not a significant part of OSHA's reasoning process that led to this provision.[26] The requirements of this standard were based on the possible leukemia hazard associated with exposure to benzene, 43 Fed.Reg. 5918, 5948, and our review must be of the reasoning process of the agency at the time it promulgated the standard based on the record before it. *Dry Color Manufacturers' Association, Inc. v. Department of Labor,* 486 F.2d 98, 104 n.8 (3d Cir. 1973).

The user petitioners contend that substantial evidence and the best available evidence do not support a finding that the dermal contact provisions are reasonably necessary to provide safe or healthful employment, and in addition they contend the dermal contact prohibition is not feasible since it is impossible for certain industries to operate without some dermal contact with liquids containing small amounts of benzene. Since the amendment to the standard on June 21, 1978, significantly affects the feasibility issue, we will not address that issue in this opinion. We agree with the users, however, that OSHA has not shown the dermal contact prohibition to be reasonably necessary to protect workers from contracting benzene-related leukemia since readily available evidence of the kind Congress required OSHA to consider was neglected. The record therefore fails to support the finding that benzene is absorbed through the skin. Since entry to the body by dermal contact was not established, the record will not support a finding that the prohibition of all dermal contact with benzene will result in quantifiable benefits in terms of a reduced risk of leukemia justifying the costs of the provision. Thus reasonable necessity is lacking here too.

Studies of whether benzene is absorbed by the skin of animals, conducted in the first half of this century, are re-

26. At one point in the statement of reasons for the benzene standard OSHA did state that "[o]ne purpose of the protective clothing and equipment requirement is to protect employees from dermatitis and burns." 43 Fed.Reg. 5953. The reason for this standard as a whole, however, and the primary reason for the absolute prohibition of dermal contact with benzene (to which the protective clothing and equipment provision is tied), is to protect workers from a suspected carcinogen. It is within the context of OSHA's policy of reducing exposure to carcinogens to the lowest feasible level that we must review the dermal contact prohibition.

Dermal diseases can pose significant hazards in the workplace, and regulatory action following proceedings specifically focusing on such hazards may be appropriate. OSHA recently announced the formation of a standards advisory committee on cutaneous hazards to "identify the occupational exposures in industry which pose a hazard to the skin and/or the use of the skin as a portal of entry." 43 Fed.Reg. 10,647–48 (1978).

ferred to in this record during the course of expert testimony and as background material in later studies of whether benzene can be absorbed by human skin. Though these studies reached different conclusions, their relevance with respect to the issue of absorption of benzene by human skin has been questioned since there are important differences between the permeability of the skins of animals and humans. The studies concluding that benzene penetrates skin of certain animals have also been criticized since the possibility of benzene inhalation was not excluded and since there was no guarantee that the skin remained intact through the course of the experiment.

Between 1946 and 1961, experiments were conducted to determine whether human skin absorbed benzene. Although the first several of these studies conducted in the late 1940's and mid-1950's had negative results, one study published in 1961 found that some absorption had occurred and concluded that "the absorption of benzene throughout the skin must not be neglected." The record reveals problems in the interpretation of all of these studies, however. In particular, the 1961 study reporting positive results used a technique, compressing benzene-soaked cotton against the skin with a glass plate for prolonged periods, that is recognized today as an efficient way to drive molecules into the skin.

The oral testimony on the issue of skin absorption of benzene is very limited. Representatives of the National Institute of Occupational Safety and Health testified that they were of the opinion that benzene can be absorbed through the skin, and that absorption is more likely when the skin is damaged or when the benzene is contained in a solvent which itself is absorbed. Except for a passing reference to what appears to be the 1961 positive study, these witnesses did not attempt to support their opinions by reference to empirical data.

The one expert dermatologist who testified in depth on the issue of skin absorption of benzene, Dr. Howard Maibach of the University of California Medical Center, after summarizing and discussing critically the studies that have been conducted to date, concluded that "in 1977 it is extremely difficult, if not impossible, to balance all of the information that is available. Admittedly, the overwhelming majority of the observations suggest that benzene does not penetrate the skin. One observation suggests that it does." Dr. Maibach testified that he did not know whether benzene is absorbed through the skin; that he did not know whether benzene would be more readily absorbed through damaged skin than intact skin, although the assumption, unsupported by any data, is that it would be; and that he did not know whether benzene would be absorbed more readily if it is in another solvent.

[7] Were this the extent of the record on the issue of skin absorption, OSHA's finding that dermal contact with benzene poses a cancer risk could pass muster. When available evidence of equivalent quality is conflicting, a finding in accordance with one view or the other should be considered to be supported by substantial evidence. *See Universal Camera Corp. v. NLRB*, 340 U.S. 474, 488, 71 S.Ct. 456, 465, 95 L.Ed. 456 (1951). This record speaks further on the issue of skin absorption, however, and in light of OSHA's statutory command this additional evidence removes the support for OSHA's actions.

[8] Dr. Maibach, following his conclusion that the studies conducted to date were not definitive on the issue of

whether human skin absorbed benzene, stated:

> Today we have a much simpler and a much more direct way of answering this . . . because now radioactive benzene is available, and one simply would apply radioactive benzene, some Carbon 14 benzene, to the skin of the arm of an appropriate animal that has permeability characteristics similar to the people in this room . . . and then would simply look for the radioactivity excreted into the urine, the feces and the breath.
>
> This is a simple technique. It has been done for over 100 organic compounds in the last decade, measuring the amount of transport to the skin, and it would then tell us definitively, without argument, and efficiently, just how much of any benzene penetrates the skin.

Dr. Maibach testified that this experimental technique can answer a number of questions other than whether any benzene penetrates the skin, including demonstrating any differences in existence and extent of absorption of various parts of the body which may be exposed; whether benzene applied to the skin has the same toxic potential as benzene inhaled; whether multiple exposures result in correspondingly greater absorption than a single exposure; whether it is possible for one to protect himself by wearing protective clothing; whether and to what extent the amount of benzene absorbed through the skin is dependent upon benzene concentration; whether, because of its volatility, benzene splashed onto the skin evaporates more rapidly or goes through the skin more rapidly; and whether benzene is absorbed more readily if it is in another solvent. Dr. Maibach testified that the experiment would be relatively short term in length (six to twelve weeks), that the techniques are straightforward and reliable, and that the experiment could be done by anybody having the analytic facilities available. This testimony about the availability and reliability of modern experimental techniques is unrefuted in the record.

OSHA's decision to regulate on the basis of dated, inconclusive data when modern experimental methods can quickly and efficiently provide reliable information contravenes the directive from Congress to promulgate standards on the basis of the "best available evidence," "research, demonstrations, experiments, and such other information as may be appropriate," and "the latest available scientific data in the field." 29 U.S.C.A. § 655(b)(5). This is not a case where there is testimony that additional sophisticated research could be attempted, but might not shed new light on a subject. To the contrary, unrefuted testimony reveals the existence of simple experimental techniques, tried and proved effective for over 100 organic compounds, that can provide accurate information on the factual issues OSHA admits are unresolved by the past studies.[27] When such factual information is so readily available, 29 U.S.C.A. § 655(b)(5) requires OSHA to acquire that information before promulgating regulations which would require an established industry to change long-followed work processes that are not demonstrably unsafe.

In light of unrefuted testimony on the ready availability of conclusive evidence

27. In their brief the petitioners represent that Dr. Maibach is now conducting one such study.

on the subject, OSHA's choice to rely on old and inconclusive evidence that there is a possibility of absorption of benzene through the skin which might cause cancer is in clear disregard of the congressional directive as to the kinds of evidence OSHA is required to consider. Therefore, the provision of the standard prohibiting dermal contact with liquid benzene cannot stand on the present record.

VI.

[9] The reduction of the permissible exposure limit and the prohibition of dermal contact are the provisions of the benzene standard to which all the standard's other requirements are tied. Since neither of these provisions can be upheld on the present record, it follows that the standard as a whole must be set aside.

Although we vacate the labeling provision in conjunction with the rest of the standard, this or some similar requirement is sure to be considered by OSHA on remand. Therefore, we address the user petitioners' jurisdictional attack on one aspect of that provision. The labeling provision generally requires the employer to assure that caution labels are affixed to all containers of benzene and benzene-containing products. In the aspect of the provision under attack, OSHA further requires each employer to "assure that the caution labels remain affixed when the benzene or products containing benzene are sold, distributed or otherwise leave the employer's workplace."

By requiring caution labels to remain affixed when benzene products leave an employer's workplace, OSHA intended to assure that all employees along the product's distribution chain are apprised of the hazardous nature of benzene exposure. 43 Fed.Reg. 5960. It relied on the authority given to it by 29 U.S.C.A. § 655(b)(7) to require the use of warning labels in standards, and it concluded that this authority was not limited to requiring an employer to warn his own employees of the hazardous products he manufactures. Since the manufacturer of a product containing a toxic substance (and subsequent employers who have been informed of the hazard) is in the best position to know of the hazard and warn others down the distribution chain, OSHA concluded that the protective purposes of the Act would best be served by requiring the manufacturers to refrain from taking steps designed to withhold information concerning the dangers of the products from downstream workers.

