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MANUFACTURING CHEMISTS ASSOCIATION

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Copy to R. E. Bladen
From R. E. Bladen

December 21, 1977

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LAW DEPT.

TO: Occupational Health Committee
Chemical Regulations Advisory Committee
Intercommittee Task Group on OSHA Cancer Policy

SUBJECT: Draft Alternatives to proposed OSHA generic
regulation on carcinogens

Attached is a memorandum prepared by the American Industrial Health Council's Alternatives Committee setting out the reasons why the OSHA generic standard must be modified. The document is in two parts: a preamble setting out in summary form the reasons underlying the proposed modification and a proposed alternative classification system which rejects the questionable scientific and economic principles which OSHA embraced. For your convenience an executive summary is attached.

The alternatives statement is obviously not yet complete. It will be fleshed out by papers and testimony of company as well as Association witnesses and outside AIHC consultants.

The document is not yet ready for general distribution. It is being sent to you confidentially for comment, so that the concept could also be incorporated into MCA's response to OSHA.

Because of the time constraints we have to receive your comments no later than December 30, 1977, so a final document can be prepared as soon as possible.

Please telecopy (202/265-9351), telex (89617, MCA-WSH) or deliver your written comments to me. Phone comments will be accepted, but because of the numbers involved written comments are greatly preferred. If you have critical comments, suggest alternative words if possible. There will be little time to discuss proposed changes and alternative expressions will be most helpful. Reactions to the overall approach are also solicited.

We hope to have the AIHC alternative ready for general distribution to member companies early in January for their information and possible use in preparing their individual responses to OSHA.

Milton Frefield
Milton Frefield
Secretary
Occupational Health Committee

MF:jg
Enclosure

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EXECUTIVE SUMMARY

At an early point in the review of the Occupational Safety and Health Administration's (OSHA) generic carcinogen proposal (42 Fed. Reg. 54147 (October 4, 1977)) industry concluded that it should offer an affirmative, constructive, scientifically sound, alternative to the OSHA proposal. It was recognized that it was not possible to draft an alternative which met universal acceptance. The alternative was to be drafted with a view that a large cross-section of industry could endorse the alternative in whole or in part and would not feel obliged to openly oppose the proposal.

The American Industrial Health Council (AIHC), accordingly, established an Alternatives Committee with the mandate to develop such a document. The document is in two parts: a preamble designed to outline the main scientific principles upon which the proposed alternative was based. The preamble is not intended as a definitive statement and will be supported by papers and testimony of expert witnesses.

The document proposes that the most scientifically sound method of dealing with the exposure of workers to potential carcinogens is to materially improve OSHA's existing method of dealing with the suspect chemicals. If OSHA improved its ability to perform adequate risk assessment and established reasonable priorities, most of the benefits which OSHA sees from a categorization system would be achieved with none of the disadvantages inherent in any categorization system. However, if OSHA insists on a categorization scheme as we expect, it must be sound scientifically and allow for the careful necessary analysis of each

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substance in each category before establishing exposure limits. Such an analysis includes a study of risk, hazard, cost and benefits. No automatic non cost effective exposure levels can be mandated; the exposure levels must reflect potency and economic feasibility. The document sets out an alternative categorization scheme incorporating these principles.

The principal distinguishing features of the alternative classification system are as follows:

- (1) Recognition is given to the varying potency of suspect carcinogens by means of a more precise categorization scheme and providing exposure levels reflecting potency.
- (2) Establishes criteria for determining the validity of experimental animal data and adopts in vitro tests as a screening device only;
- (3) Permissible exposure limits are set at socially acceptable risk levels rather than at the lowest level technically and economically feasible;
- (4) Establishes a reasonable regulatory response and abandons the automatic issuance of a temporary emergency standard and a final standard in six months;
- (5) Contemplates less costly, but effective, means of compliance with permissible exposure limits;
- (6) OSHA is precluded from banning substances and requiring substitution of products;
- (7) Substances or mixtures containing small amounts of suspect carcinogens are exempted from the regulation; and

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(8) Laboratory workplaces and suspect carcinogenic substances found only in foreign workplaces are exempted from the regulation; and

(9) Authorizes reclassification upon presentation of requisite data by industry.

For convenience, set out below in tabular form are the principal features which distinguish the proposed alternative from that recommended by OSHA.

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OSHA

1. Categories

- I. Confirmed carcinogens
- II. Suspect carcinogens
- III. Substances for which there is insufficient information to reach a conclusion on carcinogenicity
- IV. Substances of carcinogenic potential not found in American workplaces

2. Categorization Criteria

Category I - Increased incidence of tumors or statistically significant decreased latency period between exposure and onset in (1) humans, (2) two mammalian species, (3) a single mammalian species if the test is replicated or supported by short-term tests, or (4) other acceptable evidence.

Category II - "Suggestive" evidence of carcinogenicity in humans or animal tests; scientific concern is raised but evidence is not persuasive or statistically significant, or other acceptable evidence.

Category III - Substances for which there are insufficient data to categorize them in Category I or II.

Category IV - Substances which would be potential occupational carcinogens but for the fact that they are not found in an American workplace.

3. Categorization Authority

OSHA is categorization authority. No standards for validity of animal testing.

Alternative

1. Categories

- I. Known human carcinogen with distinctions in potency
- II. Confirmed animal oncogen with distinctions in potency
- III. Possible animal oncogen
- IV. Cleared substances

2. Categorization Criteria

Category I - Valid statistically significant positive human epidemiological data.

Category II - Valid statistically significant positive mammalian tests in two or more species.

Category III - Positive mammalian tests of questionable significance and not meeting Category I or II criteria.

Category IV - Substances not meeting Category I, II or III criteria.

3. Categorization Authority

Categorization authority to be established outside of OSHA; nine member board within National Cancer Institute to be selected by National Academy of Sciences. Standards for validity of animal tests established.

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4. Regulatory Response to Categorization

Category I --

Emergency temporary standard must automatically issue.

Substitution - If OSHA determines there is a less hazardous suitable substitute for a Category I substance, it can require no exposure, in effect, a ban.

Permissible exposure limits (PEL) to be set at lowest level technically feasible in all cases.

Engineering and work practice controls must be used to achieve lowest level technically feasible unless the employer can show such controls are not technically feasible.

Category II --

OSHA must propose rule establishing PEL at present OSHA standard or, if none exists, or present PEL is inadequate to guard against acute or non-carcinogenic chronic effects, at such level as will guard against such effects.

Engineering and work practice controls must be utilized as in Category I.

4. Regulatory Response to Categorization

Category I and II --

Emergency temporary standard to issue only when requisite statutory findings can be made; discretionary guidelines established related to potency.

Substitution - OSHA may not require substitution.

Permissible exposure limits (PEL) established on basis of socially acceptable risk using criteria for hazard and benefit analysis.

Compliance with PEL can be achieved through use of engineering controls to the extent technically and economically feasible augmented by administrative controls and personal protection equipment as necessary.

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Category III --

OSHA must transmit to other federal agencies its findings along with a request that such agencies determine whether they have additional information which might bear on reclassification.

Category IV --

OSHA must publish notice of its findings in Federal Register and upon introduction of substances into American workplace initiate appropriate regulatory response.

5. Mixtures

Mixtures are covered by the proposal.

6. Laboratories

Laboratory workplaces are covered by the proposal.

7. Suspect Substances in Foreign Workplaces

These substances are covered by the proposal. See Category IV above.

Category III --

Reference to Interagency Testing Committee for possible further testing.

OSHA may propose rule establishing PEL at present OSHA standard, or if none exists, or present PEL is inadequate to guard against acute or non-carcinogenic chronic effects, at such level as will which guard against such effects.

Means for complying with PEL same as for Category I and II.

Category IV --

No regulatory response.

5. Mixtures

Mixtures containing less than specified percentage of the substance being regulated are to be exempted in accordance with specified criteria.

6. Laboratories

Laboratory workplaces are to be exempted from the regulation.

7. Suspect Substances in Foreign Workplaces

These are not to be subject to the regulation.

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Summary Analysis of Reasons
To Modify OSHA Proposal*

DRAFT

I. The Problem in Proper Perspective.

A. Alleged increase in incidence of cancer.

The rationale advanced by OSHA in support of its proposal implies that this nation is in the midst of an epidemic of cancer and that the epidemic is largely if not entirely attributable to increased usage of industrial chemicals. As for the starting point for this argument, the increase in cancer, it is noteworthy that, using the turn of the century as a time against which to measure the present circumstances, while there has been an increase in the incidence of cancer it is entirely attributable to increases in longevity (the incidence of cancer increasing with age), and increased smoking of tobacco. When appropriate adjustments are made for these two forces, no overall increase in cancer is apparent 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 stomach cancer. However, the lung cancer rate has tripled from 4.0/100,000 in 1950 to 12.3 in 1974."

