AIHC

AMERICAN INDUSTRIAL HEALTH COUNCIL

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AIHC RECOMMENDED ALTERNATIVES TO OSHA'S GENERIC CARCINOGEN PROPOSAL

January 9, 1978

Recommendations of American Industrial Health Council on OSHA Regulation of Potential Occupational Causes of Cancer

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AIHC RECOMMENDED ALTERNATIVES

TO OSHA'S GENERIC CARCINOGEN PROPOSAL

PREFACE

Identifying and regulating carcinogens in the American workplace is a formidable but most necessary task, one which requires the best thinking of the most informed representatives of science, government, labor, business, and public interest groups.

It will be a challenge for these groups to work cooperatively toward a national policy on carcinogens in the workplace. But the stakes are high and we in industry feel the job must be done.

Mistakes and success in the area of occupational health will not be measured for years. In the interim -- while we cooperatively work together finding and reducing hazards -- the need for good judgment, objectivity and an acceptance of the fact that life cannot be made risk-free must be understood. Such understanding, of course, cannot be allowed to breed complacency.

(A) The Proposed OSHA Standard.

The U.S. Occupational Safety and Health Administration, seeking to develop a national standard for protecting workers from carcinogens, published its proposal for such a standard, "Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk", on October 4, 1977, and invited interested parties to comment on the proposal.

Obviously, OSHA's proposal is of great interest and import to American industry. Shortly after the publication of the proposal, a group of companies and trade associations formed The American

Industrial Health Council to develop a broadly-based commentary on it.

AIHC shares OSHA's view that there is a need to reduce employee exposure to cancer-causing substances in the workplace. Every substantiated cause of cancer, regardless of exposure site, must be subjected to very stringent control.

Experience has shown that some industrial chemicals can cause cancer. The best available evidence, however, indicates that these chemicals are a relatively small factor in the "environmental cancer" problem. Life-style factors such as diet and smoking are considered to be of far more significance.

While industrial chemicals represent only a small portion of the national cancer problem -- no more than 5 percent -- AIHC believes that all chemical substances should be managed at a socially acceptable risk level.

To provide the most authoritative analysis possible of the OSHA proposal, AIHC organized a committee of scientific, engineering and regulatory experts who subjected the proposal to intense study. This AIHC "Alternatives Committee", assisted by a specially-impanelled Scientific Committee, has issued a point-by-point summary of suggested changes in the proposal.

Fundamentally, the AIHC suggestions are offered in two basic areas -- standards for determining (a) what is a carcinogen, and (b) how to implement a workable system of protecting employees from substances that scientific experts agree are carcinogenic.

Central to the entire AIHC report is the establishment of a nine-member "substance categorization" board, to be selected by

the National Academy of Sciences. In effect, AIHC is saying that identification and regulation of carcinogens is too important and too complicated to be left to government regulators alone.

Before summarizing the principal modifications to the OSHA proposal offered by AIHC, it is important to note:

1. That OSHA's final generic carcinogen regulation will most likely have national significance far beyond the workplace. Other federal agencies, including the Environmental Protection Agency, the Food and Drug Administration and the Consumer Product Safety Commission, are considering patterning their regulation of carcinogens on OSHA's final standard. In effect, OSHA is developing what may become the national standard for regulation of carcinogens.

2. The new AIHC suggestions for modification, although likely to win broad support from American industry, are by no means the position of American business. Some in the business community may find the alternative proposals unnecessarily stringent. Nevertheless, the AIHC proposals represent a consensus of industry experts who have given intense study to the problem of protecting workers from cancer causing substances.

(B) Principal Desirable Modifications in the OSHA Proposal.

1. AIHC opposes the zero risk concept implied in OSHA's proposed rules: Rather, recognition is given to the potency or dose-

response data of suspect carcinogens through a much more precise categorization process than that proposed by OSHA.

AIHC recognizes the need for determining acceptable exposure levels and proposes that the permissible levels be fixed after a careful evaluation of the risks and benefits and a determination of technical and economic feasibility of control.

2. Recognition of the complexity and evolutionary nature of the scientific principles involved: The OSHA plan would "freeze" the science as of now with no provisions to take into account new scientific developments applicable to specific cases.

3. Recognition that carcinogens pose varying risks to humans: The OSHA plan does not recognize variation in potency of carcinogens and therefore the degree of hazard to employees in the workplace. AIHC would categorize substances according to relative potency and trigger regulatory activity appropriate to hazard.

4. Recognition of the social benefits, including economic benefits, as well as risks and the establishment of acceptable exposure levels or acceptable risks: In society the principle of acceptable risk is well established. In fact, it is inherent in any human endeavor. The laws under which OSHA operates recognize the idea of acceptable risk. Legislative history is clear that Congress did not intend to protect employees by putting their employers out of business. We do not, and cannot, have a risk-free society and it is not useful to propose regulation rooted in such an idea.

5. A different approach to animal data: OSHA is indiscriminate in attributing significance to animal data and in extrapolating those data to human exposure. Animal data must play an

important role in providing the basis for a regulatory system but their limitations must be recognized.

6. The role of "short-term" tests: OSHA's regulatory proposal for carcinogens would attribute some potentially significant consequences to the results of short-term in vitro tests. Short-term tests have value as screening tools and as guides for more complete tests and studies but the results of such tests are so unreliable as predictors of human response as to be unsuitable as a basis for regulatory decisions.

7. Recognition of the value of epidemiologic data: AIHC would place more emphasis on valuable epidemiologic data than would the OSHA plan, which would hold such data as subordinate to positive results in an experimental bioassay. Since human epidemiologic data are free from the uncertainties of extrapolation from animal tests, it seems quite unscientific not to use such data when available. Epidemiologic data reflects what happens in the real world and often supplies results quite different from what might be suggested from animal tests alone. Under the OSHA proposal, animal tests would outweigh the fact that decades of experience indicate human exposure to many substances which cause tumors in animal tests is not a problem.

8. Regulatory priorities: The AIHC alternative suggests regulating first those materials that are known to be human carcinogens or highly potent animal carcinogens. If the aim of the entire effort is to protect workers rather than to write regulations, it would appear prudent to attack real problems ahead of those that are speculative in nature.

9. Expert performance of the categorization function: Unlike the OSHA proposal, the AIHC alternative would rely on a scientific body separate from the regulatory function to categorize substances by their carcinogenic potential. This approach would promote efficiency and consistency throughout the regulatory agencies, all of which could accept the results of classifications made by a truly qualified panel.

Another reason for the creation of such a panel outside of the structure of the regulatory agency would be to separate the classification process from the wide variety of political and other pressures to which the regulatory agencies are subject. Regardless of intent, a regulatory agency must make decisions that are politically acceptable at that time with somewhat less attention to the validity of the scientific basis for the decision. An independent panel of scientists will provide some degree of insulation from such pressures.

10. A different approach to issuance of Emergency Temporary Standards: ETS must be reserved for those unusual situations where a life-threatening hazard is known to exist. Such action should not be automatic, but rather, should represent a reasonable regulatory response process.

11. Removal of the mandate for engineering controls: The industry proposes less costly, but just as effective, means of compliance which are keyed to actual occupational needs. Those industrial sites which may use a carcinogen should not arbitrarily be required to install very expensive additional engineering controls to achieve a permissible exposure level when a combination of

engineering controls and personal protective devices effectively protects the worker.

12. Substances or mixtures containing small amounts of suspect carcinogens should be exempted from the regulation: Given the great sensitivity of analytic methods, with parts per billion and in some cases per trillion being measured, the failure to provide for exclusions of mixtures has great potential for economic disruption, adverse environmental impact and employment dislocation. Furthermore, costly regulation of minute trace amounts of substances will often be of no discernible health benefit.

13. Laboratory workplaces and the construction industry should be separately regulated: Regulation of laboratories and construction raises special problems and they should be separately regulated. Regulation of laboratories is being considered by the Environmental Protection Agency and the Food and Drug Administration.

(C) Needed: Early Cooperative Effort.

This AIHC report is being made available at this time so that OSHA and other interested parties can give it thoughtful study before public hearings on the OSHA proposal begin on April 4.

AIHC urges all such interested parties to thus play a part in the development of what undoubtedly will become the most far-reaching regulatory action ever made in connection with the American workplace.

Earliest possible attention to this matter is required. Written notices of intent to appear at the OSHA hearings, as well as copies of actual planned hearings testimony, must be filed by January 30th.

January 9, 1978

Recommendations of American Industrial Health Council on
OSHA Regulation of Potential Occupational Causes of Cancer

I. The Problem in Proper Perspective.

A. The incidence of cancer.

The reasons advanced by OSHA to support its proposal[1/] imply that this nation is suffering an epidemic of cancer and that the epidemic is largely if not entirely attributable to increased manufacture and use of industrial chemicals. Factual evidence does not support that view. If we use the turn of the century as a time against which to compare today's cancer problem, there has indeed been an increase in the incidence of cancer -- but the increase is predominantly attributable to (1) greater longevity (the incidence of cancer increases with age), and (2) pandemic cigarette smoking. With adjustments for these two forces, as documented by both the American Cancer Society and United States government statistics, no overall increase in cancer incidence appears for the United States. According to the American Cancer Society (1977 Cancer Facts and Figures, p. 6):

> "The overall incidence of cancer has decreased slightly in the past 25 years. . . . For men, the cancer death rate per 100,000 population has increased by over 50% since 1950 for blacks and by 20% for whites. The increased death rate is mainly the result of lung cancer which rose from 18 deaths per 100,000 in 1950 to 52 deaths per 100,000 in 1974. For women, since 1950 the death rate has declined by 5% for blacks and 10% for whites. This is due mainly to a sharp reduction in deaths caused by cancer of the uterine cervix which is attributed to increased use of Pap tests and regular checkups. There was also a decline in

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1/ The OSHA proposal, entitled "Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk", appears as Part VI of the October 4, 1977, Federal Register, 42 F.R. 54148-54247.

stomach cancer. However, the lung cancer rate has tripled from 4.0 per 100,000 in 1950 to 12.3 in 1974."

Similarly, government statistics (e.g., DHEW, "Cancer Rates and Risks", 2d Ed. 1974, p. 14), adjusted for increase in longevity and increased cigarette smoking, show that there is no overall increase in cancer in the United States. Figure 1 shows that the total age-adjusted cancer death rate for men is increasing but that if cancer of the respiratory system is eliminated, the cancer death rate is decreasing. Figure 2 shows that the "total" age-adjusted death rate for women from all cancers has been decreasing and has been approximately constant for more than a decade. Finally, Figures 3 and 4 show that with the exception of lung cancer, which is primarily attributable to increased cigarette smoking, age-adjusted cancer death rates for men and women from specific types of cancer have not increased significantly in most cases and have in fact significantly decreased in others.

Moreover, it should be noted that in general, except for the kinds of cancers commonly associated with tobacco smoking, the same kinds of cancers are prevalent today as at the turn of the century. This suggests that causes in addition to cigarette smoking which may account for current cancer rates were, in general, present prior to the turn of the century, and thus are not new industrial developments. This is not to imply that no exceptions exist, or that wholly different agents cannot cause the same kinds of cancer. Neither does this imply that more than one agent cannot be a significant contributor to the causation of a kind of cancer; indeed, a prominent example of synergism in carcinogenesis is the combination of asbestos fiber inhalation and cigarette smoke inhalation in causing increased incidence of lung cancer in asbestos workers.

Age-Adjusted Total Cancer Death Rates In the United States For Men

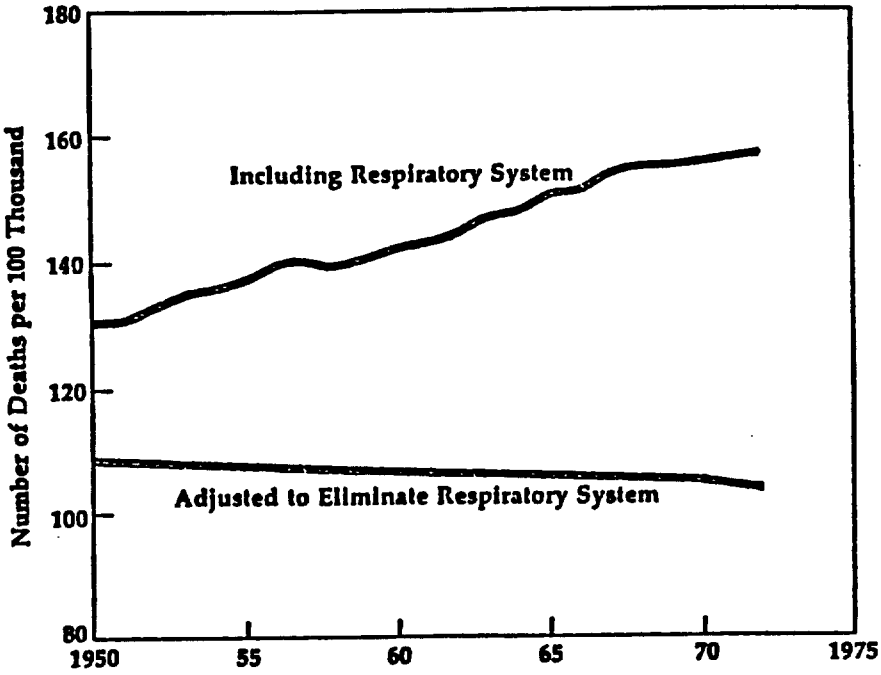

FIGURE 1

Age-Adjusted Total Cancer Death Rates In the United States For Women

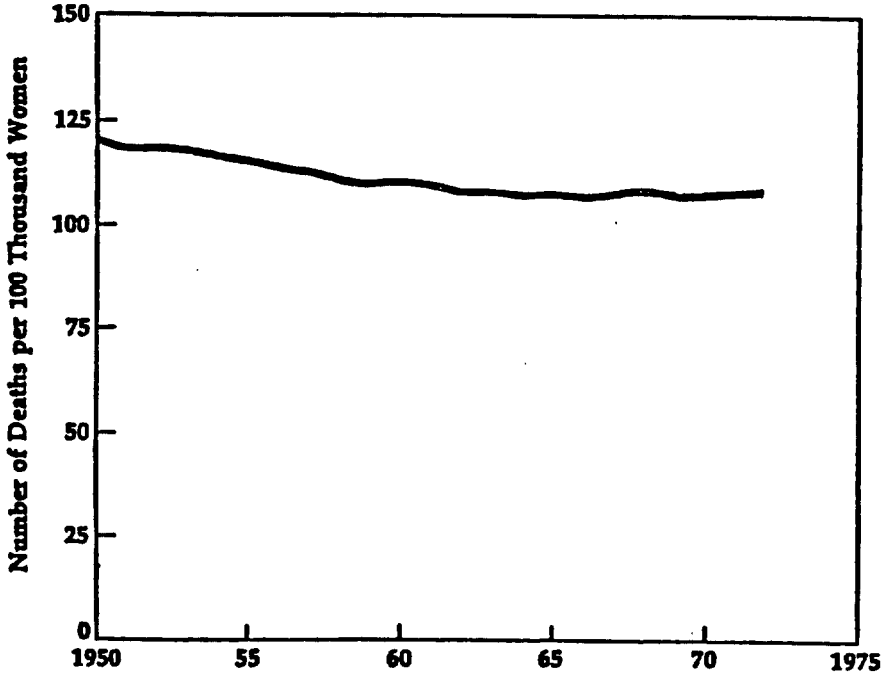

FIGURE 2

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Age-Adjusted Cancer Death Rates In the United States For Men

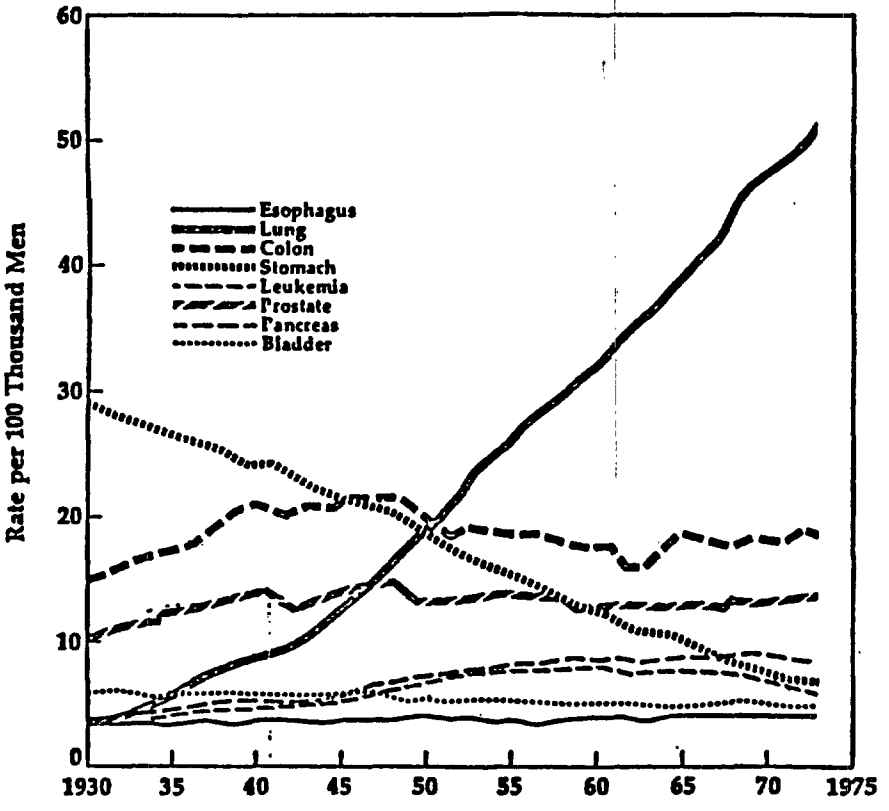

FIGURE 3

Age-Adjusted Cancer Death Rates In the United States For Women

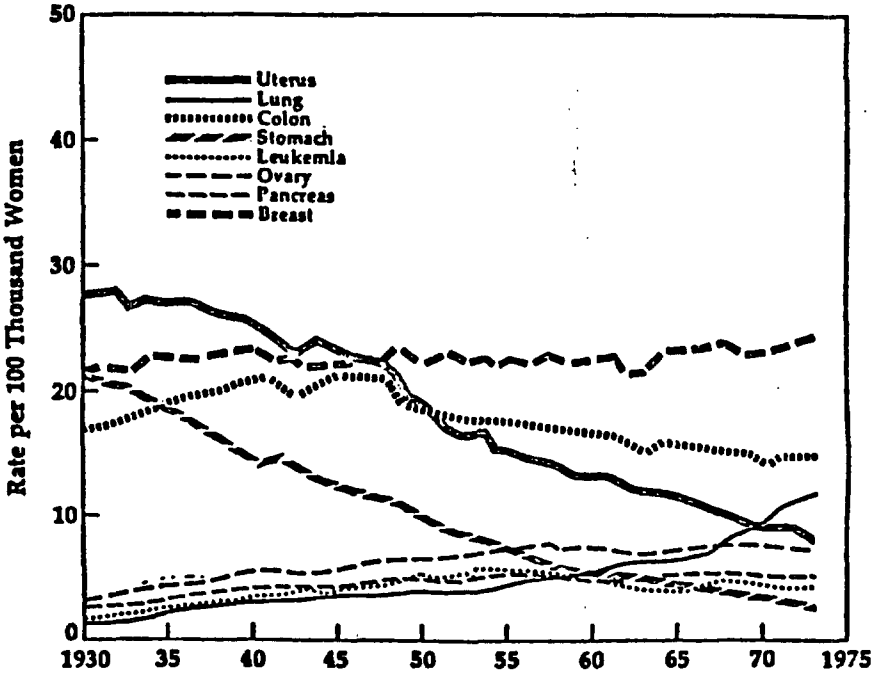

FIGURE 4

It should be noted also that males and females differ in risk of development of specified forms of cancer (Figures 3 and 4), and for most but not all forms of the disease the risk of development increases logarithmically with age. Therefore, in comparing the incidence of any form of cancer in two populations (e.g., an exposed population and an unexposed control population), it is essential to consider males and females separately and to take into account the age structures of the two populations. It is also necessary to take into account the possible changes in the background incidence of any particular form of cancer with the passage of time.

Thus, the risk that a man aged 70 in 1970 will develop a particular form of cancer before he is 71 may be different from that of a man who celebrated his 70th birthday in 1930. The possible reasons for this are numerous. The former for instance might have been of a generation exposed to mustard gas during the First World War while the latter was too old to enlist. In order to allow for differences of this kind, it is necessary to use cohort analysis procedures whereby men or women born during the span of say 5 years are considered to constitute a cohort for which the risk of development of particular forms of cancer during each year or group of 5 years of life can be calculated separately.

When this is done, for instance, for men born in England and Wales during the period 1861-1901, one finds that for each successive 5-year cohort and at each age from 40 to 80+ the risk of death from lung cancer increased. For example, the risk of dying from lung cancer between the ages of 65 and 70 was 0.1 per 1000

for men born during the 5 years around 1861, but increased to 2.9 per 1000 for men born around 1886 -- a 29 fold difference in only 25 years. Thus, in assessing whether an industrial chemical is increasing the incidence of death for any particular form of cancer, it is necessary to compare the observed incidence in the exposed population with the incidence to be expected in an unexposed population not only of the same sex and age-structure but also of the same cohort-structure. In England and Wales, where better data are available than for the United States, the death rates for cancers of various kinds in each sex have been compared for different cohorts with birthdates from 1851 onwards, and, with rare exception (the foremost of which is cancer of the lung in both sexes), these data show no recent evidence of an increasing risk of death from cancer. On the contrary, the death rates have actually been falling for several forms of the disease. Case, R. A. M. "Cohort Analysis of Cancer Mortality in England and Wales, 1911-1954, by Site and Sex", Br. J. Preventive and Social Medicine 10, 172 (1956).

In the OSHA proposal (42 F.R. 54150, Column 2, first paragraph), it is stated that the death rate from cancer today is higher than expected even after allowing for greater longevity as a consequence of lower death rates from infectious diseases and other advances in medicine, and for improved diagnosis. This is not accurate in view of the American Cancer Society, United States Government, and England and Wales statistics, when increased cigarette smoking is taken into account.

B. Industrial chemicals represent a minor fraction of environmental causes of cancer.

It is often stated that perhaps as much as 90 percent of

cancers are "environmentally related".[1/] It is important to note that the OSHA preamble (42 F.R. 54150-51) repeats this common statement in such a way that many might infer that industrial activity accounts for 90 percent of all cancers. Such an inference would be demonstrably wrong. The most ubiquitous, most prevalent, and the most significant cancer-causing factors are not industrial chemicals, but rather are factors associated with the ordinary process of living, for example smoking, diet, and exposure to solar radiation.[2/] Dr. Guy R. Newell, Acting Director, National Cancer Institute, testified to a subcommittee of the House Committee on Government Operations on June 15, 1977, that:

> "The term 'environment' must be defined. 'Environment', in its broadest sense, is the sum of everything around us--the water we drink and bathe in, the food we eat, and the air we breathe and are almost constantly immersed in. Yes, even tobacco products we smoke or are smoked by others in our 'environment'.
>
> 'By "environment" we mean not only our air and water, but also food, drink, smoking, the workplace and the home, sunlight, and all other aspects of our personal lifestyle.'" ("Report on Progress and Activities of the National Cancer Institute", p. 8.)

With "environmental" factors so defined, it is critical to consider the importance of the major specific ones. A team of researchers from the American Health Foundation and the National Cancer Institute have estimated that diet, exclusive of food additives

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1/ E.g., J. H. Weisburger, "Environmental Cancer", 18 J.O.M. No. 4, pp. 245-252 (April, 1976); Wynder and Gori, JNCI April, 1977.

2/ The very great majority of cancers associated with solar radiation are curable.

and contaminants, may contribute to as much as 50 percent of cancer.[1/] The American Cancer Society estimates that smoking cigarettes may account for as much as 80 percent of all lung cancers -- the leading cause of cancer deaths in males in the United States.[2/] Non-ionizing radiation, mostly in sunlight, has been estimated by NCI officials to account for 5 to 8 percent of all cancers. (Dr. Newell's testimony of June 15, 1977 (page 20), noted above, estimated 5 percent; Dr. Gio B. Gori, also of NCI, estimated 8 percent for male and 8 percent for female in a letter to Mr. E. V. Anderson dated May 10, 1977.) Dr. Newell's testimony also estimated (page 20) that alcohol, when combined with use of tobacco products, accounted for about 2 percent of cancers annually.

The best estimate is that industrial chemicals have accounted for about 1 to 5 percent of all cancers.[3/] This is not

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1/ Statement by Gio B. Gori, Ph.D., Deputy Director, Division of Cancer Cause and Prevention, National Cancer Institute, presented before the Select Committee on Nutrition and Human Needs, United States Senate, Wednesday, July 28, 1976. Figure 19: "Percent of total cancer incidence related to diet 40.9% male; 60.1% female."

2/ "Lung cancer - Cigarette smoking causes at least 80% of lung cancer." American Cancer Society, 1977 Cancer Facts and Figures, page 5; "Lung cancer constitutes 22% of cancers in males." American Cancer Society, "Cancer Incidence by Site and Sex", Ca-a Cancer Journal for Clinicians", January/February 1977, Volume 27, No. 1, Page 26.

3/ Dr. Newell's June 15, 1977, testimony (page 20) estimated "5 percent related to occupational exposures such as asbestos, vinyl chloride, benzene, beta-napthylamine and others." Dr. Gori's letter of May 10, 1977, to Mr. E. V. Anderson estimates occupational causation at 3 percent for males and less than 1 percent for females. A guest editorial by Ernest L. Wynder, M.D., and Dr. Gori in the April, 1977, issue of the Journal of the National Cancer Institute, (p. 825) states at page 830:

"Bailar (personal communication) estimated that the occupational contribution to total cancer incidence in males lies between 1 and 5%, and a similar estimate was made by Nelson (personal communication). General estimates of the percentage of all human cancers related to occupational exposure range between 1 and 10%."

an insignificant number of cancers, but it is reasonable to question whether the public is being well-served by being led to believe that industrial chemicals are the overwhelming cause of cancer in this country. A public so convinced would expect, if not demand, that the concentration of governmental "corrective" action be focused upon industrial activities in the expectation of preventing the great majority of the malignancies. Such a misconception could have very grave consequences, diverting society from pursuit of additional preventive measures.

It is difficult to justify the implication in OSHA's preamble that the total cost to society of all cancers should be compared with the cancers attributable to exposure to industrial chemicals (42 F.R. 54150). While it is indeed reasonable to compare costs and benefits in discussing even so emotional a subject as the causes of cancer, it is also reasonable to compare the problems caused by the use of industrial chemicals with the benefits that are derived from them.

In order to place industrial chemicals in proper perspective in any analysis of cancer causation, it is necessary to recognize that they are a small part of the total cancer problem. Nonetheless, the part they play is important because any cause of cancer is important. All would agree that wherever and 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 regardless of whether any regulations have been promulgated. A prudent employer would in fact act to reduce exposure to any suspect carcinogen, more promptly than any regulatory process can force him to. Fortunately, recent years have seen an increased awareness

of the possibility of occupational hazards, and greatly improved measures have come into common use to reduce employee exposure to potentially harmful industrial chemicals. See, e.g., Ferber, Hill & Cobb, American Industrial Hygiene Association Journal, January, 1976, pp. 61-68 (control of potential exposure to benzidine).

C. The alleged failure of prior OSHA regulatory efforts and need for a generic standard.

To justify the oversimplifications and arbitrary rigidity of its proposed categorical approach, OSHA makes much of its supposed inadequacies over the past seven years in the regulation of industrial carcinogens. One can question the accuracy of this self-effacing criticism and thus suspect its motivation.

In 1972 OSHA wrote to its expert advisor, NIOSH, requesting information on all known industrial carcinogens. NIOSH responded by carrying out a literature survey and by publicly requesting information -- on 15 substances -- in a notice published in the Federal Register on July 6, 1972. NIOSH subsequently advised OSHA that there appeared to be 15 occupational carcinogens of which some were known human carcinogens and some were implicated solely on the basis of bioassay experiments. This advice was subsequently modified by the deletion of one of the materials, dimethyl sulfate, leaving 14 carcinogens that NIOSH believed to be in use then, or to have previously been in use, in American workplaces. In 1973 OSHA promulgated an Emergency Temporary Standard limiting employee exposure with respect to all 14 chemicals and commenced a permanent rulemaking which was completed in January of 1974.[1/] What more OSHA could have been

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1/ See 39 F.R. 3756 (Jan. 29, 1974). The 14 included a number regarded as known human carcinogens, and (continued on next page)

expected to have accomplished by then is left unsaid by the current self-criticism, which also ignores the fact that in 1977 OSHA demonstrated that it could act very promptly to regulate industrial substances implicated as potential carcinogens (DBCP).[1/]

Much of the apparent subsequent gap between the regulatory need and OSHA's response is attributable not so much to lack of zeal on OSHA's part as to a number of other considerations. Two, but only two, considerations are the striking increase in recent years in the amount of experimental testing of chemical substances for evidence of carcinogenicity, and the acceleration of the reporting of the results of these tests. Another consideration, however, has been a very controversial modification in OSHA's operative criteria for assessing carcinogenicity. It was the informed view of NIOSH in 1973 that clear evidence of carcinogenicity should be required in two mammalian species before a substance could appropriately be regarded as posing a carcinogenic risk to man insofar as regulatory activities are concerned, but OSHA now proposes to use much less reliable evidence as a basis for regulations.

To justify this shift in position, and to demonstrate a need for its new proposal, OSHA points to the "large number of potential carcinogens already identified by NIOSH", an apparent

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(continued from previous page) several regarded only as known or highly suspect animal carcinogens. The 14 are: 2-Acetylamino fluorene; 4-Amino diphenyl; Benzidine; 3,3'-Dichlorobenzidine; 4-Dimethylaminoazobenzene; alpha-Naphthylamine; beta-Naphthylamine; 4-Nitrobiphenyl; N-Nitrosodimethylamine; beta-Proprolactone; bis (chloromethyl) ether; Chloromethyl Methyl ether; 4,4'-Methylene-bis (2-chloroaniline); and Ethyleneimine.

