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AMERICAN INDUSTRIAL HEALTH COUNCIL

Scientific Position

Introduction

This document is intended to set forth in relatively brief outline form the scientific position of the American Industrial Health Council (AIHC) on the issues raised by OSHA's generic carcingoen proposal. 42 Fed. Reg. 54147 (October 4, 1977). This document should assist the AIHC, expert witnesses it retains, and member (and non-member) companies in focusing their attention on appropriate and important scientific issues.

Discussion

1. OSHA's inference of a cancer epidemic is misleading. Occupationally-related cancers are not increasing and occupationally-related cancer is not a substantial portion of all human cancers. Cigarettes, alcohol and diet are significant factors in cancer etiology. OSHA's implied assertion that drastic action (e.g., wholesale use of emergency standards) is necessary to combat an epidemic is therefore incorrect. An overemphasis on industrial chemical causes of cancer is counterproductive in that it gives individuals who continue to smoke, drink and improperly eat a false sense of security.

2. Although there is scientific dispute as to whether there are thresholds or "no effect" levels for carcinogens, there is a strong body of scientific opinion that there are thresholds. Further, there is evidence of a no effect level for many substances (e.g., NCTR-2-AFF study; Oakridge radiation study). Modern toxicology is based on experimental evidence demonstrating that toxic substances follow a dose-response relationship and that there is some level below which no response occurs.

3. Attention should be focused on socially acceptable risks rather than only debating what is a "no effect" level. The law (OSH Act and other analogous acts) and logic support this concept. Absolute safety is an impossibility. Relative risk and risk above background levels must be examined. Occupational exposure risks associated with exposure to suspect carcinogens must be related to other occupational and non-occupational risks (e.g., building a bridge or highway and traveling by airplane or automobile). Careful assessment of the benefits of substances is also necessary. There are many valuable substances in everyday use which have produced tumors in animals but not humans, e.g., egg yolks, vitamin D, and calcium. The recent experience with saccharin has been a useful lesson. Criteria for evaluting risk (a function of exposure potential and the intrinsic carcinogenicity of a substance) and evaluating benefit (a function of the improved quality of life and better utilization of resources) will be suggested to OSHA. Among the criteria to be suggested for evaluating risk and benefit will be the risk to the worker, the impact on employment, the impact on the economy, the impact on consumers, the protection of life, the increase in knowledge and the reduction in waste.

4. OSHA's proposal fails to take sufficient account of the following scientific principles and data, necessary to a reasoned evaluation of the risks and hazards of substances:

(a) Dose-response -- thresholds and dose-response curves have been established for many substances.

(b) Time to tumor -- in making extrapolations to humans, time to tumor may often exceed life expectancy.

(c) Route of exposure -- relevance to occupational exposure.

(d) Interspecies variation and species sensitivity -- validity of mouse as model and of extrapolating from mouse data to human exposure is questionable in many circumstances.

(e) Relevant, sound negative human epidemiology and negative animal data.

(f) Lack of comparability in many replicated animal studies -- failure to take account of variations in test procedures and conditions, e.g., number of animals per cage, statistical treatment

data and presence of other volatile toxic substances in the room.

(g) Definition of the term "tumor" -- more definitional precision is necessary.

(h) Basis for scientific judgment on extrapolating from animal data to human exposure generally.

(i) Metabolic, pharmacokinetic, and biochemical data.

(ii) Dose -- amount which does not overwhelm detoxification mechanisms; secondary effects due to high dose level may confuse data.

(iii) Detoxification and repair (including DNA) mechanisms.

(iv) Immunology -- may become an important area in better understanding cancer mechanisms; example of fast developing area where OSHA would essentially foreclose further regulatory inquiry; effort will be made to show relevance of immunology to extrapolation, e.g., varying responses in animals due to immunological differences.

5. OSHA's proposed classification scheme blurs distinctions between the relative potency of substances, estimated to range up to 10^7. Regulatory policy should be based on the risk posed by a particular substance rather than combining those substances posing a small risk with those posing a great risk.

6. OSHA is correct in rejecting chemical structure and injection site tumors as bases for categorization. It is anticipated that others participating in the rulemaking will challenge OSHA's position on these issues.

7. The definition of "short term tests" should be clarified. Such tests are of limited value as regulatory classification criteria.

8. An alternative to the OSHA proposal will be advanced, including a scientific rationale therefore consistent with the scientific position outlined in this document. The alternative proposes an alternate classification scheme

and alternate classification criteria; suggests different regulatory responses thereto; and requires the establishment of an independent scientific classification authority or board outside OSHA premised on the theory that classification requires scientific judgment and that OSHA alone does not have sufficient expertise or resources to make classification judgments and to otherwise implement its generic proposal.

9. OSHA does not have the authority to, in effect, ban substances by requiring no exposure; nor does it have the expertise to do so.

10. OSHA should exempt some mixtures containing carcinogenic substances from the scope of the regulation. Criteria to be applied in subsequent rulemakings on individual substances will be suggested for establishing the point below which mixtures containing carcinogenic substances should be exempted. Examples will be cited of the potentially disruptive impact of the failure to provide for such an exemption (e.g., many aerospace propellants and lubes contain trace amounts of carcinogenic substances which cannot be eliminated). OSHA has previously recognized the need for an exemption for mixtures containing carcinogens in its standards for the fourteen carcinogens. This is a precedent on which OSHA should draw.

11. OSHA's failure to distinguish between laboratory and non-laboratory workplaces is unreasonable. OSHA's proposal imposes many burdensome and unnecessary requirements on laboratory workplaces and may, indeed, have the unintended effect of impeding important cancer and other research.

12. The inflexible procedures and automatic regulatory responses embodied in the OSHA proposal may result in irrational and unscientific rulemakings in that these procedures and responses will take out of OSHA's hands the ability to rationally set regulatory priorities. For example, under the OSHA proposal, OSHA could, upon the filing of a "citizen petition," be required to give equal regulatory priority to such seemingly unequal problems as selenium and nickel (essential body nutrients), peanuts, asphalt and carbon tetrachloride.

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MEMORANDUM FOR THE
DRAFT BRIEF REVIEW COMMITTEE

To assist you in evaluating the potential post-hearing brief issues, I am enclosing a memorandum prepared at the close of the OSHA presentation on the status of the issues.

It may be helpful also to separate out the "big money" issues.

(1) Lowest feasible: OSHA has shown no departure from this position.

(2) Mouse: The NCI position makes it unlikely AIHC will prevail.

(3) Monitoring.

(4) Medical surveillance: note union opposition to company doctors.

(5) Preference for engineering controls: no modification visible in OSHA's position.

(6) Suitable substitutes: OSHA's position is unclear.

There are several issues where OSHA seems in strong opposition.

(1) Independent panel.

(2) Acceptable risk.

(3) Primacy of engineering controls.

(4) MTD.

(5) Mouse.

OSHA's position is somewhat more ambiguous on several issues.

(1) Potency.

(2) Risk assessment/extrapolation to low doses.

(3) Priorities.

(4) More flexibility in standards.

R.W. Barnard