* 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.

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Moreover, leaving aside the kinds of cancers commonly associated with tobacco smoking, in general the same kinds of cancers prevalent today prevailed at the turn of the century, indicating that whatever causes other than longevity and tobacco that 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 here is the combination of asbestos and smoking tobacco in the causation of lung cancer.

It should be noted also that males and females differ in risk of development of specified forms of cancer and for most but not all forms of the disease the risk of development increases logarithmically with age. In comparison the incidence of any form of cancer in two populations (e.g., an exposed population and an unexposed control population), therefore, 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 fact that there may be 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 years cohort and at each age from 40 to 80+ the risk of death from lung cancer increased. For instance, a man born during the 5 years around 1861 experienced a 0.1 per 1000 living risk of dying from lung cancer between the ages of 65 and 70 whereas men born around 1886 had a 2.9 per 1000 living risk of dying from the disease between the ages of 65 and 70 -- a 29 fold difference. In assessing whether an industrial chemical is increasing the incidence of death for any particular, if any, form of cancer, therefore, 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-structure and age-structure but also of the same cohort-structure.

In the OSHA proposal (Fed. Reg. p. 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. In England and Wales, for which 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 with few exceptions, and except for cancer of the lung in both sexes, there has been no evidence during recent years of an increasing risk of death from cancer and for several forms of the disease the death rates have actually been falling. (Reference Case RAM - ?_

B. The relative significance of industrial chemicals.

While it may be true that perhaps as much as 90 percent of cancers are environmentally related, it is important to note, as the OSHA preamble does not, that the great majority of environmental factors are not industrial chemicals, but rather are matters such as smoking habits, dietary habits, and exposure to solar radiation. As stated by Dr. Guy R. Newell, Acting Director, National Cancer Institute in his testimony to a subcommittee of the House Committee on Government Operations on June 15, 1977,

"The term 'environment' must be defined. 'Environment', in its broadest sense, is the sum of everything around us--the water we drink and bath 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 may be instructive to consider the importance of the principal such factors. A team of researchers from the American Health Foundation and the National Cancer Institute have estimated that diet, exclusive of

food additives and contaminants, may contribute to as much as 50 percent of the causes 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/}

Radiation, mostly through sunlight, has been estimated by NCI officials to account for 5 percent 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, gave radiation figures of 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 estimates are that industrial chemicals have accounted for about 1 to 3 percent of the total cancers.^{3/} While

1/ Statement by Gio B. Gori, PhD, 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. 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-naphthylamine 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 (continued on following page)

this is not an insignificant consideration, it is questionable whether the public is being well served if it is led to believe that industrial chemicals are the overwhelming cause of cancer in this country, since that would indicate that the concentration of preventive effects upon industrial activities would take care of the great majority of the problem. That notion is thoroughly misleading and could have very grave consequences for our society as a whole. For example, Dr. Harry B. Demopoulos, until recently the Director of the Cancer Institute of New Jersey, testified on November 5, 1976, before the New Jersey Senate Commission on the Incidence of Cancer, that:

"Industry-related cancers form a very small and rather insignificant percentage of our cancer statistics. . . . I have figured out about 600 excess deaths in New Jersey every year that you might blame on industry, or industry-related factors. This is 600 deaths out of 14,000. And, I submit that given a choice of where to focus, I would rather focus on the 13,400 deaths where we have no known relationship to industry and where we know some of the other factors that we can control through education and early detection. . . ."

Similarly, it is difficult to justify OSHA's preambular comparison, by implication in many places, of the total cost to our society of all cancers, with those (unspecified number of) cancers

3/ (Continued from previous page) 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:

"Bailor (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%"

attributable to exposure to industrial chemicals. While it is reasonable to compare costs and benefits even in such an emotion-laden area as cancer, it is only reasonable to compare the problems caused by the use of industrial chemicals with the benefits that are derived from them.

In any event, it seems clear that there is substantial reason to take stringent action regardless of regulatory responsibility where confirmed or highly probable causes of cancer have been identified as present in the workplace. In all probability, however, the extent of such causation is being reduced rather than increased, since there is increased awareness of the possibility of occupational hazard and greatly increased measures in common use to reduce employee exposure to industrial chemical substances.

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

To justify the oversimplifications and stringency of its proposed categorical approach, OSHA makes much of its alleged inadequacies over the past seven years to regulate industrial carcinogens. One can question the accuracy, and thus suspect the motivation, for this self-debasing criticism. In 1972 OSHA wrote to its expert advisor NIOSH requesting information on all known industrial carcinogens. NIOSH responded by making a literature survey and by requesting information -- on fifteen substances -- by publication in the Federal Register on July 6, 1972. NIOSH subsequently advised OSHA that there appeared to be fifteen occupational carcinogens, some known human carcinogens and some implicated solely on the basis of bioassay experiments. This advice was subsequently modified by the deletion of one of the materials, dimethyl sulfate,

leaving fourteen carcinogens that NIOSH then believed to be in use, or previously to have been used, in American workplaces. In 1973 OSHA promulgated an emergency temporary standard limiting employee exposure to all fourteen chemicals and commenced a permanent rule-making which itself was completed in January of 1974. See 39 Fed. Reg. 3756 (Jan. 29, 1974.) What more OSHA could have been expected to have accomplished by then is left unsaid by the current self-debasement, which also ignores the more vigorous efforts OSHA has made during 1977 to regulate industrial substances that have been implicated as carcinogens.

Much of the apparent subsequent gap between the regulatory need and OSHA's response is attributable not so much to short-comings on OSHA's part as to a number of other considerations. One, but only one factor here is the substantial increase in recent years in experimental testing of chemical substances for evidence of carcinogenicity, and acceleration of the reporting of the results of the tests. Another factor, however, has been a very questionable modification in OSHA's operative criteria for assessing carcinogenicity. Thus, 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 were concerned. Now, however, OSHA proposes to use much less reliable evidence as a basis for regulations.

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

"Suspected Carcinogens" subfile of the Registry of Toxic Effects of Chemical Substances. 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 may be the case. Rather, the subfile is an uncritical compilation of published data about the chemicals; many perhaps as many as 510, are listed simply because some government agency has indicated an interest in testing them. 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 may require further research and evaluation."

As the Preface indicates, NIOSH itself does not regard the subfile as more than a "guide to the literature". It is, of course, necessary to establish priorities in this area; NIOSH has done so in selecting materials to be covered by Criteria Documents. An example of the difference between the subfile and Criteria Document is 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.

D. 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 into account the fact that the scientific aspects of the causation of cancer are extraordinarily complex, and the fact that, as the result of various substantial commitments of research and testing commitments to ascertaining individual causes of cancer and to understanding the mechanisms of such causation, the state of the art is currently evolving very rapidly. This being so, it would be inappropriate to "freeze" science as of the present time, which the OSHA proposal would in large measure do. The inappropriateness of OSHA's approach appears clearly from the advice of the Subcommittee on Environmental Carcinogenesis of the National Cancer Advisory Board, 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 subcommittee 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 cri-

teria appropriate for one agent may not necessarily apply to another." (58 J. Nat'l Cancer Inst. 461, Feb. 1977.)

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 reflects conclusions expressed seven or more years ago; many of these are already outdated and imprecise or otherwise inaccurate in light of current references. Indeed, even at best the cited references reflect only a single bias or perspective on the problems of occupational carcinogenesis. For example, they fail to reflect the very considerable body of learning supporting the no-effect level hypothesis.

It is manifestly unwise to disregard not only the developments of the past few years in better understanding the causes of cancer, but also to ignore for the foreseeable future developments currently underway or soon to be realized. Such a response is also quite questionable on a statutory basis 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, we think that federal regulatory authorities should plan on making a general reassessment of the state of the relevant science at least every five years, and should also reassess prior decisions in light of whatever additional data have become available. Particularly in an area of rapidly developing science and data, it would be unwise to proceed on the assumption that one could now make a decision that would be good for all time.

E. The illusion of a no-risk society.

The OSHA preamble makes much of the uncertainties or

difficulties with respect to confidence in any safe level of exposure to a known or suspect carcinogen. Implicit in this notion, if not explicit, is the concept that "safe" within the meaning of the Act means entirely risk free, and the correlative notion that industrial or other useful activity can occur on a completely safe, risk-free basis. Neither proposition is warranted attainable, or sustainable. There are risks associated with all societal activities, and indeed there are 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, fright-laden context such as cancer, sound public policy must take into account the inevitability of some risk, and the necessity of evaluating such risk not only against alternative risk but also in light of the benefits of the substance being regulated.