1/ 1977 also demonstrated the imprudence of undue resort to the ETS procedure -- with respect to benzene.

reference to the "Suspected Carcinogens" subfile of the Registry of Toxic Effects of Chemical Substances (42 F.R. 54169, Column 3). The Second Edition of this subfile, published in 1976, lists 2,415 substances. This does not at all indicate that there are that many carcinogens, or even that NIOSH believes that to be the case.[1/] Rather, the subfile is an uncritical compilation of published data about the chemicals; many, perhaps 510, are listed simply because some government agency has indicated an interest in testing them.[2/] As the Editor of the subfile has noted in the Preface:

> "This publication does not indict a substance as a human carcinogen. Rather it reports published data which suggest that the substance has caused neoplastic or carcinogenic effects. The experimental designs used in the cited studies may be unsuitable for prediction of human effects. Their inclusion in the Registry does not reflect an evaluation with respect to the adequacy of the data, or consideration of negative or contradictory studies.
>
> "The National Institute for Occupational Safety and Health (NIOSH) identifies a substance as a potential human carcinogen by means of the criteria document process. This involves exhaustive literature review and careful consideration by experts leading to a definitive conclusion. This subfile is published to serve as a guide to the literature, and as an indication of those substances which

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1/ OSHA's preamble itself quotes, for other purposes, evidence suggesting that there are only "perhaps a few dozen" carcinogens (42 F.R. 54151, Middle Column). As a matter of regulatory principle, OSHA cannot justify its proposal with directly conflicting propositions.

2/ Many of the listed chemicals are simply laboratory-produced analogs of carcinogens tested in an effort to correlate structure with effect, or to examine possible metabolites, i.e., compounds of no industrial or occupational significance. Others are pesticides listed by EPA as having "data gaps" according to proposed guidelines which would require an oncogenicity study in a second species of rodents, generally the mouse.

may require further research and evaluation." (emphasis added).1/

It is, of course, necessary to establish priorities in this area; NIOSH has done so in selecting substances to be covered by its Criteria Documents.2/ A good example of the difference between the Subfile and a Criteria Document is the case of formaldehyde. This substance is reported in the subfile as having produced neoplastic effects, but the NIOSH Criteria Document on Formaldehyde dated December 1976 does not conclude that the material presents a carcinogenic hazard.

It is also relevant, with respect to the alleged need for the regulation OSHA has proposed, that OSHA does not have authority, under the Occupational Safety and Health Act of 1970 ("the Act") or otherwise, to adopt a generic regulation in which inflexible standards are set for all substances meeting predetermined criteria, without reference to the requirements of Section 6(b)(5) of the Act, 29 U.S.C. § 655(b)(5), regarding the promulgation of standards for toxic materials, and without affording interested parties an effective opportunity to comment on the impact of the proposed regulation on specific substances. A single, inflexible regulation

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1/ It is understood that, in recognition of these points, NIOSH intends to change the title of the subfile to something other than "Suspected Carcinogens."

2/ NIOSH's Criteria Document Development Process includes comprehensive reviews of available information to recommend health standards including "the concentration of a substance in the occupational environment which has been found to cause no adverse effects in people exposed for a normal working lifetime." "Schedule of Development for Criteria Documents", NIOSH Division of Criteria Documentation and Standards Development, p. 2 (October, 1977).

is inappropriate in light of: (a) the diversity and lack of uniformity among substances, and their effects, that are potentially covered; and (b) the wide diversity among workplaces such as factories, laboratories and construction sites. To apply a single inflexible regulation to such widely divergent circumstances is arbitrary and capricious. The inappropriateness of this type of regulation, which requires automatic application of pre-determined standards in all subsequent proceedings on individual substances, is exacerbated by OSHA's rulemaking procedures which have the effect of reducing the opportunity for interested parties to comment or present testimony on the manner in which specific substances will be affected. The regulation is further rendered defective by the lack of any variance or waiver procedure that would permit a risk-benefit analysis, or otherwise take account of marked differences among substances, in specific cases.

Moreover, even assuming arguendo that Congress had delegated to OSHA the authority to promulgate such a regulation, such a delegation would be unconstitutional. (See pages 55-56 below.)

OSHA has stated its "intention, once this proposal is duly promulgated, to foreclose, in subsequent 6(b) rulemakings on individual substances, the rehearing of the validity of the OSHA's proposed classification system and most other policy determinations made in OSHA's proposal, including the procedural structure intended to be followed". (42 F.R. 54154). To foreclose consideration of scientific and other evidence is contrary to the mandate of Section 6(b)(5) of the Act dealing with toxic substances or harmful physical agents, to consider "the best available evidence . . .,"

including "the latest available scientific data in the field." Further, to the extent that issues are preempted in hearings on individual substances under Section 6(b), the proposed regulation and OSHA's contemplated procedure will deprive employers of their statutory hearing rights on those issues.

OSHA also does not have the authority, under the Act or otherwise, to require that in all cases permissible exposure limits be set "as low as feasible." Even if OSHA had that authority, its proposed regulation is impermissibly vague in this regard.

In partial summary: OSHA's past regulatory efforts have been much better than OSHA's preamble suggests; OSHA has not demonstrated the need for the inflexible and oversimplified regulation it has proposed; and that proposal is beyond OSHA's statutory authority.

D. Regulation of individual chemicals.

Although AIHC does recommend a more reasonable general approach to regulation of suspect carcinogens, OSHA should expedite its formulation of occupational health standards for individual chemicals known or suspected to be carcinogens. In doing so, OSHA should develop regulatory priorities based on such matters as the strength of the evidence implicating the chemical as a carcinogen, the carcinogenic potency of a chemical, the number of employees exposed, the extent of exposure, and the likelihood of a carcinogenic event.

OSHA could readily expedite individual rulemakings for chemicals with known or suspected carcinogenic potential by applying accepted principles of risk assessment and hazard evaluation in

conjunction with expanded manpower resources. These modifications could be implemented readily without a simplistic, unrealistic categorization scheme and simultaneously solve the concerns expressed by OSHA in its preamble to the proposed generic standard: specifically,

1. OSHA's problem of relitigating certain issues in each and every rulemaking could be greatly reduced or eliminated by general agreement on criteria for categorization and by a complete risk assessment. This would resolve basic, heretofore contentious, questions in a practical, acceptable manner and establish priorities for regulation.

2. The taxing of witnesses through repetitive public hearings would be relieved by complete risk assessment prior to rulemaking, and/or by adoption of general principles (such as the use of mammalian test data) to be followed except where countervailing evidence was presented to the Data Evaluation and Classification Panel that AIHC recommends or during an OSHA rulemaking.

3. Continuity of approach in regulating carcinogens would be achieved by basing proposed regulations on the results of hazard evaluations for specific substances. These evaluations would review such factors as chemical and physical properties, conditions of use in the workplace, extent of production, nature of the processes, etc.

4. Use of priorities and proper risk assessments should improve regulatory efficiency. If OSHA should still regard its efforts as inadequate, then OSHA could petition Congress for additional manpower. This would be far less costly to the nation than OSHA's proposed categorization and model standard scheme, which would often impose enormous cost increments with no concomitant enhancement

of health.

5. OSHA can avoid futile rulemakings by proposing regulations based on valid risk analysis and hazard evaluation and on the likely costs and benefits, rather than utilizing a non-specific generic approach.

E. Complexity and rapid evolution of scientific learning with respect to carcinogenicity.

Sound and well-informed decision making with respect to occupational exposure to potential carcinogens ought to take account of the fact that the causation of cancer is known to scientists to be an extraordinarily complex matter. It ought also to recognize that the state of the art is currently undergoing rapid evolutionary change, as the result of various major research programs and tests to ascertain individual causes of cancer and to understand the mechanisms of cancer causation. Since this is so, it is particularly inappropriate to "freeze" science at this moment, something which the OSHA proposal would in effect do. The obtuseness of OSHA's approach appears clearly from the advice of the Subcommittee on Environmental Carcinogenesis of the National Cancer Advisory Board (NCAB), a group charged by the Director of the National Cancer Institute (NCI) with developing criteria for assessing evidence of carcinogenicity which cautioned that:

> "in assembling these criteria, the sub-committee recognizes that at present there is no simple and universal definition of either carcinogenesis or neoplasia. The criteria which are described are general guidelines and not rigid, universal criteria. 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 aspects of that agent, its intended use(s), the data

> available at the time that 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 for one agent may not necessarily apply to another." (58 J. Nat'l Cancer Inst. 461, Feb. 1977.) (emphasis added)

Although OSHA's preamble does cite the work of the NCAB Subcommittee (while ignoring its advice), many of the references cited elsewhere in the preamble reflect views expressed seven or more years ago; many of these are already outdated, imprecise or otherwise inaccurate in light of current references, or are superseded by the more recent NCI statement. Indeed, the references cited by OSHA in support of its proposal reflect a single biased perspective of the problems of occupational carcinogenesis. For example, the references fail to report the very considerable body of learning supporting the no-effect level hypothesis concerning cancer causation.

It is manifestly unwise to disregard the discoveries made in the past few years by cancer researchers and to ignore for the foreseeable future developments currently underway or soon to be realized. In fact, such an approach is, as noted above, beyond OSHA's authority since the Occupational Safety and Health Act requires that health standards shall reflect "the latest available scientific data in the field" among other considerations. Indeed, federal regulatory authorities should plan on making a general reassessment of the state of the relevant science at least every five years, if not continuously, and should also reassess prior decisions in light of whatever additional data have become

available.[1/] Particularly in an area of rapidly developing science and data, OSHA should not proceed on the assumption that it can now make decisions that will be valid for the foreseeable future.

F. The illusion of a no-risk society.

The OSHA preamble gives too much emphasis to the uncertainty and difficulty of knowing the safe level of exposure to any known or suspect carcinogen with any degree of confidence. Having made so much of the matter, the preamble declares that the only reasonable way to deal with any carcinogen is to assume that there is no safe level of exposure. Implicit in this notion, if not explicit, is the concept that "safe" within the meaning of the Act means entirely risk-free. There is a correlative notion that industrial or any other useful activity can occur on a completely safe, risk-free basis. Neither proposition is warranted or attainable. There are risks associated with all societal activities. (There are even risks associated with efforts to avoid activity.) Moreover, in enacting the Occupational Safety and Health Act of 1970, Congress explicitly recognized the impossibility of assuring American workers a risk-free workplace. It follows, therefore, that there is a legitimate role for the evaluation of relative risk and the acceptance of some degree of risk, a concept commonly regarded as "acceptable risk". Even in an emotional context such as cancer, sound public policy must take into account the inevitability of some risk, and the necessity of evaluating such risk not only against

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1/ For example aniline was once regarded as a carcinogen, but the development of further data indicated otherwise.

alternative risk but also in light of the benefits of the substance being regulated.

G. The Occupational Health and Safety Act of 1970 requires consideration of benefits and risks in determining an acceptable occupational exposure.

The Occupational Safety and Health Act requires that OSHA, in promulgating standards, "shall set the standard which most adequately assures, to the extent feasible . . . that no employee will suffer material impairment of health or functional capacity." § 6 (b)(5) 29 U.S.C. and 655(b)(5) (emphasis supplied).

In addition to the text of the Act, its legislative history, and administrative and judicial decisions construing the meaning and intent of the Act support the conclusion that economic issues must be considered in evaluating feasibility of proposed standards. The legislative history demonstrates a serious concern on the part of Congress to insure that economic and practical considerations as well as technical considerations are factored into the standard-setting process. Senator Javits, author of the key amendment which added the "feasibility" requirement of the Act, explained its meaning as follows:

> "As a result of this amendment the Secretary, in setting standards, is expressly required to consider feasibility of proposed standards. This is an improvement over the Daniels bill, which might be interpreted to require absolute health and safety in all cases, regardless of feasibility, and the Administration bill, which contains no criteria for standards at all." [Legislative History of the Occupational Safety and Health Act of 1970, Senate Committee on Labor and Public Welfare, 92nd Cong., 1st Sess. 197 (Comm. Print June, 1971) ("Legislative History").]

Similarly, Senator Saxbe expressed concern about the

impact of standards which might not consider economic factors:

> "we have seen great industrial nations which have lost their ability to compete. By that I do not mean to indicate, in connection with this bill, that we have to have a dangerous operation or an unsafe operation to compete. But I do know that in the competitive world of business today, we should not attach to safety unnecessary or harassing measures that would, in effect, limit production in areas that are not necessarily going to increase safety.
>
> * * *
>
> . . . About 12 years ago [the English Government] adopted a number of safety bills that were very idealistic in their concept, but so restraining to the place of work and so restraining on the assignment of employees that they served not to make the plant safer and to increase production, but rather to make the business less competitive, and, as a result, [England] lost business to German manufacturers producing the same item.
>
> This is something that we must be objective about. We want ideal and safe working conditions. At the same time, we must have one eye on this and the other eye on permitting the manufacturer to be competitive, not at the expense of the workmen, but rather in a cooperative effort." (Legislative History at 321-327; see also Legislative History at 147-148, 464, 471-472.)

The courts of appeals have accordingly concluded that economic factors are an appropriate consideration in setting "feasible" standards for toxic substances. In Industrial Union Department, AFL-CIO v. Hodgson, 499 F.2d 467 (D.C. Cir. 1974), Judge McGowan, in reviewing the OSHA standard for exposure to asbestos dust, concluded that the factors entering into the Secretary's conclusion could properly include problems of economic "feasibility". 499 F.2d at 477. He amplified this conclusion as follows:

> "There can be no question that OSHA represents a decision to require safeguards for the health of employees even if such measures substantially increase production costs. This is not, however,

> the same thing as saying that Congress intended to require immediate implementation of all protective measures technologically achievable without regard for their economic impact. To the contrary, it would comport with common usage to say that a standard that is prohibitively expensive is not 'feasible.'" 499 F.2d at 477. (Footnote omitted; underscoring added.)

In AFL-CIO v. Brennan, 530 F.2d 109 (3d Cir. 1975), Judge Gibbons, in reviewing an OSHA safety standard for mechanical power presses, also ruled that the Secretary "may in the weighing process consider the economic consequences of his quasi-legislative standard-setting:"

> "Congress did contemplate that the Secretary's rulemaking would put out of business some businesses so marginally efficient or productive as to be unable to follow standards otherwise universally feasible. But we will not impute to congressional silence a direction to the Secretary to disregard the possibility of massive economic dislocation caused by an unreasonable standard. An economically impossible standard would in all likelihood prove unenforceable, inducing employers faced with going out of business to evade rather than comply with the regulation. The Act does vest the Secretary with authority to enforce his regulations, but the burden of enforcing a regulation uniformly ignored by a majority of industry members would prove overwhelming." (530 F.2d 123; footnotes omitted.)

In Florida Peach Growers Ass'n v. United States Department of Labor, 489 F.2d 120 (5th Cir. 1974), the Fifth Circuit was of the same opinion.

> "The promulgation of any standard will depend upon a balance between the protection afforded by the requirement and the effect upon economic and market conditions in the industry. As articulated by the Chairman of the Subcommittee on Pesticides, who resigned in 'shock' upon finding that the recommended standards were issued on the emergency basis: 'It is essential

> that employees be protected against exposure to highly toxic materials, but this should be done without eliminating the agriculture enterprise and the associated job.'" 489 F.2d at 120.

As the Court of Appeals wrote in the IUD (asbestos) case, "Congress does not appear to have intended to protect employees by putting their employers out of business -- either by requiring protective devices unavailable under existing technology or by making financial viability generally impossible." 499 F.2d at 478. Among other things, these authorities indicate that OSHA should not ban the use of any substance, which would generally be the result of a "no exposure" requirement.

The Review Commission, in interpreting OSHA's noise standard to "effectuate the Congressional purposes underlying the Act," concluded that economics is indeed an integral part of feasibility, stating:

> "[W]e conclude that the standard should be interpreted to require those engineering and administrative controls which are economically, as well as technologically feasible. Controls may be economically feasible even though they are expensive and increase production costs. 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." Secretary v. Continental Can Co., OSHRC Docket No. 3973 et al. (Decided August 24, 1976) (citations omitted).1/

Finally, in Turner Company v. Secretary of Labor, 561

1/ Accord, KLI, Inc., 1977-1978 CCH OSHD ¶ 22,350 (OSHRC 1977); Castle & Cooke Foods, 1977-1978 CCH OSHD ¶ 21,854 (OSHRC 1977), petition for review filed, No. 77-2565 (9th Cir., July 14, 1977); Great Falls Tribune Company, 1977-1978 CCH OSHD ¶ 21,844 (OSHRC 1977); West Point Pepperell, Inc. 1977-1978 CCH OSHD ¶ 21,751 (OSHRC 1977).

F.2d 82, 83 (7th Cir. 1977), the Court considered an OSHRC decision requiring Turner to adopt an engineering noise abatement program, at an estimated cost of up to $30,000, to bring the company into compliance with the federal noise exposure standard. That standard, 29 CFR § 1910.95(b)(1), provides that "[w]hen employees are subjected to sound levels exceeding those listed in Table G-16, feasible administrative or engineering controls shall be utilized." (561 F.2d at 83, n. 2; emphasis supplied by the Court.) In construing the word "feasible" in the standard, the Court held that the word "must be given its ordinary and commonsense meaning of 'practicable'" and that this "construction is in accord with the clear intent of Congress and the purpose of the Occupational Safety and Health Act." (561 F.2d at 83.) The Court concluded that "the Commission must realistically consider the hazards presented by the excessive noise . . . and determine whether the health benefits to employees who are already equipped with personal protective equipment [earplugs] justify the $30,000 cost to Turner". (561 F.2d at 86.)

H. Other federal regulatory statutes require consideration of benefits and risks in determining an appropriate regulatory response.

Numerous federal regulatory statutes have been enacted in the past few years to control potential hazards. These new laws have uniformly required a balancing of benefits and risks in determining the proper regulatory action to protect the public.

The Consumer Product Safety Act was enacted in 1972 to provide protection against a wide variety of hazards that might be posed by consumer products, including the hazard of chemical carcinogens. The CPSA authorizes CPSC to establish consumer product

safety rules to protect against "unreasonable risk of injury." Section 9 of the Act requires that CPSC take into account the following considerations in promulgating these standards:

> "(b) A consumer product safety rule shall express in the rule itself the risk of injury which the standard is designed to eliminate or reduce. In promulgating such a rule the Commission shall consider relevant available product data including the results of research, development, testing, and investigation activities conducted generally and pursuant to this Act. In the promulgation of such a rule the Commission shall also consider and take into account the special needs of elderly and handicapped persons to determine the extent to which such persons may be adversely affected by such rule.
>
> "(c)(1) Prior to promulgating a consumer product safety rule, the Commission shall consider, and shall make appropriate findings for inclusion in such rule with respect to --
>
> (A) the degree and nature of the risk of injury the rule is designed to eliminate or reduce;
>
> (B) the approximate number of consumer products, or types or classes thereof, subject to such rule;
>
> (C) the need of the public for the consumer products subject to such rule, and the probable effect of such rule upon the utility, cost, or availability of such products to meet such need; and
>
> (D) any means of achieving the objective of the order while minimizing adverse effects on competition or disruption or dislocation of manufacturing and other commercial practices consistent with the public health and safety."

The Medical Devices Amendments of 1976 amended the Federal Food, Drug, and Cosmetic Act to add stringent new controls over potentially hazardous medical devices. Section 513(a)(2) of the amended Federal Food, Drug, and Cosmetic Act specifically requires that the safety and effectiveness of medical devices be determined

by weighing any "probable benefit" against any "probable risk," and Section 514(g)(2) requires that any standard for medical devices consider "the benefit to the public from the device."

The Toxic Substances Control Act similarly requires consideration of both benefits and risks in determining appropriate controls for chemical substances. Section 2(b) specifically recognizes, as the policy of the United States, that:

> "(3) authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment."

Section 2(c) states the intent of Congress:

> ". . . that the Administrator shall carry out this Act in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes to take under this Act."

Section 4(a) permits EPA to establish testing requirements for chemicals which may present "an unreasonable risk of injury," including the risk of cancer. Section 6(c) authorizes regulatory restrictions on chemicals to prevent "unreasonable risks" after EPA considers:

> "(A) the effects of such substance or mixture on health and the magnitude of the exposure of human beings to such substance or mixture.
>
> (B) the effects of such substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture.
>
> (C) the benefits of such substance or mixture for various uses and the availability of substitutes for such uses, and

(D) the reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national econony, small business, technological innovation, the environment, and public health."

It is inconceivable that Congress intended that benefits be considered in regulating all of these public hazards, and others as well, but be ignored in regulating occupational hazards.

I. Government agencies have approved carcinogenic risks from chemicals under other regulatory laws.

The Food and Drug Administration has a broad mandate to assure the safety of all food. Yet the agency has allowed the following food substances to remain available for daily consumption in spite of unquestioned scientific studies showing that each is carcinogenic in at least one species of mammalian test animals:

Egg yolk and egg white 1/
Vitamin D2 2/
Calcium 3/
Lactose and maltose 4/
Selenium 5/
Beverage alcohol 6/
Caffeine 7/

Similarly, FDA has failed to remove bacon and ham from the market

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

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

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

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

5/ 38 F.R. 10458 (April 27, 1973); 39 F.R. 1355 (Jan. 8, 1974).

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

7/ Press Release, Japan Times, September 22, 1977, quoting Japanese Cancer Research Inst.

although they are known to contain nitrosamines or to produce nitrosamines in the body when consumed. FDA has also failed to exercise its jurisdiction over restaurants to prevent the charcoal broiling of meat, which produces carcinogenic benz-a-pyrene. Indeed, FDA has set tolerances for aflatoxin in peanuts and corn, which by FDA's own estimates raise a risk of 66 lifetime cancers per 100,000 persons.[1/]

Congress has, in the Saccharin Study and Labeling Act, endorsed FDA's unwillingness to remove known carcinogens from the market without a benefit/risk analysis. The congressional moratorium was enacted with the understanding that saccharin presents a risk of approximately 1500-2000 cases of bladder cancer per year within the United States.[2/]

J. Non-chemical risks are a part of daily life.

In everyday life, man is exposed to numerous risks of fatalities which society accepts. Some of these risks pose quantifiable risks of cancer:

Activity	Risk of cancer fatality/year
Cosmic Ray	
- One transcontinental flight/year	$.05 \times 10^{-5}$
- Commercial Airline Pilot (50 hrs./month at 35,000 feet)	5.00×10^{-5}

1/ Food Chemical News, November 14, 1977, pp. 3-4; see also page 43 below.

2/ Sen. Rep. No. 95-253, 95th Cong., 1st Sess., p. 6 (1977). This report states that these figures were derived from Canadian studies and conclusions, and were confirmed by FDA Commissioner Kennedy. These conclusions may be debatable; the point is that Congress was willing to accept their possible validity, but nonetheless decided that saccharin should continue to be available.

- Frequent airline passengers 1.50×10^{-5}

Other Radiation

- Average U.S. Diagnostic Medical X-Ray 1.00×10^{-5}
- Sea level natural background 1.50×10^{-5}

Others pose equal risks of a different nature. The risk of one transcontinental airline trip per year is 0.3×10^{-5}. The risk of electrocution is 0.5×10^{-5}. The risk of accidental poisoning by solids and liquids is 0.6×10^{-5}, and by gases or vapors is 0.7×10^{-5}. The risk of suffering a fatal fall is 7.7×10^{-5}.

In its pursuit of recreation the human race engages in and tolerates many activities of relatively high risk. The following activities and their degree of risk are illustrative:

Activity		Risk/Year
Football	Averaged order participants	4×10^{-5}
Automobile racing		$1,200 \times 10^{-5}$
Horse racing		$1,300 \times 10^{-5}$
Motorcycle racing		$1,800 \times 10^{-5}$
Power boating		170×10^{-5}
Amateur boxing	40 hours/year engaged in sport	2×10^{-5}
Skiing		3×10^{-5}
Canoeing		40×10^{-5}
Rock climbing		100×10^{-5}
Sunbathing (curable skin cancer)		500×10^{-5}
Fishing (drowning)		1.7×10^{-5}
Drowning (all recreational causes)		1.9×10^{-5}

Society has chosen not to prohibit any of these activities, or even activities with much higher risks (e.g., the Indianapolis 500).

There are relatively few activities which pose such a high risk that society has banned them completely (e.g., going over Niagara Falls in a barrel or attempting suicide).

Nor are these risks limited to recreational activity. The following annual risks of death from causes other than cancer in selected occupations show that benefits are considered in public regulation of occupational hazards as well:

Coal mining[1/]	- Black lung disease	$10{,}000 \times 10^{-5}$
Coal mining	- Accident	$1{,}500 \times 10^{-5}$
Airline pilot	- Accident	50×10^{-5}
Typical jet flying	- Air accident	10×10^{-5}
Manufacturing (total)		5×10^{-5}
Fire fighters		$1{,}000 \times 10^{-5}$
Steel worker		60×10^{-5}
Railroad worker	(accident risk)	400×10^{-5}

(The principal references for the foregoing risk figures are B. G. Ferris, New Eng. J. Med., 268 540 (1964); F. D. Sowby, Health Phys., 11 879 (1965); C. Starr, Science, 165 1232 (1969); K. S. Clarke, J. Am. Med. Assoc. 197 894 (1966); Statistical Bulletin, Metropolitan Life Insurance Co. (May 1977.)

II. Principal Desirable Modifications in the OSHA Proposal.

A. Recognition of the complexity and evolution of the science.

It seems only realistic to modify the OSHA proposal, as AIHC recommends, so as not to regard the present (or the past) state

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1/ In view of the very high risks of coal mining, which surely should be reduced, the Administration's energy policy, which encourages coal mining, highlights the need to consider the benefits.

of the relevant science as frozen. The OSHA proposal "freezes" science in two ways: in the manner and extent to which regulatory propositions are to be foreclosed from future consideration in individual chemical rulemakings; and in the proposed obstacles that OSHA would create to allowing itself to take advantage of, or to utilize, improvements or developments in relevant learning. The latter problem arises from the fact that OSHA would not entertain any modifications of the rigidities of its proposed approach except by way of a formal rulemaking that would modify the pending categorical rulemaking proposal. The problems of obtaining even a very clearly warranted modification of such a rulemaking appear to be truly formidible. Enormous bureaucratic inertia would have to be overcome, and even if that were possible, very substantial time would be required.

The AIHC proposal 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. In the absence of such countervailing evidence, it may be appropriate for OSHA to use general principles, without having to support them with personal testimony time and again. For example, the AIHC proposal would permit use, prima facie, of mammalian test data to categorize a chemical as posing some occupational carcinogenic risk. AIHC would not, however, preclude interested parties

who believed they had compelling evidence, from attempting to persuade OSHA that its general principles should not be regarded as warranting such regulatory action (e.g., in the particular circumstances of some improperly designed mammalian test or some future unforeseeable case).

B. Recognition that not all carcinogens pose the same risk to humans.

The amounts of different chemicals known to have non-carcinogenic toxic effects can vary by several orders of magnitude;[1/] a different permissible exposure limit for each is therefore appropriate and justified. Since it has been demonstrated that the carcinogenic exposure level of different materials can likewise differ by a million fold or more,[2/] it seems irrational for the OSHA proposal to proceed on the basis that all known and potential carcinogens pose equivalent risks (by requiring the "lowest feasible" permissible exposure level in all cases). Carcinogens, like non-carcinogen toxins, should be classified or ranked in terms of potency, and regulated according to the degree of hazard that their use or uses present to employees. For example, bischloromethylether is a very potent known human carcinogen; vinyl chloride is much less potent. More severe controls clearly are warranted for the former.

1/ Modern toxicology is based on experimental evidence demonstrating that a dose-response relationship exists for toxic substances and that there is some dose level below which no response occurs. Although there may be scientific dispute at present whether there are threshold or no-effect levels for carcinogens, there is a strong body of scientific opinion embracing this concept, supported by the current NCIR study on 2-Acetylaminofluorene and the Oak Ridge radiation study.

2/ Compare, for example, aflatoxin with saccharin.

Greater priority should be accorded to regulating a substance that is a potent carcinogen than a substance that is a weak carcinogen, where the extent of employee exposure is the same.

The AIHC alternative calls for categorizing both human and animal carcinogens in terms of the potency of carcinogenic response, "high", "intermediate", or "low". These classifications are provided primarily to assist in establishing regulatory priorities. (However, a low potency carcinogen may warrant high priority if exposures are high and extensive.) The potency distinctions also would be an indicator of the regulatory controls to be imposed: more stringent controls for the more potent carcinogens. However, the categories would not inflexibly determine the regulatory controls. Such controls, including the means of achieving the permissible exposure level, would be determined on a case-by-case basis in light of assessments of risks and benefits. Controls and exposure levels could easily differ for two substances in the same category, depending on the circumstances of each case.

The OSHA proposal would group all "carcinogens" (as defined by OSHA's "policy decisions") into one group, Category I. The AIHC proposal recognizes the many-fold differences in degree of potency as measured by the size of the dose that (a) results in cancer and (b) affects the latent period (the time from first exposure to development of a tumor).

Although OSHA has ignored dose-response data, there are many references in the literature to the presence of dose-response relationships for carcinogens. Just-released data from the National Center for Toxicological Research (NCTR) on the liver

and bladder carcinogen 2-Acetylaminofluorene ("2-AAF") eloquently demonstrate the dose-response phenomenon. This singular study, which utilized large numbers of animals and multiple dose levels, also demonstrated that latency, expressed as time-to-tumor from first dose, is clearly a function of dose, confirming Druckrey's classical observations on latency and dose-response. Set out below in Figure 5 is a graph contained in the NCTR draft study which clearly illustrates the dose-response relationship in liver tumorigenesis for 2-AAF.[1/]

The principal ways by which the AIHC proposal would take into account dose-response and time-to-tumor data include determining the actual hazards presented by a chemical (which must include consideration of how it is in fact used), and otherwise ascertaining socially acceptable or permissible exposure levels. It is proper and logical for OSHA to set a lower exposure level for a highly potent carcinogen than for one shown to be only weakly potent.