The petitioners contend that the Act gives OSHA the jurisdiction to regulate workplaces, not products. They argue that OSHA here is claiming the authority to regulate finished products leaving the workplace, an authority that would transform what was intended to be a federal workplace safety code into a federal product safety code. The petitioners contend that Congress intended to place the responsibility for protecting each employee on his or her own employer, an allocation of responsibility that has proved workable in all but unusual circumstances such as the multiemployer construction worksite; and that, since all employers would be required to assure that benzene-containing products in their own workplaces are labeled, and the usual allocation of responsibility for labeling would be workable and effective.

Cases involving multiemployer construction worksites have recognized a duty on an employer to comply with OSHA standards in order to protect the employees of another employer. See *Brennan v. Occupational Safety &*

Health Review Commission and Underhill Construction Corp., 513 F.2d 1032 (2d Cir. 1975) (*Underhill*); *Marshall v. Knutson Construction Co.*, 566 F.2d 596 (8th Cir. 1977); *Beatty Equipment Leasing, Inc. v. Secretary of Labor*, 577 F.2d 534 (9th Cir. 1978). These cases involved citations for violations of 29 U.S.C.A. § 654(a), which imposes two duties on employers:

> Each employer—
>
> (1) shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees;
>
> (2) shall comply with occupational safety and health standards promulgated under this chapter.

In holding that the § 654(a)(2) duty could be violated even though the cited employer's employees were not shown to have been exposed to the hazard created by the violation, the *Underhill* court emphasized that the § 654(a)(2) duty, unlike the § 654(a)(1) duty, was "in no way limited to situations where a violation of a standard is linked to exposure of *his* employees to the hazard." 513 F.2d at 1038 (emphasis in original). In reaching its conclusion, the court relied on the broad remedial purpose of the Act and on the fact that the cited employer had created the hazard and maintained the area where it was located. In agreeing with this analysis, the *Beatty* court stated:

> [This interpretation of the statute] facilitates the broad remedial purpose of the Act which Congress declared is "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions." 29 U.S.C.A. § 651. As this court has stated, "Congress clearly intended to require employers to eliminate all foreseeable and preventable hazards." [citation omitted] We agree with the Commission that this policy can best be effectuated by placing the responsibility for hazards on those who create them.

577 F.2d at 537. The duty on one employer to comply with OSHA standards for the benefit of employees of another employer, however, has only been expressly recognized in the multiemployer construction worksite context.

In deciding whether an OSHA standard can require an employer to assure that a warning label remains affixed when a benzene-containing product leaves his workplace in order to protect downstream employees, we too must keep in mind the Act's overall purpose "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions." 29 U.S.C.A. § 651(b). In this light the provision of the statute requiring OSHA to prescribe labeling of hazards is broad in scope:

> Any standard promulgated under this subsection shall prescribe the use of labels or other appropriate forms of warning as are necessary to insure that employees are apprised of all hazards to which they are exposed . . .

29 U.S.C.A. § 655(b)(7). Unlike some sections of the Act, this provision does not expressly limit the employer's obligation of informing employees of hazardous conditions to the employer's own employees.

The ability of downstream employers to protect their own employees is also an appropriate consideration in determining where the duty to warn should lie. *Cf. Anning-Johnson Co. v. Occupational*

Safety and Health Review Commission, 516 F.2d 1081, 1086–91 (7th Cir. 1975). This record reveals that the presence of benzene in a workplace is often a hidden hazard. Some industries refer to benzene under code or trade names, and many products containing benzene are sold only under trade names with no listing of contents. Under such circumstances it is apparent that the manufacturer of a benzene-containing product is in a far better position to warn downstream employees in operations using the benzene-containing product of the benzene hazard than is a downstream employer.

Considering the purpose of the Act to protect every working person in the nation, the express and broad statutory authorization for OSHA to prescribe warning labels in standards, and the fact that the presence of benzene in a product is often a concealed hazard, we agree with OSHA that it has the authority to prohibit an employer from removing the warning labels from containers of benzene and benzene products when those containers leave his workplace. This is not a situation where OSHA is imposing a heavy regulatory burden on an employer solely for the benefit of the employees of another. Rather, the regulation says no more than that an upstream employer may not take affirmative steps to withdraw from downstream employees a protection that he must furnish to his own employees. The obvious reluctance of the maker of a product to intimate or suggest to his consumers that his product is less than totally desirable is understandable. Such a consideration may even be shown to have such deleterious effect on sales that it affects the reasonable necessity for this feature of the regulation. *See, Aqua Slide*, 569 F.2d at 840–43. In such a case, OSHA may choose to eliminate the requirement altogether. It may also choose to moderate the label's description to more precisely describe the nature or extent of the hazard.

Placing the responsibility to warn downstream employees of concealed hazards on those upstream employers who create the hazards and know of the hazards is consistent with the remedial purpose of the Act and is within OSHA's broad authority to prescribe warning labels. If on remand OSHA decides to promulgate a new benzene standard which includes warning labels, OSHA may require an employer in the chain of distribution of those products to assure that such warning labels remain affixed when the product leaves the employer's workplace, provided, of course, the labeling requirement as a whole is shown to be reasonably necessary to provide safe workplaces.

The user petitioners also contend that OSHA's authority to require labeling of products containing benzene has been preempted under 29 U.S.C.A. § 653(b)(1)[28] by the Consumer Product Safety Commission, which has promulgated regulations under the Federal Hazardous Substances Act, 15 U.S.C.A. § 1261 *et seq.*,[29] requiring the labeling of products containing benzene. *See* 16

28. 29 U.S.C.A. § 653(b)(1) states:

> Nothing in this chapter shall apply to working conditions of employees with respect to which other Federal agencies . . . exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health.

29. The Consumer Product Safety Commission has authority to promulgate regulations under the Federal Hazardous Substances Act by virtue of 15 U.S.C.A. § 2079.

C.F.R. § 1500.14(a)(3), (b)(3) (1977). We reject this argument. The preemption provision was intended to avoid the "duplication that would result where another federal agency was also providing for the occupational safety of a class of workers." *Organized Migrants in Community Action, Inc. v. Brennan*, 172 U.S. App.D.C. 147, 153, 520 F.2d 1161, 1167 (1975). It applies only when the preempting regulation is "directed at a working condition," *Southern Pacific Transportation Co. v. Usery*, 539 F.2d 386, 391 (5th Cir. 1976), which the promulgating agency has authority to regulate. The Consumer Product Safety Commission's regulation is not designed to protect a class of workers and it is not directed at the working conditions of employees. Although an existing requirement for labeling under another act may affect the reasonable necessity for an OSHA requirement, 29 U.S.C.A. § 653(b)(1) does not prohibit OSHA from requiring containers of benzene products to bear the warning labels authorized by 29 U.S.C.A. § 655(b)(7).

Conclusion

The petitions for review are granted. The reduction of the airborne permissible exposure limit from 10 ppm to 1 ppm is set aside since the present record does not show that such a reduction is reasonably necessary to provide safe or healthful employment. The dermal contact prohibition is set aside since this provision was not based on the best available evidence or the latest available scientific data in the field. The remaining provisions of the standard are also vacated since they are ancillary to the permissible exposure limit reduction and the dermal contact prohibition.

Adm. Office, U.S. Courts—West Publishing Company, Saint Paul, Minn.

Appendix C - AIHC, A Proposal To Achieve A Cohesive, National Cancer Policy, Exhibit 62

A PROPOSAL TO ACHIEVE

A

COHESIVE, NATIONAL CANCER POLICY

Summary: The essence of AIHC's proposal for achieving a more cohesive, national cancer policy is to recognize that the determination of whether a material is carcinogenic or not, and its potency, involve scientific, rather than regulatory judgments. We believe these determinations should be made by a panel of eminent scientists selected by the National Academy of Science. This panel would be located somewhere in government (e.g., HEW, OSTP, etc.) to serve on a continuing basis with appointed members serving terms of two-to-four years. The panel would have its own staff. While not making a specific recommendation as to where the panel should be housed, AIHC believes that the panel should be located separate from the various agencies whose regulatory actions would be affected by the panel's determinations.

The panel's cancer determinations would be binding upon the various regulatory agencies, but these determinations would be limited to scientific issues and would not intrude upon the regulatory responsibilities of the individual agencies involved. We recognize that these regulatory responsibilities, quite properly, do differ from one agency to another.

American Industrial
Health Council
5/24/78

A PROPOSAL TO ACHIEVE

A

COHESIVE, NATIONAL CANCER POLICY

Data Evaluation and Classification Panel: Determinations of carcinogenicity and potency are scientific, not regulatory issues. These determinations should be made:

1. Outside of regulatory authorities, such as OSHA.

2. Based on the critical, scientific evaluation of all available data.

3. By a panel of appropriately qualified and experienced scientists.

The American Industrial Health Council (AIHC) proposes that a Data Evaluation and Classification Panel ("the Panel") should be established to ensure the scientific validation of the determinations and to promote efficiency, consistency, and accuracy in the regulatory process. At the outset, the Panel would serve OSHA's purposes, but AIHC intends that it would come to serve other regulatory agencies as well in determining whether a material is carcinogenic or not, and its potency. Ideally, new legislation would be the best method to create the Panel. It could, however, without awaiting legislation, be created by Executive Order issued pursuant to the Reorganization Act of 1977, 5 U.S.C. § 901 et seq. (See Attachment I).