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 the following recommendation would do, so as not to regard the present (or the past) state 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 (at least for the time being) from future consideration in individual chemical

rulemakings; and 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 formidable. Enormous bureaucratic inertia would have to be overcome, and even if that were possible, very substantial time would be required.

The following proposal proceeds on the basis that although a categorical approach may be warranted, in the absence of countervailing data and expertise to enable OSHA to deal responsibly with currently accumulating evidence of carcinogenic or tumorigenic effects, there is now no warrant for precluding interested parties from presenting, on a case-by-case basis, evidence to counter any inference of actual occupational hazard that might otherwise be drawn from evidence tending to show carcinogenic potential of a chemical substance. For example, by use of a general principle that all mammalian test data were appropriate to warrant regulatory precautions against carcinogenic potential, OSHA could avoid the burden of establishing that proposition through direct testimony in individual rulemakings, and yet allow interested parties who believed they had compelling evidence to attempt to persuade OSHA that such evidence should not, in the particular circumstances of some improperly designed mammalian test or future unforeseeable case, be regarded as warranting such regulatory action.

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

It is widely recognized that non-carcinogenic toxic effects of chemicals can differ by several orders of magnitude, and that different regulatory limitations are accordingly appropriate. Since it is demonstrable that carcinogenic effects also can differ by a million fold, it seems inappropriate for the OSHA proposal to proceed on the basis that all known and potential carcinogens pose equivalent risks. Rather, carcinogens should be classified or ranked in terms of carcinogenic potency, and regulated accordingly. For example, bischloromethylether is a very potent known human carcinogen; vinyl chloride is much less potent. Greater precautions clearly are warranted for the former. Moreover, greater priority should be accorded to regulating a substance that is a potent carcinogen than a substance that is a weak carcinogen. The following proposal calls for categorizing both human and animal carcinogens as "potent", "intermediate", or "weak"; these classifications are provided primarily to set regulatory priorities. They also would be a rough indicator of the regulatory controls to be imposed, with more stringent controls for the more potent carcinogens. However, the categories would not inflexibly determine the regulatory controls; such controls, including primarily the permissible exposure level, would be determined on a case-by-case basis in light of assessments of risks, hazards, benefits, and costs. Such controls, and such exposure levels, could, for example, differ for two substances in the same category, depending on the particular circumstances of each case.

[Comment: In contrast to the foregoing approach, it has been argued that the regulatory controls should be determined by the categorization, along the following lines, which reflect a two-part rather than a tripartite subdivision of the human category:

I. Human Potent - best available technology without economic consideration, if necessary personal protection allowed up to one hour/day/man.

Human Weak - best practicable technology defined as use of engineering controls to the extent technically and economically feasible. When engineering controls do not attain the permissible level, install engineering controls and supplement with personal protection. Review every two years and install adequate practicable engineering controls.

II. Highly Potent, Animal - same as "human potent".

Intermediate Potency, Animal - same as "human weak".

Low Potency, Animal - same as human weak except no "two-year" review.]

In particular, the following proposed alternative would attribute regulatory significance to dose-response data, to data about the time between exposure to a chemical and induction of tumors, and other indications of relative potency of various known or suspect carcinogens. The principal mechanism through which the alternative would take into account these variables is in analyzing risks and otherwise ascertaining acceptable or permissible exposure levels. The proposal thus contemplates that it would be entirely appropriate for OSHA to set a lower exposure level for a potent carcinogen than for one that was shown to be only a very weak carcinogen.

Indeed, it is not inconceivable that in some circumstances it would be appropriate to establish a lower level for a carcinogen that appeared to be very highly potent only on the basis of animal tests, than for a known human carcinogen of relatively low potency.

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

The following proposal 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. A key aspect of the assessment of risk is the quantification of carcinogenic risk, that is, assessment of the likelihood of a carcinogenic event at a particular level of exposure. It is not presumed that there is presently any broad agreement on a particular method for quantification of such risk, or that any of the more frequently used or advocated methods to quantify risk is precise. Indeed, the ones commonly used are generally regarded as erring considerably on the side of safety and conservatism with respect to the calculation of the occurrence of carcinogenic risk. The proposal proceeds on the basis, however, that efforts to quantify risks can serve a useful purpose in comparing risks of exposure to a particular chemical with other occupational risks and with other risks commonly encountered and accepted, in our society.

Coal mining could serve as a useful example of a high risk occupation. There are about 100,000 coal miners in the United States. Although the incidence of black lung disease in 1977 is not yet available, in 1974 it was 800/yr, and each case led to a reduction in life expectancy of about .15 years. The accident rate in

coal mines is 150-200/yr, leading to an overall risk of one percent
(10⁻²) per year. This risk is accepted -- but barely so. Society
now correctly insists that it be reduced.

Many examples can be suggested for intermediate-risk activities where risks are judged acceptable, where the risk is one in ten thousand per year or greater, and neither workers nor society take any particular note of them. For example, a commercial airline pilot in the United States, flying close to the FAA maximum of 50 hr/month, flies 300,000 miles per year -- for a risk, if equal to that of his passengers -- of 3×10^{-4} /year.⁻⁴ Many businessmen, consultants and even professors, fly 100,000 miles per year for a risk of 10⁻⁴ /year. These risks are well known from experience and there is no conservatism in their estimation.

Similar calculations show the general acceptance of risks that will usually be quantitatively bigger than the risks expected for well controlled occupational exposure to suspect carcinogens. Examples [to be amplified] here include swimming, truck driving, the use of automobiles. These all involve choice, for example the choice of living over a shop one owns, or in which one works, and living in the suburbs 15 miles away, which necessitates 30 miles of motoring per workday.

The biggest cancer risk to which Americans expose themselves is from cigarette smoking. This risk is so great than even those in a room 30 m³ occupied by one smoker^{1/} can be exposed to

^{1/} Particular Polycyclic Organic Matter Study, by National Academy of Sciences - National Research Council, 1972, p. 29.

1 mg/m³ of benzo(a) pyrene -- equivalent to 1 cigarette every 10 days, or a risk of 2.5×10^{-5} . This is accepted without question by most people; this suggests that lesser occupational risks would be reasonable.

Indeed, by refusing to declining to regulate smoking in the workplace -- to avoid criticism from its labor constituency among others -- OSHA has decided that the risks of such smoking are acceptable.

The concept of acceptable exposure level and acceptable risk also reflects the congressional realization that a perfectly free workplace is not attainable and that safety and health standards must be economically as well as technologically feasible. We believe that in many cases these levels would be higher than what OSHA intends as "lowest feasible" levels, with correspondingly different economic impact and employment dislocation.

The Act requires that OSHA in promulgating standards for toxic materials or harmful physical agents, "shall set the standard which most adequately assures, to the extent feasible, . . . that no employee will suffer material impairment of health or functional capacity (underscoring added)." § 6(b)(5), 29 U.S.C. § 655(b)(5). The Act further requires that such standards "shall be based upon research, demonstrations, experiments and such other information as may be appropriate" and that among "other considerations shall be . . . the feasibility of the standards (emphasis supplied)." Id.

In addition to the text of the Act, its legislative history and decisions construing the Act support the conclusion that economic issues must be considered in evaluating feasibility of pro-

posed 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 to 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 standards for toxic substances which are "feasible." 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." 530 F.2d at 123.

While the courts in the above-cited cases were not faced

with the precise question whether the Secretary was required to consider economic feasibility, the Secretary having in fact done so, the unmistakable language of the Act makes clear that the duty is mandatory, not permissive, and this is clearly reflected in the court decisions. 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.

In addition, while OSHA itself has reflected "feasibility" requirements in a number of prior rulemakings, 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 technically 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).

The courts have proved to be of the same view. In Turner Co. v. Secretary of Labor, 561 F.2d 82, 83 (1977), the Court of Appeals for the Seventh Circuit held that "feasible" included both

economic and technological aspects and thus meant "practicable", a construction "in accord with the clear intent of Congress and the purpose of the Occupational Safety and Health Act".

D. Different approach to animal data.

The OSHA proposal is relatively indiscriminate in attributing significance to mammalian test data irrespective of the size of dosage used, the overwhelming of normal detoxification mechanisms, and other experimental test conditions that are unrealistic for occupational purposes. Two biological circumstances dramatize the need for careful appraisal of animal data. Estrogens and androgens are carcinogenic to experimental species, and for estrogens, the occurrence of disease in humans has been documented. Yet estrogenic hormones are ever present at subthreshold or no-effect levels in the entire earth's population and are essential to life. Similarly, metals such as chromium, nickel, cobalt, selenium, and perhaps even arsenic are essential to man in small amounts but carcinogenic in excessive amounts. The following proposal would substantially differentiate among test results depending upon such criteria.