C. Recognition of benefits, including economic benefits, as well as risks; establishment of acceptable exposure levels or acceptable risks.

The AIHC alternative does not proceed on the illusory basis that a risk-free industrial environment is attainable. Rather, it deals candidly with assessment of risk and benefits.

The first step in this process is the assessment of carcinogenic risk, that is, assessment of the likelihood of a carcinogenic event at a particular level of exposure. It is not presumed

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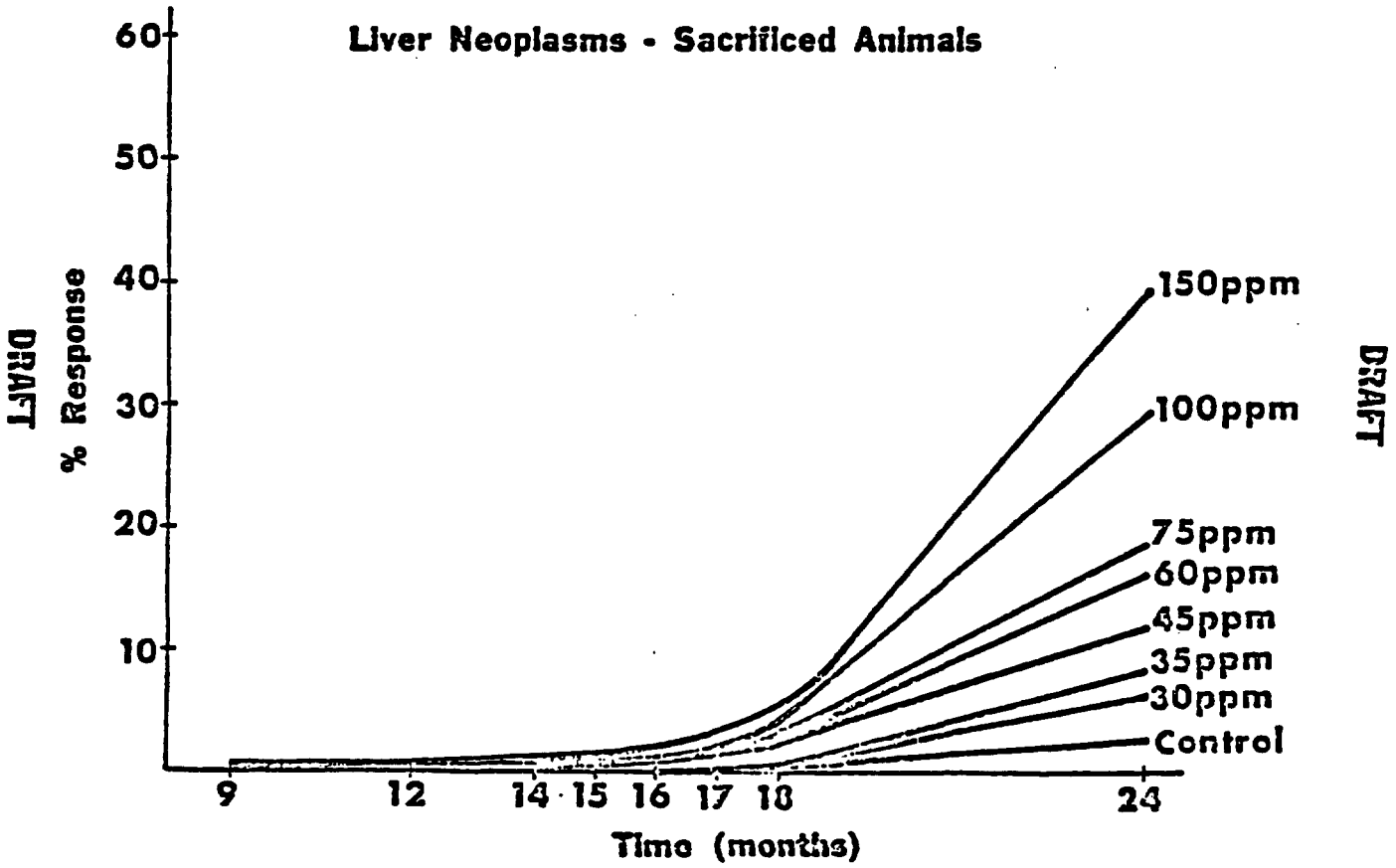
1/ The NCTR data on 2-AAF show a no-effect level for the kidney.

FIGURE 5



(NCTR Study on 2-AAF)

that at present there is any broad agreement on a particular method for quantification of such risk, or that any of the more frequently used or advocated methods to quantify risk are precise. The ones commonly used are generally regarded as erring considerably on the side of safety and conservatism in estimating carcinogenic risk. The AIHC alternative proceeds on the basis, however, that efforts to assess risks can serve a useful purpose in comparing risks of exposure to a particular chemical with other occupational risks and with other risks commonly encountered and accepted in our society (see pages 27-30 above), and in weighing these risks against the benefits of the chemical in question.

The second step in this process is the assessment of the benefits derived from the chemical which raises a carcinogenic risk, and the costs involved in reducing that risk. No one questions that any step which would reduce a carcinogenic risk at little or no cost, and thus without reduction of benefits, should promptly be undertaken. In most instances, however, regulatory requirements involve substantial costs that can drastically reduce or eliminate important societal benefits.

The third step in this process involves the balancing of benefits and risks in determining an appropriate regulatory response. Since it is usually impossible to quantify either benefits or risks with mathematical precision, it is surely impossible to establish any formula for balancing the two or arriving at the ultimate decision of an acceptable exposure for any particular carcinogen. The AIHC alternative would therefore require that OSHA, like other government agencies, specifically recognize all of the various

factors which comprise the risks and benefits, and specify how each is taken into account in reaching its final regulatory decision. The AIHC alternative lists various risk and benefit factors to be included in this decisional process.

D. Different approach to animal data.

The OSHA proposal is indiscriminate in attributing significance to mammalian test data and, for all practical purposes, automatically extrapolating therefrom to human exposure. Mammalian test data are used by OSHA as the basis for making regulatory decisions without regard to the dose used, the overwhelming of normal detoxification mechanisms, the mechanism of cancer induction (where known), the route of exposure or other test conditions no matter how irrelevant to human occupational exposures.

Mammalian test data have an important role to play in regulatory decision-making, but their limitations need to be clearly recognized. The value of professional scientific judgment in analyzing and interpreting such data, and their applicability to any given occupational exposure situation, need to be fully understood. The OSHA proposal is deficient in both respects. Further, OSHA ignores or fails to take sufficient account of numerous well-established scientific principles essential for valid and meaningful extrapolation from animal data to man.

Most importantly, OSHA fails adequately to consider that when the dosage for an animal is massive, its natural detoxification systems or defense mechanisms (often a liver enzyme or series of enzymes) are usually overwhelmed. Dr. H. F. Kraybill of NCI in

a recent paper[1] expresses serious concern about the unrealistically high doses currently being used in animal experiments. He concludes that "[f]indings from such studies are almost science fiction and there is a good chance for overstatement of the risk." The result of such high doses, according to Dr. Kraybill, is that the detoxification mechanisms of the host become incapable of providing the necessary protection.[2] Dr. Kraybill urges, quoting extensively from a recent article by Dr. Jerome Cornfield (Science, 18 November 1977), pp. 683-694), that saturation levels should therefore be factored into predictive models. "The fallacies of massive dosing," concludes Dr. Kraybill, "for many cases must be appreciated and comprehended prior to any assessment of carcinogenicity."

OSHA's proposal sanctions extrapolation from mammalian test data to human exposure but ignores major metabolic, pharmacokinetic and biochemical differences which exist between species of animals and man. And, because of certain species' peculiar ability to develop neoplastic responses to a wide variety of apparently safe substances (injection of ordinary penicillin under the skin of a mouse causes sarcoma, the most malignant kind of cancer), there is always considerable margin for toxicological experts to doubt the application even of any replicated finding to man, especially where the replication is in but one species.

1/ Paper presented at the December 19, 1977, meeting of the Chemical Selection Subgroup of the Clearinghouse on Environmental Carcinogens (Clearinghouse) entitled "Biochemical Intermediates as Research Probes in Carcinogenesis Methodology," pages 3-5.

2/ A good example of the ability of a host system to repair itself if the dose does not overwhelm the defense mechanisms or if the insult is removed is the increased longevity of those smokers who stop smoking as compared with those who continue to smoke. See U.S. Dept. of HEW, Cancer Rates and Risks (1974) p. 63.

By sanctioning a replicated test in a single mammalian species to corroborate a positive result and to categorize a chemical as a carcinogen (extrapolating from such animal data to humans), the OSHA proposal ignores the lack of validity in many such "replicated' animal studies which may be the result of variations in test procedures and conditions. Among these variations might be interspecies differences in metabolism, methodological differences in statistical treatment of data, differences in the basic diets fed to the animals, differences as to the applicability of certain tumor systems (e.g., hepatomas in mice), the presence of other volatile toxic substances where an experiment was conducted, and differences in animal husbandry.[1/]

Two biological circumstances also dramatize the need for careful appraisal of animal data. Estrogens and androgens are carcinogenic to experimental species, and for estrogens, carcinogenicity in humans has been documented. Yet estrogens are ever-present at sub-threshold or no-effect levels in the entire earth's population and are essential to life. Similarly, metals such as chromium and cobalt and perhaps nickel, selenium, even arsenic, are essential to man in small amounts but carcinogenic in excessive amounts.[2/]

The AIHC proposal would substantially differentiate among animal test results depending on the experimental test procedures

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1/ Merely changing the type of wood shavings beneath mouse cages from pine to redwood will set off epidemic cancer in certain strains.

2/ Dr. Kraybill of NCI, in another paper presented to the Chemical Selection Subgroup of the Clearinghouse on Environmental Carcinogens on February 2, 1977, entitled "Some Concepts and Remarks on Presumptive Negative Chemicals, Biological Intermediates, Endogenous Chemicals, Nutrients," discusses additional substances which are required by the body physiologically, biochemically (continued on next page)

and conditions. The proposal would examine those experimental procedures and conditions and attribute regulatory significance to the test data appropriate to the procedures and conditions of the test. This approach is radically different from the OSHA approach which, essentially, automatically assigns equal regulatory significance to all animal tests.

While the AIHC proposal would require positive results in two different mammalian species in well-designed and conducted experiments to warrant regulation of a substance as a carcinogen, it would not preclude OSHA from instituting a normal Section 6(b) rulemaking on a specific substance on the basis of a single such experiment where, in light of the best information available at the time, regulation because of carcinogenic hazards might be appropriate.

The AIHC proposal is in accord with OSHA's in rejecting injection site tumors as a basis for categorization and in rejecting similarities in chemical structure between known carcinogens and other untested substances as a basis for categorization as carcinogenic.

E. The role of short-term tests.

OSHA's proposal would attribute some potentially significant regulatory consequence to the results of so-called short-term tests. The proposal is remarkably unspecific as to what is intended here; unanswered questions include how many tests are

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2/ (continued from previous page) or nutritionally and which have produced tumors in animals under certain test conditions. See also 39 F.R. 1355 (Jan. 8, 1974) for FDA approval of the "safe use of selenium as a nutrient in the complete feed of" swine, chickens, and turkeys.

required, what results in various tests would be sufficient for regulatory purposes, and what kinds of tests would be sufficient. In contrast, the AIHC proposal reflects the general state of the art, which is to the effect that short-term tests are currently so much more unreliable as predictors of human responses as not to be sufficient to warrant regulatory action other than to serve as guides for requiring conventional bioassay, biochemical, or metabolic testing. The AIHC proposal finds support in the "General Criteria for Assessing the Evidence of Carcinogenicity of Chemical Substances" prepared by the Subcommittee on Environmental Carcinogenesis of the National Cancer Advisory Board and published in 58 Journal of the National Cancer Institute 58:463 (February 1977):

> "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 agent in long-term animal bioassays, particularly if there are other reasons for testing. Negative results in a short-term test, however, do not establish the safety of the agent.
>
> "This Subcommittee is enthusiastic about the possible future use of *in vitro* tests as part of a screening system for potential carcinogens and believes that their future development and validation deserve high priority."1/

While the AIHC proposal would not preclude subsequent attribution of regulatory significance to short-term tests, depending upon advances in scientific learning, it would at present limit their use to serving as guides for further testing.

1/ The reliability of the short-term tests is also discussed in Purchase, *et al.*, Nature 624, Dec. 16, 1976.

F. Recognition of the value of human experience and epidemiologic data.

OSHA is correct in recognizing that most epidemiologic studies which claim to demonstrate -- even qualitatively -- that an excessive incidence of cancer is caused by a single chemical are suspect because of: (a) mixed chemical exposures; (b) unknown, non-occupational exposures (e.g., smoking); and (c) poor estimations of exposure levels. However, studies which do not show excessive cancer incidence ("negative studies") are seldom criticized from these standpoints. Therefore, any well-executed study[1/] utilizing universally accepted techniques deserves consideration in the categorization of chemicals. In fact, it should be the primary decision-making criterion.

The AIHC proposal would attribute more significance to available epidemiologic data (human experience) than would the OSHA proposal which would even subordinate any such negative data to positive results seen in an experimental bioassay. Since human data are free from the difficulties of extrapolating from animals, it is quite arbitrary and otherwise unscientific not to use these data whenever they are available.

Human data could play a significant role in several ways. First, such data could suffice to classify a substance as a known human carcinogen; it is recognized that relatively few chemicals would be so classified. Second, where appropriate, such data,

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1/ AIHC recognizes that the quality and statistical significance of epidemiologic data often vary; the fact that some such data are inconclusive is not a logical basis for ignoring all such data.

with exposure level information, could indicate potency. On the other hand, such data could in some cases preclude carcinogenic classifications that might otherwise seem indicated on the basis of positive animal data. More generally, such data must be considered relevant, along with the results of animal studies, in any risk assessment.

There is good reason to attribute significance to epidemiologic data, whenever such data are available. For example, aflatoxin is one of the most potent carcinogens in various mammalian species, but there is ample epidemiologic evidence that, where the material is not ingested in gross quantities it does not produce harmful effects in man, despite widespread exposure to it in peanuts, corn, maize and sorghum. This has been recognized recently by the Food and Drug Administration, allowing aflatoxin levels of 20 ppb in shelled peanuts and human food products such as peanut butter; epidemiologic evidence in the United States was favorable, but contrary to experimental results of induction of tumors in animals at dose levels of 15 ppb and, in one experiment, 1 ppb. (39 F.R. 42748 (Dec. 6, 1974).) FDA there reviewed the aflatoxin data and proposed to reduce the level to 15 ppb but stated that the 20 ppb level would continue until and unless the proposal were adopted, which it has not been. FDA has very recently established an aflatoxin level in milk of 0.5 ppb. (42 F.R. 61630 (Dec. 6, 1977).)

Similarly, 3,3'-Dichlorobenzidine has produced tumors in animals, but epidemiologic data show no unusual incidence of cancer

or other disease.[1/]

Further, there is evidence that micro nutrients, such as selenium, which in low doses produce no harmful effects on man, indeed may be necessary to life, produce well defined toxic effects, including carcinogenicity, in animals. See page 39 above. And the human nutrient calcium fed to bulls at only 3.5 to 5.9 times the amounts the National Research Council has concluded they require, has produced ultimobranchial tumors in the thyroid glands in 30 percent of the animals.[2/] Clearly, humans are not at risk the same way from calcium.

Negative human data on the toxicity of carcinogenic materials are seldom seen in scientific journals, and certainly never in the popular press. These data are for the most part in "company files" and there is little incentive for making them known -- much less for developing more data -- since, as the OSHA proposal demonstrates, little importance is attached to this information relative to positive animal studies. The AIHC proposal attempts to rectify this unscientific attitude.

G. Regulatory priorities.

The OSHA proposal contemplates what appears to be a haphazard approach to regulatory priorities: It is suggested that the large number of materials on the NIOSH subfile of "suspect carcinogens"

1/ See Gerarde & Gerarde, J. Occup. Med. 16(5), 322-344 (1974); MacIntyre, J. Occup. Med. 17(1), 23-26 (1975).

2/ L. Krook, et al., "Dietary Calcium, Ultimobranchial Tumors and Osteopetrosis in the Bull", 22 Amer. Journal of Clinical Nutrition, No. 2, pp. 115-118, February, 1969.

may be considered in alphabetical order (42 FR. 54169, Column 3), and priorities for additional materials would depend upon the happenstance of the timing of OSHA's receipt of information from any source. The latter 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 and nickel (essential human nutrients), peanuts, asphalt, and carbon tetrachloride.

The AIHC proposal reflects the view that OSHA should retain the flexibility to exercise informed judgment and should consider regulating first those materials that are known or seriously alleged to be human carcinogens or highly potent animal carcinogens. (Priority should also depend upon the degree and extent of employee exposure.) Materials in this category are surely a much more manageable number 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. This approach would enable greater benefits to be achieved, and ensure greater acceptance by those being regulated, in view of its manifest reasonableness. Such acceptance is highly desirable in a democratic society.

H. Categorization of substances not found in domestic workplaces.

Unlike the OSHA proposal, the AIHC alternative would not call for formal categorization, by publication in the Federal Register, of a material that might be, within OSHA's scheme, a Category I,

II, or III material but which is not present in United States workplaces. This aspect of the OSHA proposal appears to have virtually no ascertainable benefits. The basket category contemplated here, that is, chemicals that possibly could be regarded as within OSHA Categories I, II, or III, is so broad as to be practically meaningless; all that one could readily conclude from assignment to such a category would be that the substance is not found in United States workplaces. There could be no reasonable objection to OSHA's communicating with EPA so as to be alerted if anyone should propose to import or manufacture within this country a material as to which there was some, unevaluated, information of potential carcinogenicity. It would be reasonable to rely upon EPA's premarket notification scrutiny to provide appropriate warning of such a potential development.

I. Avoidance of controversy, uncertainties, and mistakes concerning substitutes.

Unlike the OSHA proposal, the AIHC alternative would not call for OSHA to decide whether substitutes are available for a chemical (in one or more uses or processes) being regulated as a carcinogen, and would not call for a zero-exposure limit (generally, a ban of the substance) where substitutes are thought to be available.

First, the banning of any substance is beyond OSHA's legal authority. As noted above, standards must be feasible, and Congress did not intend OSHA to protect workers by eliminating their jobs. The OSHA Act, with its feasible-standard authorization, stands in sharp contrast with the Toxic Substances Control Act, which does specifically authorize EPA to ban manufacture or use of a substance

where certain conditions are met. Moreover, the proposed requirement for "no exposure" would be tantamount to requiring a cessation of operations without adherence to the specific criteria and procedures set forth in §§ 9 and 13 of the Act, 29 U.S.C. §§ 658 and 662. Even if it were within OSHA's authority to impose a "no exposure" standard, the "suitable substitute" test set forth in OSHA's proposed regulation is impermissibly vague. Any effort to read the authority to ban a substance into the general language of the OSHA Act would raise serious questions as to the constitutionality of such an expansive delegation of legislative authority. But even as a policy matter, OSHA should not concern itself with substitutes.

One policy objection to the OSHA proposal on substitutes is that it is largely unnecessary where good substitutes are -- or subsequently become -- available. Industry experience demonstrates that materials discovered to be carcinogenic generally have been replaced, over time, by other materials. The incentives to make such shifts include health factors, as well as avoidance of the expenses of complying with carcinogen regulation. For example, industry has largely displaced asbestos-bearing insulation materials for new and replacement process equipment insulation. Also, industry had entirely discontinued use of a number of the "14 carcinogens" before OSHA regulated them; some of them possessed benefits that, in the absence of adequate substitutes, have resulted in their continued use in established applications, but the imposition of regulation has essentially eliminated this group from serious consideration in new process research and development.

It should be noted here that the six months that the OSHA proposal contemplates as the maximum rulemaking period will generally not provide adequate time for OSHA to determine whether substitutes are presently available. Substitution can be a very complex question for a single use of a chemical; where, as is common, the uses are quite varied, the difficulties of deciding about substitutes becomes much greater. In addition, the rulemaking could not anticipate subsequent development of substitutes, and thus could never do a complete job. Neither could a rulemaking anticipate future new uses for the chemical, which could be quite beneficial -- but impossible because it had been banned.

Another objection is that OSHA might, under the pressure of the six-month limit and other pressures, err in deciding that adequate substitutes are available. Such decisions can only be correctly made on technical, rather than political, grounds. It would be difficult for OSHA generally to have or obtain the necessary information and expertise to judge what effect the substitution would have on product quality, utility, effectiveness, and stability, on processing parameters such as output, equipment changes, energy consumption, and maintenance requirements, or on direct and indirect economic effects on suppliers and customers as well as the user of the banned substance. Substitution decisions often involve a trade-off in hazards (e.g., carcinogenicity vs. flammability or corrosiveness); the apparent relative safety of potential substitutes will in some cases depend on the lack of comparable data. Substitute decisions take time -- to find the best substitute, to pilot the process, to allow customers to test the product, and finally to

engineer and build process equipment modifications. New uses of the substitute material may also invoke the premarket notification provisions of the Toxic Substances Control Act.

Thus, while it may be easy to require a substitute, it may be difficult to accomplish. The consequences of such errors could be very substantial, for consumers -- who will generally bear any increased costs -- and employees as well as employers. Our nation's balance of trade could also suffer; poorly conceived -- or compelled -- substitutes might not be viable in world markets because of economic and performance requirements. In light of these considerations, it appears likely that very substantial controversy would generally attend OSHA's rulemakings if substitutes were at issue. This would unnecessarily tax the limited personnel resources which OSHA hopes to utilize better by the current proposal.

J. Decreased resort to Emergency Temporary Standards; guidelines.

The OSHA proposal would require, in every case of a Category I classification within its scheme, automatic invocation of the Emergency Temporary Standards approach that is authorized by Section 6(c) of the Act. This requirement is unlawful. Section 6(c) requires the Secretary of Labor in each case to make specific, prescribed factual findings prior to issuance of an ETS. And, particularly where a chemical is not a known human carcinogen, this requirement is contrary to the decision of the United States Court of Appeals for the Third Circuit, Dry Color Manufacturers Ass'n, Inc. v. Dept. of Labor, 486 F.2d 98, 104-105 (1973). There the court stated that even though cancer was a possibility, the

question remained of establishing a "sufficient probability of harm to man"; for a valid ETS to issue, there must be a showing of "more than some possibility that a substance may cause cancer in man." The court then said that the record before it failed to show "more than some possibility that DCB and EI may cause cancer in man", indicating that the record did not warrant an ETS.[1/] The evidence then before the court included the reports of laboratory rodent experiments on 3,3' Dichlorobenzidine and Ethyleneimene 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.

The court stressed the value Congress had intended that the normal rulemaking procedure would have, noting that it was clear that Congress had provided for an ETS as "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 is specifically designed to bring out the relevant facts."

As a policy matter, the ETS approach seems undesirable whenever complex factual issues are involved, and must be resolved in a permanent rulemaking to be instituted and completed within only

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1/ The court set aside the ETS on another ground, having clearly indicated its views that an ETS would not generally be warranted on the basis of animal data alone.

six months from the promulgation of an ETS. This is particularly so when controversy may be expected, as would generally be the case considering the stringent controls and far-reaching implications that attend a carcinogenic rulemaking. These reservations are all supported by the history of reaction to OSHA's prior uses of the ETS approach to substances being regulated only because of carcinogenic potential.

The AIHC proposal thus rejects the notion of automatic resort to the ETS procedure, and contemplates that each case would be considered in light of the Act and applicable court decisions, and that informed judgment would be exercised on the basis of all available information.

There will inevitably -- perhaps often -- be occasions where common sense and prudence dictate that some action be taken virtually immediately to reduce employee exposure, without regard to the rulemaking process. In such circumstances it would be appropriate for OSHA to promulgate guidelines that inform the public of risks, that recommend prompt remedial action, and that set forth the basis for the recommended action. Such guidelines would achieve substantially the same results as would an ETS, without the adverse effects of an ETS. OSHA has promulgated such guidelines on a number of occasions, as recently as August 1, 1977, on "DBCP", and December, 1977, on ethylene dibromide.

K. Provision for exclusion of mixtures.

The OSHA proposal is silent on exclusion of mixtures containing very low concentrations of the material being regulated. Given the recently greatly increased sensitivity of analytical methods,

with parts per billion and even per trillion now being measured, the failure to provide for exclusions of mixtures[1/] has great potential for economic disruption, adverse environmental impact, and employment dislocation. For example, many aerospace propellants and aviation lubricants contain trace amounts of carcinogens which cannot be eliminated. Failure to provide exemptions would have enormous adverse impacts, as OSHA itself recognized in providing exclusions in the 14 carcinogens rulemaking.

The appropriateness of such exclusions is further warranted because there will often be no discernible health benefit from the application of a costly (or prohibitive) regulation to a mixture containing very low concentrations of the substance being regulated. AIHC thus favors such exclusions.

L. Provision for partial exemption for workplaces consistently below permissible exposure levels.

To reduce the burdens of compliance with regulations and to reduce the economic and inflationary impact of additional regulations, the AIHC alternative would, unlike the OSHA proposal, result in partial exemptions for workplaces consistently below permissible exposure levels. In general, the scope of the exemptions would include monitoring, medical surveillance, and record-keeping requirements. OSHA precedent for this approach (on vinyl chloride, 39 F.R. 35893, Oct. 4, 1974) has enabled significant economies to be realized, without perceptibly altering employee

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1/ The exclusions would exempt not only mixtures but also workplaces where the mixtures were present. The exclusions would apply not only to products manufactured from carcinogens but also to substances in which the carcinogens appear as contaminants or by-products, provided the concentration of the carcinogen was below a specified level.

protection. Indeed, by freeing industrial hygiene resources of unnecessary regulatory burdens, the exemption should promote employee protection in other areas.

M. Special regulatory approaches to laboratories and construction.

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 consequence 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.

Similarly, construction presents very special problems, as OSHA has recognized in regulation of asbestos, and special regulation for construction activity would be necessary.

Thus, while the categorization aspects of the AIHC proposal could apply to laboratories and construction, the regulatory response would generally be different than it would be for production operations.

N. Appropriate timing and scope of assessment of economic environmental impacts; due process.

The AIHC proposal does not itself deal with issues as to the timing or scope of assessment of economic and environmental impacts of implementation. Because of the comparative flexibility of that proposal, it should be appropriate to assess those impacts

during the regulation of individual chemical substances; indeed, the AIHC alternate contemplates that the results of such impact analyses would play a major role in shaping the regulation, particularly with respect to how to achieve the permissible exposure level.

In contrast, the OSHA proposal would automatically require in all "Category I" cases that exposure be reduced to the lowest feasible level solely by use of engineering and work practice controls, and would permit use of personal protective devices and administrative controls only when the employer proves that engineering and work practice controls are not feasible to reduce exposure to the permissible level. Since OSHA would place many important chemicals into its Category I, the economic impact of its proposal would be enormous. OSHA has failed to make an economic impact assessment, contrary to Executive Orders that require that such an assessment be made in connection with a generic regulation of the type proposed by OSHA. See Executive Orders 11821 (39 F.R. 41501) and 11949 (42 F.R. 1017).

OSHA has also failed to file an adequate draft environmental impact statement and therefore is in violation of the requirements of the National Environmental Policy Act ("NEPA"), the guidelines of the Council on Environmental Quality ("CEQ") and the regulations of the Department of Labor. Indeed, OSHA's proposal to assess economic and environmental impacts only after it has adopted a rigid framework -- rigid both as to substance and procedure -- and only in the context of individual-substance rulemakings implementing its categorical approach, would make such assessments futile exercises.

Why assess impacts when no regulatory choice remains? The point here is obvious; OSHA's pending proposal renders nugatory any assessment of economic or environmental impact.

A corollary of OSHA's failure to comply with the NEPA requirements, the CEQ guidelines and the Department's regulations, is that AIHC members and other interested persons have not been provided with information sufficient to comment fully on the proposed regulation, and therefore have been denied notice and an opportunity to comment upon the proposed regulation, in violation of the Administrative Procedure Act and in violation of the right of due process.

Moreover, the rulemaking procedures established by OSHA in connection with the proposed regulation provide that public comments and testimony must be submitted prior to the testimony of OSHA witnesses, and that there is no opportunity to respond formally to the statements of OSHA witnesses.[1/] OSHA also has failed to provide a list of substances in commercial use which are likely to be classified in Category I or Category II under its proposed regulation.

These and other defects in OSHA's rulemaking process have effectively denied AIHC members and other interested persons adequate

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1/ OSHA was also arbitrary and capricious in making "policy decisions" on scientific and technical matters in disregard of advice from NACOSH and without consulting its statutory advisor on scientific and technical matters, NIOSH. Further, the defects of notice and opportunity to be heard are compounded by OSHA's failure to define the term "suitable substitute" (§ 1990.112) and the phrase "as low as feasible" (§ 1990.112). Other impermissibly vague aspects of the regulation include the definition of "suggestive" (§ 1990.102), the "other evidence" criterion (§§ 1990.110(b) and 1990.120(b)), and the rebuttal criteria of §§ 1190.111(a) and 1990.121(a).

notice and an opportunity to participate in the public hearing on the regulation. These defects are so fundamental and of such magnitude as to constitute a denial of statutory procedural rights under the Administrative Procedure Act and a denial of due process of law.

These defects are aggravated by the fact that OSHA's proposal purports to freeze scientific issues and to fix standards which automatically will apply in future hearings on individual substances. It thus is of crucial potential importance to all users and manufacturers of chemicals. To conduct a hearing that is expected to last 10 weeks or more on such a broad regulation makes it impossible for business concerns, and especially smaller concerns, to participate effectively. The expense of attending all sessions, to be able to cross examine witnesses, object to testimony or make appropriate motions effectively excludes small business participation.