The Panel's determination of carcinogenicity classification would be administratively final (subject to appropriate judicial review). OSHA (and other regulatory agencies) would then proceed to assess occupational health hazards, and other pertinent matters and define necessary controls or priorities for regulation based on the Panel's determination and the agency's hazard assessment.

The Panel would consist of nine members, representing a cross-section of expertise and experience in disciplines such as toxicology, pharmacokinetics, cancer research and therapy, epidemiology, and occupational medicine. Candidates would be proposed on the basis of scientific expertise and professional qualifications by relevant professional groups such as:

National Cancer Institute

The Society of Toxicology

American Chemical Society

American Academy of Occupational Medicine

American Academy of Veterinary Pathologists

American Occupational Medical Association

American Cancer Society

American Industrial Hygiene Association

American Academy of Industrial Hygiene

Panelists would be selected from the candidate list by the National Academy of Science to serve with staggered appointments for terms from two-to-four years. They would not serve on any other government panel, committee, or agency during their service on the Panel. The Panel would have a staff. The Panel and staff would be housed within HEW, OSTP, the NAS or, perhaps, some other organization agreeable to the Interagency Regulatory Liaison Group (IRLG). The Panel would be substantively independent of whatever organization in which it may be housed.

It is proposed that the Panel would apply the Classification Categories and criteria recommended by AIHC 1/, but could revise them from time to time, upon public notice and opportunity to be heard in accordance with the rulemaking provisions of the Administrative Procedure Act. The Panel would, in appropriate circumstances, classify, reclassify, and declassify chemical substances.

Categorization: The Panel shall determine whether to assign a chemical substance to one of the following categories: Known Human Carcinogen; Confirmed Animal Oncogen; and Substances for Further Testing. Such assignment shall be accomplished as soon as possible following receipt of information, by petition or otherwise, that the Panel judges warrants consideration of making an initial categorization or of changing an existing categorization.

In deciding the order in which to categorize various chemical substances, including those listed in the NIOSH subfile of suspect carcinogens, the Panel shall give priority to those alleged or appearing to be known human carcinogens or confirmed potent animal carcinogens, and shall consider the total available literature and industrial history for the substance.

1/ AIHC Recommended Alternatives to OSHA's Generic Carcinogen Proposal, February 24, 1978 (pp. 60-85). OSHA Docket No. H-090.

It is suggested that the Panel shall use the criteria developed in AIHC's Recommended Alternatives to OSHA's Generic Carcinogen Policy proposal (pages 60-85), for categorizing chemical substances or other agents. The Panel may from time to time propose revisions of the categorization scheme or the criteria, in light of scientific advancements, additional information, or experience with the categorization scheme. Reasonable notice of intended changes and an opportunity to comment are to be afforded the public, in accordance with the Administrative Procedure Act.

Operating Procedures: Requests for an initial categorization or to change an existing categorization are to be submitted to OSHA, and OSHA will initially determine whether any proposal warrants fruther consideration. In having OSHA rather than the Panel make the initial determination of the merit of a submission, AIHC is concerned that the Panel not be overburdened with frivolous submissions.

If OSHA determines that data submitted warrants consideration of an initial categorization, it will publish notice of receipt of that data in the Federal Register together with a request for written comments or data bearing on the categorization. (OSHA can also initiate a Panel classification in the absence of a request.) After an adequate comment period, time would be allowed for responses to comments submitted by other persons, although on a more expedited schedule (perhaps like a briefing schedule). The Panel may also seek its own data from other government agencies, private and other public sources, etc.

With respect to the time periods allowed for submission of comments and for Panel decisions, AIHC is concerned that there be adequate time for valid scientific deliberation and felt it would be preferable that a fixed time limit not be prescribed. Rather, AIHC recommends that as much time as practicable be allowed in each instance with the intention that the Panel is to make its decision as expeditiously as possible, consistent with the urgency of the review, the quality of the data available, and as allowed by procedures developed to guide the Panel in its efforts to achieve scientifically sound, equitable determinations.

AIHC does not recommend that the Panel hold public hearings, because such hearings could impose additional time demands upon Panel members and potentially subject the Panel's determinations to undue influence. While not explicitly recommended, it is recognized that the Panel's meetings will, in all likelihood, be public, and procedures will have to be developed so the Panel's determinations have a public record (e.g., summary minutes), but AIHC recommends against transcribing Panel deliberations. The Panel should have the right to close certain meetings. However, AIHC believes that operating procedures for the Panel are

extremely important, both in making changes in criteria and in determining individual categorizations. The operations of NCI can serve as a possible model.

AIHC expresses strong concern for the confidentiality of information submitted to the Panel; however, AIHC recognizes that confidentiality of information may be limited by the provisions of the Freedom of Information Act, the Government in the Sunshine Act, and other statutes.

Status of Panel Recommendations: The Panel's categorization of a chemical substance would be administratively final, subject to appropriate judicial review. The Panel's determinations and the reasons therefor would be provided to OSHA and published in the Federal Register.

Future Panel Activity: AIHC recommends that the Panel initially make carcinogenicity determinations only with respect to OSHA. However, it believes that the Panel should be structured with a view towards having it at some future time make carcinogenicity determinations for other agencies (such as FDA, EPA, and CPSC) in order to promote consistency. (It is recognized the Panel will have a major role in structuring its own operating procedures. How the Panel operates in executing its responsibilities will depend to a great extent on the nature, background, and composition of its members.)

Location: AIHC does not recommend a particular organization for locating the Panel within government, believing this can be better decided by the Administration. However, the National Research Council has recommended the following:

> "The decision to inform those in affected workplaces of the hazard of a chemical is not to be taken lightly, as it involves the commitment of substantial resources. For that reason we believe it essential that a single national source, such as DHEW, be charged with making the decision that workers are at risk. This source 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 remote 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." 2/

2/ U.S. Department of Commerce: NTIS; PB-269-599 Informing Workers and Employers About Occupational Cancer (Prepared for OSHA); NRC - 6/77.

It may be that the concept for coordinating regulatory action, now served by IRLG, should become institutionalized, in which case the Panel could become a part of the resulting structure. Again, the Administration is probably in a better position to decide than industry is to recommend whether the function could be better located in HEW, OSTP, NAS or the Domestic Council, etc.; but the concept of separating the Panel from the regulatory bodies needs to be continually emphasized.

Organization: For a panel of nine rotating members, a permanent staff of three doctoral level professionals (e.g., toxicologists, epidemiologists, etc.), one lawyer, and two professional support technical personnel (e.g., writers, researchers, etc.), along with appropriate clerical and secretarial support, would seem a reasonable estimate for an organization formed to aid the Panel in its determinations.

Considering salary, benefits, travel, supplies, and space, as well as some allowance for consulting fees and computer time, it is estimated that the total cost to the government for the Panel would be about two-million dollars per year.

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May 9, 1978

Dr. Elwood P. Blanchard
Chairman, Alternatives Committee
American Industrial Health Council
1075 Central Park Avenue
Scarsdale, New York 10583

Dear Dr. Blanchard:

This letter is in response to your request for our opinion on whether the process of executive branch reorganization could be utilized to transfer the authority to classify and categorize chemical substances with respect to carcinogenicity from those agencies which would otherwise exercise such functions to an independent panel of scientists located somewhere within the executive branch. While the panel would be headquartered within an existing governmental entity, it would be independent of regulatory bodies such as the Occupational Safety and Health Administration, the Consumer Product Safety Commission, the Environmental Protection Agency, and the Food and Drug Administration, and its determinations would be binding upon all such agencies.

On the basis of our research, we have concluded that those classification and categorization functions currently vested in a regulatory agency within the executive branch, such as OSHA, could be transferred to the panel, provided the panel were not established as a new "executive department or independent regulatory agency." We have also concluded that the President's authority under the Reorganization Act of 1977 (the "Act"), 5 U.S.C.A. § 901 et seq., includes the power to transfer functions vested in an independent regulatory agency such as the Consumer Product Safety Commission, provided the reorganization plan does not abolish that agency, transfer all its functions to another agency, or consolidate it with another independent regulatory agency.

The President's power to reorganize the executive branch is derived from the Reorganization Act of 1977, 5 U.S.C.A. § 901 et seq. Section 903(a) of the Act authorizes the President, after investigation and whenever he finds it necessary to carry out any of the policies enunciated in § 901(a),[1] to prepare a reorganization plan. Such a plan may provide for:

1/ Section 901(a) provides:

The Congress declares that it is the policy of the United States --

(1) to promote the better execution of the laws, the more effective management of the executive branch and of its agencies and functions, and the expeditious administration of the public business;

(2) to reduce expenditures and promote economy to the fullest extent consistent with the efficient operation of the Government;

(3) to increase the efficiency of the operations of the Government to the fullest extent practicable;

(4) to group, coordinate, and consolidate agencies and functions of the Government, as nearly as may be, according to major purposes;

(5) to reduce the number of agencies by consolidating those having similar functions under a single head, and to abolish such agencies or functions thereof as may not be necessary for the efficient conduct of the Government; and

(6) to eliminate overlapping and duplication of effort.