While the following proposal would require positive results in two different mammalian species in well designed and conducted experiments to warrant regulation 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 for carcinogenic hazards might be appropriate.

E. The role of short-term tests.

OSHA's proposal would attribute some potentially signi-

ficant 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 required, what results in various tests would be sufficient for regulatory purposes, what kinds of tests would be sufficient, and so forth. In contrast, the following 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 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 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 further development and validation deserve high priority."

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

Recognition of the value of epidemiological data.

The following proposal would attribute more significance to available epidemiological data than would the OSHA proposal which would even subordinate such data to positive results in an experimental bioassay. Since human data is free from the difficulties of extrapolating from animals, it seems quite arbitrary and otherwise unscientific not to use it whenever it is available.

Human data could play a significant role in several aspects of the following proposal. First, such data could suffice to classify a substance as a known human carcinogen. Second, where appropriate, such data, with exposure level data, 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 would be relevant in any risk assessment.

There is ample evidence to attribute significance to epidemiological data, whenever such data is available. For example, aflatoxin is a potent carcinogen in various mammalian species, but there is ample epidemiological evidence that, where nutrition is good, the material does not produce harmful effects in man, despite widespread exposure to it in peanuts, corn, maize and sorghum. Indeed, the FDA has recently specified acceptable food levels for aflatoxin of 1 part per billion, a level that has produced cancer in some animals. Similarly, there are micro nutrients such as selenium that in low doses produce no harmful effects on man, indeed are necessary to life, and yet that produce well defined toxic effects in animals including carcinogenicity. And calcium fed to bulls at

only 3.5 to 5.8 times the National Research Council's recommended daily allowance for humans has produced tumor incidence of 30 percent.^{1/}

G. Regulatory priorities.

The OSHA proposal contemplates what appears to be a haphazard approach to regulatory priorities, depending upon the happenstance of the timing of receipt of information not presently available, and suggesting for processing of the large number of materials on the NIOSH subfile of "suspect carcinogens" approaches such as alphabetical order. The following proposal reflects the view that OSHA should regulate first those materials that are known to be human carcinogens or highly potent animal carcinogens. 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 actual occupational hazards being encountered in domestic workplaces. This approach would enable greater benefits to be achieved, and 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 following one would not call for formal categorization, by publication in the Federal

^{1/} Dr. H. F. Kraybill, Scientific Coordinator for Environmental Cancer, NCI, "Some Concepts and Remarks on Presumptive Negative Chemicals, Biological Intermediates, Endogenous Chemicals, Nutrients", paper delivered February 2, 1977, at the NCI Clearinghouse.

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 virtually 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. While there would be no objection to OSHA's merely 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 pre-market 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 following proposal 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 adding them to the unemployment rolls. 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. 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 have generally 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.

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 given 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 months limits and other pressures, err in deciding that

adequate substitutes are available. It is all well and good for someone to say ban a material or use a substitute. Unfortunately, those who glibly make such statements are often unaware of what is entailed in finding suitable substitutes. Compositions must generally be tested for stability and functionality. Processing equipment, shipping containers and users' processes must also be evaluated. In addition, before any substitution is made, extensive testing is necessary to insure that the substitute is safer than the original product. Such testing would generally include, for example, an evaluation of carcinogenic potential and other toxic potentialities, and such physical/chemical properties as reactivity and flammability. All this takes time, ranging from months to years. Thus, while it may be easy to say substitute, it may be difficult to accomplish. The consequences of such errors could be very substantial, for consumers and employees as well as employers.

Further, very substantial controversy would generally attend OSHA's rulemakings if substitutes were at issue, unnecessarily taxing the limited personnel resources which OSHA hopes to utilize better by the current proposal.

J. Decreased resort to emergency temporary standards.

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. The following alternate proposal would be more selective, for several reasons. First, the ETS route is authorized only when there really is a "grave hazard." This term has a connotation of immediacy of injury that generally is not presented

by low-level exposure to a suspect or potential carcinogen; it is the possible immediacy of the injury that warrants the extraordinary step of bypassing the normal rulemaking process.

This is not to say that serious consequences including death could not result in the long term. This, however, is true of most industrial hazards. It is true of many in the short term; for example, sulfuric acid can have dire results, depending on the degree of contact. We think it clear, however, that the ETS approach was authorized by Congress only when immediate action was needed to avert serious short-term injury hazards. The ETS approach thus is generally not warranted where a suspect or potential carcinogen is involved.

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 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 OSHA's prior uses of the ETS approach to substances being regulated only because of carcinogenic potential.

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 not uncommon, the failure to provide for exclusions of mixtures has great potential

for economic disruption, adverse environmental impact, and employment dislocation. On the other hand, 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. Examples can readily be produced, for example, of maximum airborne concentrations emanating from commercially very important mixtures in the parts per billion, examples drawn from OSHA's own regulatory experience (e.g., the "14 carcinogens" rulemaking) and otherwise.

L. Expert performance of categorization function.

Unlike the OSHA proposal, the following proposal 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 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. 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 such a panel or similar authority for each of a variety of regulatory agencies. The activities and decisions of the Panel would be governed by the Administrative Procedure Act.

III. Tentative Nature of Endorsement of Categorical Approach.

A. Regulation of individual chemicals.

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 readily implemented without a simplistic, unrealistic categorization scheme and simultaneously solve the concerns expressed by OSHA in the preamble to the proposed generic standard: specifically,

1. OSHA's problem of relitigating certain issues in each and every rulemaking could be eliminated by a complete risk assessment which would resolve such questions in a practical 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 counter-vailing evidence was presented to the Classification Panel or during an OSHA rulemaking.

3. Continuity of approach in regulating carcinogens would be achieved by basing proposed regulations on the results of substance-by-substance hazard evaluations. 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. OSHA should petition Congress for additional manpower resources to effectively regulate materials with carcinogenic potential. Additional manpower would be far less costly to the nation than would OSHA's proposed categorization and model standard scheme, which would often impose enormous cost increments not related to incremental enhancement of health.

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

B. Need for flexibility and exercise of judgment in each case; doubts as to regulatory efficiency.

The following proposal does not proceed on the basis of agreement with OSHA's assertions of a compelling need to simplify science and facts by categorization. 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 following 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 is 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 pro-

ceeding 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 evidence available at the time of a rulemaking on any given substance, the following proposal may be more efficient from an overall regulatory standpoint than would the OSHA proposal, which seems to assume that the process terminates with promulgation of a standard in the Federal Register.

IV. Appropriate Timing and Scope of Assessment of Economic and Environmental Impacts.

The following 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 the following proposal, it should be appropriate to assess those impacts in the regulation of individual chemical substances; indeed, the following proposal contemplates that the results of such impact analyses would play a major role in shaping the regulation, particularly the permissible exposure level. However, because of the rigidity of the OSHA proposal, it seems clear that to the maximum extent currently possible, the economic and environmental impact of implementation of that proposal should have been assessed before the OSHA proposal had proceeded to the

current regulatory phase. Such impacts are likely to be enormous if indeed not catastrophic, and much further study than has been essayed so far is clearly warranted to inform decision-making at OSHA before any further movement is made toward implementation of the pending proposal.

Moreover, 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.

V. Laboratories.

In general, regulations appropriate for the industrial workplace are not appropriate for laboratories, whether quality-control, pure research, or some admixture of both. Probably a single work-practices oriented regulation for laboratories would be sufficient; there clearly should be separate regulations for laboratories.

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 Classification Panel would be established by Executive Order issued pursuant to the Reorganization Act of 1977, 5 U.S.C. § 901 et seq. 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, etc., 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 in toxicology, pharmacokinetics, cancer research and therapy, epidemiology, occupational medicine, etc. 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 Academy of Occupational Medicine
American Academy of Veterinary Pathologists
American Occupational Medical Association
American Cancer Society
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. The Panel would have a staff; the Panel and staff would be housed within the National Cancer Institute.

The Panel could revise the Classification Categories and criteria from time to time, upon public notice and opportunity to be heard.

Categorization

The Classification 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 ones alleged or appearing to be known human carcinogens or highly potent confirmed 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. The Panel may from time to time revise the categorization scheme or revise the criteria, in light of scientific advancements, additional information, or experience with the categorization scheme, provided that reasonable notice of intended changes and an opportunity to comment are afforded to the public.

CATEGORY I. Known Human Carcinogen.

- A. Potent carcinogens.
- B. Intermediate carcinogens.
- C. Weak carcinogens.

Criteria: A substance shall be classified as a known human carcinogen on the basis of valid epidemiological 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-exposure 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.