O. Expert performance of data evaluation and categorization function.

Unlike the OSHA proposal, the AIHC alternate would rely upon a scientific body separate from federal regulatory authorities to make the essential scientific judgment or decision as to the appropriate categorization of a particular chemical substance with respect to carcinogenic potential. There are a number of reasons for separating these functions. One is simply efficiency and consistency throughout the regulatory agencies, all of which, it is proposed, should accept the results of classifications made by the proposed Data Evaluation and Classification Panel. Another is to separate the scientific process of classification from the

variety of political and other pressures to which regulatory agencies are subjected, including perceived needs to respond to the expressed wishes of their historical constituencies. A further reason would be to improve the expertise of those making the categorizations, by improving utilization of expert resources. There is no abundance or surplus of good scientific talent in this area; it seems reasonable to expect that the federal government would on the average enlist the services of better qualified individuals if it needed to provide only a single classification panel, rather than a panel or similar authority for each of a variety of regulatory agencies. The AIHC proposal contemplates that the activities and decisions of the Panel would be governed by the Administrative Procedure Act. The Panel would be established pursuant to the Reorganization Act.

III. Tentative Nature of AIHC Endorsement of Categorical Approach.

The AIHC alternate does not proceed on the basis of agreement with OSHA's assertions of a compelling need to simplify science and facts by categorization. (See pages 10-19 above.) Accordingly, the following proposal is only a conditional endorsement of a categorical approach, an endorsement that depends in material respects upon greater flexibility and potential for individual consideration of particular chemical substances than would be afforded by the general approach of the OSHA proposal.

Similarly, the AIHC proposal does not proceed on the basis of agreement with OSHA's assertion that its proposal would result in significant savings of time and effort in carrying out its regulatory mandate. Such efficiencies are asserted to be principal reasons for OSHA's categorical approach. It is, however,

quite questionable whether these efficiencies will indeed be achieved, when the total regulatory process, which includes enforcement proceedings and judicial review or the opportunity for judicial review thereof, are considered. Initially, it may be ventured that even if the pending OSHA proposal were adopted, subsequent rulemaking proceedings on individual chemicals will surely be controversial, on matters such as whether a chemical has been correctly categorized and whether OSHA has accurately or validly ascertained feasible exposure limits, a matter which can vary quite significantly with different uses of the same chemical.

It also seems reasonable to anticipate that such future rulemakings will not be entirely self-enforcing, and that individual enforcement proceedings through citations and adjudications before the Review Commission will be necessary. In such Review Commission proceedings, the economic feasibility of standards would be at issue. Moreover, in judicial review proceedings, aggrieved employers would be entitled to judicial consideration not only of the standards for individual chemicals but also of the categorical standard that OSHA now proposes. Since in many cases several years would have elapsed between OSHA's adoption of the present proposed categorical standard, "freezing" the science and shutting off consideration of information developed in the future, and such an enforcement proceeding arising under a particular rulemaking promulgated in implementing the categorical approach, it seems reasonable to anticipate that there would be litigation not only before the Review Commission but also the courts as to the propriety of the issues that OSHA now seeks to put at rest by a categorical rulemaking approach. In brief,

the supposed efficiencies may well prove to be illusory; OSHA's efforts to shortcut debate may be counterproductive. By providing more flexibility to consider, and attribute significance to, all the evidence available at the time of a rulemaking on any given substance, the AIHC proposal should be more efficient from an overall regulatory standpoint than the OSHA proposal, which seems to assume that the process terminates with promulgation of a standard in the Federal Register.

The AIHC Recommended Alternative

DATA EVALUATION AND CLASSIFICATION PANEL

Determination of carcinogenicity is a scientific, not a regulatory question. This determination 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.

A Data Evaluation and Classification Panel ("the Panel") should be established by Executive Order issued pursuant to the Reorganization Act of 1977, 5 U.S.C. § 901 et seq. Such action should promote efficiency, consistency, and accuracy in the regulatory process. At the outset the Panel would serve OSHA's purposes, but it could come to serve other regulatory agencies as well.

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 hazard, 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, 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. They would 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, and would devote all their working time to the Panel. The Panel would have a staff. The Panel and staff would be housed within the NAS or some other organization agreeable to the Interagency Regulatory Liaison Group. The Panel would be substantively independent of whatever organization in which it may be housed.

The Panel would apply the following Classification Categories and criteria, 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 assign a chemical substance to one of the following categories. 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.

The Panel shall use the criteria listed below in 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.

CATEGORY I. KNOWN HUMAN CARCINOGEN.

A. Carcinogens of High Potency.

B. Carcinogens of Intermediate Potency.

C. Carcinogens of Low Potency.

Criteria: A substance shall be classified as a known human carcinogen on the basis of valid epidemiological data or other valid human data. Such data should be evaluated in light of:

1. The magnitude of the association between exposure and excessive age-standardized risk (as measured by relative risk analysis or Standard Mortality Rate) and the statistical confidence limits.

2. The size of a study population and the number of cases of cancer.

3. The specificity of the type and site of cancer.

4. Confirmation, or lack of confirmation, by other independent studies.

5. The suitability of the control group used for the confirmation of excessive risk, particularly the extent to which exposed and control groups are similar in respects other than exposure to the suspect agent, e.g., ethnic, socio-economic, dietary, exposure to other chemicals, use of tobacco.

6. Whether there is evidence of a dose-response relationship.

7. Whether the observed carcinogenic effect is likely to be direct or indirect, e.g., explicable in terms of a biological mechanism which is irrelevant to the occupational exposure.

8. Whether well-documented individual case reports or studies show that the substance in question has in fact, or with a high degree of probability, caused cancer in humans, even though the number of cases is too small to apply epidemiologic or statistical tests.

Potency shall be determined on the basis of epidemiologic or other human experience data where exposure data are available or where exposure intensities can reasonably be estimated. In the absence of such information, any available mammalian bioassay dose-response data shall be used. Where good exposure data are lacking, potency shall be assessed as follows:

Where epidemiologic evidence shows that exposure under in-use conditions has increased the age-standardized risk of development of any form of cancer by a factor of 10-fold or more, the agent shall be regarded as a potent carcinogen. (Examples here include heavy cigarette smokers, nickel plating operations, and occupational

exposure a few decades ago to beta-naphthylamine.)

Where such an increase is by a factor greater than 2-fold but less than 10-fold, the agent shall be regarded as an intermediate potency carcinogen. Examples here include chrome worker exposures.

Where such an increase is by a factor of 2-fold or less, the agent shall be regarded as a weak carcinogen.

In evaluating mammalian test data for relative potency, the guides set forth in Category II, (Subpart E below, page 67) for assessing the potency of confirmed animal oncogens shall be used.

CATEGORY II. CONFIRMED ANIMAL ONCOGENS.

A. Oncogens of High Potency.

B. Oncogens of Intermediate Potency.

C. Oncogens of Low Potency.

Criteria: Well documented results of adequate mammalian bioassays in at least two different species showing a statistically significant increased age-standardized risk of tumor development in test animals over that occurring in matched and exposed controls, where an appropriate route of administration was used and where the doses were not excessive, shall be sufficient, in the absence of countervailing information, to warrant classification as a confirmed animal oncogen.

1/ It is recognized that dose-response data would as a matter of toxicology be preferable to "attack rate" data. However, dose information is often not available. In addition, attack-rate data are significant in terms of priorities of regulatory action.

A. Definition of Oncogen. A number of the terms used in this general criterion are more fully stated below. This general criterion contemplates attribution of some regulatory significance to malignant and benign tumors observed in bioassays, hence the term "oncogen". This does not signify that they are the same, but rather reflects present uncertainty on this matter and prudence in protecting employees. Such uncertainties may receive appropriate attention during the assessment of risks. The general criterion also accepts, as prudent, use of mammalian test results as guides to carcinogenic risks to man. This is accepted despite very substantial scientific complexities and uncertainties about extrapolating from animals to man; in exceptional cases those uncertainties may be so formidable as to preclude such extrapolation.

B. Excessive doses. The criterion accepts as valid the judgment of the American Conference of Governmental and Industrial Hygienists to the effect that no substance is to be considered a Category II occupational carcinogen on the basis of having reacted oncogenically by the following routes above the following doses.[1/]

1. Dose via the respiratory route exceeds 1,000 mg/m^3 for the mouse and hamster or 2,000 mg/m^3 for the rat.

2. Dose by the dermal route exceeds 1,500 mg/kg for the mouse and hamster or 3,000 mg/kg for the rat.

3. Dose by the gastrointestinal route exceeds 500 mg/kg/d for a lifetime, equivalent to about 10 g. total lifetime dose

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1/ ACGIH, "Threshold Limit Values for Chemical Substances and Physical Agents in the Workroom Environment with Intended Changes for 1977", p. 40.

for the mouse and hamster, and 100 g. total lifetime dose for the rat.

The results of experiments using excessive doses may warrant classification in Category III.

C. Appropriate routes of administration. Appropriate routes of administration are respiratory (inhalation or intratracheal installation), skin application, and gastrointestinal (including gavage unless this is associated with gross distortion of blood or tissue levels compared with human exposure).

D. Adequacy of bioassay for evaluating oncogenic potential.[1/]

The following factors, among others, shall be considered in assessing the adequacy of the protocols, conduct, and results of a bioassay:

-- the experimental design and its conformity to accepted protocols

-- the appropriateness of the method of exposure

-- the appropriateness of the route of exposure

-- the appropriateness of the animal species and strain used, and in particular the propensity of untreated animals to develop tumors of various kinds

-- whether test populations were randomized

-- size of each dosage group

-- existence and adequacy of concurrent controls

-- character and type of animal housing; type of bedding if any; number of animals per cage

-- non-tumor responses to test agents; influence on tumor yield

-- duration of exposure

1/ Many of these factors are discussed in "Guidelines for Carcinogen Bioassay in Small Rodents", NCI Carcinogenesis Technical Report Series No. 1, February, 1976, by James M. Sontag, Norbert P. Page, and Umberto Saffiotti.

-- schedule of intercurrent sacrifice

-- period of observation relative to the lifespan of the test species

-- metabolic and pharmacokinetic data, if available

-- number, type and site of tumors

-- number of animals developing tumors

-- temporal pattern of tumor appearance, taking into account the distinctions between (i) fatal and non-fatal tumors, (ii) tumors which are evident during life (e.g., skin and sub-cutaneous tumors) and tumors which can only be discovered at necropsy

-- the quality of the pathology studies, both microscopic and macroscopic

-- method of statistical analysis and statistical significance of positive results

-- dose response relationships

-- adequacy of reporting of the bioassay

E. Relative potency of response. The general concept of the relationship between the magnitude of the dose resulting in tumors in experimental animals and the potential risk to man from industrial substances, as advanced by the ACGIH,[1/] is reasonable and sensible; modifications from the ACGIH numbers are used to accord with current accepted test protocols. The additional concept of induction period (time from first contact to the appearance of tumors) is also applied in the definitions of potency of response to exposure to industrial substances in experimental mammalian studies. Accordingly, responses for which adequate bioassay results of statistically significant tumor occurrence are available shall be categorized

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1/ ACGIH, "Threshold Limit Values for Chemical Substances and Physical Agents in the Workroom Environment with Intended Changes for 1977", pages 41-43.

by potency in light of the following guidelines for bioassays of the hamster, mouse, or rat:

1. Response to respiratory route exposure.

A. Response of high potency.

(1) Inhalation exposure 6 to 7 hours per day, five days per week, for a major portion of a lifetime, to dosages below 1 mg/m^3 with an excess of tumors appearing at any time during the study;

(2) Inhalation exposure 6 to 7 hours per day, five days per week, for a major portion of a lifetime, to any non-excessive dosage with tumors appearing in 12 months or less; or

(3) Exposure to a single intratracheally administered dose not exceeding 1 mg of particulate, or liquid, per 100 ml or less of animal minute respiratory volume, with an excess of tumors appearing at any time during the study.

B. Response of intermediate potency.

(1) Inhalation exposure 6 to 7 hours per day, five days per week, for a major portion of a lifetime, with dosages between 1 and 10 mg/m^3 with an excess of tumors appearing at any time during the study; or

(2) Inhalation exposure 6 to 7 hours per day, five days per week, for a major portion of a lifetime, to any non-excessive dosage with tumors first appearing in 12 to 18 months, or

(3) Exposure to a single intratracheally administered dose from 1 mg to 10 mg of particulate, or liquid, per 100 ml or less of animal minute respiratory volume, with an excess of tumors appearing at any time during the study.

C. Response of low potency.

(1) Inhalation exposure 6 to 7 hours per day, five days

per week, for a major portion of a lifetime, with dosages greater than 10 mg/m^3, but non-excessive, with an excess of tumors appearing at any time during the study; or

(2) Inhalation exposure 6 to 7 hours per day, five days per week, for a major portion of a lifetime, with any non-excessive dosage with tumors appearing after 18 months; or

(3) Exposure to intratracheally administered (non-excessive) dosages totaling more than 10 mg of particulate or liquid per 100 ml or more of animal minute respiratory volume, with an excess of tumors appearing at any time during the study.

2. Response to skin application exposure.

A. Response of high potency. Exposure by repeated skin application with tumors appearing in 6 months or less.

B. Response of intermediate potency. Exposure by repeated skin application with tumors appearing within 6 to 18 months.

C. Response of low potency. Exposure by repeated skin application with tumors appearing after 18 months.

3. Response to gastrointestinal exposure.

A. Response of high potency.

(1) Exposure by any form of repeated peroral dosing at a dosage less than 1 mg/kg/day, with an excess of tumors appearing at any time during the study; or

(2) Exposure by repeated peroral dosing of any non-excessive dosage with tumors appearing in 12 months or less.

B. Response of intermediate potency.

(1) Exposure by repeated peroral dosing at dosage between 1 and 50 mg/kg/day, with an excess of tumors appearing at any time during the study; or

(2) Exposure by repeated peroral dosing at any non-excessive dosage with tumors appearing in 12 to 18 months.

C. Response of low potency.

(1) Exposure by repeated peroral dosing at a dosage greater than 50 mg/kg/day, but non-excessive, with an excess of tumors appearing at any time during the study; or

(2) Exposure by repeated peroral dosing at any non-excessive dosage with tumors appearing after 18 months.

CATEGORY III. Substances for Further Testing.

Criteria:

Mammalian bioassays that do not satisfy Category II requirements but that do show statistically significant increases in tumors, for examples: positive results in a single species; positive results but only in studies using excessive doses; positive results but only in studies where the route of administration, or exposure conditions, are of questionable relevance to human exposure.[1/]

RECATEGORIZATION

It is recognized that some, perhaps most, chemical substances will be categorized on the basis of less than definitive data, and that subsequent scientific advancements as well as additional data may suggest that a prior categorization was erroneous and should be reconsidered. Accordingly, any interested party may petition the panel for reclassification of a chemical on the basis of significant data or scientific learning that were not considered

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1/ Results of "short-term" tests would serve as guides to further testing, and would not themselves warrant categorization. See pages 40-42 above.

at the time of the prior classification. Depending on the information and its assessment during the categorization process, a substance could be reclassified to a higher or a lower category, or removed entirely from the categories.

Removal could occur where a Category III classification had been followed by completion of adequate[1/] mammalian testing or epidemiologic studies, with no statistically significant evidence of carcinogenicity in the particular testing or study results.

It is not contemplated that where more than one valid bioassay report is available and some reports are negative and others positive, a substance would be removed from the categories. The inconsistency of the reports would, however, be considered by OSHA in assessing risks.

In some cases, however, epidemiologic studies showing no increased incidence of cancers could warrant removal from the categories, despite positive bioassay reports. This might be appropriate, for example, where substantial differences were shown between the test species and man with respect to metabolism of the tested substance.

Where reclassification results, OSHA shall promptly consider modification of its standards.

1/ See Subpart D in Category II, page 66 above, for criteria to assess bioassays.

OSHA Regulatory Response to Classification

A. Category I classification.

1. Emergency temporary standard. Upon classification of a substance as a known human carcinogen, OSHA shall as soon as possible decide, in each case, whether actual employee exposures constitute a "grave danger" within the purview of Section 6(c) of the Act and whether an Emergency Temporary Standard is necessary to protect employees from such danger. Such determination shall consider (a) 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 (b) evaluation of actual hazards (e.g., physical and chemical properties, degree of occupational exposure, likelihood of a carcinogenic event).

Upon completion of such a determination, OSHA shall immediately commence the development of an ETS if the criteria specified in Section 6(c) for such issuance have been satisfied. In developing an ETS (as well as in developing a permanent standard), OSHA shall perform analyses of risks and benefits in accordance with Subpart C below.

(a) Where an ETS is to be issued and where there are available dose-response data in one or more appropriate mammalian species or other appropriate information sufficient to quantify risks to employees, OSHA shall, in light of such information, specify permissible exposure levels that reflect analyses of risks and benefits. In deciding upon such a level, OSHA shall perform analyses of risks and benefits in accordance with Subpart C below, to the extent

such analyses can be very promptly performed. Where the available epidemiologic data are sufficient to help evaluate dose-response and potency issues, such data shall be considered in establishing permissible exposure levels. These exposure levels shall generally be achieved by means of engineering controls, to the extent technically and economically feasible, augmented by administrative controls and personal protective equipment as necessary. OSHA shall require that this exposure level be achieved as soon as feasible, and may require as an interim measure that exposure levels be reduced immediately through a readily available practical combination of engineering and administrative controls and personal protective equipment.

The permissible exposure levels may vary from chemical to chemical, depending upon the analyses of risks and from one use of a chemical to another, and benefits.

(b) Where an ETS is to be issued and sufficient data are not available to quantify risks to employees, OSHA shall advise the Interagency Testing Committee established pursuant to the Toxic Substances Control Act of the desirability of requiring testing under that Act. The ETS shall specify a permissible exposure level that can be achieved immediately through a practical combination of readily available engineering and administrative controls and personal protective equipment.

(c) The ETS shall exclude mixtures containing less than specified percentages of the substance being regulated and shall not apply to workplaces where the substance is present only in such

a mixture. Such percentages may differ for different uses or mixtures, and shall be determined in light of analyses of risks and benefits performed in accordance with Subpart C below, to the extent such analyses can be promptly performed.

(d) The ETS shall provide partial exemptions for workplaces below an "action level".

2. Permanent Standard.

(a) Where an ETS has specified an acceptable exposure level reflecting data sufficient to quantify risks to employees, the permanent standard shall require achievement or maintenance of that limitation.

(b) Where an ETS not based on data sufficient to quantify risks has been issued, and such data become available during the maximum statutory life (six months) of the ETS, a regular permanent standard shall issue to require achievement of an acceptable exposure level derived in part from such data. OSHA shall also consider, in setting permissible exposure levels, the analyses of risks and benefits. Different levels may be set for different chemicals and for different uses of the same chemical. Compliance with the permissible exposure limits shall require use of engineering controls to the extent technically and economically feasible, augmented by administrative controls and personal protective equipment as appropriate.

(c) Where an ETS not based on data sufficient to quantify risks has been issued and such data do not become available within six months, an "interim" permanent standard similar to the ETS shall be issued, to be in effect no longer than five years. If during that three years' period such data become available, a revised per-

manent standard may be issued that establishes an acceptable exposure level derived in part from such data, and also from analyses of risks, hazards, costs, and benefits. If such data do not become available, the regular permanent standard shall establish an exposure level that is the lowest level technically and economically achievable. Compliance with permissible exposure levels shall generally require all feasible use of engineering controls, augmented as appropriate by administrative controls and personal protective equipment.

(d) A permanent standard shall exclude mixtures containing less than specified percentages of the substance being regulated, (or shall specify with particularity the mixtures that are being regulated), and shall not apply to workplaces where the substance is present only in excluded mixtures. Such percentages may differ for different uses or mixtures and shall be determined in light of analyses of risks and benefitss performed in accordance with Subpart C below.

(e) A permanent standard shall provide partial exemptions for workplaces below an action level.

(f) Where OSHA decides not to issue an ETS, it shall consider institution of a permanent rulemaking under Section 6(b) of the Act based on regulatory priorities, unless it shall determine that such a rulemaking is not necessary to protect employees. As part of such a rulemaking, OSHA should advise the ITC of the need for dose-response data if they do not exist. Permissible exposure levels and other regulatory provisions should be established in the same manner as called for in the preceding subparagraphs (a) through (e).

3. Provisions of Standards Other than Ones Related to Permissible Exposure Levels.

Such provisions, which are not the subject of detailed AIHC recommendations at this time, should reflect the degree of hazard present in the workplaces.

B. Category II Classification.

1. Emergency temporary standard. Upon classification of a substance as a Confirmed Animal Oncogen, OSHA shall as soon as possible decide, in each case, whether actual employee exposures constitute a "grave danger" within the purview of Section 6(c) of the Act and whether an Emergency Temporary Standard is necessary to protect employees from such danger. Such determination shall consider (a) the evidence of potential carcinogenic risks (e.g., carcinogenic potency as indicated by experimental data, dose-response relationships, metabolism, duration and amount of exposure, route of exposure); (b) evaluation of actual hazards (e.g., physical and chemical properties, degree of occupational exposure, likelihood of a carcinogenic event); and (c) epidemiologic or other human experience evidence.

Upon completion of such a determination, OSHA shall immediately commence the development of an ETS if the criteria specified in Section 6(c) for such issuance have been satisfied. In developing an ETS (as well as in developing a permanent standard), OSHA shall perform analyses of risks and benefits in accordance with Subpart C below.

(a) Where an ETS is to be issued and where there are available dose-response data in one or more appropriate mammalian

species or other appropriate information sufficient to quantify risks to employees, OSHA shall, in light of such information, specify permissible exposure levels that reflect analyses of risks and benefits. In deciding upon such a level, OSHA shall perform analyses of risks and benefits in accordance with Subpart C below, to the extent such analyses can be very promptly performed. Any available epidemiologic or other human experience data shall be considered in establishing permissible exposure levels. These exposure levels shall generally be achieved by means of engineering controls, to the extent technically and economically feasible, augmented by administrative controls and personal protective equipment as appropriate. OSHA shall require that this exposure level be achieved as soon as feasible, and may require as an interim measure that exposure levels be reduced immediately through a readily available practical combination of engineering and administrative controls and personal protective equipment.

The permissible exposure levels may vary from chemical to chemical and from one use of a chemical to another, depending upon the analyses of risks and benefits.

(b) Where an ETS is to be issued and sufficient data are not available to quantify risks to employees, OSHA shall advise the Interagency Testing Committee established pursuant to the Toxic Substances Control Act of the desirability of requiring testing under the Act. The ETS shall specify a permissible exposure level that can be achieved immediately through a practical combination of readily available engineering and administrative controls and

personal protective equipment.

(c) The ETS shall exclude mixtures containing less than specified percentages of the substance being regulated and shall not apply to workplaces where the substance is present only in such a mixture. Such percentages may differ for different uses or mixtures, and shall be determined in light of analyses of risks and benefits performed in accordance with Subpart C below, to the extent such analyses can be promptly performed.

(d) The ETS shall provide partial exemptions for workplaces below an "action level".

2. Permanent standard.

(a) Where an ETS has specified an acceptable exposure level reflecting data sufficient to quantify risks to employees, the permanent standard shall require achievement or maintenance of that limitation.

(b) Where an ETS not based on data sufficient to quantify risks has been issued, and such data become available during the maximum statutory life (six months) of the ETS, a regular permanent standard shall issue to require achievement of an acceptable exposure level derived in part from such data. OSHA shall also consider, in setting permissible exposure levels, the analyses of risks and benefits. Different levels may be set for different chemicals and for different uses of the same chemical. Compliance with the permissible exposure limits shall require use of engineering controls to the extent technically and economically feasible, augmented by administrative controls and personal protective equipment as appropriate.

(c) Where an ETS not based on data sufficient to quantify risks has been issued and such data do not become available within six months, an "interim" permanent standard similar to the ETS shall be issued, to be in effect no longer than five years. If during that five year period such data become available, a revised permanent standard may be issued that establishes an acceptable exposure level derived in part from such data, and also from analyses of risks and benefits. If such data do not become available, the regular permanent standard shall establish an exposure level that is the lowest level technically and economically achievable. Compliance with permissible exposure levels shall generally require all feasible use of engineering controls, augmented as appropriate by administrative controls and personal protective equipment.

(d) A permanent standard shall exclude mixtures containing less than specified percentages of the substance being regulated, (or shall specify with particularity the mixtures that are being regulated), and shall not apply to workplaces where the substance is present only in excluded mixtures. Such percentages may differ for different uses or mixtures and shall be determined in light of analyses of risks and benefits performed in accordance with Subpart C below.

(e) A permanent standard shall provide partial exemptions for workplaces below an action level.

(f) Where OSHA decides not to issue an ETS, it shall consider institution of a permanent rulemaking under Section 6(b) of the Act based on regulatory priorities, unless it shall determine that

such a rulemaking is not necessary to protect employees. As part of such a rulemaking, OSHA should advise the ITC of the need for dose-response data if they do not exist. Permissible exposure levels and other regulatory provisions should be established in the same manner as called for in the preceding subparagraphs (a) through (e).

C. Analyses of risks and benefits for Category I and Category II Substances.

In establishing permissible exposure levels and other requirements of a specific standard, OSHA shall analyze risks (including hazards) and benefits to society (including costs to society) and shall state in writing the manner in which each of the factors listed below, among others, has been considered.

1. Risks. As used herein, risks refers to the observed carcinogenic or tumorogenic properties or propensities of a chemical substance. It is anticipated that the decision of the Data Evaluation and Classification Panel would generally include adequate discussion of risk factors. Risk factors include:

(a) evidence of carcinogenic potency, whether epidemiologic or experimental animal evidence;

(b) dose-response relationships and associated metabolic and pharmacokinetic data, if available;

(c) where only experimental animal evidence tends to implicate a chemical substance, evidence of favorable human or epidemiologic experience with the substance. It is recognized that while epidemiologic evidence cannot conclusively show that a substance is not

carcinogenic to humans, favorable epidemio-- logical evidence would be relevant and could be material in assessing risks (under established or prior conditions of use);

(d) whether the evidence of carcinogenicity consists only of experimental results, as opposed to epidemiology;

(e) the number of mammalian species for which evidence of carcinogenicity exists;

(f) the number and quality of any negative mammalian experiments;

(g) the kind of mechanism, or combination of mechanisms, producing observed carcinogenic effects.

2. Hazards. As used herein, hazards refers to conditions relevant to the likelihood, given certain risks within the foregoing definition, of a carcinogenic event due to use of a chemical substance in the workplace. Hazard factors shall be evaluated as and when necessary and shall include:

(a) the number of workplaces in which the substance is present;

(b) the number of employees in such workplaces;

(c) the conditions of manufacture or use of such substance in various workplaces;

(d) the frequency, duration, and intensity of exposure of employees (1) at present, and/or (2) at proposed permissible exposure levels.

(e) the physical and chemical properties of the substance, and its inherent warning properties;

(f) non-carcinogenic toxic properties of the substance;

(g) the foregoing factors, as applicable to workplaces where the substance is present in other substances in contaminant or trace amounts;

(h) statistical or other methods of quantifying the likelihood of a carcinogenic event in light of the foregoing factors;

(i) hazards of use of likely substitutes for the substance being regulated;

(j) comparisons with hazards of other contemporaneous activities, occupational and non-occupational.

3. Benefits to Society. As used herein, benefits include health benefits of reductions in actual employee exposures to the substance and benefits of continued use of the substance or mixtures containing the substance. An analysis of benefits shall include consideration of the following factors:

(a) benefits of reductions in actual employee exposure to the substance being regulated, including health benefits, reductions in costs of health care, reductions in lost employment, psychological and emotional

benefits to employees and their families;

(b) economic benefits of production and use of the substance, including volume and dollar amount of sales, number of employees, competiveness of domestic industry, and cost advantages or benefits to consumers of products made from or with the substance being regulated; balance-of-payments advantages; enhancement of productivity; improvement of cost effectiveness; reduction of waste; retardation of deterioration.

(c) "quality of life" non-economic benefits of production and use of the substance, including any safety or health benefits, e.g., prolongation of productive life, reduction of loss of life, limbs and health; reduction of other burdens; increases in knowledge; cultural values; uniqueness, vis-a-vis likely or possible substitutes.

4. Costs to Society. As used herein, costs include environmental and economic consequences of compliance with regulation, including adverse aspects of shifts to, and use of, substitutes that might result, as a by-product or otherwise, from imposition of regulation. Cost factors include:

(a) increases in energy or other raw material requirements, due to compliance with regulation or shifts to substitutes, and adverse environmental impacts of any resulting need

to exploit additional natural resources or to exploit existing resources more aggressively;

(b) economic feasibility of compliance with regulation;

(c) technological feasibility aspects of compliance with regulation;

(d) employment dislocation resulting from responses to the other costs of regulation, including direct local increases in unemployment and related economic and psychologic effects;

(e) indirect adverse economic effects of any reduction in direct employment.

In considering costs, particular importance should be attributed to incremental costs, in comparison with incremental benefits. Generally, the incremental costs of reducing employee exposure will increase exponentially as very low levels are approached, but there will not be substantial data to indicate any health benefit increment would be achieved by further reductions.

Consideration of costs will also include the social costs of increased economic concentrations that may result in response to regulatory action. The appropriateness of these considerations in this area is suggested by the Toxic Substances Control Act, which recognizes the desirability of avoiding imposition of unnecessary regulatory burdens on small businesses, and the desirability of preserving an economic system with diversity of size.

D. Category III Classification.

1. Reference to ITC for possible further testing.

2. Within 60 days OSHA may issue a notice of proposed rulemaking to establish permissible exposure limits at (1) the present OSHA standard or (2) where none exists, an appropriate level based on acute or chronic effects of exposure to the toxic substance other than carcinogenicity or (3) where acute or chronic effects indicate that the present OSHA standard is inadequate, the exposure level shall be lowered to the level found appropriate by the Secretary.

E. DECLASSIFICATION.

If the Data Evaluation and Classification Panel decide to remove a previously classified substance from the classification categories entirely, OSHA shall immediately advise its enforcement personnel with appropriate guidance as to subsequent enforcement policy, and shall promptly initiate appropriate revisions in any relevant health standards.