Centralization of all authority to classify and categorize chemical substances for carcinogenicity in the panel would arguably further a number of these policies, including the promotion of economy and efficiency, the coordination and consolidation of governmental functions according to major purpose, and the elimination of overlapping and duplication of effort.

(1) the transfer of the whole or a part of an agency, or of the whole or a part of the functions thereof, to the jurisdiction and control of another agency;

(2) the abolition of all or a part of the functions of an agency, except that no enforcement function or statutory program shall be abolished by the plan;

(3) the consolidation or coordination of the whole or part of an agency, or of the whole or a part of the functions thereof, with the whole or a part of another agency or the functions thereof;

(4) the consolidation or coordination of a part of an agency or the functions thereof with another part of the same agency or the functions thereof;

(5) the authorization of an officer to delegate any of his functions; or

(6) the abolition of the whole or a part of an agency which agency or part does not have, or on the taking effect of the reorganization plan will not have, any functions.2/

Section 903(a) does not explicitly authorize the President to prepare a reorganization plan which creates a new entity such as the classification panel. The President can transfer the functions of an "agency"3/ to the jurisdiction and control of another agency, or consolidate and

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2/ A reorganization plan becomes effective sixty calendar days of continuous Congressional session after the President transmits the plan to Congress, unless either house passes a resolution disapproving the plan within that time. Section 906(a).

3/ "Agency" is defined, for purposes of the Reorganization Act, as

"(A) an executive agency or part thereof; and
"(B) an office or officer in the executive branch".

§ 902(1). It appears that OSHA, CPSC, EPA, and FDA would all constitute "agencies" under the Act, and that their functions could therefore be transferred to the panel. The question of whether the Act authorizes the President to transfer functions vested in independent regulatory agencies such as CPSC is considered in more depth below. The National Academy of Sciences, however, probably does not constitute an "agency", as is also discussed more fully below.

coordinate agencies and their functions with the whole or part of another agency or its functions. Whether such a transfer or consolidation can be made with respect to a new entity as well as an existing agency is not apparent on the face of the statute.

We believe, however, that the President's authority under § 903(a) does encompass the transfer of functions to a newly created entity such as the classification panel. The Act, in § 905(a)(1), clearly prohibits a reorganization plan from creating a new "executive department or independent regulatory agency." Since you do not propose that the panel be established in the form of a new "executive department or independent regulatory agency", but rather as an independent body housed within an existing department or agency,4/ the

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4/ It should be noted that the National Academy of Sciences is probably not an "agency" for purposes of the Reorganization Act, and thus § 903(a)(1) would not authorize the transfer of agency functions to a subdivision of that corporate entity. This conclusion is based on Judge Sirica's opinion in Lombardo v. Handler, 397 F. Supp. 792 (D.D.C. 1975), affirmed, 546 F.2d 1043 (1976), cert. denied, 431 U.S. 932 (1977). The court held there that NAS was not an "agency" for purposes of either the Federal Advisory Committee Act ("FACA"), 5 U.S.C.A. App. I, or the Freedom of Information Act ("FOIA"), 5 U.S.C.A. § 552. Both statutes define the term "agency" broadly. Under the FACA, which incorporates the definition used in the Administrative Procedure Act, 5 U.S.C.A. § 551(1), an "agency" is "each authority of the Government of the United States, whether or not it is within or subject to review by another agency." Under the FOIA, an "agency" includes "any executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency." 5 U.S.C.A. § 552(e). Despite the fact that NAS was established by Act of Congress, reports to Congress, is obligated to perform investigations for the departments of the federal government when requested, and is subject to limitation by Congress with respect to the amount of real estate it may acquire, the court held that it was not an agency for purposes of either the FACA (and thus, by extension, of the APA) or the FOIA. The Court found it significant that NAS' decisions were not binding on EPA (another reason why NAS appears to be an inappropriate place in which to locate the classification panel), that it does not exercise "substantial independent governmental authority", that it neither functioned under nor was created by Congress or the President, and that no significant government control of the corporation could be shown.

limitations of § 905(a)(1) would not seem to apply.[5/]

The legislative history of the Act supports this analysis. Senator Ribicoff, one of the floor managers of S. 626, which was eventually enacted as the Reorganization Act, expressed the view that the legislative purpose was to grant broad reorganization authority to the President. He stated in floor debate that

> "[b]y authorizing the President to propose plans to reorganize the government any way he deems best, the Act permits the President to change the way the government operates. He may transfer and consolidate any functions he wishes, or make any other changes in the government's organization short of abolishing the programs themselves."[6/]

(123 Congressional Record S. 3438 (March 3, 1977) (Emphasis added).)

5/ It should be noted that the Reorganization Act contemplates that a private group such as the American Industrial Health Council may suggest a reorganization plan to the President, since § 901(c) provides that

> [i]t is the intent of Congress that the President should provide appropriate means for broad citizen advice and participation in restructuring and reorganizing the executive branch.

6/ The House debate reflects the same sentiment. For example, Mr. Brooks responded affirmatively to the following question of Mr. Kazen:

> "[Can] the President reorganize several agencies, either put them together or separate functions or do whatever he wants to, but reorganize various agencies at one time under one package that he would submit to the Congress?"

Id. at H. 2668. (Emphasis added).

More specifically, Senator Ribicoff also stated that:

> "[u]nder the reorganization authority that would be renewed by this bill, the President may propose to create or eliminate agencies, and transfer functions between agencies. The Act specifically prohibits the use of the reorganization authority, however, to create or abolish cabinet-level departments of the government. For that, regular legislation will continue to be required." (Id. (emphasis added).)

Senator Muskie agreed that the bill "will give the President the authority to create or abolish agencies and to transfer functions between agencies unless one house of Congress disapproves within 60 days."7/ (Id. at S. 3445).

Thus, it would appear that the President has sufficient authority under the Act to vest classification and categorization functions with the independent panel, provided it is established as an executive agency or part thereof or as an office in the executive branch, but not as a new executive department or independent regulatory agency.

You have also asked us to consider whether the President's reorganization authority includes the power to transfer to the panel functions currently vested in independent regulatory agencies, such as the Consumer Product Safety Commission.8/ It is our conclusion that the President is

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7/ Senator Percy, the other floor manager in the Senate, stated that reorganization plans "cannot create, abolish, or transfer an executive department or an independent regulatory agency," id. at S. 3440, but he did not say the President was prohibited from creating a body like the proposed classification panel at other than the cabinet level, as a division of another department or agency. Moreover, Senator Percy clearly stated that realignment of functions "within or among" agencies was permissible. Id.

8/ It is the opinion of the Office of Management and Budget that CPSC, but not EPA, is an "independent Federal regulatory agency," at least for purposes of the Federal Reports Act, 44 U.S.C.A. § 3502. See OMB Circular No. A-40 and Attachment A thereto (November 5, 1976).

authorized by the Act to transfer functions vested in an independent regulatory agency to another agency, provided the reorganization plan does not abolish the independent regulatory agency, transfer all its functions to another agency, or consolidate it with another independent regulatory agency.

As we have discussed above, the President is authorized by the Act to prepare a reorganization plan which provides for "the transfer of the whole or a part of an agency, or of the whole or a part of the functions thereof, to the jurisdiction and control of another agency." (§ 903(a)(1)). The term "agency" is defined to mean

> "(A) an Executive agency or part thereof; and
> "(B) an office or officer in the executive branch."

(§ 902(1)). Since an independent regulatory agency is an Executive agency,9/ the President is authorized by § 903(a)(1) to transfer the functions of such an agency to another agency.

The Act's express limitations on the President's power do not alter this conclusion. A reorganization plan may not provide for or have the effect of

> "abolishing or transferring an...independent regulatory agency, or all the functions thereof, or consolidating two or more...independent regulatory agencies, or all the functions thereof." (§ 905(a)(1)).

However, this provision appears to prohibit only those reorganization plans which transfer all of the functions of an independent regulatory agency to another agency. The transfer of less than the totality of such functions would thus be appropriate.

This interpretation of the limiting provisions of § 905(a)(1) is confirmed by the discussion of that section contained in the House Report on the Act. (H. Rep. No. 95-105, Extension of Reorganization Authority of the President, 95th Congress, 1st Session (1977), hereinafter referred to as the "House Report"). The Act's treatment of independent regulatory

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9/ Cf. Acron Investments, Inc. v. Federal Savings and Loan Insurance Co., 363 F.2d 236 (9th Cir.), cert. denied, 385 U.S. 970 (1966) (concluding that because FSLIC was subject to more than "custodial or incidental" congressional control, and was deemed by statute to be included within the Home Loan Bank Board, an "independent agency" and "an instrumentality of the United States", FSLIC was an "agency" for purposes of 28 U.S.C. § 1345, which establishes jurisdiction in federal district courts of all civil actions commenced by any "agency" of the U.S.)

agencies was explained as follows:

> "Under the expired reorganization authority, independent regulatory agencies were treated as other agencies in the executive branch, and they were subject to reorganization in the same manner. The bill recognizes the unique status of independent regulatory agencies and their special relationship to the Congress by providing that the whole of independent regulatory agencies or all of their functions may not be abolished or transferred nor may two or more such agencies or all their functions be consolidated. This does not mean that such agencies are totally exempt from reorganization authority, but such authority is limited as described heretofore." (House Report, at 8 (emphasis added).)