Potency shall be determined on the basis of (1) epidemiological data where exposure data are available or where exposure intensities can reasonably be estimated, (2) mammalian bioassay data where dose-response data are available, or (3) by both kinds of evidence when both are available.

Where epidemiological 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, occupational exposure a few decades ago to beta-naphthylamine and to nickel plating operations.

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. Examples here include exposure to coke oven emissions.

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

CATEGORY II. Confirmed Animal Oncogens.

Criteria: Well documented results of adequate mammalian bioassays in at least two different species showing a statistically significant increase in tumors in test animals over that occurring in negative 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.

A. A number of the terms used in this general criterion are more fully stated below. The general criterion does not differentiate between 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. The general criterion also accepts, as prudential, 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 Industrial Hygienists that no substance is to be considered an occupational carcinogen of any practical significance on the basis of having reacted oncogenically by the following routes above the following doses.

1. Dosage exceeds via the respiratory route, $1,000 \text{ mg/m}^3$ for the mouse and hamster or $2,000 \text{ mg/m}^3$ for the rat.

2. Dosage exceeds, by the dermal route, $1,500 \text{ mg/kg}$ for the mouse and hamster or $3,000 \text{ mg/kg}$ for the rat.

3. Dosage exceeds, by the gastrointestinal route, 500 mg/kg/d for a lifetime, equivalent to about 10 g. T.D. for the mouse and hamster, and 100 g. T.D. for the rat.

C. Appropriate routes of administration. Appropriate routes of administration are respiratory, skin application, and gastrointestinal.

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

^{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.

- the appropriateness of the route of exposure
- the appropriateness of the animal species and strain used
- whether test populations were randomized
- size of each dosage group
- 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
- schedule of intercurrent sacrifice
- experiment termination date
- metabolic and pharmacokinetic data, if available
- number, type and site of tumors
- number of animals developing tumors
- temporal pattern of tumor appearance
- the quality of the pathology
- method of statistical analysis and statistical significance of positive results
- dose response relationships
- adequacy of reporting of the bioassay

E. Relative potency. The 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 in their "TLVs, Threshold Limit Values," is reasonable and sensible. The additional relationship of latency period (time from first contact to the appearance of tumors) is also applied in the definitions of industrial substances

of high, intermediate, or low potency as the result of experimental mammalian studies. Accordingly, agents for which adequate bioassay results of statistically significant tumor occurrence are available shall be categorized by potency in light of the following guidelines for bioassays of the hamster, mouse, or rat.

1. Respiratory route exposure.

A. Potent.

(1) Inhalation exposure 6 to 7 hours per day, five days³ per week, for a major portion of a lifetime, to dosages below 1 mg/m³ 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;

B. 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/m³ 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 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 volume.

C. Weak.

(1) Inhalation exposure to 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;

(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.

2. Skin application exposure.

A. Potent. Exposure by repeated skin application with tumors appearing in 6 months or less.

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

C. Weak. Exposure by repeated skin application with tumors appearing after 18 months.

3. Gastrointestinal exposure.

A. Potent.

(1) Exposure by 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. 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. Weak.

(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. Possible Animal Oncogens.

Criteria:

A. Mammalian bioassays that do not satisfy Category II requirements but that do show statistically significant increases in tumors.

CATEGORY IV. "Cleared" List.

A. Criteria. Completion of adequate mammalian testing or epidemiological 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 placed in this category. The contrariety of the reports would, however, be considered by OSHA in assessing risks.

In some cases, however, epidemiological studies showing no increased incidence of cancers could warrant categorization here, despite positive bioassay reports, for example where substantial metabolic differences were shown.

RECATORIZATION

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 for reclassification of a chemical on the basis of significant data or scientific learning that were not considered 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. Where such reclassification results, OSHA shall promptly consider modification of its standards.

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 epidemiological data; animal experimental factors, 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 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, hazards, costs 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 an acceptable level of risk. In deciding upon such a level, OSHA shall perform analyses of risks, hazards, benefits and costs in accordance with Subpart C below, to the extent such analyses can be very promptly performed. Where the available epidemiological 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 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, hazards, costs 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 immediately achieved 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. Such percentages may differ for different uses or mixtures, and shall be determined in light of analyses of risks, hazards, and costs and benefits, performed in accordance with Subpart C below, to the extent such analyses can be promptly performed.

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 becomes 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, hazards, costs and benefits. Different levels may be set for different

chemicals. 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 necessary.

(c) Where an ETS not based on data sufficient to quantify risks has been issued and such data does not become available within six months, an interim permanent standard similar to the ETS shall be issued, to be in effect no longer than three years. If during that three years' period such data become available, a regular permanent standard shall 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 does 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 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. Such percentages may differ for different uses or mixtures and shall be determined in light of analyses of risks, hazards, benefits, and costs performed in accordance with Subpart C below.

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 proceeding, OSHA should advise the ITC of the desirability of dose-response data if it does not exist. Permissible exposure levels should be established in the same manner as called for in the preceding subparagraphs (a) through (d).

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

[To be developed; some degree of uniformity seems desirable, but some flexibility to accommodate particular circumstances of a given chemical seems necessary.]

B. Category II Classification. OSHA shall consider issuance or non-issuance of an ETS in the same manner as provided above for the regulatory response to a Category I classification. Similarly, OSHA shall prepare analyses of risks, hazards, benefits and costs, as called for there, and shall consider them in establishing permissible exposure levels and other regulatory provisions. Also, OSHA shall proceed to promulgate permanent standards, or to consider such action, according to the provisions for response to a Category I classification.

Permissible exposure levels may vary from chemical to chemical, depending on the analyses of risks (including the strength of the evidence of carcinogenic potential), hazards, costs and benefits. Such exposure levels need not correspond with permissible exposure levels, or the range of such levels, that may be specified for Category I substances, and could be higher or lower.

C. Analyses of Risks, Hazards, Benefits, and Costs for
for Category I and Category II Substances.

In establishing permissible exposure levels, OSHA shall analyze risks, hazards, benefits and costs and shall state in writing the

manner in which each of the factors listed below has been considered.

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

Risk factors include:

- (a) evidence of carcinogenic potency, whether epidemiological 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 epidemiologic experience with the substance. It is recognized that while epidemiological evidence cannot conclusively show that a substance is not carcinogenic to humans, favorable epidemiological 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.

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 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 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. 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 and friends;
- (b) economic benefits of production and use of the substance, including volume and dollar amount of sales, number of employees, competitiveness 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, limits and health; reduction of other burdens; increases in knowledge; cultural values; uniqueness, vis-a-vis likely or possible substitutes.

4. Costs. 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 psychological 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 zero is 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. Only with reluctance should costs be imposed that can be borne only by the largest corporations, or that will be somewhat less severe but still have harsh impacts upon small businesses. 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.

[Comment: It is recognized that benefits could be expressed as costs (reductions), and vice versa. It may be desirable, however, to suggest risk/risk, benefit/benefit, cost/cost analyses of the substance being regulated versus substitutes, for refined analyses and to avoid unwarranted appearances of advocating a simplistic trade-off of health benefits versus economic costs.]

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. [Basically Section 1990.122 of proposed standard.]

E. Category IV Categorization.

No regulatory action is to be taken other than classification (or reclassification) as "cleared". It is recognized that a substance may subsequently be removed from this category, in the light of additional information.

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A. J. DOW



4-955-1 3

CHEMICAL MANUFACTURERS ASSOCIATION

November 5, 1980

To: OSH Contacts

Subject: OSHA Candidate List

The CMA Library has obtained copies of the references supporting the inclusion of the substances on the OSHA carcinogen candidate list. We are making them available to member companies at cost.

Documents supporting the inclusion of 107 substances identified by OSHA are available on microfiche. These will be available only as the entire set, covering all 107 substances, for \$25.00.

Documents for the EPA Carcinogen Assessment Group (CAG) list of substances which were incorporated by reference by OSHA are in a separate set, also at \$25.00. EPA did not release information on several of these chemicals as they were reported to contain confidential information. These include Aldrin, Chlorambucil, Diethylstilbestrol, N-Nitroso-N-ethylurea, N-Nitroso-N-methylurea, Phenacetin, TCDD (Dioxin), Thioacetamide, and Tris (2,3-dibromo-propyl) phosphate.

Summary risk assessments for the following are included with the CAG set:

Aldrin/Dieldrin	Ethylene Dichloride
Asbestos	Ethylene Oxide
Cadmium	Formaldehyde
Chlordane and Heptachlor	Halomethanes
Chlorinated Benzenes	Hexachlorobutadiene
Chlorinated Ethanes	Methyl Iodide
Chloroalkyl Ethers	→ Nickel
Chloroform	Nitrosamines
DDT	TCDD
→ 2,4-Dinitrotoluene	Tetrachloroethylene
1,2-Diphenylhydrazine	Toxaphene
Ethylene Dibromide	Trichloroethylene
	Vinylidene Chloride

Order sets of documents from Jane Rasmussen, Librarian, (202) 328-4229.