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AIHC

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AIHC RECOMMENDED ALTERNATIVES TO OSHA'S GENERIC CARCINOGEN PROPOSAL

January 9, 1978

Recommendations of American Industrial Health Council on
OSHA Regulation of Potential Occupational Causes of Cancer

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AIHC RECOMMENDED ALTERNATIVES

TO OSHA'S GENERIC CARCINOGEN PROPOSAL

PREFACE

Identifying and regulating carcinogens in the American workplace is a formidable but most necessary task, one which requires the best thinking of the most informed representatives of science, government, labor, business, and public interest groups.

It will be a challenge for these groups to work cooperatively toward a national policy on carcinogens in the workplace. But the stakes are high and we in industry feel the job must be done.

Mistakes and success in the area of occupational health will not be measured for years. In the interim -- while we cooperatively work together finding and reducing hazards -- the need for good judgment, objectivity and an acceptance of the fact that life cannot be made risk-free must be understood. Such understanding, of course, cannot be allowed to breed complacency.

(A) The Proposed OSHA Standard.

The U.S. Occupational Safety and Health Administration, seeking to develop a national standard for protecting workers from carcinogens, published its proposal for such a standard, "Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk", on October 4, 1977, and invited interested parties to comment on the proposal.

Obviously, OSHA's proposal is of great interest and import to American industry. Shortly after the publication of the proposal, a group of companies and trade associations formed The American

Industrial Health Council to develop a broadly-based commentary on it.

AIHC shares OSHA's view that there is a need to reduce employee exposure to cancer-causing substances in the workplace. Every substantiated cause of cancer, regardless of exposure site, must be subjected to very stringent control.

Experience has shown that some industrial chemicals can cause cancer. The best available evidence, however, indicates that these chemicals are a relatively small factor in the "environmental cancer" problem. Life-style factors such as diet and smoking are considered to be of far more significance.

While industrial chemicals represent only a small portion of the national cancer problem -- no more than 5 percent -- AIHC believes that all chemical substances should be managed at a socially acceptable risk level.

To provide the most authoritative analysis possible of the OSHA proposal, AIHC organized a committee of scientific, engineering and regulatory experts who subjected the proposal to intense study. This AIHC "Alternatives Committee", assisted by a specially-impanelled Scientific Committee, has issued a point-by-point summary of suggested changes in the proposal.

Fundamentally, the AIHC suggestions are offered in two basic areas -- standards for determining (a) what is a carcinogen, and (b) how to implement a workable system of protecting employees from substances that scientific experts agree are carcinogenic.

Central to the entire AIHC report is the establishment of a nine-member "substance categorization" board, to be selected by

the National Academy of Sciences. In effect, AIHC is saying that identification and regulation of carcinogens is too important and too complicated to be left to government regulators alone.

Before summarizing the principal modifications to the OSHA proposal offered by AIHC, it is important to note:

1. That OSHA's final generic carcinogen regulation will most likely have national significance far beyond the workplace. Other federal agencies, including the Environmental Protection Agency, the Food and Drug Administration and the Consumer Product Safety Commission, are considering patterning their regulation of carcinogens on OSHA's final standard. In effect, OSHA is developing what may become the national standard for regulation of carcinogens.
2. The new AIHC suggestions for modification, although likely to win broad support from American industry, are by no means the position of American business. Some in the business community may find the alternative proposals unnecessarily stringent. Nevertheless, the AIHC proposals represent a consensus of industry experts who have given intense study to the problem of protecting workers from cancer causing substances.

(B) Principal Desirable Modifications in the OSHA Proposal.

1. AIHC opposes the zero risk concept implied in OSHA's proposed rules: Rather, recognition is given to the potency or dose-

response data of suspect carcinogens through a much more precise categorization process than that proposed by OSHA.

AIHC recognizes the need for determining acceptable exposure levels and proposes that the permissible levels be fixed after a careful evaluation of the risks and benefits and a determination of technical and economic feasibility of control.

2. Recognition of the complexity and evolutionary nature of the scientific principles involved: The OSHA plan would "freeze" the science as of now with no provisions to take into account new scientific developments applicable to specific cases.

3. Recognition that carcinogens pose varying risks to humans: The OSHA plan does not recognize variation in potency of carcinogens and therefore the degree of hazard to employees in the workplace. AIHC would categorize substances according to relative potency and trigger regulatory activity appropriate to hazard.

4. Recognition of the social benefits, including economic benefits, as well as risks and the establishment of acceptable exposure levels or acceptable risks: In society the principle of acceptable risk is well established. In fact, it is inherent in any human endeavor. The laws under which OSHA operates recognize the idea of acceptable risk. Legislative history is clear that Congress did not intend to protect employees by putting their employers out of business. We do not, and cannot, have a risk-free society and it is not useful to propose regulation rooted in such an idea.

5. A different approach to animal data: OSHA is indiscriminate in attributing significance to animal data and in extrapolating those data to human exposure. Animal data must play an

important role in providing the basis for a regulatory system but their limitations must be recognized.

6. The role of "short-term" tests: OSHA's regulatory proposal for carcinogens would attribute some potentially significant consequences to the results of short-term in vitro tests. Short-term tests have value as screening tools and as guides for more complete tests and studies but the results of such tests are so unreliable as predictors of human response as to be unsuitable as a basis for regulatory decisions.

7. Recognition of the value of epidemiologic data: AIHC would place more emphasis on valuable epidemiologic data than would the OSHA plan, which would hold such data as subordinate to positive results in an experimental bioassay. Since human epidemiologic data are free from the uncertainties of extrapolation from animal tests, it seems quite unscientific not to use such data when available. Epidemiologic data reflects what happens in the real world and often supplies results quite different from what might be suggested from animal tests alone. Under the OSHA proposal, animal tests would outweigh the fact that decades of experience indicate human exposure to many substances which cause tumors in animal tests is not a problem.

8. Regulatory priorities: The AIHC alternative suggests regulating first those materials that are known to be human carcinogens or highly potent animal carcinogens. If the aim of the entire effort is to protect workers rather than to write regulations, it would appear prudent to attack real problems ahead of those that are speculative in nature.

9. Expert performance of the categorization function: Unlike the OSHA proposal, the AIHC alternative would rely on a scientific body separate from the regulatory function to categorize substances by their carcinogenic potential. This approach would promote efficiency and consistency throughout the regulatory agencies, all of which could accept the results of classifications made by a truly qualified panel.

Another reason for the creation of such a panel outside of the structure of the regulatory agency would be to separate the classification process from the wide variety of political and other pressures to which the regulatory agencies are subject. Regardless of intent, a regulatory agency must make decisions that are politically acceptable at that time with somewhat less attention to the validity of the scientific basis for the decision. An independent panel of scientists will provide some degree of insulation from such pressures.

10. A different approach to issuance of Emergency Temporary Standards: ETS must be reserved for those unusual situations where a life-threatening hazard is known to exist. Such action should not be automatic, but rather, should represent a reasonable regulatory response process.

11. Removal of the mandate for engineering controls: The industry proposes less costly, but just as effective, means of compliance which are keyed to actual occupational needs. Those industrial sites which may use a carcinogen should not arbitrarily be required to install very expensive additional engineering controls to achieve a permissible exposure level when a combination of

engineering controls and personal protective devices effectively protects the worker.

12. Substances or mixtures containing small amounts of suspect carcinogens should be exempted from the regulation: Given the great sensitivity of analytic methods, with parts per billion and in some cases per trillion being measured, the failure to provide for exclusions of mixtures has great potential for economic disruption, adverse environmental impact and employment dislocation. Furthermore, costly regulation of minute trace amounts of substances will often be of no discernible health benefit.

13. Laboratory workplaces and the construction industry should be separately regulated: Regulation of laboratories and construction raises special problems and they should be separately regulated. Regulation of laboratories is being considered by the Environmental Protection Agency and the Food and Drug Administration.

(C) Needed: Early Cooperative Effort.

This AIHC report is being made available at this time so that OSHA and other interested parties can give it thoughtful study before public hearings on the OSHA proposal begin on April 4.

AIHC urges all such interested parties to thus play a part in the development of what undoubtedly will become the most far-reaching regulatory action ever made in connection with the American workplace.

Earliest possible attention to this matter is required. Written notices of intent to appear at the OSHA hearings, as well as copies of actual planned hearings testimony, must be filed by January 30th.

January 9, 1978

Recommendations of American Industrial Health Council on
OSHA Regulation of Potential Occupational Causes of Cancer

I. The Problem in Proper Perspective.

A. The incidence of cancer.

The reasons advanced by OSHA to support its proposal[1/] imply that this nation is suffering an epidemic of cancer and that the epidemic is largely if not entirely attributable to increased manufacture and use of industrial chemicals. Factual evidence does not support that view. If we use the turn of the century as a time against which to compare today's cancer problem, there has indeed been an increase in the incidence of cancer -- but the increase is predominantly attributable to (1) greater longevity (the incidence of cancer increases with age), and (2) pandemic cigarette smoking. With adjustments for these two forces, as documented by both the American Cancer Society and United States government statistics, no overall increase in cancer incidence appears for the United States. According to the American Cancer Society (1977 Cancer Facts and Figures, p. 6):

> "The overall incidence of cancer has decreased slightly in the past 25 years. . . . For men, the cancer death rate per 100,000 population has increased by over 50% since 1950 for blacks and by 20% for whites. The increased death rate is mainly the result of lung cancer which rose from 18 deaths per 100,000 in 1950 to 52 deaths per 100,000 in 1974. For women, since 1950 the death rate has declined by 5% for blacks and 10% for whites. This is due mainly to a sharp reduction in deaths caused by cancer of the uterine cervix which is attributed to increased use of Pap tests and regular checkups. There was also a decline in

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1/ The OSHA proposal, entitled "Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk", appears as Part VI of the October 4, 1977, Federal Register, 42 F.R. 54148-54247.

stomach cancer. However, the lung cancer rate has tripled from 4.0 per 100,000 in 1950 to 12.3 in 1974."

Similarly, government statistics (e.g., DHEW, "Cancer Rates and Risks", 2d Ed. 1974, p. 14), adjusted for increase in longevity and increased cigarette smoking, show that there is no overall increase in cancer in the United States. Figure 1 shows that the total age-adjusted cancer death rate for men is increasing but that if cancer of the respiratory system is eliminated, the cancer death rate is decreasing. Figure 2 shows that the "total" age-adjusted death rate for women from all cancers has been decreasing and has been approximately constant for more than a decade. Finally, Figures 3 and 4 show that with the exception of lung cancer, which is primarily attributable to increased cigarette smoking, age-adjusted cancer death rates for men and women from specific types of cancer have not increased significantly in most cases and have in fact significantly decreased in others.

Moreover, it should be noted that in general, except for the kinds of cancers commonly associated with tobacco smoking, the same kinds of cancers are prevalent today as at the turn of the century. This suggests that causes in addition to cigarette smoking which may account for current cancer rates were, in general, present prior to the turn of the century, and thus are not new industrial developments. This is not to imply that no exceptions exist, or that wholly different agents cannot cause the same kinds of cancer. Neither does this imply that more than one agent cannot be a significant contributor to the causation of a kind of cancer; indeed, a prominent example of synergism in carcinogenesis is the combination of asbestos fiber inhalation and cigarette smoke inhalation in causing increased incidence of lung cancer in asbestos workers.

Age-Adjusted
Total Cancer Death Rates
In the United States For Men

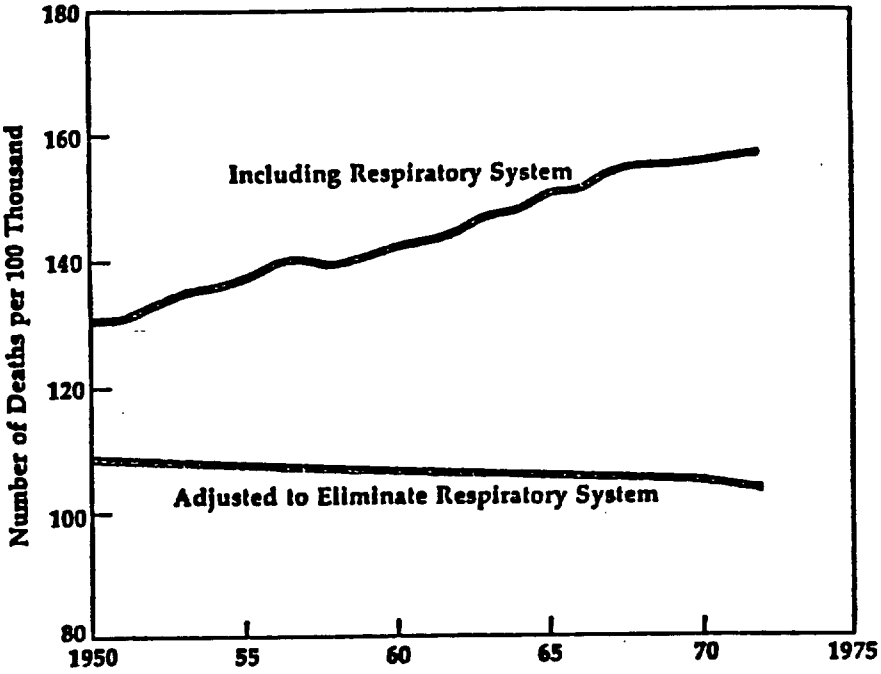

FIGURE 1

Age-Adjusted
Total Cancer Death Rates
In the United States For Women

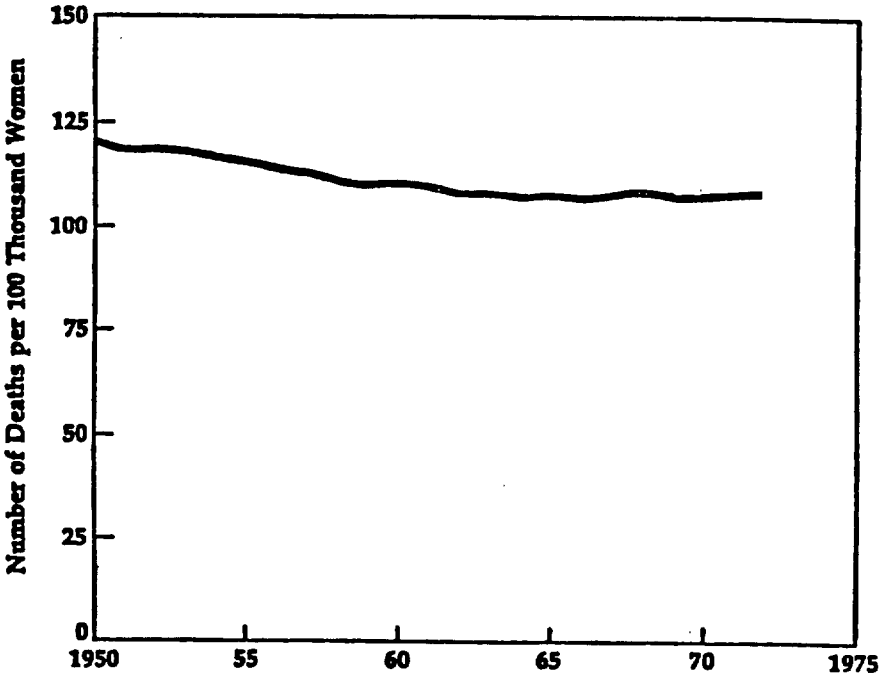

FIGURE 2

ALCOA0004137

Age-Adjusted Cancer Death Rates In the United States For Men

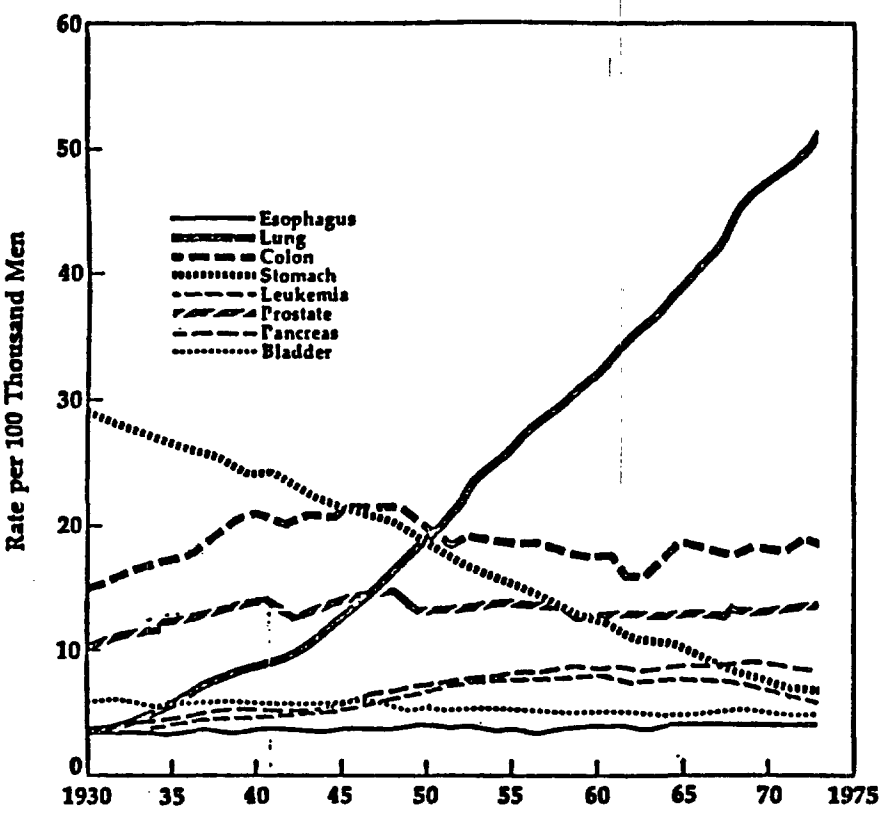

FIGURE 3

Age-Adjusted Cancer Death Rates In the United States For Women

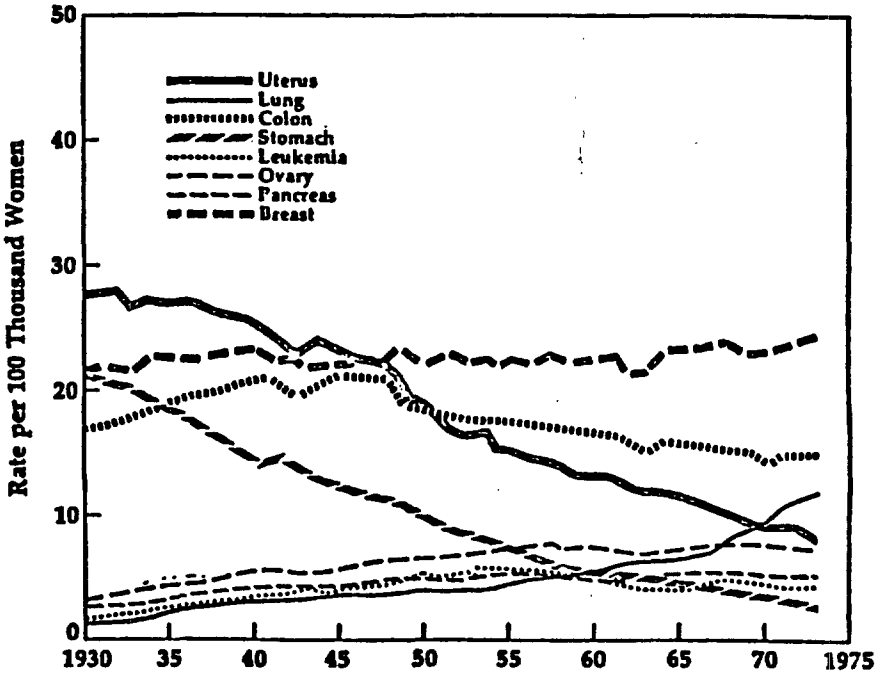

FIGURE 4

It should be noted also that males and females differ in risk of development of specified forms of cancer (Figures 3 and 4), and for most but not all forms of the disease the risk of development increases logarithmically with age. Therefore, in comparing the incidence of any form of cancer in two populations (e.g., an exposed population and an unexposed control population), it is essential to consider males and females separately and to take into account the age structures of the two populations. It is also necessary to take into account the possible changes in the background incidence of any particular form of cancer with the passage of time.

Thus, the risk that a man aged 70 in 1970 will develop a particular form of cancer before he is 71 may be different from that of a man who celebrated his 70th birthday in 1930. The possible reasons for this are numerous. The former for instance might have been of a generation exposed to mustard gas during the First World War while the latter was too old to enlist. In order to allow for differences of this kind, it is necessary to use cohort analysis procedures whereby men or women born during the span of say 5 years are considered to constitute a cohort for which the risk of development of particular forms of cancer during each year or group of 5 years of life can be calculated separately.

When this is done, for instance, for men born in England and Wales during the period 1861-1901, one finds that for each successive 5-year cohort and at each age from 40 to 80+ the risk of death from lung cancer increased. For example, the risk of dying from lung cancer between the ages of 65 and 70 was 0.1 per 1000

for men born during the 5 years around 1861, but increased to 2.9 per 1000 for men born around 1886 -- a 29 fold difference in only 25 years. Thus, in assessing whether an industrial chemical is increasing the incidence of death for any particular form of cancer, it is necessary to compare the observed incidence in the exposed population with the incidence to be expected in an unexposed population not only of the same sex and age-structure but also of the same cohort-structure. In England and Wales, where better data are available than for the United States, the death rates for cancers of various kinds in each sex have been compared for different cohorts with birthdates from 1851 onwards, and, with rare exception (the foremost of which is cancer of the lung in both sexes), these data show no recent evidence of an increasing risk of death from cancer. On the contrary, the death rates have actually been falling for several forms of the disease. Case, R. A. M. "Cohort Analysis of Cancer Mortality in England and Wales, 1911-1954, by Site and Sex", Br. J. Preventive and Social Medicine 10, 172 (1956).

In the OSHA proposal (42 F.R. 54150, Column 2, first paragraph), it is stated that the death rate from cancer today is higher than expected even after allowing for greater longevity as a consequence of lower death rates from infectious diseases and other advances in medicine, and for improved diagnosis. This is not accurate in view of the American Cancer Society, United States Government, and England and Wales statistics, when increased cigarette smoking is taken into account.

B. Industrial chemicals represent a minor fraction of environmental causes of cancer.

It is often stated that perhaps as much as 90 percent of

cancers are "environmentally related".[1/] It is important to note that the OSHA preamble (42 F.R. 54150-51) repeats this common statement in such a way that many might infer that industrial activity accounts for 90 percent of all cancers. Such an inference would be demonstrably wrong. The most ubiquitous, most prevalent, and the most significant cancer-causing factors are not industrial chemicals, but rather are factors associated with the ordinary process of living, for example smoking, diet, and exposure to solar radiation.[2/] Dr. Guy R. Newell, Acting Director, National Cancer Institute, testified to a subcommittee of the House Committee on Government Operations on June 15, 1977, that:

> "The term 'environment' must be defined. 'Environment', in its broadest sense, is the sum of everything around us--the water we drink and bathe in, the food we eat, and the air we breathe and are almost constantly immersed in. Yes, even tobacco products we smoke or are smoked by others in our 'environment'.
>
> 'By "environment" we mean not only our air and water, but also food, drink, smoking, the workplace and the home, sunlight, and all other aspects of our personal lifestyle.'" ("Report on Progress and Activities of the National Cancer Institute", p. 8.)

With "environmental" factors so defined, it is critical to consider the importance of the major specific ones. A team of researchers from the American Health Foundation and the National Cancer Institute have estimated that diet, exclusive of food additives

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1/ E.g., J. H. Weisburger, "Environmental Cancer", 18 J.O.M. No. 4, pp. 245-252 (April, 1976); Wynder and Gori, JNCI April, 1977.

2/ The very great majority of cancers associated with solar radiation are curable.

and contaminants, may contribute to as much as 50 percent of cancer.[1/] The American Cancer Society estimates that smoking cigarettes may account for as much as 80 percent of all lung cancers -- the leading cause of cancer deaths in males in the United States.[2/] Non-ionizing radiation, mostly in sunlight, has been estimated by NCI officials to account for 5 to 8 percent of all cancers. (Dr. Newell's testimony of June 15, 1977 (page 20), noted above, estimated 5 percent; Dr. Gio B. Gori, also of NCI, estimated 8 percent for male and 8 percent for female in a letter to Mr. E. V. Anderson dated May 10, 1977.) Dr. Newell's testimony also estimated (page 20) that alcohol, when combined with use of tobacco products, accounted for about 2 percent of cancers annually.

The best estimate is that industrial chemicals have accounted for about 1 to 5 percent of all cancers.[3/] This is not

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1/ Statement by Gio B. Gori, Ph.D., Deputy Director, Division of Cancer Cause and Prevention, National Cancer Institute, presented before the Select Committee on Nutrition and Human Needs, United States Senate, Wednesday, July 28, 1976. Figure 19: "Percent of total cancer incidence related to diet 40.9% male; 60.1% female."

2/ "Lung cancer - Cigarette smoking causes at least 80% of lung cancer." American Cancer Society, 1977 Cancer Facts and Figures, page 5; "Lung cancer constitutes 22% of cancers in males." American Cancer Society, "Cancer Incidence by Site and Sex", Ca-a Cancer Journal for Clinicians", January/February 1977, Volume 27, No. 1, Page 26.

3/ Dr. Newell's June 15, 1977, testimony (page 20) estimated "5 percent related to occupational exposures such as asbestos, vinyl chloride, benzene, beta-napthylamine and others." Dr. Gori's letter of May 10, 1977, to Mr. E. V. Anderson estimates occupational causation at 3 percent for males and less than 1 percent for females. A guest editorial by Ernest L. Wynder, M.D., and Dr. Gori in the April, 1977, issue of the Journal of the National Cancer Institute, (p. 825) states at page 830:

"Bailar (personal communication) estimated that the occupational contribution to total cancer incidence in males lies between 1 and 5%, and a similar estimate was made by Nelson (personal communication). General estimates of the percentage of all human cancers related to occupational exposure range between 1 and 10%."

an insignificant number of cancers, but it is reasonable to question whether the public is being well-served by being led to believe that industrial chemicals are the overwhelming cause of cancer in this country. A public so convinced would expect, if not demand, that the concentration of governmental "corrective" action be focused upon industrial activities in the expectation of preventing the great majority of the malignancies. Such a misconception could have very grave consequences, diverting society from pursuit of additional preventive measures.

It is difficult to justify the implication in OSHA's preamble that the total cost to society of all cancers should be compared with the cancers attributable to exposure to industrial chemicals (42 F.R. 54150). While it is indeed reasonable to compare costs and benefits in discussing even so emotional a subject as the causes of cancer, it is also reasonable to compare the problems caused by the use of industrial chemicals with the benefits that are derived from them.

In order to place industrial chemicals in proper perspective in any analysis of cancer causation, it is necessary to recognize that they are a small part of the total cancer problem. Nonetheless, the part they play is important because any cause of cancer is important. All would agree that wherever and 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 regardless of whether any regulations have been promulgated. A prudent employer would in fact act to reduce exposure to any suspect carcinogen, more promptly than any regulatory process can force him to. Fortunately, recent years have seen an increased awareness

of the possibility of occupational hazards, and greatly improved measures have come into common use to reduce employee exposure to potentially harmful industrial chemicals. See, e.g., Ferber, Hill & Cobb, American Industrial Hygiene Association Journal, January, 1976, pp. 61-68 (control of potential exposure to benzidine).

C. The alleged failure of prior OSHA regulatory efforts and need for a generic standard.

To justify the oversimplifications and arbitrary rigidity of its proposed categorical approach, OSHA makes much of its supposed inadequacies over the past seven years in the regulation of industrial carcinogens. One can question the accuracy of this self-effacing criticism and thus suspect its motivation.

In 1972 OSHA wrote to its expert advisor, NIOSH, requesting information on all known industrial carcinogens. NIOSH responded by carrying out a literature survey and by publicly requesting information -- on 15 substances -- in a notice published in the Federal Register on July 6, 1972. NIOSH subsequently advised OSHA that there appeared to be 15 occupational carcinogens of which some were known human carcinogens and some were implicated solely on the basis of bioassay experiments. This advice was subsequently modified by the deletion of one of the materials, dimethyl sulfate, leaving 14 carcinogens that NIOSH believed to be in use then, or to have previously been in use, in American workplaces. In 1973 OSHA promulgated an Emergency Temporary Standard limiting employee exposure with respect to all 14 chemicals and commenced a permanent rulemaking which was completed in January of 1974.[1/] What more OSHA could have been

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1/ See 39 F.R. 3756 (Jan. 29, 1974). The 14 included a number regarded as known human carcinogens, and (continued on next page)

expected to have accomplished by then is left unsaid by the current self-criticism, which also ignores the fact that in 1977 OSHA demonstrated that it could act very promptly to regulate industrial substances implicated as potential carcinogens (DBCP).[1/]

Much of the apparent subsequent gap between the regulatory need and OSHA's response is attributable not so much to lack of zeal on OSHA's part as to a number of other considerations. Two, but only two, considerations are the striking increase in recent years in the amount of experimental testing of chemical substances for evidence of carcinogenicity, and the acceleration of the reporting of the results of these tests. Another consideration, however, has been a very controversial modification in OSHA's operative criteria for assessing carcinogenicity. It was the informed view of NIOSH in 1973 that clear evidence of carcinogenicity should be required in two mammalian species before a substance could appropriately be regarded as posing a carcinogenic risk to man insofar as regulatory activities are concerned, but OSHA now proposes to use much less reliable evidence as a basis for regulations.

To justify this shift in position, and to demonstrate a need for its new proposal, OSHA points to the "large number of potential carcinogens already identified by NIOSH", an apparent

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(continued from previous page) several regarded only as known or highly suspect animal carcinogens. The 14 are: 2-Acetylamino fluorene; 4-Amino diphenyl; Benzidine; 3,3'-Dichlorobenzidine; 4-Dimethylaminoazobenzene; alpha-Naphthylamine; beta-Naphthylamine; 4-Nitrobiphenyl; N-Nitrosodimethylamine; beta-Proprolactone; bis (chloromethyl) ether; Chloromethyl Methyl ether; 4,4'-Methylene-bis (2-chloroaniline); and Ethyleneimine.