Thus, the President can transfer functions currently vested in an independent regulatory agency, as long as the reorganization plan does not abolish that agency, divest it of all its functions, or consolidate it with another such agency.

The authority granted to the President under the Reorganization Act is, with some modifications, an extension of the same authority granted to previous presidents periodically since enactment of the Reorganization Act of 1949. Past use of reorganization authority may thus be an indication of the scope of power granted by the present Act. For example, in the Senate Report on the extension of reorganization authority enacted in 1971, a letter from OMB to the Senate is quoted, stating that among the significant uses the President had made of this power in the past was the creation of: a new Office of Telecommunications Policy in the executive office of the President through the transfer of certain functions from the Office of Emergency Preparedness; a new Domestic Council to deal with questions regarding the authority of OMB; a new separate Environmental Protection Agency bringing together key programs for setting environmental standards and abating pollution; and the National Oceanic and Atmospheric Administration in the Department of Commerce, assembling major programs for dealing with environmental problems. The letter further states that Congress allowed all these measures to become effective. (S. Rep. No. 920485 92d Cong., 1st Sess., reprinted in [1971] U.S. Code Cong. & Ad. News 2081, 2089-90).

One further point in favor of broadly construing the 1977 Act to allow the establishment of the classification panel is that if the Congress feels that the President has exceeded the scope of the authority delegated to him, it can reject the plan by passing a resolution of disapproval in either house.

Very truly yours,

CLEARY, GOTTLIEB, STEEN & HAMILTON

presented for the purpose of drawing conclusions or inferences. The analytic method should be presented clearly and in sufficient detail to enable the reader to fully understand the calculations and to accept, as appropriately applied, the procedures or techniques utilized. The following categories are suggested as a guideline for use in describing the analytic method employed in an epidemiologic investigation or report being critically evaluated.

A. Data Presentation

1. Summary data and their derivation supporting the major conclusions reached in the text should be adequately presented in tables, graphs, etc.
2. Data displays (graphs, tables, etc.) should be clearly defined and labeled.
3. Data presented should be internally consistant.

B. Data Analysis

A description of the rationale for the major analytic procedures used should be provided, either in the text or in noted references. These procedures may include:

1. Statistical methods used - rates, proportions, person-years, indices of association, and summary statistics such as, standardized mortality ratios, proportionate mortality ratios, relative risks, attributable risks, standardized morbidity ratios and confidence limits.
2. Significance tests employed - Chi-square, "t" test, etc.
3. Statement of the α and β error levels selected and the

minimum excess risk the study is designed to be able to detect.

4. Analytic methods - analysis of variance, regression, survivorship analysis, etc.
5. Methods for handling confounding variables - matching, adjustment (direct or indirect), stratification, etc.

III. Evaluation of Results and Their Interpretation

A. Hypothesis Testing - The author's conclusions and interpretations should be clearly stated. The hypothesis to be tested should be appropriate to the data base and the analytic method used. Additional hypothesis tested from the same data base should be indicated. The findings should be internally consistent and presented in sufficient detail to allow for judgment of the validity of the results. The description of the study population and comparison groups and their exposures should justify a reasonable conclusion that their significant difference is the result of their exposure to the item under consideration. The individual case histories should relate closely to the tested hypothesis. The reviewers should be able to determine whether the hypothesis the author is actually testing is the same as the hypothesis that was initially stated.

B. Limitations - All studies have limitations inherent in the type of data collected and the analytic methods used. Further limitations are introduced in the carrying out of the study because of the inability to collect all the desired data and

because of the difficulties of adjusting for confounding variables. The analytic method and data reduction may limit the testing of the desired hypothesis, assuming that the study has sufficient power (defined in D below) to test the hypothesis. The authors should frankly discuss the limitations of their own study.

C. Bias - Bias may be introduced in a study by the choice of the criteria that define the study population and observation period, the looseness of definition of the health effect evaluated, the procedural differences in counting health effects among the various risk groups to be compared, the care with which each aspect of the study is professionally carried out. It is of utmost importance that the criteria defining the study population and the observation period be established independent of knowledge of the characteristics of the individuals demonstrating the health effect and prior to the conduct of the study.

D. Power - The power of a study is dependent upon the size of each population, the frequency of the event being observed, as well as the difference in frequency of events among the various groups to be compared. The power of a study is the likelihood that it could observe a given frequency of an event or outcome at a given level of statistical significance. A typical power statement might be that, if the real frequency in the study population were twice that of the comparison population, the study would have had an 80% chance of observing a difference that is significant at the 0.05 level (two-tailed test).

Whether a study observes an excess or not, it should indicate the confidence limits of its result. These confidence limits will indicate the probable range of values which might exist for the real frequency (based on the observed frequency) and will indicate the probability that the real frequency will be within that range. A study is classically considered to be "positive" (show an effect) when the upper confidence limit of the frequency in the comparison population falls below the lower confidence limit of the frequency in the study population and this difference is not explained by the study's limitations, biases, or confounding variables.

PART B - Use of Epidemiologic Studies in Evaluating Human Risk from Occupational Exposure

I. Judgment on Utility of Specific Study

Based on a review of the description of the study conducted and the analytic methods used and an evaluation of the study's results and interpretation, it may reasonably be concluded that a particular study has been well conducted and has demonstrated a rejection or acceptance of a specific hypothesis.

An additional judgment has to be made placing this study in the context of the results of other epidemiologic studies, biological knowledge (particularly concerning the health effect of this substance) and knowledge of use and exposures of the substance under consideration. Such professional judgments are necessary for determining the likelihood of a significant health risk for a specific exposure.

An individual study may or may not demonstrate that an increased risk of a specific health effect is statistically associated with a specific exposure. Additional studies may indicate the effect to be attributable to the exposure. Judgment on the causal and dose relationships of a substance depends upon the totality of epidemiologic, toxicologic, biologic, and industrial hygiene data. The utility of each specific study in assisting in that judgment must be determined.

II. Consistency with Other Epidemiologic Data - The conclusions based on published and unpublished reports and studies of human experience with the compound must be compared. Inconsistencies and contradictions must be identified and explained. "Positive" epidemiological studies can be used to estimate the magnitude of risk of a specific health outcome from a specific exposure. "Negative" epidemiological studies can be used to calculate an upper limit to the estimate of human risk. "Positive" and "negative" epidemiologic studies may be compatible, based on their exposure ranges and their sensitivities. A critical review of "positive" and "negative" studies may identify situations in which excess risk may be observed, situations in which excess risk is unlikely to be observed, and situations in which the evidentiary probability would indicate that either there is a small likelihood of the substance causing the health effect or that the substance is only weakly able to cause the health effect.

III. Biologic Consistency - A specific study may indicate a particular substance is associated with an excess frequency of a certain health effect. Before concluding that the excess frequency is attributable to that exposure or caused by that substance, it is necessary to develop additional information demonstrating the biological reasonableness of the hypothesis. Consistency with animal studies or other laboratory studies including human pathology must be considered and inconsistencies explained. Cases where human epidemiologic studies do not support the conclusions of laboratory studies, particularly of non-human animal studies, call for further evaluation of each study. The laboratory studies should be reproduced and extended. Additional epidemiologic studies should explore various human experiences with the substance. Differences in human and non-human animal responses to exposure may reflect differences in exposure dose or route or differences in metabolic handling or sensitivity, the further study or which may be necessary. Until such differences are resolved an estimate of human risk or at least an upper limit to the estimate of human risk can be calculated from the human epidemiologic data.

IV. Dose-Relationships - The totality of human and animal studies should be reviewed to determine the degree of relationship between the dose of the substance and the frequency of the observed health effect. A direct dose-effect relationship showing increased excess frequency of health effect with increasing dose of substance

would greatly strengthen the judgment that the substance is responsible for the excess health effect. Linear or curvilinear characteristics of the relationship should be evaluated. Additionally, review of the dose-effect relationship may indicate exposure levels at which an excess frequency of the health effect would be very unlikely.

Judgments have to be made as to when exposures may have effects whose significance may be theoretical, statistical, biological, or clinical.

V. Risk Assessment - The final determination of the health effect risk of occupational exposure to a given substance will depend upon:

(1) a determination that there is a specific increased risk of an identifiable health effect from exposure and that this risk increases with increased exposure level;

(2) an estimate of the magnitude of the health risk at specific exposure levels; and

(3) an estimate of the number of workers who would be occupationally exposed to the substance at different levels.

An estimate can be made of the magnitude of the total risk from occupational exposure and from exposures above certain levels. Thus, an estimate can be made of the magnitude of the benefits to be gained (reduction of risk) from establishing different levels of maximally permitted exposure. These potential benefits can be compared with the estimated feasibility and cost of their attainment.

Appendix E

EPA's Seventeen "Principles"*/

1. "Cancer is a major and increasing cause of death and morbidity in man. It imposes upon society an immense burden of death, suffering and economic loss."

2. "Cancer may be induced by many factors including exposure to chemicals."