(con't)

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AP00048704

Letter to OSH Contacts
November 5, 1980

Please coordinate requests with your company to
avoid duplication of orders.

Jane Rasmussen
Jane Rasmussen
Librarian

cc: OSHC
CRAC Contacts
Environmental Contacts

JR:jb

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8C RF
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APR 18 1980

J. BARR

Retention Limit: 7/81

April 7, 1980

TO: SCIENTIFIC COMM.
AND SUBCOMMITTEES

4-985-13

FROM: AIHC

DATE: 4/16/80

TO: Don Hughes

FROM: E. L. Behrens

SUBJECT: OSHA Cancer Policy - Laboratories

Dr. Bob Smerko at ACS told me, as I understand, that OSHA has approached NSF with the suggestion that the science community petition OSHA to gain general exemption or some other relief for laboratories from the OSHA carcinogen regulation. NSF had held a meeting on the subject at which Bob expressed concern that there was no industry representation.

If there is industry interest in participating, Bob has suggested that we contact him. His address and telephone number are as follows:

Dr. Robert G. Smerko
Department of Chemical and Public Affairs
American Chemical Society
1144 16th Street, N. W.
Washington, DC 20036
(202) 872-4474

Will you please handle through the AIHC Science Committee and through P&G as appropriate? Thanks.

Edwin L. Behrens

ELB:jdk

cc: R. Barnard ✓
J. Browning
D. Hooker
T. W. Mooney
J. E. Stevenot

AP00048706

Air Products

4. 988 L B

Date 17 March 1980

INTEROFFICE
MEMORANDUM

Subject Recommended CMA Position Regarding
OSHA Cancer Policy

To Distribution

(Location, Organization, or Department)

From W. M. Smith

Scientific Affairs - Allentown Labs
(Location, Organization, or Department)

Distribution:

J. T. Barr
R. Fleming
J. R. Lovett
R. H. Schenck
L. B. Tepper

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MAR 17 1980

LAIR

This brief position supports AIHC's.

WMS
W. M. Smith

WMS:jr
Attach.

(320)

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RECOMMENDED CMA POSITION
REGARDING OSHA REGULATION
ON CANCER POLICY

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RESEARCH & DEVELOPMENT

MAR 13 1980

W. M. SMITH

Background

On January 22, 1980, OSHA issued its final Policy on the Identification, Classification, and Regulation of Potential Occupational Carcinogens. The regulation sets out the policy framework under which chemicals will be evaluated for carcinogenic potential in the context of workplace exposure. It describes the procedures which OSHA must follow in regulating such chemicals. It resolves for regulatory purposes some of the scientific issues which are uncertain presently, and provides for periodic review and updating in light of "substantive" new information. A science panel can be convened by the Secretary at his discretion under the auspices of the National Cancer Institute, the National Institute for Environmental Health Sciences, and the National Institute for Occupational Safety and Health. It defines criteria which must be met by negative studies before they may be considered. And finally, it provides that OSHA publish a candidate list and two "priority lists" to allow the public to become involved in the process at the earliest possible stage.

AIHC's objections to the policy are both procedural and scientific. They question the independence of the science panel and the discretion of the Secretary to ignore the recommendations of the panel, or not to call the panel. The criteria for considering negative studies create very high barriers. There are a number of other objections which are more legal than scientific issues.

Recommended CMA Position

CMA agrees with the American Industrial Health Council's analysis of the regulation as outlined in Mr. Barnard's memorandum of January 17, 1980. We should oppose the policy as arbitrary, capricious and not in accordance with the law. We should promote a sound national policy on the regulation of carcinogens, based on a realistic perspective on the causes of cancer and careful analysis of the risks and benefits in regulation. We should pursue a course designed to influence the implementation of the final OSHA regulation on cancer policy to protect the interests of the chemical industry and put CMA in a position of recognized expertise and interest. This can lead to a more productive relationship with OSHA. The following actions are necessary to accomplish this objective:

- We should document, in each applicable instance, failures to consider risk-benefits, excesses, arbitrary decisions, and problems resulting from inappropriate applications of the rule.

AP00048708

- We should encourage a clear distinction between scientific evaluations and regulatory judgment.
- We should participate in OSHA rulemaking that sets precedents and ensure that regulations are based on the best scientific judgments and advice available.
- We should interact in every way with OSHA staff in discussing the policy and its application.
- We should publicize any of OSHA's conclusions that are weakly supported that lead to extremes.

Action Required

Approval of above.

CMA

EC 3/11/80

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RESEARCH & DEVELOPMENT

JUL 8 1978

W. M. SMITH

4-988-12-3

BEFORE THE

UNITED STATES DEPARTMENT OF LABOR

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

WASHINGTON, D.C. 20210

RECEIVED

AUG 03 1978

LAW DEPT.

In Re:

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

OSHA Docket No. 090

Statement

of

Alphonse Chapanis

On Behalf Of

The Polyurethane Manufacturers Association

July 17, 1978

AP00048710

TESTIMONY OF ALPHONSE CHAPANIS

My name is Alphonse Chapanis, I am 61 years old and I live at 12 Running Fox Road, Glen Arm, Maryland 21057. I am a Professor at The Johns Hopkins University, Baltimore, Maryland.

My professional specialty is human factors engineering, or, as it is widely called in Europe and elsewhere in the world, ergonomics. Ergonomics is a word compounded of two Greek words, *ergon* and *nomos*, and it means the science of work. Human factors engineering, or ergonomics, is primarily concerned with the design of tools, machines, systems, jobs, and work environments so that they best match human capacities and limitations. The goals of the field are to increase efficiency, increase productivity, increase comfort, decrease worker boredom and fatigue, reduce errors, increase safety, and increase job satisfaction.

I am generally considered to be one of the founders of the field of human factors engineering. My first book, *Applied Experimental Psychology: Human Factors in Engineering Design*, was the first textbook in the field. I have written over one hundred and twenty scientific books, scientific articles, and encyclopedia articles. I have been President of the Human Factors Society and of The Society of Engineering Psychologists. I am currently President of the International Ergonomics Association, an organization that comprises 15 ergonomic and human factors societies around the world. In 1963 I received the Franklin V. Taylor

AP00048711

Award from the Society of Engineering Psychologists "for outstanding contributions to the field of engineering psychology." In 1973 I received the Paul M. Fitts Award from the Human Factors Society "for outstanding contributions to human factors education."

One of my particular interests within the field of human factors engineering is the design and evaluation of signs, warnings, instructions and manuals. I wrote what I believe is the first article to call attention to these problems in 1965. I have been a consultant to a company that had the task of preparing a guide for the preparation of instruction manuals for the Army. I was the human factors consultant responsible for the design of signs in the first standard approved by the Consumer Product Safety Commission. I have been used as an expert witness on the adequacy of warnings and instructions in several product liability lawsuits.

More complete biographical and bibliographical information is contained in the exhibits attached to this testimony.

I was asked by the Polyurethane Manufacturers Association (PMA) to present my views on the adequacy of the signs and labels in the proposed OSHA standards for the "Identification, classification and regulation of toxic substances posing a potential occupational carcinogenic risk." (*Federal Register*, Volume 42, Number 192, Tuesday, October 4, 1977, Part VI, Pages 54148-54247).

Let me start with a specification for accident prevention signs (USA Standard Z35.1-1968, Revision of Z35.1-1959). This standard has only one short paragraph about the wording of signs. It is:

AP00048712

"6.2 Nature of Wording. The wording of any sign should be easily read and concise. The sign should contain sufficient information to be easily understood. The wording should make a positive, rather than a negative suggestion, and should be accurate in fact."

For human factors engineers a much more complete specification of the requirements to be met by good warning signs is contained in a recent article by Sell (1977). The following is taken from his summary:

"To be really effective they [that is, safety posters and safety propaganda] should:

1. Be specific to a particular task and situation.
2. Back-up a training programme.
3. Give a positive instruction.
4. Be placed close to where the desired action is to take place.
5. Build on existing attitudes and knowledge.
6. Emphasize non-safety aspects.

"They should not:

1. Involve horror, because in the present state of our knowledge this appears to bring in defense mechanisms in the people at whom the propaganda is most directed.
2. Be negative, because this can show the wrong way of acting when what is required is the correct way.
3. Be general, because almost all people think they act safely.