1/ 1977 also demonstrated the imprudence of undue resort to the ETS procedure -- with respect to benzene.

reference to the "Suspected Carcinogens" subfile of the Registry of Toxic Effects of Chemical Substances (42 F.R. 54169, Column 3). The Second Edition of this subfile, published in 1976, lists 2,415 substances. This does not at all indicate that there are that many carcinogens, or even that NIOSH believes that to be the case.[1/] Rather, the subfile is an uncritical compilation of published data about the chemicals; many, perhaps 510, are listed simply because some government agency has indicated an interest in testing them.[2/] As the Editor of the subfile has noted in the Preface:

> "This publication does not indict a substance as a human carcinogen. Rather it reports published data which suggest that the substance has caused neoplastic or carcinogenic effects. The experimental designs used in the cited studies may be unsuitable for prediction of human effects. Their inclusion in the Registry does not reflect an evaluation with respect to the adequacy of the data, or consideration of negative or contradictory studies.
>
> "The National Institute for Occupational Safety and Health (NIOSH) identifies a substance as a potential human carcinogen by means of the criteria document process. This involves exhaustive literature review and careful consideration by experts leading to a definitive conclusion. <u>This subfile is published to serve as a guide to the literature, and as an indication of those substances which</u>

1/ OSHA's preamble itself quotes, for other purposes, evidence suggesting that there are only "perhaps a few dozen" carcinogens (42 F.R. 54151, Middle Column). As a matter of regulatory principle, OSHA cannot justify its proposal with directly conflicting propositions.

2/ Many of the listed chemicals are simply laboratory-produced analogs of carcinogens tested in an effort to correlate structure with effect, or to examine possible metabolites, i.e., compounds of no industrial or occupational significance. Others are pesticides listed by EPA as having "data gaps" according to proposed guidelines which would require an oncogenicity study in a second species of rodents, generally the mouse.

may require further research and evaluation." (emphasis added).1/

It is, of course, necessary to establish priorities in this area; NIOSH has done so in selecting substances to be covered by its Criteria Documents.2/ A good example of the difference between the Subfile and a Criteria Document is the case of formaldehyde. This substance is reported in the subfile as having produced neoplastic effects, but the NIOSH Criteria Document on Formaldehyde dated December 1976 does not conclude that the material presents a carcinogenic hazard.

It is also relevant, with respect to the alleged need for the regulation OSHA has proposed, that OSHA does not have authority, under the Occupational Safety and Health Act of 1970 ("the Act") or otherwise, to adopt a generic regulation in which inflexible standards are set for all substances meeting predetermined criteria, without reference to the requirements of Section 6(b)(5) of the Act, 29 U.S.C. § 655(b)(5), regarding the promulgation of standards for toxic materials, and without affording interested parties an effective opportunity to comment on the impact of the proposed regulation on specific substances. A single, inflexible regulation

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1/ It is understood that, in recognition of these points, NIOSH intends to change the title of the subfile to something other than "Suspected Carcinogens."

2/ NIOSH's Criteria Document Development Process includes comprehensive reviews of available information to recommend health standards including "the concentration of a substance in the occupational environment which has been found to cause no adverse effects in people exposed for a normal working lifetime." "Schedule of Development for Criteria Documents", NIOSH Division of Criteria Documentation and Standards Development, p. 2 (October, 1977).

is inappropriate in light of: (a) the diversity and lack of uniformity among substances, and their effects, that are potentially covered; and (b) the wide diversity among workplaces such as factories, laboratories and construction sites. To apply a single inflexible regulation to such widely divergent circumstances is arbitrary and capricious. The inappropriateness of this type of regulation, which requires automatic application of pre-determined standards in all subsequent proceedings on individual substances, is exacerbated by OSHA's rulemaking procedures which have the effect of reducing the opportunity for interested parties to comment or present testimony on the manner in which specific substances will be affected. The regulation is further rendered defective by the lack of any variance or waiver procedure that would permit a risk-benefit analysis, or otherwise take account of marked differences among substances, in specific cases.

Moreover, even assuming arguendo that Congress had delegated to OSHA the authority to promulgate such a regulation, such a delegation would be unconstitutional. (See pages 55-56 below.)

OSHA has stated its "intention, once this proposal is duly promulgated, to foreclose, in subsequent 6(b) rulemakings on individual substances, the rehearing of the validity of the OSHA's proposed classification system and most other policy determinations made in OSHA's proposal, including the procedural structure intended to be followed". (42 F.R. 54154). To foreclose consideration of scientific and other evidence is contrary to the mandate of Section 6(b)(5) of the Act dealing with toxic substances or harmful physical agents, to consider "the best available evidence . . .,"

including "the latest available scientific data in the field." Further, to the extent that issues are preempted in hearings on individual substances under Section 6(b), the proposed regulation and OSHA's contemplated procedure will deprive employers of their statutory hearing rights on those issues.

OSHA also does not have the authority, under the Act or otherwise, to require that in all cases permissible exposure limits be set "as low as feasible." Even if OSHA had that authority, its proposed regulation is impermissibly vague in this regard.

In partial summary: OSHA's past regulatory efforts have been much better than OSHA's preamble suggests; OSHA has not demonstrated the need for the inflexible and oversimplified regulation it has proposed; and that proposal is beyond OSHA's statutory authority.

D. Regulation of individual chemicals.

Although AIHC does recommend a more reasonable general approach to regulation of suspect carcinogens, OSHA should expedite its formulation of occupational health standards for individual chemicals known or suspected to be carcinogens. In doing so, OSHA should develop regulatory priorities based on such matters as the strength of the evidence implicating the chemical as a carcinogen, the carcinogenic potency of a chemical, the number of employees exposed, the extent of exposure, and the likelihood of a carcinogenic event.

OSHA could readily expedite individual rulemakings for chemicals with known or suspected carcinogenic potential by applying accepted principles of risk assessment and hazard evaluation in

conjunction with expanded manpower resources. These modifications could be implemented readily without a simplistic, unrealistic categorization scheme and simultaneously solve the concerns expressed by OSHA in its preamble to the proposed generic standard: specifically,

1. OSHA's problem of relitigating certain issues in each and every rulemaking could be greatly reduced or eliminated by general agreement on criteria for categorization and by a complete risk assessment. This would resolve basic, heretofore contentious, questions in a practical, acceptable manner and establish priorities for regulation.

2. The taxing of witnesses through repetitive public hearings would be relieved by complete risk assessment prior to rulemaking, and/or by adoption of general principles (such as the use of mammalian test data) to be followed except where countervailing evidence was presented to the Data Evaluation and Classification Panel that AIHC recommends or during an OSHA rulemaking.

3. Continuity of approach in regulating carcinogens would be achieved by basing proposed regulations on the results of hazard evaluations for specific substances. These evaluations would review such factors as chemical and physical properties, conditions of use in the workplace, extent of production, nature of the processes, etc.

4. Use of priorities and proper risk assessments should improve regulatory efficiency. If OSHA should still regard its efforts as inadequate, then OSHA could petition Congress for additional manpower. This would be far less costly to the nation than OSHA's proposed categorization and model standard scheme, which would often impose enormous cost increments with no concomitant enhancement

of health.

5. OSHA can avoid futile rulemakings by proposing regulations based on valid risk analysis and hazard evaluation and on the likely costs and benefits, rather than utilizing a non-specific generic approach.

E. Complexity and rapid evolution of scientific learning with respect to carcinogenicity.

Sound and well-informed decision making with respect to occupational exposure to potential carcinogens ought to take account of the fact that the causation of cancer is known to scientists to be an extraordinarily complex matter. It ought also to recognize that the state of the art is currently undergoing rapid evolutionary change, as the result of various major research programs and tests to ascertain individual causes of cancer and to understand the mechanisms of cancer causation. Since this is so, it is particularly inappropriate to "freeze" science at this moment, something which the OSHA proposal would in effect do. The obtuseness of OSHA's approach appears clearly from the advice of the Subcommittee on Environmental Carcinogenesis of the National Cancer Advisory Board (NCAB), a group charged by the Director of the National Cancer Institute (NCI) with developing criteria for assessing evidence of carcinogenicity which cautioned that:

> "in assembling these criteria, the sub-committee recognizes that at present there is no simple and universal definition of either carcinogenesis or neoplasia. The criteria which are described are general guidelines and not rigid, universal criteria. 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 aspects of that agent, its intended use(s), the data

> available at the time that 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 for one agent may not necessarily apply to another." (58 J. Nat'l Cancer Inst. 461, Feb. 1977.) (emphasis added)

Although OSHA's preamble does cite the work of the NCAB Subcommittee (while ignoring its advice), many of the references cited elsewhere in the preamble reflect views expressed seven or more years ago; many of these are already outdated, imprecise or otherwise inaccurate in light of current references, or are superseded by the more recent NCI statement. Indeed, the references cited by OSHA in support of its proposal reflect a single biased perspective of the problems of occupational carcinogenesis. For example, the references fail to report the very considerable body of learning supporting the no-effect level hypothesis concerning cancer causation.

It is manifestly unwise to disregard the discoveries made in the past few years by cancer researchers and to ignore for the foreseeable future developments currently underway or soon to be realized. In fact, such an approach is, as noted above, beyond OSHA's authority since the Occupational Safety and Health Act requires that health standards shall reflect "the latest available scientific data in the field" among other considerations. Indeed, federal regulatory authorities should plan on making a general reassessment of the state of the relevant science at least every five years, if not continuously, and should also reassess prior decisions in light of whatever additional data have become

available.[1/] Particularly in an area of rapidly developing science and data, OSHA should not proceed on the assumption that it can now make decisions that will be valid for the foreseeable future.

F. The illusion of a no-risk society.

The OSHA preamble gives too much emphasis to the uncertainty and difficulty of knowing the safe level of exposure to any known or suspect carcinogen with any degree of confidence. Having made so much of the matter, the preamble declares that the only reasonable way to deal with any carcinogen is to assume that there is no safe level of exposure. Implicit in this notion, if not explicit, is the concept that "safe" within the meaning of the Act means entirely risk-free. There is a correlative notion that industrial or any other useful activity can occur on a completely safe, risk-free basis. Neither proposition is warranted or attainable. There are risks associated with all societal activities. (There are even risks associated with efforts to avoid activity.) Moreover, in enacting the Occupational Safety and Health Act of 1970, Congress explicitly recognized the impossibility of assuring American workers a risk-free workplace. It follows, therefore, that there is a legitimate role for the evaluation of relative risk and the acceptance of some degree of risk, a concept commonly regarded as "acceptable risk". Even in an emotional context such as cancer, sound public policy must take into account the inevitability of some risk, and the necessity of evaluating such risk not only against

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1/ For example aniline was once regarded as a carcinogen, but the development of further data indicated otherwise.

alternative risk but also in light of the benefits of the substance being regulated.

G. The Occupational Health and Safety Act of 1970 requires consideration of benefits and risks in determining an acceptable occupational exposure.

The Occupational Safety and Health Act requires that OSHA, in promulgating standards, "shall set the standard which most adequately assures, to the extent feasible . . . that no employee will suffer material impairment of health or functional capacity." § 6 (b)(5) 29 U.S.C. and 655(b)(5) (emphasis supplied).

In addition to the text of the Act, its legislative history, and administrative and judicial decisions construing the meaning and intent of the Act support the conclusion that economic issues must be considered in evaluating feasibility of proposed standards. The legislative history demonstrates a serious concern on the part of Congress to insure that economic and practical considerations as well as technical considerations are factored into the standard-setting process. Senator Javits, author of the key amendment which added the "feasibility" requirement of the Act, explained its meaning as follows:

> "As a result of this amendment the Secretary, in setting standards, is expressly required to consider feasibility of proposed standards. This is an improvement over the Daniels bill, which might be interpreted to require absolute health and safety in all cases, regardless of feasibility, and the Administration bill, which contains no criteria for standards at all." [Legislative History of the Occupational Safety and Health Act of 1970, Senate Committee on Labor and Public Welfare, 92nd Cong., 1st Sess. 197 (Comm. Print June, 1971) ("Legislative History").]

Similarly, Senator Saxbe expressed concern about the

impact of standards which might not consider economic factors:

> "we have seen great industrial nations which have lost their ability to compete. By that I do not mean to indicate, in connection with this bill, that we have to have a dangerous operation or an unsafe operation to compete. But I do know that in the competitive world of business today, we should not attach to safety unnecessary or harassing measures that would, in effect, limit production in areas that are not necessarily going to increase safety.
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> * * *
>
> . . . About 12 years ago [the English Government] adopted a number of safety bills that were very idealistic in their concept, but so restraining to the place of work and so restraining on the assignment of employees that they served not to make the plant safer and to increase production, but rather to make the business less competitive, and, as a result, [England] lost business to German manufacturers producing the same item.
>
> This is something that we must be objective about. We want ideal and safe working conditions. At the same time, we must have one eye on this and the other eye on permitting the manufacturer to be competitive, not at the expense of the workmen, but rather in a cooperative effort." (Legislative History at 321-327; see also Legislative History at 147-148, 464, 471-472.)

The courts of appeals have accordingly concluded that economic factors are an appropriate consideration in setting "feasible" standards for toxic substances. In Industrial Union Department, AFL-CIO v. Hodgson, 499 F.2d 467 (D.C. Cir. 1974), Judge McGowan, in reviewing the OSHA standard for exposure to asbestos dust, concluded that the factors entering into the Secretary's conclusion could properly include problems of economic "feasibility". 499 F.2d at 477. He amplified this conclusion as follows:

> "There can be no question that OSHA represents a decision to require safeguards for the health of employees even if such measures substantially increase production costs. This is not, however,

> the same thing as saying that Congress intended to require immediate implementation of all protective measures technologically achievable without regard for their economic impact. To the contrary, it would comport with common usage to say that a standard that is prohibitively expensive is not 'feasible.'" 499 F.2d at 477. (Footnote omitted; underscoring added.)

In AFL-CIO v. Brennan, 530 F.2d 109 (3d Cir. 1975), Judge Gibbons, in reviewing an OSHA safety standard for mechanical power presses, also ruled that the Secretary "may in the weighing process consider the economic consequences of his quasi-legislative standard-setting:"

> "Congress did contemplate that the Secretary's rulemaking would put out of business some businesses so marginally efficient or productive as to be unable to follow standards otherwise universally feasible. But we will not impute to congressional silence a direction to the Secretary to disregard the possibility of massive economic dislocation caused by an unreasonable standard. An economically impossible standard would in all likelihood prove unenforceable, inducing employers faced with going out of business to evade rather than comply with the regulation. The Act does vest the Secretary with authority to enforce his regulations, but the burden of enforcing a regulation uniformly ignored by a majority of industry members would prove overwhelming." (530 F.2d 123; footnotes omitted.)

In Florida Peach Growers Ass'n v. United States Department of Labor, 489 F.2d 120 (5th Cir. 1974), the Fifth Circuit was of the same opinion.

> "The promulgation of any standard will depend upon a balance between the protection afforded by the requirement and the effect upon economic and market conditions in the industry. As articulated by the Chairman of the Subcommittee on Pesticides, who resigned in 'shock' upon finding that the recommended standards were issued on the emergency basis: 'It is essential

> that employees be protected against exposure to highly toxic materials, but this should be done without eliminating the agriculture enterprise and the associated job.'" 489 F.2d at 120.

As the Court of Appeals wrote in the IUD (asbestos) case, "Congress does not appear to have intended to protect employees by putting their employers out of business -- either by requiring protective devices unavailable under existing technology or by making financial viability generally impossible." 499 F.2d at 478. Among other things, these authorities indicate that OSHA should not ban the use of any substance, which would generally be the result of a "no exposure" requirement.

The Review Commission, in interpreting OSHA's noise standard to "effectuate the Congressional purposes underlying the Act," concluded that economics is indeed an integral part of feasibility, stating:

> "[W]e conclude that the standard should be interpreted to require those engineering and administrative controls which are economically, as well as technologically feasible. Controls may be economically feasible even though they are expensive and increase production costs. 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." Secretary v. Continental Can Co., OSHRC Docket No. 3973 et al. (Decided August 24, 1976) (citations omitted).1/

Finally, in Turner Company v. Secretary of Labor, 561

1/ Accord, KLI, Inc., 1977-1978 CCH OSHD ¶ 22,350 (OSHRC 1977); Castle & Cooke Foods, 1977-1978 CCH OSHD ¶ 21,854 (OSHRC 1977), petition for review filed, No. 77-2565 (9th Cir., July 14, 1977); Great Falls Tribune Company, 1977-1978 CCH OSHD ¶ 21,844 (OSHRC 1977); West Point Pepperell, Inc. 1977-1978 CCH OSHD ¶ 21,751 (OSHRC 1977).

F.2d 82, 83 (7th Cir. 1977), the Court considered an OSHRC decision requiring Turner to adopt an engineering noise abatement program, at an estimated cost of up to $30,000, to bring the company into compliance with the federal noise exposure standard. That standard, 29 CFR § 1910.95(b)(1), provides that "[w]hen employees are subjected to sound levels exceeding those listed in Table G-16, feasible administrative or engineering controls shall be utilized." (561 F.2d at 83, n. 2; emphasis supplied by the Court.) In construing the word "feasible" in the standard, the Court held that the word "must be given its ordinary and commonsense meaning of 'practicable'" and that this "construction is in accord with the clear intent of Congress and the purpose of the Occupational Safety and Health Act." (561 F.2d at 83.) The Court concluded that "the Commission must realistically consider the hazards presented by the excessive noise . . . and determine whether the health benefits to employees who are already equipped with personal protective equipment [earplugs] justify the $30,000 cost to Turner". (561 F.2d at 86.)

H. Other federal regulatory statutes require consideration of benefits and risks in determining an appropriate regulatory response.

Numerous federal regulatory statutes have been enacted in the past few years to control potential hazards. These new laws have uniformly required a balancing of benefits and risks in determining the proper regulatory action to protect the public.

The Consumer Product Safety Act was enacted in 1972 to provide protection against a wide variety of hazards that might be posed by consumer products, including the hazard of chemical carcinogens. The CPSA authorizes CPSC to establish consumer product

safety rules to protect against "unreasonable risk of injury." Section 9 of the Act requires that CPSC take into account the following considerations in promulgating these standards:

> "(b) A consumer product safety rule shall express in the rule itself the risk of injury which the standard is designed to eliminate or reduce. In promulgating such a rule the Commission shall consider relevant available product data including the results of research, development, testing, and investigation activities conducted generally and pursuant to this Act. In the promulgation of such a rule the Commission shall also consider and take into account the special needs of elderly and handicapped persons to determine the extent to which such persons may be adversely affected by such rule.
>
> "(c)(1) Prior to promulgating a consumer product safety rule, the Commission shall consider, and shall make appropriate findings for inclusion in such rule with respect to --
>
> (A) the degree and nature of the risk of injury the rule is designed to eliminate or reduce;
>
> (B) the approximate number of consumer products, or types or classes thereof, subject to such rule;
>
> (C) the need of the public for the consumer products subject to such rule, and the probable effect of such rule upon the utility, cost, or availability of such products to meet such need; and
>
> (D) any means of achieving the objective of the order while minimizing adverse effects on competition or disruption or dislocation of manufacturing and other commercial practices consistent with the public health and safety."

The Medical Devices Amendments of 1976 amended the Federal Food, Drug, and Cosmetic Act to add stringent new controls over potentially hazardous medical devices. Section 513(a)(2) of the amended Federal Food, Drug, and Cosmetic Act specifically requires that the safety and effectiveness of medical devices be determined

by weighing any "probable benefit" against any "probable risk," and Section 514(g)(2) requires that any standard for medical devices consider "the benefit to the public from the device."

The Toxic Substances Control Act similarly requires consideration of both benefits and risks in determining appropriate controls for chemical substances. Section 2(b) specifically recognizes, as the policy of the United States, that:

> "(3) authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment."

Section 2(c) states the intent of Congress:

> ". . . that the Administrator shall carry out this Act in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes to take under this Act."

Section 4(a) permits EPA to establish testing requirements for chemicals which may present "an unreasonable risk of injury," including the risk of cancer. Section 6(c) authorizes regulatory restrictions on chemicals to prevent "unreasonable risks" after EPA considers:

> "(A) the effects of such substance or mixture on health and the magnitude of the exposure of human beings to such substance or mixture.
>
> (B) the effects of such substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture.
>
> (C) the benefits of such substance or mixture for various uses and the availability of substitutes for such uses, and

(D) the reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national econony, small business, technological innovation, the environment, and public health."

It is inconceivable that Congress intended that benefits be considered in regulating all of these public hazards, and others as well, but be ignored in regulating occupational hazards.

I. Government agencies have approved carcinogenic risks from chemicals under other regulatory laws.

The Food and Drug Administration has a broad mandate to assure the safety of all food. Yet the agency has allowed the following food substances to remain available for daily consumption in spite of unquestioned scientific studies showing that each is carcinogenic in at least one species of mammalian test animals:

Egg yolk and egg white 1/
Vitamin D2 2/
Calcium 3/
Lactose and maltose 4/
Selenium 5/
Beverage alcohol 6/
Caffeine 7/

Similarly, FDA has failed to remove bacon and ham from the market

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

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

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

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

5/ 38 F.R. 10458 (April 27, 1973); 39 F.R. 1355 (Jan. 8, 1974).

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

7/ Press Release, Japan Times, September 22, 1977, quoting Japanese Cancer Research Inst.

although they are known to contain nitrosamines or to produce nitrosamines in the body when consumed. FDA has also failed to exercise its jurisdiction over restaurants to prevent the charcoal broiling of meat, which produces carcinogenic benz-a-pyrene. Indeed, FDA has set tolerances for aflatoxin in peanuts and corn, which by FDA's own estimates raise a risk of 66 lifetime cancers per 100,000 persons.[1/]

Congress has, in the Saccharin Study and Labeling Act, endorsed FDA's unwillingness to remove known carcinogens from the market without a benefit/risk analysis. The congressional moratorium was enacted with the understanding that saccharin presents a risk of approximately 1500-2000 cases of bladder cancer per year within the United States.[2/]

J. Non-chemical risks are a part of daily life.

In everyday life, man is exposed to numerous risks of fatalities which society accepts. Some of these risks pose quantifiable risks of cancer:

Activity	Risk of cancer fatality/year
Cosmic Ray	
- One transcontinental flight/year	$.05 \times 10^{-5}$
- Commercial Airline Pilot (50 hrs./month at 35,000 feet)	5.00×10^{-5}

1/ Food Chemical News, November 14, 1977, pp. 3-4; see also page 43 below.

2/ Sen. Rep. No. 95-253, 95th Cong., 1st Sess., p. 6 (1977). This report states that these figures were derived from Canadian studies and conclusions, and were confirmed by FDA Commissioner Kennedy. These conclusions may be debatable; the point is that Congress was willing to accept their possible validity, but nonetheless decided that saccharin should continue to be available.

- Frequent airline passengers	1.50×10^{-5}
Other Radiation	
- Average U.S. Diagnostic Medical X-Ray	1.00×10^{-5}
- Sea level natural background	1.50×10^{-5}

Others pose equal risks of a different nature. The risk of one transcontinental airline trip per year is 0.3×10^{-5}. The risk of electrocution is 0.5×10^{-5}. The risk of accidental poisoning by solids and liquids is 0.6×10^{-5}, and by gases or vapors is 0.7×10^{-5}. The risk of suffering a fatal fall is 7.7×10^{-5}.

In its pursuit of recreation the human race engages in and tolerates many activities of relatively high risk. The following activities and their degree of risk are illustrative:

Activity		Risk/Year
Football	Averaged order participants	4×10^{-5}
Automobile racing		$1,200 \times 10^{-5}$
Horse racing		$1,300 \times 10^{-5}$
Motorcycle racing		$1,800 \times 10^{-5}$
Power boating		170×10^{-5}
Amateur boxing		2×10^{-5}
Skiing	40 hours/year engaged in sport	3×10^{-5}
Canoeing		40×10^{-5}
Rock climbing		100×10^{-5}
Sunbathing (curable skin cancer)		500×10^{-5}
Fishing (drowning)		1.7×10^{-5}
Drowning (all recreational causes)		1.9×10^{-5}

Society has chosen not to prohibit any of these activities, or even activities with much higher risks (e.g., the Indianapolis 500).

There are relatively few activities which pose such a high risk that society has banned them completely (e.g., going over Niagara Falls in a barrel or attempting suicide).

Nor are these risks limited to recreational activity. The following annual risks of death from causes other than cancer in selected occupations show that benefits are considered in public regulation of occupational hazards as well:

Coal mining[1/]	- Black lung disease	$10{,}000 \times 10^{-5}$
Coal mining	- Accident	$1{,}500 \times 10^{-5}$
Airline pilot	- Accident	50×10^{-5}
Typical jet flying	- Air accident	10×10^{-5}
Manufacturing (total)		5×10^{-5}
Fire fighters		$1{,}000 \times 10^{-5}$
Steel worker		60×10^{-5}
Railroad worker	(accident risk)	400×10^{-5}

(The principal references for the foregoing risk figures are B. G. Ferris, New Eng. J. Med., 268 540 (1964); F. D. Sowby, Health Phys., 11 879 (1965); C. Starr, Science, 165 1232 (1969); K. S. Clarke, J. Am. Med. Assoc. 197 894 (1966); Statistical Bulletin, Metropolitan Life Insurance Co. (May 1977.)

II. Principal Desirable Modifications in the OSHA Proposal.

A. Recognition of the complexity and evolution of the science.

It seems only realistic to modify the OSHA proposal, as AIHC recommends, so as not to regard the present (or the past) state

1/ In view of the very high risks of coal mining, which surely should be reduced, the Administration's energy policy, which encourages coal mining, highlights the need to consider the benefits.

of the relevant science as frozen. The OSHA proposal "freezes" science in two ways: in the manner and extent to which regulatory propositions are to be foreclosed from future consideration in individual chemical rulemakings; and in the proposed obstacles that OSHA would create to allowing itself to take advantage of, or to utilize, improvements or developments in relevant learning. The latter problem arises from the fact that OSHA would not entertain any modifications of the rigidities of its proposed approach except by way of a formal rulemaking that would modify the pending categorical rulemaking proposal. The problems of obtaining even a very clearly warranted modification of such a rulemaking appear to be truly formidible. Enormous bureaucratic inertia would have to be overcome, and even if that were possible, very substantial time would be required.

The AIHC proposal 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. In the absence of such countervailing evidence, it may be appropriate for OSHA to use general principles, without having to support them with personal testimony time and again. For example, the AIHC proposal would permit use, prima facie, of mammalian test data to categorize a chemical as posing some occupational carcinogenic risk. AIHC would not, however, preclude interested parties

who believed they had compelling evidence, from attempting to persuade OSHA that its general principles should not be regarded as warranting such regulatory action (e.g., in the particular circumstances of some improperly designed mammalian test or some future unforeseeable case).

B. Recognition that not all carcinogens pose the same risk to humans.

The amounts of different chemicals known to have non-carcinogenic toxic effects can vary by several orders of magnitude;[1/] a different permissible exposure limit for each is therefore appropriate and justified. Since it has been demonstrated that the carcinogenic exposure level of different materials can likewise differ by a million fold or more,[2/] it seems irrational for the OSHA proposal to proceed on the basis that all known and potential carcinogens pose equivalent risks (by requiring the "lowest feasible" permissible exposure level in all cases). Carcinogens, like non-carcinogen toxins, should be classified or ranked in terms of potency, and regulated according to the degree of hazard that their use or uses present to employees. For example, bischloromethylether is a very potent known human carcinogen; vinyl chloride is much less potent. More severe controls clearly are warranted for the former.

1/ Modern toxicology is based on experimental evidence demonstrating that a dose-response relationship exists for toxic substances and that there is some dose level below which no response occurs. Although there may be scientific dispute at present whether there are threshold or no-effect levels for carcinogens, there is a strong body of scientific opinion embracing this concept, supported by the current NCIR study on 2-Acetylaminofluorene and the Oak Ridge radiation study.

2/ Compare, for example, aflatoxin with saccharin.

Greater priority should be accorded to regulating a substance that is a potent carcinogen than a substance that is a weak carcinogen, where the extent of employee exposure is the same.

The AIHC alternative calls for categorizing both human and animal carcinogens in terms of the potency of carcinogenic response, "high", "intermediate", or "low". These classifications are provided primarily to assist in establishing regulatory priorities. (However, a low potency carcinogen may warrant high priority if exposures are high and extensive.) The potency distinctions also would be an indicator of the regulatory controls to be imposed: more stringent controls for the more potent carcinogens. However, the categories would not inflexibly determine the regulatory controls. Such controls, including the means of achieving the permissible exposure level, would be determined on a case-by-case basis in light of assessments of risks and benefits. Controls and exposure levels could easily differ for two substances in the same category, depending on the circumstances of each case.

The OSHA proposal would group all "carcinogens" (as defined by OSHA's "policy decisions") into one group, Category I. The AIHC proposal recognizes the many-fold differences in degree of potency as measured by the size of the dose that (a) results in cancer and (b) affects the latent period (the time from first exposure to development of a tumor).

Although OSHA has ignored dose-response data, there are many references in the literature to the presence of dose-response relationships for carcinogens. Just-released data from the National Center for Toxicological Research (NCTR) on the liver

and bladder carcinogen 2-Acetylaminofluorene ("2-AAF") eloquently demonstrate the dose-response phenomenon. This singular study, which utilized large numbers of animals and multiple dose levels, also demonstrated that latency, expressed as time-to-tumor from first dose, is clearly a function of dose, confirming Druckrey's classical observations on latency and dose-response. Set out below in Figure 5 is a graph contained in the NCTR draft study which clearly illustrates the dose-response relationship in liver tumorigenesis for 2-AAF.[1/]

The principal ways by which the AIHC proposal would take into account dose-response and time-to-tumor data include determining the actual hazards presented by a chemical (which must include consideration of how it is in fact used), and otherwise ascertaining socially acceptable or permissible exposure levels. It is proper and logical for OSHA to set a lower exposure level for a highly potent carcinogen than for one shown to be only weakly potent.