*/ These principles are set out in a Motion To Take Official Notice of Certain Facts filed by EPA on June 27, 1975 in a proceeding to suspend the registrations of pesticides containing heptachlor and chlordane in In Re Velsicol Chemical Corporation, FIFRA Docket No. 336 et al. The principles are also set out in a slightly revised form in the EPA Administrator's Notice of Intent to Suspend the Registrations of Pesticides Containing Heptachlor and Chlordane, 41 Fed. Reg. 7552, 7554 (February 19, 1976).

"Policy Determinations" and "Concepts" on Which OSHA Relies in its Cancer Policy Proposals**/

"Cancer is a particularly dreaded and costly disease." (42 Fed. Reg. at 54149)

"The economic and social impacts of cancer in the United States are massive. . . ." (42 Fed. Reg. at 54150)

"[H]eart disease and cancer . . . now lead the nation's list of killers."

"Among the causes of cancer, those most prominent are believed to be traceable to environmental factors singularly or in conjunction with genetic or other substitutes."

* * * *

"The extent to which the observed incidence of cancers are attributable to man made chemicals cannot be estimated with any precision." (42 Fed. Reg. at 54150)

**/ 42 Fed. Reg. 54147 (October 4, 1977).

3. "Chemical carcinogenesis is characterized by a long latency period which in humans may be as long as 20, 30 or 40 years between exposure and the appearance of symptoms of the disease."	"In man . . . the latent period of chemical carcinogens is often as long as a major portion of a lifetime . . . It has been found to be as long as 15, 20, 30 or more years in man. . . ." (42 Fed. Reg. at 54152)
4. "Once a carcinogenic response has been triggered the development of cancer is irreversible."	"Following [initiation of a neoplastic change in a target cell], exposure to the carcinogen is no longer required to maintain the initial alteration that leads ultimately to a cancer cell, which is then capable of autonomous growth. Thus a single biological event produced by a very small number of molecules of the carcinogen may be sufficient to initiate the irreversible development of a tumor." (42 Fed. Reg. at 54152)
5. "Given the long latency period of cancer and its irreversibility, in the case of a chemical for which there is widespread human exposure and thus no adequate control group it is virtually impossible to determine a carcinogenic effect by direct observation in man."	"The long latency period between exposure and symptoms [in man] and the irreversibility of the disease often makes it medically and scientifically impossible to identify carcinogens in the environment." (42 Fed. Reg. at 54156)
6. "The use of experiments with animals to test chemicals for carcinogenic hazard to humans is accepted by the scientific community and by public policy-making agencies in the United States."	"The validity of using animal data as a qualitative indication of potential human effects has long been recognized by scientific advisory committees and other governmental bodies. . . ." (42 Fed. Reg. at 54157)
7. "Mice and rats are preferred experimental animal species for carcinogenesis	"OSHA relies in general only upon results found in testing of mammalian

	testing because their relatively short lifespan permits lifetime testing covering the entire latency period of tumors within a reasonable time, and because the development of tumors in these species is well known."	species. In that regard, the rat and mouse (and to a lesser extent the hamster) have traditionally been the species of choice for carcinogenicity testing. . . ." (42 Fed. Reg. at 54160)
8.	"All chemicals known to cause cancer in man with one exception have been shown to cause cancer in animals, especially mice and rats."	"All chemical substances or mixtures that have been proven carcinogenic by direct observation in man have also been shown to be carcinogenic in experimental animals (with the possible exception of arsenic and benzene, still under experimental study)." (42 Fed. Reg. at 54146)
9.	"Pathological development of chemically induced tumors in experimental animals and in humans is very similar."	"The choice of the rat and mouse is not only dictated by considerations of convenience but because of their known susceptibility to agents known to be carcinogenic in humans as well as the similarity in mechanisms of tumor induction." (42 Fed. Reg. at 54160)
10.	"Since the number of animals used in laboratory tests is extremely small when compared to the hundreds of millions of people who are involuntarily exposed to widespread chemical contaminants and since the variability of human response to chemical carcinogens is generally greater than that of laboratory animals, a positive oncogenic effect in any test animal is sufficient to characterize the chemical as posing a cancer risk to man and negative results in animal tests have only limited significance and should normally be superceded by positive results."	"[P]ositive results in tests with experimental animals . . . should generally supercede negative results, both because of the aforementioned insensitivity of laboratory bioassays conducted with limited number of animals, which may frequently lead to false negative results, and also because of interspecies differences in susceptibility." (42 Fed. Reg. at 54161)

11.	"A carcinogenic substance is one which increases benign or malignant tumors or neoplasia in exposed animals; shortens the latency period between the exposure and the development of tumors or neoplasia; or which results in unusual tumors."	"[A] toxic substance will be classified qualitatively as a 'potential occupational carcinogen' if . . . OSHA believes that it has been shown (a) to cause . . . an increased incidence of malignant or benign neoplasms . . . , or (b) . . . decreases the latency period between exposure and onset of neoplasm formation." (43 Fed. Reg. at 54169) "A presumption exists that a toxic substance shall be classified by the Secretary as a 'Category I Toxic Substance' if . . . the Secretary finds that any other evidence is sufficient to convince him that the toxic substance should be classified as a Category I Toxic Substance." (43 Fed. Reg. at 54185) "This basis is meant to include evidence, for example, of those substances that might possess a unique property, e.g., a substance that generates nonstatistically significant but extremely rare or unusual tumors. . . ." (43 Fed. Reg. at 54171)
12.	"Since many benign tumors can develop into cancers, for the purposes of carcinogenicity testing there is no valid distinction between the induction of benign or malignant tumors and they should be considered synonymous."	OSHA "proposes to place as much weight on an experiment in which only benign tumors are observed, as upon experiments in which both malignant and benign tumors are induced." (42 Fed. Reg. at 54163-64)
13.	"Chemical carcinogenesis is a specific biological process which is induced by a relatively few classes of chemicals. Thus, it is not true that all chemicals induce cancer at sufficiently high doses."	"[T]here has been [a] tendency for some to suspect that all chemicals are capable of causing cancer if administered to experimental animals at sufficiently high doses. This claim appears to be based on the belief that carcinogenesis

14. "High doses are administered in animal carcinogenicity tests because limited numbers of animals render the tests relatively insensitive to carcinogenic effects. Consequently, a substance which induces tumors at any dose level represents a warning signal of great significance."

15. "There is no scientific basis for the existence of a "no effect" level for carcinogens. In principle no dose of a chemical carcinogen is too small to induce tumors in susceptible individuals."

is a non-specific kind of biological process associated with any substance under the right conditions, namely that test animals, bred for their sensitivity to carcinogens, when fed maximum tolerated doses of a substance for their lifetime become very ill and may be more susceptible to carcinogenic effects. However, there is evidence that renders this suspicion very unlikely to be true.

* * * *

[T]he available evidence provides strong indication indeed that not all chemicals are capable of causing cancer and that only a small number of the total is so capable." (43 Fed. Reg. at 54151)

"The testing of chemicals at constant high exposure levels, at or approaching the maximum tolerated dose level, is not inappropriate and is indeed required to overcome the statistically insensitivity of laboratory bioassays conducted with the limited number of animals that can be handled in practical laboratory conditions." (43 Fed. Reg. at 54161 [see also definition of "potential occupational carcinogen" as a substance which is oncogenic "at any level of exposure or dose" -- Proposal § 1990.102]

"[A] no-effect or threshold level may theoretically exist for any specific carcinogen. As yet, however, there is no satisfactory scientific basis for determining such levels for any given population. Thus, as has been proposed,

16. "Carcinogens are not specific to particular test species, nor are they specific to certain strains of test species."

17. "Most carcinogens are not organ specific. Thus, a carcinogen which induces liver tumors in mice might, for example, produce mammary tumors in rats and lung tumors in humans."

any human exposure to a carcinogen . . . would be considered by OSHA to present a potential cancer risk as a policy matter." (42 Fed. Reg. at 54174)

"[A] chemical that causes cancer in one animal species is likely to do so in most other species tested." (42 Fed. Reg. at 54157)

"There can be no presumption that the organ affected in animal experiments would be that at risk in man." (43 Fed. Reg. at 54162)

Appendix F - An Excerpt From The AIHC Alternative Entitled "Health Program Management"

M. Health Program Management

The AIHC recognizes that there will be combinations of carcinogen classifications and risks/hazards that may differ for different chemicals - or will differ in each workplace for similar chemicals. In fact, the AIHC classification proposal, which contains 7 categories, when cross-referenced with only two risk/hazard levels will contain 14 different possible situations to be covered by a standard. For this reason the AIHC feels that the 2 or 3 model standards using a rigid format as proposed by OSHA are not appropriate. As an alternative we present basic principles which should be addressed in any standard, but which must be tailored to the classification - risk/hazard combinations which will be encountered in the workplace.

To ensure prompt and reasonable action to limit employee exposure to know or suspect carcinogens, and to ensure compliance with a permanent standard, each employer should prepare and implement a written plan. Because workplaces vary substantially in terms of how a substance is used, the number of employees present, the age of the plant, the duration, intensity, and frequency of exposure, and many other variables - it will often be appropriate for different employers to take different actions to reduce employee exposures to known or suspect carcinogens. A plan for compliance addresses the following item and delineates the actions to achieve the performance objectives stipulated therein. AIHC recommends that for each workplace the employer use the best practicable combination of engineering, administrative, and work practice controls, and personal protection.