This type of propaganda is thus seen as only relevant to other people." (Page 213)

Amplification of some of these points appears in another publication by Laner and Sell (1960):

"A poster enjoining its target population to ACT SAFELY, to take SAFETY FIRST measures or even to MIND YOUR HANDS does not contain any clear directives as to the *actual behaviour* required... Logically a poster should therefore be an extension, a reinforcement, a reminder, of training procedures, or a specific directive immediately applicable to the situation on the site where it is displayed. PUSH THIS LEVER UP BEFORE YOU START WORK tells the man exactly what is wanted of him. Similarly, KEEP THIS TOOL HANDY; PLACE YOUR HANDS THIS WAY; LIFT THE LOAD THIS WAY; THIS IS HOW A SLING MUST BE FIXED; THROW THE MAIN SWITCH *BEFORE* CHANGING THE FUSE; SHUT THIS DOOR; STAND BACK; WATCH THE DRIVER...Any reference to CAUTION, BE CAREFUL, TAKE CARE, should be avoided; there is good evidence to show that warnings of unknown and unspecified dangers tend to produce nervousness and reduce the level of skill and thereby may lead to accidents. ...Incidentally, the basic objections to so-called horror posters are again that instead of appropriate responses, emotional ones are evoked, which are known to affect skillful behaviour adversely."

(Pages 168-169)

These recommendations, incidentally, are not the results of armchair philosophizing, but are based on tests of various kinds of signs in seven factories over a period of several months.

Similar concepts have also been tested experimentally by Leventhal (1967). Leventhal measured the effectiveness of warnings that had messages producing various degrees of fear: some were mild, some moderate,

AP00048714

and others strong or terrifying. The warnings were associated with the effects of tetanus, the risks of cancer from smoking, and taking precautions while driving. An important feature of Leventhal's work is that he tested not only what people said and thought, but also what they later did. That is, he determined whether people actually did get tetanus shots, and whether they actually did stop or cut down on smoking. His results showed that fear messages by themselves were not very effective and that the effectiveness of a warning was not necessarily related to the amount of fear produced by its message. In fact, sometimes the reverse occurred. The more fear-producing the warning, the less effective it was.

Then Leventhal combined the warning messages with statements about positive actions a person could take, for example, with recommendations about getting tetanus shots and where they could be obtained, or with a large number of positive suggestions about ways of cutting down on smoking. The results were now impressive. To quote Leventhal:

"A person is less likely to feel hopeless or paralyzed when he has, in addition to a specific goal, a clear idea of what he is to do and when he has to do it...Combining fear communications with specific instructions always produced the best results." (Page 631)

Against that background what can we say about the sign proposed by OSHA in the regulation under consideration. It is:

DANGER

XXXXXX

(insert appropriate trade or common names)

CANCER HAZARD

AUTHORIZED PERSONNEL ONLY

AP00048715

I'm afraid I have to conclude that this sign is a failure on almost all counts. The sign does not contain sufficient information to be easily understood; it is not specific, or, conversely, it is too general; it is negative, that is, it does not give a positive instruction about actual behavior to be taken by a worker; and it involves horror.

As a human factors expert on such matters, I feel that the most serious shortcoming of the proposed sign is that it does not tell a worker what he can do in a positive way. In this respect, it shares the same defect as signs that say BIOLOGICAL HAZARD or RADIATION HAZARD. What exactly is a person supposed to do in the vicinity of such a sign? Keep his hands in his pockets? Close his eyes? Not touch anything? Stop breathing? Where exactly is the hazard? All around? In the air? Behind the sign? Such a sign is a failure because it contains absolutely no useful information. There is nothing sensible that a person can do in the presence of such a sign, except to ignore it, or beat a hasty retreat from the immediate vicinity. And, of course, neither course of action may be really appropriate under the circumstances.

To conclude this point: In my opinion, a good sign should be positively worded. It should tell the worker *precisely where* the hazard exists. It should identify the *exact extent or amount* of the hazard. Finally, it should tell the worker exactly *what kind of positive, constructive, or defensive action* he can take in the vicinity of the warning.

To turn now to another, quite different point: OSHA's avowed intent in specifying the sign in question. The intent is contained in the

AP00048716

following quotation, taken from 16. *Paragraph (p). Signs and Labels.*

"OSHA believes that it is important...that appropriate forms of warning, as necessary, be used to apprise employees of the hazards to which they are exposed in the course of their employment. OSHA believes, as a matter of policy, that employees should be given the opportunity to make informed decisions as to whether to work at a job under the particular conditions extant..." (*Federal Register*, op. cit., Page 54178).

Let me turn to the question: Does OSHA's proposed sign really convey the kind of information that would allow workers to make *informed decisions*?

It is well known in human factors engineering that a designer must not trust his own judgment in matters of design. In fact, I would say that this is a basic principle of human factors work. There are many quotations I could give to support my statement. Let me merely use the following from the Department of the Defence Military Specification MIL-HDBK-759:

"Not all safety problems can be anticipated from studying concepts and blueprints. Thorough safety analysis requires realistic tests with mockups and prototypes. No matter how simple and foolproof a concept looks on paper, try it before finalizing the design."

(Page 423)

The same applies to instructions and warning signs. In an article written some time ago (Chapanis, 1965) I showed in numerous examples how the words that someone had written for an instruction or warning meant something entirely different to the people who read the words. Broadbent (1977)

gives more recent examples. I want to emphasize that there may be no deliberate attempt on any one's part to deceive. It is simply that words usually mean different things to different people. For this reason, human factors engineers are empirical. They always try things out, and they try them out on the people who are to use them.

In connection with this case, I have read the testimony of several experts about the meaning of OSHA's proposed sign. I'm afraid that I wouldn't really trust any of those opinions, unless I had seen them verified in actual tests. Since none seemed to have been made, I conducted some tests of my own to find out what OSHA's sign means to various people. I must emphasize that my tests were not extensive. I was not authorized to conduct extensive tests by the PMA, nor was I allocated sufficient funds for that purpose. However, my tests were enough to convince me of what I had suspected all along: OSHA's proposed sign does not convey the understanding that its originators think it conveys.

Here briefly is what I did. I drew up a replica of OSHA's sign as follows:

D A N G E R

4,4'-methylene-bis(2-chloroaniline)

"MOCA"

C A N C E R H A Z A R D

AUTHORIZED PERSONNEL ONLY

I gave each person a standard set of instructions and a standard scenario. Specifically, I asked each person to imagine that he was reporting for an employment interview at a particular chemical company

and that on his way to the personnel office he encountered the sign above.

I then asked each person to think carefully about what his reactions would be to such a sign. In particular I asked:

1. "What would be your immediate, emotional, or "gut" response upon seeing such a sign?"
2. "What kind of an understanding would such a sign convey to you about the hazards of working at this plant? Quantify your understanding, if you can."

Altogether I solicited responses from 13 colleagues and students. The responses varied enormously. In response to the first question, I received varied answers ranging from rather mild expressions ("curiosity and intrigue, interest") to strong emotional responses ("fear, dismay, shock"). There is no question that the immediate, emotional response, however, is overwhelmingly in the negative direction.

However, my more immediate concern is with the responses to the second question. How much of an understanding does this sign convey about the actual hazards of working at such a plant? Here, once again, the responses varied enormously. Below, I quote some verbatim answers:

1. "The sign conveys the implication to me that MOCA may present a chance of cancer to the unauthorized, naive visitor. But not to the authorized personnel who are permitted to enter."
2. "This sign would tell me little since I'm not acquainted with the dangerous substance and because such signs are fairly common in industrial settings and are probably required by law for levels below what may be really dangerous."
3. "I'd understand that the company either used or produced "MOCA," a cancer hazardous substance. But I wouldn't understand to what degree it was a hazard, what kind and length

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and amount of exposure was hazardous, exactly where the hazard was (in the hall, throughout the entire plant, in certain areas), or to whom it was a hazard (everybody, those working with it, in a certain location of the plant)."

4. "I would not be scared of working in a plant where such chemicals were used, but would not trust any company that did not keep such chemicals in an isolated and secure area. I would suspect the company of lax security, and feel the hazards are high."
5. "Very little understanding of the true hazard. I'd say, on a scale from 1 to 10, probably 2 or 3 (1 = little understanding; 10 = clear understanding)."

Those quotations are, I think, sufficient to make my point. The proposed sign evokes quite different degrees of understanding among the various people I tested. On the whole, the most general impression is that it conveys very little precise information about the hazard. So once again I must conclude that the proposed sign fails to meet OSHA's avowed intention.