C. Recognition of benefits, including economic benefits, as well as risks; establishment of acceptable exposure levels or acceptable risks.

The AIHC alternative does not proceed on the illusory basis that a risk-free industrial environment is attainable. Rather, it deals candidly with assessment of risk and benefits.

The first step in this process is the assessment of carcinogenic risk, that is, assessment of the likelihood of a carcinogenic event at a particular level of exposure. It is not presumed

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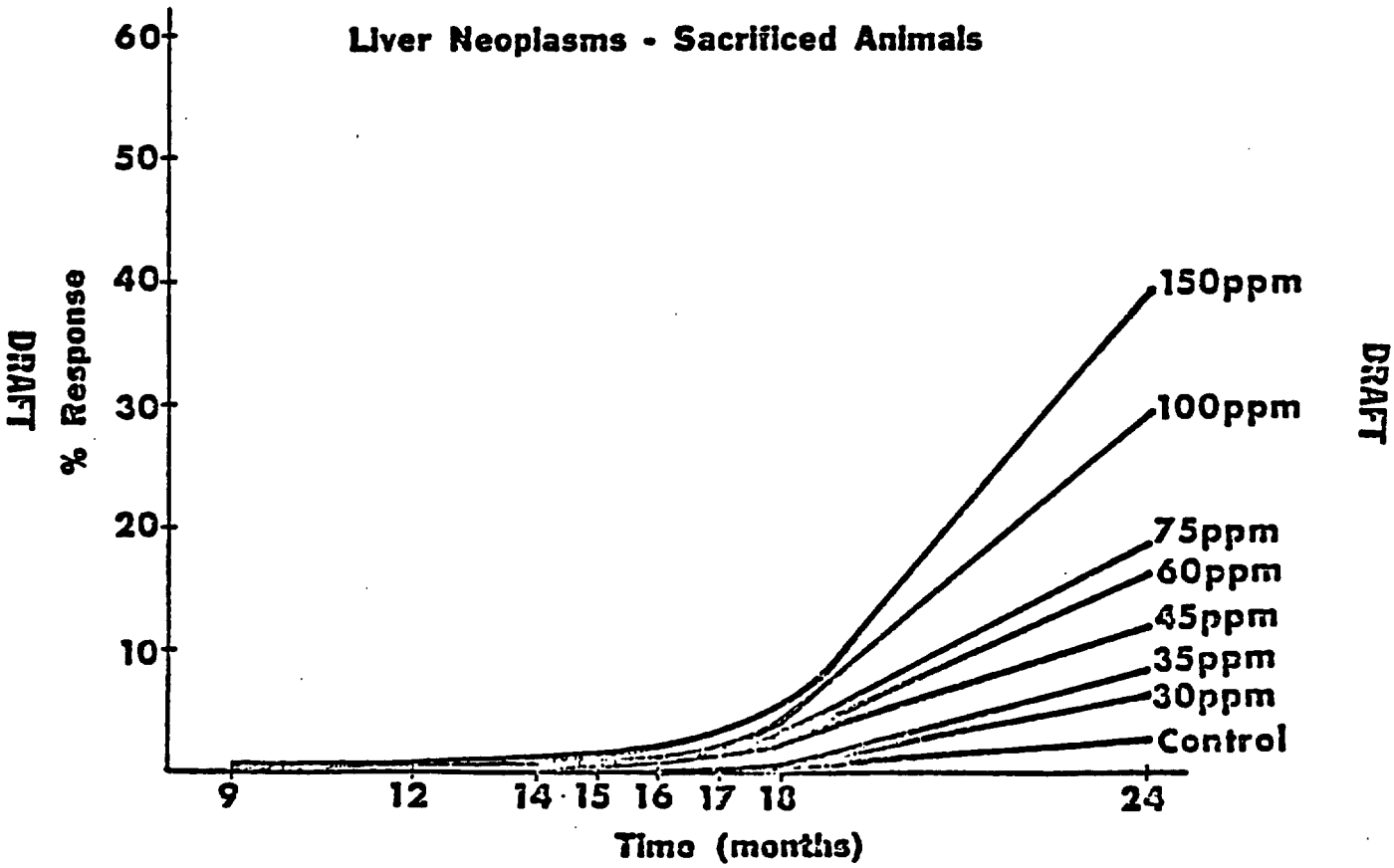
1/ The NCTR data on 2-AAF show a no-effect level for the kidney.

FIGURE 5



(NCTR Study on 2-AAF)

that at present there is any broad agreement on a particular method for quantification of such risk, or that any of the more frequently used or advocated methods to quantify risk are precise. The ones commonly used are generally regarded as erring considerably on the side of safety and conservatism in estimating carcinogenic risk. The AIHC alternative proceeds on the basis, however, that efforts to assess risks can serve a useful purpose in comparing risks of exposure to a particular chemical with other occupational risks and with other risks commonly encountered and accepted in our society (see pages 27-30 above), and in weighing these risks against the benefits of the chemical in question.

The second step in this process is the assessment of the benefits derived from the chemical which raises a carcinogenic risk, and the costs involved in reducing that risk. No one questions that any step which would reduce a carcinogenic risk at little or no cost, and thus without reduction of benefits, should promptly be undertaken. In most instances, however, regulatory requirements involve substantial costs that can drastically reduce or eliminate important societal benefits.

The third step in this process involves the balancing of benefits and risks in determining an appropriate regulatory response. Since it is usually impossible to quantify either benefits or risks with mathematical precision, it is surely impossible to establish any formula for balancing the two or arriving at the ultimate decision of an acceptable exposure for any particular carcinogen. The AIHC alternative would therefore require that OSHA, like other government agencies, specifically recognize all of the various

factors which comprise the risks and benefits, and specify how each is taken into account in reaching its final regulatory decision. The AIHC alternative lists various risk and benefit factors to be included in this decisional process.

D. Different approach to animal data.

The OSHA proposal is indiscriminate in attributing significance to mammalian test data and, for all practical purposes, automatically extrapolating therefrom to human exposure. Mammalian test data are used by OSHA as the basis for making regulatory decisions without regard to the dose used, the overwhelming of normal detoxification mechanisms, the mechanism of cancer induction (where known), the route of exposure or other test conditions no matter how irrelevant to human occupational exposures.

Mammalian test data have an important role to play in regulatory decision-making, but their limitations need to be clearly recognized. The value of professional scientific judgment in analyzing and interpreting such data, and their applicability to any given occupational exposure situation, need to be fully understood. The OSHA proposal is deficient in both respects. Further, OSHA ignores or fails to take sufficient account of numerous well-established scientific principles essential for valid and meaningful extrapolation from animal data to man.

Most importantly, OSHA fails adequately to consider that when the dosage for an animal is massive, its natural detoxification systems or defense mechanisms (often a liver enzyme or series of enzymes) are usually overwhelmed. Dr. H. F. Kraybill of NCI in

a recent paper[1] expresses serious concern about the unrealistically high doses currently being used in animal experiments. He concludes that "[f]indings from such studies are almost science fiction and there is a good chance for overstatement of the risk." The result of such high doses, according to Dr. Kraybill, is that the detoxification mechanisms of the host become incapable of providing the necessary protection.[2] Dr. Kraybill urges, quoting extensively from a recent article by Dr. Jerome Cornfield (Science, 18 November 1977), pp. 683-694), that saturation levels should therefore be factored into predictive models. "The fallacies of massive dosing," concludes Dr. Kraybill, "for many cases must be appreciated and comprehended prior to any assessment of carcinogenicity."

OSHA's proposal sanctions extrapolation from mammalian test data to human exposure but ignores major metabolic, pharmacokinetic and biochemical differences which exist between species of animals and man. And, because of certain species' peculiar ability to develop neoplastic responses to a wide variety of apparently safe substances (injection of ordinary penicillin under the skin of a mouse causes sarcoma, the most malignant kind of cancer), there is always considerable margin for toxicological experts to doubt the application even of any replicated finding to man, especially where the replication is in but one species.

1/ Paper presented at the December 19, 1977, meeting of the Chemical Selection Subgroup of the Clearinghouse on Environmental Carcinogens (Clearinghouse) entitled "Biochemical Intermediates as Research Probes in Carcinogenesis Methodology," pages 3-5.

2/ A good example of the ability of a host system to repair itself if the dose does not overwhelm the defense mechanisms or if the insult is removed is the increased longevity of those smokers who stop smoking as compared with those who continue to smoke. See U.S. Dept. of HEW, Cancer Rates and Risks (1974) p. 63.

By sanctioning a replicated test in a single mammalian species to corroborate a positive result and to categorize a chemical as a carcinogen (extrapolating from such animal data to humans), the OSHA proposal ignores the lack of validity in many such "replicated' animal studies which may be the result of variations in test procedures and conditions. Among these variations might be interspecies differences in metabolism, methodological differences in statistical treatment of data, differences in the basic diets fed to the animals, differences as to the applicability of certain tumor systems (e.g., hepatomas in mice), the presence of other volatile toxic substances where an experiment was conducted, and differences in animal husbandry.[1/]

Two biological circumstances also dramatize the need for careful appraisal of animal data. Estrogens and androgens are carcinogenic to experimental species, and for estrogens, carcinogenicity in humans has been documented. Yet estrogens are ever-present at sub-threshold or no-effect levels in the entire earth's population and are essential to life. Similarly, metals such as chromium and cobalt and perhaps nickel, selenium, even arsenic, are essential to man in small amounts but carcinogenic in excessive amounts.[2/]

The AIHC proposal would substantially differentiate among animal test results depending on the experimental test procedures

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1/ Merely changing the type of wood shavings beneath mouse cages from pine to redwood will set off epidemic cancer in certain strains.

2/ Dr. Kraybill of NCI, in another paper presented to the Chemical Selection Subgroup of the Clearinghouse on Environmental Carcinogens on February 2, 1977, entitled "Some Concepts and Remarks on Presumptive Negative Chemicals, Biological Intermediates, Endogenous Chemicals, Nutrients," discusses additional substances which are required by the body physiologically, biochemically (continued on next page)

and conditions. The proposal would examine those experimental procedures and conditions and attribute regulatory significance to the test data appropriate to the procedures and conditions of the test. This approach is radically different from the OSHA approach which, essentially, automatically assigns equal regulatory significance to all animal tests.

While the AIHC proposal would require positive results in two different mammalian species in well-designed and conducted experiments to warrant regulation of a substance as a carcinogen, it would not preclude OSHA from instituting a normal Section 6(b) rulemaking on a specific substance on the basis of a single such experiment where, in light of the best information available at the time, regulation because of carcinogenic hazards might be appropriate.

The AIHC proposal is in accord with OSHA's in rejecting injection site tumors as a basis for categorization and in rejecting similarities in chemical structure between known carcinogens and other untested substances as a basis for categorization as carcinogenic.

E. The role of short-term tests.

OSHA's proposal would attribute some potentially significant regulatory consequence to the results of so-called short-term tests. The proposal is remarkably unspecific as to what is intended here; unanswered questions include how many tests are

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2/ (continued from previous page) or nutritionally and which have produced tumors in animals under certain test conditions. See also 39 F.R. 1355 (Jan. 8, 1974) for FDA approval of the "safe use of selenium as a nutrient in the complete feed of" swine, chickens, and turkeys.

required, what results in various tests would be sufficient for regulatory purposes, and what kinds of tests would be sufficient. In contrast, the AIHC proposal reflects the general state of the art, which is to the effect that short-term tests are currently so much more unreliable as predictors of human responses as not to be sufficient to warrant regulatory action other than to serve as guides for requiring conventional bioassay, biochemical, or metabolic testing. The AIHC proposal finds support in the "General Criteria for Assessing the Evidence of Carcinogenicity of Chemical Substances" prepared by the Subcommittee on Environmental Carcinogenesis of the National Cancer Advisory Board and published in 58 Journal of the National Cancer Institute 58:463 (February 1977):

> "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 agent in long-term animal bioassays, particularly if there are other reasons for testing. Negative results in a short-term test, however, do not establish the safety of the agent.
>
> "This Subcommittee is enthusiastic about the possible future use of *in vitro* tests as part of a screening system for potential carcinogens and believes that their future development and validation deserve high priority."1/

While the AIHC proposal would not preclude subsequent attribution of regulatory significance to short-term tests, depending upon advances in scientific learning, it would at present limit their use to serving as guides for further testing.

1/ The reliability of the short-term tests is also discussed in Purchase, *et al.*, Nature 624, Dec. 16, 1976.

F. Recognition of the value of human experience and epidemiologic data.

OSHA is correct in recognizing that most epidemiologic studies which claim to demonstrate -- even qualitatively -- that an excessive incidence of cancer is caused by a single chemical are suspect because of: (a) mixed chemical exposures; (b) unknown, non-occupational exposures (e.g., smoking); and (c) poor estimations of exposure levels. However, studies which do not show excessive cancer incidence ("negative studies") are seldom criticized from these standpoints. Therefore, any well-executed study[1/] utilizing universally accepted techniques deserves consideration in the categorization of chemicals. In fact, it should be the primary decision-making criterion.

The AIHC proposal would attribute more significance to available epidemiologic data (human experience) than would the OSHA proposal which would even subordinate any such negative data to positive results seen in an experimental bioassay. Since human data are free from the difficulties of extrapolating from animals, it is quite arbitrary and otherwise unscientific not to use these data whenever they are available.

Human data could play a significant role in several ways. First, such data could suffice to classify a substance as a known human carcinogen; it is recognized that relatively few chemicals would be so classified. Second, where appropriate, such data,

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1/ AIHC recognizes that the quality and statistical significance of epidemiologic data often vary; the fact that some such data are inconclusive is not a logical basis for ignoring all such data.

with exposure level information, could indicate potency. On the other hand, such data could in some cases preclude carcinogenic classifications that might otherwise seem indicated on the basis of positive animal data. More generally, such data must be considered relevant, along with the results of animal studies, in any risk assessment.

There is good reason to attribute significance to epidemiologic data, whenever such data are available. For example, aflatoxin is one of the most potent carcinogens in various mammalian species, but there is ample epidemiologic evidence that, where the material is not ingested in gross quantities it does not produce harmful effects in man, despite widespread exposure to it in peanuts, corn, maize and sorghum. This has been recognized recently by the Food and Drug Administration, allowing aflatoxin levels of 20 ppb in shelled peanuts and human food products such as peanut butter; epidemiologic evidence in the United States was favorable, but contrary to experimental results of induction of tumors in animals at dose levels of 15 ppb and, in one experiment, 1 ppb. (39 F.R. 42748 (Dec. 6, 1974).) FDA there reviewed the aflatoxin data and proposed to reduce the level to 15 ppb but stated that the 20 ppb level would continue until and unless the proposal were adopted, which it has not been. FDA has very recently established an aflatoxin level in milk of 0.5 ppb. (42 F.R. 61630 (Dec. 6, 1977).)

Similarly, 3,3'-Dichlorobenzidine has produced tumors in animals, but epidemiologic data show no unusual incidence of cancer

or other disease.[1/]

Further, there is evidence that micro nutrients, such as selenium, which in low doses produce no harmful effects on man, indeed may be necessary to life, produce well defined toxic effects, including carcinogenicity, in animals. See page 39 above. And the human nutrient calcium fed to bulls at only 3.5 to 5.9 times the amounts the National Research Council has concluded they require, has produced ultimobranchial tumors in the thyroid glands in 30 percent of the animals.[2/] Clearly, humans are not at risk the same way from calcium.

Negative human data on the toxicity of carcinogenic materials are seldom seen in scientific journals, and certainly never in the popular press. These data are for the most part in "company files" and there is little incentive for making them known -- much less for developing more data -- since, as the OSHA proposal demonstrates, little importance is attached to this information relative to positive animal studies. The AIHC proposal attempts to rectify this unscientific attitude.

G. Regulatory priorities.

The OSHA proposal contemplates what appears to be a haphazard approach to regulatory priorities: It is suggested that the large number of materials on the NIOSH subfile of "suspect carcinogens"

1/ See Gerarde & Gerarde, J. Occup. Med. 16(5), 322-344 (1974); MacIntyre, J. Occup. Med. 17(1), 23-26 (1975).

2/ L. Krook, et al., "Dietary Calcium, Ultimobranchial Tumors and Osteopetrosis in the Bull", 22 Amer. Journal of Clinical Nutrition, No. 2, pp. 115-118, February, 1969.

may be considered in alphabetical order (42 FR. 54169, Column 3), and priorities for additional materials would depend upon the happenstance of the timing of OSHA's receipt of information from any source. The latter 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 and nickel (essential human nutrients), peanuts, asphalt, and carbon tetrachloride.

The AIHC proposal reflects the view that OSHA should retain the flexibility to exercise informed judgment and should consider regulating first those materials that are known or seriously alleged to be human carcinogens or highly potent animal carcinogens. (Priority should also depend upon the degree and extent of employee exposure.) Materials in this category are surely a much more manageable number 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. This approach would enable greater benefits to be achieved, and ensure greater acceptance by those being regulated, in view of its manifest reasonableness. Such acceptance is highly desirable in a democratic society.

H. Categorization of substances not found in domestic workplaces.

Unlike the OSHA proposal, the AIHC alternative would not call for formal categorization, by publication in the Federal Register, of a material that might be, within OSHA's scheme, a Category I,

II, or III material but which is not present in United States workplaces. This aspect of the OSHA proposal appears to have virtually no ascertainable benefits. The basket category contemplated here, that is, chemicals that possibly could be regarded as within OSHA Categories I, II, or III, is so broad as to be practically meaningless; all that one could readily conclude from assignment to such a category would be that the substance is not found in United States workplaces. There could be no reasonable objection to OSHA's communicating with EPA so as to be alerted if anyone should propose to import or manufacture within this country a material as to which there was some, unevaluated, information of potential carcinogenicity. It would be reasonable to rely upon EPA's premarket notification scrutiny to provide appropriate warning of such a potential development.

I. Avoidance of controversy, uncertainties, and mistakes concerning substitutes.

Unlike the OSHA proposal, the AIHC alternative would not call for OSHA to decide whether substitutes are available for a chemical (in one or more uses or processes) being regulated as a carcinogen, and would not call for a zero-exposure limit (generally, a ban of the substance) where substitutes are thought to be available.

First, the banning of any substance is beyond OSHA's legal authority. As noted above, standards must be feasible, and Congress did not intend OSHA to protect workers by eliminating their jobs. The OSHA Act, with its feasible-standard authorization, stands in sharp contrast with the Toxic Substances Control Act, which does specifically authorize EPA to ban manufacture or use of a substance

where certain conditions are met. Moreover, the proposed requirement for "no exposure" would be tantamount to requiring a cessation of operations without adherence to the specific criteria and procedures set forth in §§ 9 and 13 of the Act, 29 U.S.C. §§ 658 and 662. Even if it were within OSHA's authority to impose a "no exposure" standard, the "suitable substitute" test set forth in OSHA's proposed regulation is impermissibly vague. Any effort to read the authority to ban a substance into the general language of the OSHA Act would raise serious questions as to the constitutionality of such an expansive delegation of legislative authority. But even as a policy matter, OSHA should not concern itself with substitutes.

One policy objection to the OSHA proposal on substitutes is that it is largely unnecessary where good substitutes are -- or subsequently become -- available. Industry experience demonstrates that materials discovered to be carcinogenic generally have been replaced, over time, by other materials. The incentives to make such shifts include health factors, as well as avoidance of the expenses of complying with carcinogen regulation. For example, industry has largely displaced asbestos-bearing insulation materials for new and replacement process equipment insulation. Also, industry had entirely discontinued use of a number of the "14 carcinogens" before OSHA regulated them; some of them possessed benefits that, in the absence of adequate substitutes, have resulted in their continued use in established applications, but the imposition of regulation has essentially eliminated this group from serious consideration in new process research and development.

It should be noted here that the six months that the OSHA proposal contemplates as the maximum rulemaking period will generally not provide adequate time for OSHA to determine whether substitutes are presently available. Substitution can be a very complex question for a single use of a chemical; where, as is common, the uses are quite varied, the difficulties of deciding about substitutes becomes much greater. In addition, the rulemaking could not anticipate subsequent development of substitutes, and thus could never do a complete job. Neither could a rulemaking anticipate future new uses for the chemical, which could be quite beneficial -- but impossible because it had been banned.

Another objection is that OSHA might, under the pressure of the six-month limit and other pressures, err in deciding that adequate substitutes are available. Such decisions can only be correctly made on technical, rather than political, grounds. It would be difficult for OSHA generally to have or obtain the necessary information and expertise to judge what effect the substitution would have on product quality, utility, effectiveness, and stability, on processing parameters such as output, equipment changes, energy consumption, and maintenance requirements, or on direct and indirect economic effects on suppliers and customers as well as the user of the banned substance. Substitution decisions often involve a trade-off in hazards (e.g., carcinogenicity vs. flammability or corrosiveness); the apparent relative safety of potential substitutes will in some cases depend on the lack of comparable data. Substitute decisions take time -- to find the best substitute, to pilot the process, to allow customers to test the product, and finally to

engineer and build process equipment modifications. New uses of the substitute material may also invoke the premarket notification provisions of the Toxic Substances Control Act.

Thus, while it may be easy to require a substitute, it may be difficult to accomplish. The consequences of such errors could be very substantial, for consumers -- who will generally bear any increased costs -- and employees as well as employers. Our nation's balance of trade could also suffer; poorly conceived -- or compelled -- substitutes might not be viable in world markets because of economic and performance requirements. In light of these considerations, it appears likely that very substantial controversy would generally attend OSHA's rulemakings if substitutes were at issue. This would unnecessarily tax the limited personnel resources which OSHA hopes to utilize better by the current proposal.

J. Decreased resort to Emergency Temporary Standards; guidelines.

The OSHA proposal would require, in every case of a Category I classification within its scheme, automatic invocation of the Emergency Temporary Standards approach that is authorized by Section 6(c) of the Act. This requirement is unlawful. Section 6(c) requires the Secretary of Labor in each case to make specific, prescribed factual findings prior to issuance of an ETS. And, particularly where a chemical is not a known human carcinogen, this requirement is contrary to the decision of the United States Court of Appeals for the Third Circuit, Dry Color Manufacturers Ass'n, Inc. v. Dept. of Labor, 486 F.2d 98, 104-105 (1973). There the court stated that even though cancer was a possibility, the

question remained of establishing a "sufficient probability of harm to man"; for a valid ETS to issue, there must be a showing of "more than some possibility that a substance may cause cancer in man." The court then said that the record before it failed to show "more than some possibility that DCB and EI may cause cancer in man", indicating that the record did not warrant an ETS.[1/] The evidence then before the court included the reports of laboratory rodent experiments on 3,3' Dichlorobenzidine and Ethyleneimene 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.

The court stressed the value Congress had intended that the normal rulemaking procedure would have, noting that it was clear that Congress had provided for an ETS as "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 is specifically designed to bring out the relevant facts."

As a policy matter, the ETS approach seems undesirable whenever complex factual issues are involved, and must be resolved in a permanent rulemaking to be instituted and completed within only

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1/ The court set aside the ETS on another ground, having clearly indicated its views that an ETS would not generally be warranted on the basis of animal data alone.

six months from the promulgation of an ETS. This is particularly so when controversy may be expected, as would generally be the case considering the stringent controls and far-reaching implications that attend a carcinogenic rulemaking. These reservations are all supported by the history of reaction to OSHA's prior uses of the ETS approach to substances being regulated only because of carcinogenic potential.

The AIHC proposal thus rejects the notion of automatic resort to the ETS procedure, and contemplates that each case would be considered in light of the Act and applicable court decisions, and that informed judgment would be exercised on the basis of all available information.

There will inevitably -- perhaps often -- be occasions where common sense and prudence dictate that some action be taken virtually immediately to reduce employee exposure, without regard to the rulemaking process. In such circumstances it would be appropriate for OSHA to promulgate guidelines that inform the public of risks, that recommend prompt remedial action, and that set forth the basis for the recommended action. Such guidelines would achieve substantially the same results as would an ETS, without the adverse effects of an ETS. OSHA has promulgated such guidelines on a number of occasions, as recently as August 1, 1977, on "DBCP", and December, 1977, on ethylene dibromide.

K. Provision for exclusion of mixtures.

The OSHA proposal is silent on exclusion of mixtures containing very low concentrations of the material being regulated. Given the recently greatly increased sensitivity of analytical methods,

with parts per billion and even per trillion now being measured, the failure to provide for exclusions of mixtures[1/] has great potential for economic disruption, adverse environmental impact, and employment dislocation. For example, many aerospace propellants and aviation lubricants contain trace amounts of carcinogens which cannot be eliminated. Failure to provide exemptions would have enormous adverse impacts, as OSHA itself recognized in providing exclusions in the 14 carcinogens rulemaking.

The appropriateness of such exclusions is further warranted because there will often be no discernible health benefit from the application of a costly (or prohibitive) regulation to a mixture containing very low concentrations of the substance being regulated. AIHC thus favors such exclusions.

L. Provision for partial exemption for workplaces consistently below permissible exposure levels.

To reduce the burdens of compliance with regulations and to reduce the economic and inflationary impact of additional regulations, the AIHC alternative would, unlike the OSHA proposal, result in partial exemptions for workplaces consistently below permissible exposure levels. In general, the scope of the exemptions would include monitoring, medical surveillance, and record-keeping requirements. OSHA precedent for this approach (on vinyl chloride, 39 F.R. 35893, Oct. 4, 1974) has enabled significant economies to be realized, without perceptibly altering employee

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1/ The exclusions would exempt not only mixtures but also workplaces where the mixtures were present. The exclusions would apply not only to products manufactured from carcinogens but also to substances in which the carcinogens appear as contaminants or by-products, provided the concentration of the carcinogen was below a specified level.

protection. Indeed, by freeing industrial hygiene resources of unnecessary regulatory burdens, the exemption should promote employee protection in other areas.

M. Special regulatory approaches to laboratories and construction.

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 consequence 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.

Similarly, construction presents very special problems, as OSHA has recognized in regulation of asbestos, and special regulation for construction activity would be necessary.

Thus, while the categorization aspects of the AIHC proposal could apply to laboratories and construction, the regulatory response would generally be different than it would be for production operations.

N. Appropriate timing and scope of assessment of economic environmental impacts; due process.

The AIHC proposal does not itself deal with issues as to the timing or scope of assessment of economic and environmental impacts of implementation. Because of the comparative flexibility of that proposal, it should be appropriate to assess those impacts

during the regulation of individual chemical substances; indeed, the AIHC alternate contemplates that the results of such impact analyses would play a major role in shaping the regulation, particularly with respect to how to achieve the permissible exposure level.

In contrast, the OSHA proposal would automatically require in all "Category I" cases that exposure be reduced to the lowest feasible level solely by use of engineering and work practice controls, and would permit use of personal protective devices and administrative controls only when the employer proves that engineering and work practice controls are not feasible to reduce exposure to the permissible level. Since OSHA would place many important chemicals into its Category I, the economic impact of its proposal would be enormous. OSHA has failed to make an economic impact assessment, contrary to Executive Orders that require that such an assessment be made in connection with a generic regulation of the type proposed by OSHA. See Executive Orders 11821 (39 F.R. 41501) and 11949 (42 F.R. 1017).

OSHA has also failed to file an adequate draft environmental impact statement and therefore is in violation of the requirements of the National Environmental Policy Act ("NEPA"), the guidelines of the Council on Environmental Quality ("CEQ") and the regulations of the Department of Labor. Indeed, OSHA's proposal to assess economic and environmental impacts only after it has adopted a rigid framework -- rigid both as to substance and procedure -- and only in the context of individual-substance rulemakings implementing its categorical approach, would make such assessments futile exercises.

Why assess impacts when no regulatory choice remains? The point here is obvious; OSHA's pending proposal renders nugatory any assessment of economic or environmental impact.

A corollary of OSHA's failure to comply with the NEPA requirements, the CEQ guidelines and the Department's regulations, is that AIHC members and other interested persons have not been provided with information sufficient to comment fully on the proposed regulation, and therefore have been denied notice and an opportunity to comment upon the proposed regulation, in violation of the Administrative Procedure Act and in violation of the right of due process.

Moreover, the rulemaking procedures established by OSHA in connection with the proposed regulation provide that public comments and testimony must be submitted prior to the testimony of OSHA witnesses, and that there is no opportunity to respond formally to the statements of OSHA witnesses.[1/] OSHA also has failed to provide a list of substances in commercial use which are likely to be classified in Category I or Category II under its proposed regulation.

These and other defects in OSHA's rulemaking process have effectively denied AIHC members and other interested persons adequate

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1/ OSHA was also arbitrary and capricious in making "policy decisions" on scientific and technical matters in disregard of advice from NACOSH and without consulting its statutory advisor on scientific and technical matters, NIOSH. Further, the defects of notice and opportunity to be heard are compounded by OSHA's failure to define the term "suitable substitute" (§ 1990.112) and the phrase "as low as feasible" (§ 1990.112). Other impermissibly vague aspects of the regulation include the definition of "suggestive" (§ 1990.102), the "other evidence" criterion (§§ 1990.110(b) and 1990.120(b)), and the rebuttal criteria of §§ 1190.111(a) and 1990.121(a).

notice and an opportunity to participate in the public hearing on the regulation. These defects are so fundamental and of such magnitude as to constitute a denial of statutory procedural rights under the Administrative Procedure Act and a denial of due process of law.

These defects are aggravated by the fact that OSHA's proposal purports to freeze scientific issues and to fix standards which automatically will apply in future hearings on individual substances. It thus is of crucial potential importance to all users and manufacturers of chemicals. To conduct a hearing that is expected to last 10 weeks or more on such a broad regulation makes it impossible for business concerns, and especially smaller concerns, to participate effectively. The expense of attending all sessions, to be able to cross examine witnesses, object to testimony or make appropriate motions effectively excludes small business participation.