Once regulatory action has been taken and OSHA has promulgated permissible exposure levels, OSHA should require employers to determine, for each workplace where a regulated substance is present, whether exposure levels higher than an action level are likely to be experienced. If the determination indicates the action level is likely to be exceeded, the employer should make measurements to confirm this estimate; if confirmed, he should prepare a plan which assures compliance with permissible exposure levels. A plan shall require use of engineering controls to the extent technically and economically feasible, augmented by administrative controls and personal protective equipment as appropriate. Where engineering controls are not incorported, the plan must show why that action was not practicable or applicable and thus show that the action had been considered.

The plan should be made available upon request to any affected employee or his designated representative. It should be made available to an OSHA compliance officer upon request during his inspection. Compliance with such a plan would not excuse failure to comply with a permissible exposure level. The requirement to prepare a written plan would be in addition to the requirement to comply with a permissible exposure level.

The plan should include training potentially exposed employees to ensure that they are informed of the nature of the potential hazard. Restricting certain areas to authorized personnel may be necessary. The indiscriminate use of signs and the word "cancer" on signs designating each such area can be

counter-productive with respect to health and safety.

Any well-conceived plan would consider additional factors such as qualified personnel placement and training, housekeeping, medical monitoring, protective equipment, emergency procedures, and exposure records, along with the engineering controls, monitoring and administrative controls mentioned above.

For employees who are exposed above action levels, the employer should include in his plan a medical program prepared with the guidance of a trained physician. The employer must inform the physician of the nature and category of any substance, and of the evidence underlying the classification. Where specific effects of a substance have been identified, medical tests for those effects should be integrated with any general medical program already provided by an employer.

N. Special regulatory approaches to laboratories construction, agriculture and transportation

In general, regulations appropriate for the industrial workplace are not appropriate for laboratories, whether quality-control, pure research, or some admixture of both. OSHA's failure to distinguish between laboratory and non-laboratory workplaces is unreasonable. OSHA's proposed requirements for laboratory workplaces could lead to the unintended consequences of impeding important research on cancer and other serious health problems.

AIHC believes that special regulations for laboratories are appropriate. Probably a single work-practices oriented regulation for laboratories would be sufficient.

Appendix G - AIHC Alternative Supplement On Risk Benefit Analysis

AIHC ALTERNATIVE SUPPLEMENT RISK/BENEFIT ANALYSIS

AIHC accepts the appropriateness of the regulatory process to deal with the problem of cancer control. OSHA's generic control initiative articulates but one response to its perception of a cancer problem.

However, this proposal does not include adequate risk evaluation procedures. We agree that except in a very few instances where reliable human epidemiology is available, workplace cancer risk to humans must be assessed on the basis of available animal experiments.

The first step in any regulatory attempt to deal with workplace cancer risks must be to conduct a risk assessment on individual chemicals. An established risk assessment policy within OSHA (but applicable to other agencies as well) which demonstrates a sound scientific and regulatory approach is essential to reduce the incidence of challenge by litigation.

A risk assessment conducted on all chemicals that have been judged carcinogenic in test animals by the Evaluation and Classification Panel will permit prioritization of these chemicals by comparing relative risks of each. This comparison includes consideration of potency, numbers of workers exposed, and exposure levels. Regulatory efforts to reduce workplace cancer risks must begin with the higher priority risks and proceed systematically to the lower priority risks. Risk assessment will also permit government and industry to determine the extent to

which various possible regulatory measures can in fact reduce the risk. It will afford a reasonable basis for determining goals for risk reduction by assessming the degree of risk presented in the workplace as contrasted with the degree of risk that we all face from chemials (natural or man-made) in our everyday lives.

The big problem for risk assessment arises from selection of an appropriate model for extrapolating animal dose/response data to man. The most conservative approach is a strictly linear extrapolation which some have asserted to be scientifically supportable in a limited number of cases but which frequently leads to totally impractical and inappropriate exposure levels for occupational, environmental, or personal care considerations. Broadly applied this would place an unjustified and excessive inflationary burden on the American public through loss of or increased cost of products.

In many cases a linear model is not the best fit to experimental data and should therefore not be used for extrapolation purposes. AIHC believes that different models may be more applicable in many cases. In no event should an agency foreclose the use of the best tool available in this developing period of scientific advances toward better understanding.

In the animal to man extrapolation process, consideration of equivalent dosages per body weight or surface area, fractions of food and water intake, appropriate multipliers for route of administration, and relating the length of exposure to life span for man and animal is in order.

Whenever confronted with a large group of chemicals classed as carcinogens, OSHA should be able to estimate a degree of risk for a broad range of chemicals rapidly and to publish an ordered listing of relative risks. This would provide industry and employees alike the opportunity to evaluate their particular situation at an early date to make the most effective use of resources in taking corrective actions.

Starting with the higher priority substances, OSHA and industry would then direct their efforts to exploration of all objective and subjective benefits and risk reduction methods for regulating any particular chemicals. These efforts would include a written statement by the agency of the magnitude of the risk, how it compares with other risks whether from chemicals or other sources in our society, the benefits from the chemical, and the incremental costs of various degrees of risk reduction.

Support for this logic process in regulatory matters concerned with human health is contained in several recently published deliberations of other government agencies. The Nuclear Regulatory Commission specifically embraced the concept of reasonably achievable health risk reductions on the basis of quantified cost-benefit analyses. (1) A further example is that contained in the Food and Drug Administration's risk assessment

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1. "Low Level Radiation Exposure," Federal Register, 42 (101), 22253-22254, May 24, 1978.

for aflatoxins wherein epidemiologic data were combined with extrapolated animal data and benefit-cost analysis to arrive at an acceptable tolerance level for those toxic materials in food. (2) Finally, most recently the Council on Wage and Price Stability has published a review of OSHA's analysis of the proposed permanent standards for occupational exposure to acrylonitrile. (3) The Regulatory Analysis Review Group confirms the need for methodologies cited above as a critical element of the regulatory process for the reduction of health risks.

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2. "Assessment of Estimated Risk Resulting from Aflatoxins in Consumer Peanut Products and Other Food Commodities," Bureau of Foods, FDA, January 19, 1978.

3. Letter from the Director of the Council on Wage and Price Stability to the Assistant Secretary of Labor, May 19, 1978, transmitting the report of the Regulatory Analysis Review Group on the "Proposed Standard for Occupational Exposure to Acrylonitrile - OSHA Docket No. H-108."

Appendix H

AIHC

AMERICAN INDUSTRIAL HEALTH COUNCIL

1075 CENTRAL PARK AVENUE • SCARSDALE, NEW YORK 10583 • (914) 725-1492

October 16, 1978

Mr. Grover Wrenn
Occupational Safety and Health Administration
Department of Labor
Third Street & Constitution Avenue, N. W.
Washington, D. C. 20210

Dear Mr. Wrenn:

On July 14, 1978 OSHA released a preliminary list of chemicals tentatively classified by Clement Associates, Inc. according to the system OSHA proposed on October 4, 1977 for regulating cancer-causing substances in the workplace. Simultaneously you asked each participant in the proceedings to submit to OSHA suggestions as to how to establish priorities for OSHA examination of the tentative list.

Attached is a memorandum prepared by the American Industrial Health Council in response to your request. You noted in your memorandum accompanying the list that the final regulation may contain different criteria than those in the regulation as initially proposed. AIHC believes strongly that the proposed regulation should be modified for the reasons to be stated in our Post Hearing Brief. However, in view of your request for comments before the final regulations are issued, we have undertaken as an exercise to outline the procedure based on the AIHC Alternative which AIHC believes is the most expeditious way to establish priorities. The steps outlined in the attached memorandum may be summarized as follows:

1. The Scientific Panel proposed by AIHC would be established.

2. OSHA would immediately start to gather information on the number of employees and levels of exposure to substances for which there are human epidemiological data or two or more positive animal studies.

Mr. Grover Wrenn

3. OSHA acting jointly with the Panel would screen the list of substances based on exposure data and a preliminary evaluation of the human and animal data in the literature to select for priority scientific evaluations those substances which it appears may present the greatest employee hazard.

4. As the Panel completes the evaluation and classification of the priority substances, OSHA will make a hazard evaluation to determine regulatory priorities.

5. On a continuing basis, OSHA and the Panel would re-evaluate the selected list of substances to identify the next and subsequent priorities.

Sincerely,

Elwood P. Blanchard

Enclosure

AIHC AMERICAN INDUSTRIAL HEALTH COUNCIL
1075 CENTRAL PARK AVENUE • SCARSDALE, NEW YORK 10583 • (914) 725-1492

Proposed Procedure for Prioritizing Substances on NIOSH List Tentatively Classified in OSHA Category I by Clement Associates

On July 14, 1978 OSHA released the results of a review by Clement Associates of the 1976 NIOSH subfile on suspect carcinogens. Based on a literature review, Clement tentatively assigned substances to the OSHA categories in the proposed regulations as shown in the following table:

	List I (based on EPA TSCA candidate list)	List II (based on U.S.I.T.C. data for organics and EPA list for inorganics
Category I	269	116
Category II	218	72
Category III	396	181

The selection of substances from these lists for priority consideration by OSHA presents a number of complex problems. A prescreening method must be utilized to select for full scientific review those substances that present the highest carcinogenic risk and the highest relative hazard based on number of employees exposed, the exposure level and the relative potency of the substance. In this situation there will have to be an interaction between the scientists making the preliminary scientific review and those responsible for deter-

minations of regulatory action to assure that the selection is made for priority consideration of those substances presenting the greatest relative hazard.