From my study of the situation, it appears that the sign was devised by someone sitting in an office without any attempt to use rational, empirical methods of doing so. OSHA has the money, staff, and facilities to do a careful job. Indeed, my understanding is that the principal purpose of NIOSH is to conduct such investigations for OSHA. This issue is clearly too important to be left merely to expert opinion. The sign should be constructed on the basis of sound principles and should be scientifically tested and validated. At the very least, this requires:

1. A careful specification of precisely what information the sign is supposed to convey.
2. A careful survey of the worker population to determine what levels of reading ability, and comprehension one might expect to find in that population.

3. The tentative design of a number of alternative signs that might serve the purpose.
4. Empirical tests of the signs to discover whether they do indeed convey the information they are supposed to convey.
5. Redesign of the signs to eliminate their faults.
6. Revalidation of one or more final proposed designs.

The above may sound like an extended program of research. It is not as complicated as it looks. Human factors engineers know how to do these things and they follow such procedures routinely in the design of tools, jobs, and signs. The issue is much too important to be left as a matter of opinion, intuition, or hunches. It should have a firm scientific base. In fact, not to provide such a scientific base amounts, in my opinion, to an abrogation of the responsibility that has been conveyed upon OSHA by law.

In view of what I have just said about the necessity of testing signs and labels empirically, I hesitate to make firm recommendations about a kind of sign that would be acceptable. I have not had the opportunity to make the appropriate kinds of tests. Nonetheless, there are a couple of things that I can state with a considerable amount of assurance, and some others that I can at least suggest with some reasonable likelihood of being correct.

First, let's return to USA Standard Z35.1-1968, to which I have already referred. This standard states that:

"4.1.1 Danger signs should be used only when an immediate hazard exists..."

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"4.1.2 All employees shall be instructed that danger signs indicate immediate danger and that special precautions are necessary.

"4.2.1 Caution signs shall be used only to warn against potential hazards or to caution against unsafe practices..."

"4.2.2 All employees shall be instructed that caution signs indicate a possible hazard against which special precautions should be taken." (Page 8)

With these definitions in mind, it seems clear that the proposed OSHA signs and labels should say CAUTION and not DANGER, since there seems to be unanimous agreement that the MOCA hazard, for example, is potential and not immediate. An example of a correct use of DANGER is:

DANGER

HIGH VOLTAGE

Now let's consider the wording that identifies the hazard. It is accepted practice to identify the substance, agent, or object that constitutes the hazard. So, for example, the accepted practice is to use wordings such as:

FIRE HAZARD

RADIATION HAZARD

BIOLOGICAL HAZARD

The reasoning behind that practice is that a hazard may have any one of a number of different effects. Fire, for example, may merely singe one's hair, or it may burn one's hand, or cause asphyxiation. Similarly, radiation may have any of a number of diverse effects on the human body. In that same vein, a hazardous chemical such as "MOCA" may cause hepatitis,

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dermatitis, or pneumonitis. Thus, to follow accepted practices, and to conform to the reasoning behind those practices, the proposed OSHA signs and labels should say CHEMICAL HAZARD and not CANCER HAZARD.

Although I am somewhat less sure of what the rest of the sign should say, I will venture to make some suggestions which, based on my experience, I would judge to be probably correct. Here is my version of what the whole sign should say:

C A U T I O N

CHEMICAL HAZARD

This { factory or establishment } { manufactures or uses }
4,4'-methylene-bis(2-chloroaniline)

"MOCA"

This chemical may be hazardous to your health. Studies show that laboratory rats fed large amounts of this chemical often develop cancer. All persons entering these premises should get information first about these hazards, about exactly where the hazards are, and about ways of protecting themselves against these hazards. Free information is available at....

Notice that the wording of this sign follows the model or practice that has already been established for such warning labels as those on saccharine and on products containing saccharine. Even so, before committing myself to this sign, I would want to subject it to tests in some real environments with an appropriate sample of subjects. However, as a first approximation, I think this sign meets all the following requirements:

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1. It conforms to existing standards and practices for the wording of accident prevention and hazard signs.
2. It conforms to existing practices for the wording on products that contain substances presumed to cause cancer in humans.
3. It is honest.
4. It is correct, that is, it is consistent with the facts.
5. It serves the needs of regular employees and of casual visitors, that is, persons who do not work on the premises and so would not be expected to have gone through any kind of training or instruction.
6. It is specific.
7. It is understandable.
8. It does not involve horror.
9. It provides a positive instruction about what a person can do in the presence of such a hazard.
10. It provides information about precisely where the hazard exists, or at least it tells the person that he can get that information.

As I see it, the only disadvantage of my proposed sign is that it is long. However, whether that is sufficiently serious a disadvantage to outweigh its advantages is something that can only be determined empirically. And, of course, tests might show ways in which the sign could be abbreviated without serious loss of meaning, or distortion of intention.

So far I have concerned myself primarily with OSHA's proposed signs. OSHA's proposed labels are even less defensible, in my opinion.

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In the case of the signs, one can go on the assumption that most of the people, that is, the workers, who will see the signs will also have received some kind of training, or indoctrination, about the hazardous material, and about proper ways of safeguarding themselves against that material. In the case of labels to be "...affixed to all containers of xxxxx and of products containing xxxxx..." we can no longer go along with that simplifying assumption. I would presume that the "containers" would be handled and shipped by warehousemen, truckers, longshoremen, railwaymen, aircrews, and numerous other people who will not have had any opportunity to learn about the hazardous chemical. Further, I would presume that "products" containing the hazardous chemical might be bought, handled, and used by people in any one of a thousand different walks of life, perhaps even by ordinary citizens and householders. If my assumptions are correct, then there is no way that these people could possibly have been told, or could possibly have found out, about the hazardous chemical. All of this means, in short, that the labels must be much more carefully designed than the signs. The impression that comes through to me, however, is that OSHA has given the labels less thought than the signs. Indeed, it looks as though OSHA's labels are a kind of afterthought. I'm very much afraid that in their present form, the labels would do much more harm than good.

My most serious concern is that OSHA has not presented a clear rationale for the labels. Exactly what does OSHA want to accomplish with the labels? Exactly what is OSHA's intention in requiring these labels? What is the primary message that the labels should convey? To whom are

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the labels addressed? The answers to these questions do not come through to me at all. Until OSHA's intent is clear, I don't see how you can possibly design meaningful labels.

Let's consider the rationale. OSHA's reasoning appears to be that any product made with a hazardous chemical is itself hazardous. That concept strikes me as preposterous. I would call hydrogen, in either its gaseous or liquid forms, a hazardous chemical. But one product containing hydrogen, H_2O , is most emphatically not hazardous, or at least, it's not hazardous in the same sense. I'm sure similar analogies must be widespread in the chemical world. Chemicals which by themselves are hazardous must at least sometimes become harmless when they are combined with other chemicals, or are otherwise treated, in the manufacture of products. So to say that one should affix a CAUTION label to every product that is made with, or that contains, a hazardous chemical strikes me as nonsense.

Moreover, I can well imagine that a chemical which is potentially carcinogenic through inhalation could be manufactured into a product that gave off no fumes whatsoever. Would that product then be classed as hazardous?

It is these kinds of concerns and questions that lead me to conclude that OSHA has not really presented a clear cut rationale for its intent in requiring that labels be "...affixed to containers...of products containing xxxxx."

However, let's turn to what at first glance appears to be a clear cut case: containers of a hazardous chemical. Labels to be attached to such containers must, at the very least, conform to all the principles

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that I have enumerated for the design of signs. That is, the labels should say CAUTION and not DANGER, they should say CHEMICAL HAZARD and not CANCER HAZARD, and they should contain simple, clear, honest, and positive instructions to all persons who might have to handle the containers or come into contact with them. In this connection, the labels should contain specific instructions about what to do if the container is damaged and broken. Because that's one of the real hazards, isn't it? Exactly what is a shipper or handler supposed to do with a broken container of xxxxx? Flush it down a sewer? Call the police? Call a fire department? Neutralize it in some way? Call a poison control center? Get the hell out of there? Even ordinary medicine bottles in my medicine cabinet give me instructions about what to do if I swallow some relatively mild substance accidentally. OSHA would be criminally negligent, in my opinion, if it failed to be at least that specific with a truly hazardous substance.

To summarize for emphasis, the message on labels must be even more carefully designed than that on signs because, once again, we cannot assume that the persons who will come into contact with the containers will have had any chance to be instructed or indoctrinated about the chemical, or the hazards associated with it. However, until OSHA can define its intentions more clearly, I don't see that anything constructive can be done to design meaningful and appropriate labels. Meanwhile, if one of my students wrote on an examination that he proposed labels such as these for potentially hazardous chemicals, knowing what we know today and given the climate of social and moral responsibility that we all feel today, I would honestly have to give him an F for failure. OSHA can and should do better.

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