O. Expert performance of data evaluation and categorization function.

Unlike the OSHA proposal, the AIHC alternate would rely upon a scientific body separate from federal regulatory authorities to make the essential scientific judgment or decision as to the appropriate categorization of a particular chemical substance with respect to carcinogenic potential. There are a number of reasons for separating these functions. One is simply efficiency and consistency throughout the regulatory agencies, all of which, it is proposed, should accept the results of classifications made by the proposed Data Evaluation and Classification Panel. Another is to separate the scientific process of classification from the

variety of political and other pressures to which regulatory agencies are subjected, including perceived needs to respond to the expressed wishes of their historical constituencies. A further reason would be to improve the expertise of those making the categorizations, by improving utilization of expert resources. There is no abundance or surplus of good scientific talent in this area; it seems reasonable to expect that the federal government would on the average enlist the services of better qualified individuals if it needed to provide only a single classification panel, rather than a panel or similar authority for each of a variety of regulatory agencies. The AIHC proposal contemplates that the activities and decisions of the Panel would be governed by the Administrative Procedure Act. The Panel would be established pursuant to the Reorganization Act.

III. Tentative Nature of AIHC Endorsement of Categorical Approach.

The AIHC alternate does not proceed on the basis of agreement with OSHA's assertions of a compelling need to simplify science and facts by categorization. (See pages 10-19 above.) Accordingly, the following proposal is only a conditional endorsement of a categorical approach, an endorsement that depends in material respects upon greater flexibility and potential for individual consideration of particular chemical substances than would be afforded by the general approach of the OSHA proposal.

Similarly, the AIHC proposal does not proceed on the basis of agreement with OSHA's assertion that its proposal would result in significant savings of time and effort in carrying out its regulatory mandate. Such efficiencies are asserted to be principal reasons for OSHA's categorical approach. It is, however,

quite questionable whether these efficiencies will indeed be achieved, when the total regulatory process, which includes enforcement proceedings and judicial review or the opportunity for judicial review thereof, are considered. Initially, it may be ventured that even if the pending OSHA proposal were adopted, subsequent rulemaking proceedings on individual chemicals will surely be controversial, on matters such as whether a chemical has been correctly categorized and whether OSHA has accurately or validly ascertained feasible exposure limits, a matter which can vary quite significantly with different uses of the same chemical.

It also seems reasonable to anticipate that such future rulemakings will not be entirely self-enforcing, and that individual enforcement proceedings through citations and adjudications before the Review Commission will be necessary. In such Review Commission proceedings, the economic feasibility of standards would be at issue. Moreover, in judicial review proceedings, aggrieved employers would be entitled to judicial consideration not only of the standards for individual chemicals but also of the categorical standard that OSHA now proposes. Since in many cases several years would have elapsed between OSHA's adoption of the present proposed categorical standard, "freezing" the science and shutting off consideration of information developed in the future, and such an enforcement proceeding arising under a particular rulemaking promulgated in implementing the categorical approach, it seems reasonable to anticipate that there would be litigation not only before the Review Commission but also the courts as to the propriety of the issues that OSHA now seeks to put at rest by a categorical rulemaking approach. In brief,

the supposed efficiencies may well prove to be illusory; OSHA's efforts to shortcut debate may be counterproductive. By providing more flexibility to consider, and attribute significance to, all the evidence available at the time of a rulemaking on any given substance, the AIHC proposal should be more efficient from an overall regulatory standpoint than the OSHA proposal, which seems to assume that the process terminates with promulgation of a standard in the Federal Register.

The AIHC Recommended Alternative

DATA EVALUATION AND CLASSIFICATION PANEL

Determination of carcinogenicity is a scientific, not a regulatory question. This determination 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.

A Data Evaluation and Classification Panel ("the Panel") should be established by Executive Order issued pursuant to the Reorganization Act of 1977, 5 U.S.C. § 901 et seq. Such action should promote efficiency, consistency, and accuracy in the regulatory process. At the outset the Panel would serve OSHA's purposes, but it could come to serve other regulatory agencies as well.

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 hazard, 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, 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. They would 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, and would devote all their working time to the Panel. The Panel would have a staff. The Panel and staff would be housed within the NAS or some other organization agreeable to the Interagency Regulatory Liaison Group. The Panel would be substantively independent of whatever organization in which it may be housed.

The Panel would apply the following Classification Categories and criteria, 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 assign a chemical substance to one of the following categories. 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.

The Panel shall use the criteria listed below in 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.

CATEGORY I. KNOWN HUMAN CARCINOGEN.

A. Carcinogens of High Potency.

B. Carcinogens of Intermediate Potency.

C. Carcinogens of Low Potency.

Criteria: A substance shall be classified as a known human carcinogen on the basis of valid epidemiological data or other valid human data. Such data should be evaluated in light of:

1. The magnitude of the association between exposure and excessive age-standardized risk (as measured by relative risk analysis or Standard Mortality Rate) and the statistical confidence limits.

2. The size of a study population and the number of cases of cancer.

3. The specificity of the type and site of cancer.

4. Confirmation, or lack of confirmation, by other independent studies.

5. The suitability of the control group used for the confirmation of excessive risk, particularly the extent to which exposed and control groups are similar in respects other than exposure to the suspect agent, e.g., ethnic, socio-economic, dietary, exposure to other chemicals, use of tobacco.

6. Whether there is evidence of a dose-response relationship.

7. Whether the observed carcinogenic effect is likely to be direct or indirect, e.g., explicable in terms of a biological mechanism which is irrelevant to the occupational exposure.

8. Whether well-documented individual case reports or studies show that the substance in question has in fact, or with a high degree of probability, caused cancer in humans, even though the number of cases is too small to apply epidemiologic or statistical tests.

Potency shall be determined on the basis of epidemiologic or other human experience data where exposure data are available or where exposure intensities can reasonably be estimated. In the absence of such information, any available mammalian bioassay dose-response data shall be used. Where good exposure data are lacking, potency shall be assessed as follows:

Where epidemiologic evidence shows that exposure under in-use conditions has increased the age-standardized risk of development of any form of cancer by a factor of 10-fold or more, the agent shall be regarded as a potent carcinogen. (Examples here include heavy cigarette smokers, nickel plating operations, and occupational

exposure a few decades ago to beta-naphthylamine.)

Where such an increase is by a factor greater than 2-fold but less than 10-fold, the agent shall be regarded as an intermediate potency carcinogen. Examples here include chrome worker exposures.

Where such an increase is by a factor of 2-fold or less, the agent shall be regarded as a weak carcinogen.

In evaluating mammalian test data for relative potency, the guides set forth in Category II, (Subpart E below, page 67) for assessing the potency of confirmed animal oncogens shall be used.

CATEGORY II. CONFIRMED ANIMAL ONCOGENS.

A. Oncogens of High Potency.

B. Oncogens of Intermediate Potency.

C. Oncogens of Low Potency.

Criteria: Well documented results of adequate mammalian bioassays in at least two different species showing a statistically significant increased age-standardized risk of tumor development in test animals over that occurring in matched and exposed controls, where an appropriate route of administration was used and where the doses were not excessive, shall be sufficient, in the absence of countervailing information, to warrant classification as a confirmed animal oncogen.

1/ It is recognized that dose-response data would as a matter of toxicology be preferable to "attack rate" data. However, dose information is often not available. In addition, attack-rate data are significant in terms of priorities of regulatory action.

A. Definition of Oncogen. A number of the terms used in this general criterion are more fully stated below. This general criterion contemplates attribution of some regulatory significance to malignant and benign tumors observed in bioassays, hence the term "oncogen". This does not signify that they are the same, but rather reflects present uncertainty on this matter and prudence in protecting employees. Such uncertainties may receive appropriate attention during the assessment of risks. The general criterion also accepts, as prudent, use of mammalian test results as guides to carcinogenic risks to man. This is accepted despite very substantial scientific complexities and uncertainties about extrapolating from animals to man; in exceptional cases those uncertainties may be so formidable as to preclude such extrapolation.

B. Excessive doses. The criterion accepts as valid the judgment of the American Conference of Governmental and Industrial Hygienists to the effect that no substance is to be considered a Category II occupational carcinogen on the basis of having reacted oncogenically by the following routes above the following doses.[1/]

1. Dose via the respiratory route exceeds 1,000 mg/m^3 for the mouse and hamster or 2,000 mg/m^3 for the rat.

2. Dose by the dermal route exceeds 1,500 mg/kg for the mouse and hamster or 3,000 mg/kg for the rat.

3. Dose by the gastrointestinal route exceeds 500 mg/kg/d for a lifetime, equivalent to about 10 g. total lifetime dose

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1/ ACGIH, "Threshold Limit Values for Chemical Substances and Physical Agents in the Workroom Environment with Intended Changes for 1977", p. 40.

for the mouse and hamster, and 100 g. total lifetime dose for the rat.

The results of experiments using excessive doses may warrant classification in Category III.

C. Appropriate routes of administration. Appropriate routes of administration are respiratory (inhalation or intratracheal installation), skin application, and gastrointestinal (including gavage unless this is associated with gross distortion of blood or tissue levels compared with human exposure).

D. Adequacy of bioassay for evaluating oncogenic potential.

The following factors,[1/] among others, shall be considered in assessing the adequacy of the protocols, conduct, and results of a bioassay:

-- the experimental design and its conformity to accepted protocols

-- the appropriateness of the method of exposure

-- the appropriateness of the route of exposure

-- the appropriateness of the animal species and strain used, and in particular the propensity of untreated animals to develop tumors of various kinds

-- whether test populations were randomized

-- size of each dosage group

-- existence and adequacy of concurrent controls

-- character and type of animal housing; type of bedding if any; number of animals per cage

-- non-tumor responses to test agents; influence on tumor yield

-- duration of exposure

1/ Many of these factors are discussed in "Guidelines for Carcinogen Bioassay in Small Rodents", NCI Carcinogenesis Technical Report Series No. 1, February, 1976, by James M. Sontag, Norbert P. Page, and Umberto Saffiotti.

-- schedule of intercurrent sacrifice

-- period of observation relative to the lifespan of the test species

-- metabolic and pharmacokinetic data, if available

-- number, type and site of tumors

-- number of animals developing tumors

-- temporal pattern of tumor appearance, taking into account the distinctions between (i) fatal and non-fatal tumors, (ii) tumors which are evident during life (e.g., skin and sub-cutaneous tumors) and tumors which can only be discovered at necropsy

-- the quality of the pathology studies, both microscopic and macroscopic

-- method of statistical analysis and statistical significance of positive results

-- dose response relationships

-- adequacy of reporting of the bioassay

E. Relative potency of response. The general concept of the relationship between the magnitude of the dose resulting in tumors in experimental animals and the potential risk to man from industrial substances, as advanced by the ACGIH,[1/] is reasonable and sensible; modifications from the ACGIH numbers are used to accord with current accepted test protocols. The additional concept of induction period (time from first contact to the appearance of tumors) is also applied in the definitions of potency of response to exposure to industrial substances in experimental mammalian studies. Accordingly, responses for which adequate bioassay results of statistically significant tumor occurrence are available shall be categorized

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1/ ACGIH, "Threshold Limit Values for Chemical Substances and Physical Agents in the Workroom Environment with Intended Changes for 1977", pages 41-43.

by potency in light of the following guidelines for bioassays of the hamster, mouse, or rat:

1. Response to respiratory route exposure.

A. Response of high potency.

(1) Inhalation exposure 6 to 7 hours per day, five days per week, for a major portion of a lifetime, to dosages below 1 mg/m^3 with an excess of tumors appearing at any time during the study;

(2) Inhalation exposure 6 to 7 hours per day, five days per week, for a major portion of a lifetime, to any non-excessive dosage with tumors appearing in 12 months or less; or

(3) Exposure to a single intratracheally administered dose not exceeding 1 mg of particulate, or liquid, per 100 ml or less of animal minute respiratory volume, with an excess of tumors appearing at any time during the study.

B. Response of intermediate potency.

(1) Inhalation exposure 6 to 7 hours per day, five days per week, for a major portion of a lifetime, with dosages between 1 and 10 mg/m^3 with an excess of tumors appearing at any time during the study; or

(2) Inhalation exposure 6 to 7 hours per day, five days per week, for a major portion of a lifetime, to any non-excessive dosage with tumors first appearing in 12 to 18 months, or

(3) Exposure to a single intratracheally administered dose from 1 mg to 10 mg of particulate, or liquid, per 100 ml or less of animal minute respiratory volume, with an excess of tumors appearing at any time during the study.

C. Response of low potency.

(1) Inhalation exposure 6 to 7 hours per day, five days

per week, for a major portion of a lifetime, with dosages greater than 10 mg/m^3, but non-excessive, with an excess of tumors appearing at any time during the study; or

(2) Inhalation exposure 6 to 7 hours per day, five days per week, for a major portion of a lifetime, with any non-excessive dosage with tumors appearing after 18 months; or

(3) Exposure to intratracheally administered (non-excessive) dosages totaling more than 10 mg of particulate or liquid per 100 ml or more of animal minute respiratory volume, with an excess of tumors appearing at any time during the study.

2. Response to skin application exposure.

A. Response of high potency. Exposure by repeated skin application with tumors appearing in 6 months or less.

B. Response of intermediate potency. Exposure by repeated skin application with tumors appearing within 6 to 18 months.

C. Response of low potency. Exposure by repeated skin application with tumors appearing after 18 months.

3. Response to gastrointestinal exposure.

A. Response of high potency.

(1) Exposure by any form of repeated peroral dosing at a dosage less than 1 mg/kg/day, with an excess of tumors appearing at any time during the study; or

(2) Exposure by repeated peroral dosing of any non-excessive dosage with tumors appearing in 12 months or less.

B. Response of intermediate potency.

(1) Exposure by repeated peroral dosing at dosage between 1 and 50 mg/kg/day, with an excess of tumors appearing at any time during the study; or

(2) Exposure by repeated peroral dosing at any non-excessive dosage with tumors appearing in 12 to 18 months.

C. Response of low potency.

(1) Exposure by repeated peroral dosing at a dosage greater than 50 mg/kg/day, but non-excessive, with an excess of tumors appearing at any time during the study; or

(2) Exposure by repeated peroral dosing at any non-excessive dosage with tumors appearing after 18 months.

CATEGORY III. Substances for Further Testing.

Criteria:

Mammalian bioassays that do not satisfy Category II requirements but that do show statistically significant increases in tumors, for examples: positive results in a single species; positive results but only in studies using excessive doses; positive results but only in studies where the route of administration, or exposure conditions, are of questionable relevance to human exposure.[1/]

RECATEGORIZATION

It is recognized that some, perhaps most, chemical substances will be categorized on the basis of less than definitive data, and that subsequent scientific advancements as well as additional data may suggest that a prior categorization was erroneous and should be reconsidered. Accordingly, any interested party may petition the panel for reclassification of a chemical on the basis of significant data or scientific learning that were not considered

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1/ Results of "short-term" tests would serve as guides to further testing, and would not themselves warrant categorization. See pages 40-42 above.

at the time of the prior classification. Depending on the information and its assessment during the categorization process, a substance could be reclassified to a higher or a lower category, or removed entirely from the categories.

Removal could occur where a Category III classification had been followed by completion of adequate[1/] mammalian testing or epidemiologic studies, with no statistically significant evidence of carcinogenicity in the particular testing or study results.

It is not contemplated that where more than one valid bioassay report is available and some reports are negative and others positive, a substance would be removed from the categories. The inconsistency of the reports would, however, be considered by OSHA in assessing risks.

In some cases, however, epidemiologic studies showing no increased incidence of cancers could warrant removal from the categories, despite positive bioassay reports. This might be appropriate, for example, where substantial differences were shown between the test species and man with respect to metabolism of the tested substance.

Where reclassification results, OSHA shall promptly consider modification of its standards.

1/ See Subpart D in Category II, page 66 above, for criteria to assess bioassays.

OSHA Regulatory Response to Classification

A. Category I classification.

1. Emergency temporary standard. Upon classification of a substance as a known human carcinogen, OSHA shall as soon as possible decide, in each case, whether actual employee exposures constitute a "grave danger" within the purview of Section 6(c) of the Act and whether an Emergency Temporary Standard is necessary to protect employees from such danger. Such determination shall consider (a) 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 (b) evaluation of actual hazards (e.g., physical and chemical properties, degree of occupational exposure, likelihood of a carcinogenic event).

Upon completion of such a determination, OSHA shall immediately commence the development of an ETS if the criteria specified in Section 6(c) for such issuance have been satisfied. In developing an ETS (as well as in developing a permanent standard), OSHA shall perform analyses of risks and benefits in accordance with Subpart C below.

(a) Where an ETS is to be issued and where there are available dose-response data in one or more appropriate mammalian species or other appropriate information sufficient to quantify risks to employees, OSHA shall, in light of such information, specify permissible exposure levels that reflect analyses of risks and benefits. In deciding upon such a level, OSHA shall perform analyses of risks and benefits in accordance with Subpart C below, to the extent

such analyses can be very promptly performed. Where the available epidemiologic data are sufficient to help evaluate dose-response and potency issues, such data shall be considered in establishing permissible exposure levels. These exposure levels shall generally be achieved by means of engineering controls, to the extent technically and economically feasible, augmented by administrative controls and personal protective equipment as necessary. OSHA shall require that this exposure level be achieved as soon as feasible, and may require as an interim measure that exposure levels be reduced immediately through a readily available practical combination of engineering and administrative controls and personal protective equipment.

The permissible exposure levels may vary from chemical to chemical, depending upon the analyses of risks and from one use of a chemical to another, and benefits.

(b) Where an ETS is to be issued and sufficient data are not available to quantify risks to employees, OSHA shall advise the Interagency Testing Committee established pursuant to the Toxic Substances Control Act of the desirability of requiring testing under that Act. The ETS shall specify a permissible exposure level that can be achieved immediately through a practical combination of readily available engineering and administrative controls and personal protective equipment.

(c) The ETS shall exclude mixtures containing less than specified percentages of the substance being regulated and shall not apply to workplaces where the substance is present only in such

a mixture. Such percentages may differ for different uses or mixtures, and shall be determined in light of analyses of risks and benefits performed in accordance with Subpart C below, to the extent such analyses can be promptly performed.

(d) The ETS shall provide partial exemptions for workplaces below an "action level".

2. Permanent Standard.

(a) Where an ETS has specified an acceptable exposure level reflecting data sufficient to quantify risks to employees, the permanent standard shall require achievement or maintenance of that limitation.

(b) Where an ETS not based on data sufficient to quantify risks has been issued, and such data become available during the maximum statutory life (six months) of the ETS, a regular permanent standard shall issue to require achievement of an acceptable exposure level derived in part from such data. OSHA shall also consider, in setting permissible exposure levels, the analyses of risks and benefits. Different levels may be set for different chemicals and for different uses of the same chemical. Compliance with the permissible exposure limits shall require use of engineering controls to the extent technically and economically feasible, augmented by administrative controls and personal protective equipment as appropriate.

(c) Where an ETS not based on data sufficient to quantify risks has been issued and such data do not become available within six months, an "interim" permanent standard similar to the ETS shall be issued, to be in effect no longer than five years. If during that three years' period such data become available, a revised per-

manent standard may be issued that establishes an acceptable exposure level derived in part from such data, and also from analyses of risks, hazards, costs, and benefits. If such data do not become available, the regular permanent standard shall establish an exposure level that is the lowest level technically and economically achievable. Compliance with permissible exposure levels shall generally require all feasible use of engineering controls, augmented as appropriate by administrative controls and personal protective equipment.

(d) A permanent standard shall exclude mixtures containing less than specified percentages of the substance being regulated, (or shall specify with particularity the mixtures that are being regulated), and shall not apply to workplaces where the substance is present only in excluded mixtures. Such percentages may differ for different uses or mixtures and shall be determined in light of analyses of risks and benefitss performed in accordance with Subpart C below.

(e) A permanent standard shall provide partial exemptions for workplaces below an action level.

(f) Where OSHA decides not to issue an ETS, it shall consider institution of a permanent rulemaking under Section 6(b) of the Act based on regulatory priorities, unless it shall determine that such a rulemaking is not necessary to protect employees. As part of such a rulemaking, OSHA should advise the ITC of the need for dose-response data if they do not exist. Permissible exposure levels and other regulatory provisions should be established in the same manner as called for in the preceding subparagraphs (a) through (e).

3. Provisions of Standards Other than Ones Related to Permissible Exposure Levels.

Such provisions, which are not the subject of detailed AIHC recommendations at this time, should reflect the degree of hazard present in the workplaces.

B. Category II Classification.

1. Emergency temporary standard. Upon classification of a substance as a Confirmed Animal Oncogen, OSHA shall as soon as possible decide, in each case, whether actual employee exposures constitute a "grave danger" within the purview of Section 6(c) of the Act and whether an Emergency Temporary Standard is necessary to protect employees from such danger. Such determination shall consider (a) the evidence of potential carcinogenic risks (e.g., carcinogenic potency as indicated by experimental data, dose-response relationships, metabolism, duration and amount of exposure, route of exposure); (b) evaluation of actual hazards (e.g., physical and chemical properties, degree of occupational exposure, likelihood of a carcinogenic event); and (c) epidemiologic or other human experience evidence.

Upon completion of such a determination, OSHA shall immediately commence the development of an ETS if the criteria specified in Section 6(c) for such issuance have been satisfied. In developing an ETS (as well as in developing a permanent standard), OSHA shall perform analyses of risks and benefits in accordance with Subpart C below.

(a) Where an ETS is to be issued and where there are available dose-response data in one or more appropriate mammalian

species or other appropriate information sufficient to quantify risks to employees, OSHA shall, in light of such information, specify permissible exposure levels that reflect analyses of risks and benefits. In deciding upon such a level, OSHA shall perform analyses of risks and benefits in accordance with Subpart C below, to the extent such analyses can be very promptly performed. Any available epidemiologic or other human experience data shall be considered in establishing permissible exposure levels. These exposure levels shall generally be achieved by means of engineering controls, to the extent technically and economically feasible, augmented by administrative controls and personal protective equipment as appropriate. OSHA shall require that this exposure level be achieved as soon as feasible, and may require as an interim measure that exposure levels be reduced immediately through a readily available practical combination of engineering and administrative controls and personal protective equipment.

The permissible exposure levels may vary from chemical to chemical and from one use of a chemical to another, depending upon the analyses of risks and benefits.

(b) Where an ETS is to be issued and sufficient data are not available to quantify risks to employees, OSHA shall advise the Interagency Testing Committee established pursuant to the Toxic Substances Control Act of the desirability of requiring testing under the Act. The ETS shall specify a permissible exposure level that can be achieved immediately through a practical combination of readily available engineering and administrative controls and

personal protective equipment.

(c) The ETS shall exclude mixtures containing less than specified percentages of the substance being regulated and shall not apply to workplaces where the substance is present only in such a mixture. Such percentages may differ for different uses or mixtures, and shall be determined in light of analyses of risks and benefits performed in accordance with Subpart C below, to the extent such analyses can be promptly performed.

(d) The ETS shall provide partial exemptions for workplaces below an "action level".

2. Permanent standard.

(a) Where an ETS has specified an acceptable exposure level reflecting data sufficient to quantify risks to employees, the permanent standard shall require achievement or maintenance of that limitation.

(b) Where an ETS not based on data sufficient to quantify risks has been issued, and such data become available during the maximum statutory life (six months) of the ETS, a regular permanent standard shall issue to require achievement of an acceptable exposure level derived in part from such data. OSHA shall also consider, in setting permissible exposure levels, the analyses of risks and benefits. Different levels may be set for different chemicals and for different uses of the same chemical. Compliance with the permissible exposure limits shall require use of engineering controls to the extent technically and economically feasible, augmented by administrative controls and personal protective equipment as appropriate.

(c) Where an ETS not based on data sufficient to quantify risks has been issued and such data do not become available within six months, an "interim" permanent standard similar to the ETS shall be issued, to be in effect no longer than five years. If during that five year period such data become available, a revised permanent standard may be issued that establishes an acceptable exposure level derived in part from such data, and also from analyses of risks and benefits. If such data do not become available, the regular permanent standard shall establish an exposure level that is the lowest level technically and economically achievable. Compliance with permissible exposure levels shall generally require all feasible use of engineering controls, augmented as appropriate by administrative controls and personal protective equipment.

(d) A permanent standard shall exclude mixtures containing less than specified percentages of the substance being regulated, (or shall specify with particularity the mixtures that are being regulated), and shall not apply to workplaces where the substance is present only in excluded mixtures. Such percentages may differ for different uses or mixtures and shall be determined in light of analyses of risks and benefits performed in accordance with Subpart C below.

(e) A permanent standard shall provide partial exemptions for workplaces below an action level.

(f) Where OSHA decides not to issue an ETS, it shall consider institution of a permanent rulemaking under Section 6(b) of the Act based on regulatory priorities, unless it shall determine that

such a rulemaking is not necessary to protect employees. As part of such a rulemaking, OSHA should advise the ITC of the need for dose-response data if they do not exist. Permissible exposure levels and other regulatory provisions should be established in the same manner as called for in the preceding subparagraphs (a) through (e).

C. Analyses of risks and benefits for Category I and Category II Substances.

In establishing permissible exposure levels and other requirements of a specific standard, OSHA shall analyze risks (including hazards) and benefits to society (including costs to society) and shall state in writing the manner in which each of the factors listed below, among others, has been considered.

1. Risks. As used herein, risks refers to the observed carcinogenic or tumorogenic properties or propensities of a chemical substance. It is anticipated that the decision of the Data Evaluation and Classification Panel would generally include adequate discussion of risk factors. Risk factors include:

(a) evidence of carcinogenic potency, whether epidemiologic or experimental animal evidence;

(b) dose-response relationships and associated metabolic and pharmacokinetic data, if available;

(c) where only experimental animal evidence tends to implicate a chemical substance, evidence of favorable human or epidemiologic experience with the substance. It is recognized that while epidemiologic evidence cannot conclusively show that a substance is not

carcinogenic to humans, favorable epidemio-- logical evidence would be relevant and could be material in assessing risks (under established or prior conditions of use);

(d) whether the evidence of carcinogenicity consists only of experimental results, as opposed to epidemiology;

(e) the number of mammalian species for which evidence of carcinogenicity exists;

(f) the number and quality of any negative mammalian experiments;

(g) the kind of mechanism, or combination of mechanisms, producing observed carcinogenic effects.

2. Hazards. As used herein, hazards refers to conditions relevant to the likelihood, given certain risks within the foregoing definition, of a carcinogenic event due to use of a chemical substance in the workplace. Hazard factors shall be evaluated as and when necessary and shall include:

(a) the number of workplaces in which the substance is present;

(b) the number of employees in such workplaces;

(c) the conditions of manufacture or use of such substance in various workplaces;

(d) the frequency, duration, and intensity of exposure of employees (1) at present, and/or (2) at proposed permissible exposure levels.

(e) the physical and chemical properties of the substance, and its inherent warning properties;

(f) non-carcinogenic toxic properties of the substance;

(g) the foregoing factors, as applicable to workplaces where the substance is present in other substances in contaminant or trace amounts;

(h) statistical or other methods of quantifying the likelihood of a carcinogenic event in light of the foregoing factors;

(i) hazards of use of likely substitutes for the substance being regulated;

(j) comparisons with hazards of other contemporaneous activities, occupational and non-occupational.

3. Benefits to Society. As used herein, benefits include health benefits of reductions in actual employee exposures to the substance and benefits of continued use of the substance or mixtures containing the substance. An analysis of benefits shall include consideration of the following factors:

(a) benefits of reductions in actual employee exposure to the substance being regulated, including health benefits, reductions in costs of health care, reductions in lost employment, psychological and emotional

benefits to employees and their families;

(b) economic benefits of production and use of the substance, including volume and dollar amount of sales, number of employees, competiveness of domestic industry, and cost advantages or benefits to consumers of products made from or with the substance being regulated; balance-of-payments advantages; enhancement of productivity; improvement of cost effectiveness; reduction of waste; retardation of deterioration.

(c) "quality of life" non-economic benefits of production and use of the substance, including any safety or health benefits, e.g., prolongation of productive life, reduction of loss of life, limbs and health; reduction of other burdens; increases in knowledge; cultural values; uniqueness, vis-a-vis likely or possible substitutes.

4. Costs to Society. As used herein, costs include environmental and economic consequences of compliance with regulation, including adverse aspects of shifts to, and use of, substitutes that might result, as a by-product or otherwise, from imposition of regulation. Cost factors include:

(a) increases in energy or other raw material requirements, due to compliance with regulation or shifts to substitutes, and adverse environmental impacts of any resulting need

to exploit additional natural resources or to exploit existing resources more aggressively;

(b) economic feasibility of compliance with regulation;

(c) technological feasibility aspects of compliance with regulation;

(d) employment dislocation resulting from responses to the other costs of regulation, including direct local increases in unemployment and related economic and psychologic effects;

(e) indirect adverse economic effects of any reduction in direct employment.

In considering costs, particular importance should be attributed to incremental costs, in comparison with incremental benefits. Generally, the incremental costs of reducing employee exposure will increase exponentially as very low levels are approached, but there will not be substantial data to indicate any health benefit increment would be achieved by further reductions.

Consideration of costs will also include the social costs of increased economic concentrations that may result in response to regulatory action. The appropriateness of these considerations in this area is suggested by the Toxic Substances Control Act, which recognizes the desirability of avoiding imposition of unnecessary regulatory burdens on small businesses, and the desirability of preserving an economic system with diversity of size.

D. Category III Classification.

1. Reference to ITC for possible further testing.

2. Within 60 days OSHA may issue a notice of proposed rulemaking to establish permissible exposure limits at (1) the present OSHA standard or (2) where none exists, an appropriate level based on acute or chronic effects of exposure to the toxic substance other than carcinogenicity or (3) where acute or chronic effects indicate that the present OSHA standard is inadequate, the exposure level shall be lowered to the level found appropriate by the Secretary.

E. DECLASSIFICATION.

If the Data Evaluation and Classification Panel decide to remove a previously classified substance from the classification categories entirely, OSHA shall immediately advise its enforcement personnel with appropriate guidance as to subsequent enforcement policy, and shall promptly initiate appropriate revisions in any relevant health standards.

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