The need for interaction between the scientific and regulatory appraisal stems from several considerations. NIOSH has stated in a memo published in the BNA Chemical Regulation Reporter that the list used by Clement may contain errors both as to substances now in the registry and as to substances deleted. Moreover the literature cited in the NIOSH list is not evaluated but is uncritically listed. In addition, the literature cited is biased in the sense that many negative studies are not published. The Clement screening process involved review of the literature but did not purport to be a full scientific evaluation. Clearly, steps will have to be taken to assure that the scientific evaluation is based on all available data. Moreover, the differences between List I and List II make it apparent that many substances on List I are of negligible commercial importance. Finally, the Clement list was based on the criteria in the proposed regulation which AIHC believes should be re-evaluted for the reasons stated in the AIHC Post Hearing Brief.

The purpose of this memo is to demonstrate how the AIHC Alternative offers a reasonable and expeditious means of establishing priorities for administrative review of substances tentatively classified by Clement in Category I.

Introduction

It is important also to point out that this memorandum is based on a clear distinction between (a) the scientific function of data evaluation and risk assessment and (b) the regulatory function of assessing hazard and determining what regulatory action, if any, is appropriate.

Assessment of risk in this context means: (i) evaluation of the data to determine whether the quality of the epidemiological study or animal test provides a valid data base for a determination that a human cancer risk is presented by exposure to the substance; and (ii) evaluation of the potency of the substance with respect to human risk. This latter function includes selection of appropriate extrapolation techniques and consideration of the relevant metabolic and pharmacokinetic data as available.

The regulatory function is to assess the hazard and determine the appropriate regulatory action. The "hazard" involves determination of the number of employees exposed, levels and types of exposure and the degree of potential danger to those employees. If regulatory action is warranted, the agency would proceed in the regulatory process to consider the factors involved in determining a reasonably necessary and feasible level of control.

Procedure

This memorandum assumes that OSHA has recognized the need for independent scientific evaluation by a Panel of dis-

tinguished scientists such as that proposed by AIHC. The fact that OSHA has used Clement in the preliminary evaluation of the NIOSH list is a recognition by OSHA of the need for a scientific evaluation. The Scientific Panel proposed by AIHC accomplishes the objective of speedy and scientifically valid evaluation of this large number of substances and assures that this evaluation will be accomplished on a scientific rather than adversarial basis. This provides assurance that substances posing the highest relative hazard will be selected for priority consideration.

1. AIHC urges that OSHA immediately take the first step in assuring reasonable prioritizing of these substances by requesting the President to establish the Scientific Panel so as to permit the process of selecting members to begin promptly. While the Panel is being appointed and getting ready to begin its functions, much necessary preparatory work by OSHA described below can be undertaken.

OSHA should request the cooperation of NIOSH and the National Library of Medicine in gathering copies of articles on all substances tentatively classified in Category I, II or III for use by the Panel. A procedure should also be established to provide all references on the substances as currently published.

2. Clement screened the 1976 NIOSH subfile of suspect carcinogens. The 1977 list is expected to be published shortly and, in any event, is available to OSHA on tape from

NIOSH. In order to do an orderly job on the NIOSH list, OSHA should immediately request NIOSH (or a contractor) to screen the substances added to the NIOSH list and to review the subfile for substances deleted and for the additional information in the new literature references for substances in the 1976 list. The revised list of substances should be computer checked with EPA's revised inventory under TOSCA and with ITC data to identify the commercial substances. This revised list should be updated currently as additional information becomes available from NIOSH or other sources.

3. OSHA should begin immediately to gather information on employee exposure. Nearly 200 of the substances were identified by Clement as substances on which there were human epidemiological data (AIHC Category I) or which had been the subject of two or more positive animal studies (AIHC Category II). When the list is revised as described in (2) above, there may be other substances where the literature would tentatively appear to meet the criteria for AIHC Category I and AIHC Category II. We recommend that the OSHA efforts to collect employee exposure data concentrate on such substances.

4. There are four possible sources of information on employee exposure: The Department of Commerce, the International Trade Commission, NIOSH and the Environmental Protection Agency. These sources will have some, but probably incomplete, information as to the number of employees and levels and types of exposure for all the substances identified in (3) above. In

addition to employee exposure information, AIHC suggests that OSHA consider securing also to the extent available the names of producers and importers of the substances from these sources. AIHC recognizes that production volume has only a limited value in assessing employee exposure, but that data will be of assistance in identifying the insignificant products in the revised list. OSHA should also enlist the aid of trade associations in collecting these data.

5. Using the list of producers and importers referred to above, OSHA should begin a census of those companies requesting the following information:

(1) Number of employees exposed and the levels and types of exposure at the producer and importer establishments.

(2) Many producers may be able to give information on estimated employee exposure of down stream user plants. OSHA should also request cooperation of trade associations in gathering these data.

(3) NIOSH facilities may be available to collect the information.

6. Using the information collected on each substance OSHA should publish for comment the list of substances and the agency's best estimate of employee exposure. This list should not identify tentative classification since the data are unevaluated but should be identitified as substances in which OSHA is

gathering data to determine if regulatory action is warranted. In order to avoid unwarranted stigma, we suggest this list be entitled "List of Substances To Be Evaluated For Carcinogenic Hazard Potential."

7. As soon as the Scientific Panel is selected, OSHA should furnish to the Panel the list of substances for which OSHA has gathered exposure data. The Panel should be requested to make a preliminary screening of the literature so as to determine validity of the scientific data and the potency of the substances for which there are valid data. Through an iterative process, OSHA and the Panel should jointly select in an orderly and sequential manner, those substances presenting the highest relative hazard considering number of employees exposed, nature and type of exposure, physical and chemical properties, exposure level and potency of the substance.

8. The list of substances selected for priority scientific evaluation should be published by the Panel for comment. The notice would request information and unpublished data on the substances. The Panel should request EPA to furnish non-confidential information in health and safety studies, relevant to carcinogenicity, which have been filed with EPA under Section 8 of TOSCA on commercialized chemicals. The Panel will also take such reasonable steps it deems appropriate to secure additional scientific data and scientific comment from the public during the evaluation process.

9. The Panel will complete the evaluation of the data as promptly as possible and prepare a qualitative risk assessment of carcinogenicity. When the Panel concludes that the data provide a valid basis for a qualitative evaluation of human risk, the Panel shall evaluate all of the elements necessary to prepare a quantitative risk assessment in such form as to enable OSHA to assess hazard at current levels of exposure, and at the PEL if one is established.

The evaluation shall be based on the weight of the scientific data and shall include evaluation of all epidemiological studies and animal data. In the risk assessment the Panel will identify the extrapolation techniques most compatible with the biological mechanism to the extent known. A reasoned statement of the grounds for identification of a particular extrapolation technique and any uncertainties associated with it will be reported. Metabolic and pharmacokinetic data should be considered in the extrapolation process to the extent available.

10. (a) Upon receipt of the Panel evaluation, OSHA will publish the list of substances and the evaluation and classification by the Panel. OSHA will also issue voluntary guidelines for all substances identified as presenting a significant human risk at occupational exposure levels. The guidelines would contemplate preparation by each producer or user of the substances of a site-specific plan for reducing employee exposure promptly by economic and readily available means which would include:

work practices
clean-up and housekeeping
determination of frequency and type of monitoring or other exposure determination
containment of leaks and open operations
provision for personnel protection and medical surveillance
notification and training of employees

This plan would be available to employees and to NIOSH or OSHA upon request.

(b) Immediately upon receipt of the evaluation from the Panel, OSHA will prepare a hazard analysis of the substances. Upon review of the hazard analysis, OSHA will determine regulatory priorities which will include a determination whether the guidelines have resulted in sufficient control, considering the employees' potential danger at then current levels of exposure. The evaluation of hazard for each substance would include a determination whether an Emergency Temporary Standard is justified and necessary under the statute. Where an ETS is not warranted under the statute, a standard setting procedure would be instituted in those cases where OSHA concludes regulation is necessary and appropriate.

11. During the time the Panel is reviewing the initial priority list, OSHA would continue to gather data on other substances on the list described in (3) above with particular attention to those substances which OSHA and the Panel agreed, based on preliminary screening by the Scientific Panel and available exposure data, indicate may present the highest relative hazard potential. As additional information becomes available, OSHA will consult the Panel to determine whether the new data changes

the relative priority for scientific evaluation.

12. When the scientific evaluation of the first priority substances is complete or nearing completion, OSHA in cooperation with the Panel will make a determination as to which substances should next be selected for scientific evaluation.

Box 3 - Alcoa Documents

16. Post Hearing Brief for the American Industrial Health Council before OSHA in re: Proposed Regulation of OSHA for the Identification, Classification and Regulation of Potential Occupational Carcinogens 10/23/78

17. National Association of Carcinogens 2/28/78

18. AIHC Testimony filed by OSHA in Proceedings on Generic Carcinogen Proposal (list of those to testify with