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MEMORANDUM FOR AIHC BOARD

Ongoing efforts in the Congress and Administration to amend the food safety laws address many chronic health issues of vital interest to AIHC. The pending bills and Administration draft proposal define the term "safe", which is presently undefined in current law, to incorporate the concept of significant risk; amend the Delaney Clause to incorporate FDA's proposed constituents policy and permit the use of food additives which do not pose a significant risk; authorize the use of risk assessment in determining whether a food additive is "safe"; and create a science panel to advise FDA on scientific issues.

Most of these proposals are deemed "controversial" and have been opposed by consumer groups as efforts to weaken the regulation of food additives. There is therefore concern that the legislative process could result in "conservative" (i.e., unscientific) risk assessment procedures being mandated by law.

Food safety reform legislation is expected to be a high priority for the Congress which convenes in January 1983. The Food Safety Task Force intends to continue monitoring the development of such legislation, to present testimony on issues of concern to AIHC, and to provide support for placing food safety regulation on a scientific basis. The Task Force will also maintain contact with other interested trade associations to explain AIHC positions on various issues and to coordinate industry positions.



Richard deC. Hinds

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RECENT SCIENTIFIC PROJECTS IN SUPPORT OF AIHC OBJECTIVES

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Clean Air Amendments

- To provide scientific support to the Chemical Manufacturers Association to Clean Air Amendments, particularly with respect to §112 (hazardous air pollutants).

Chronic Health Aspects of Hazardous Waste Regulation

- To provide scientific support to CMA on chronic health aspects of hazardous waste regulations.

Scientific Data Base for Federal Chronic Health Policy Issues

- To raise the awareness of the Administration and the Congress to include the role of science in the development of Federal chronic health policies and the need for an adequate scientific data base so that the best possible societal decisions are made by Government with respect to chronic health and hazardous substances issues.

Risk Assessment Methodologies

- To review the quality of the science underlying risk assessment methodologies currently proposed in various regulations and legislation and to develop and evaluate alternative methodologies emerging from studies such as ED₀₁ and the Oak Ridge National Laboratories radiation study.

Development of AIHC's Position for a National Chronic Health Policy

- To develop as complete an AIHC position as possible on a national chronic health policy utilizing the advice and opinions of non-AIHC experts. The policy position should incorporate, insofar as is consistent with the developing views of the AIHC, itself, the views and opinions of representative renowned health experts outside AIHC. Advance review and input by recognized outside experts will greatly enhance the quality, legitimacy and acceptability of AIHC's position.

Food Safety Amendments - AIHC Science Issues

- To successfully promote the inclusion of AIHC's policies with respect to the science panel concept and risk assessment in food safety amendment legislation.

NAS Committee Study on Institutional Means for Assessment of Risk to Public Health (Science Panel Study)

- The objective of this project is to have no request from the Committee unfulfilled in connection with its study due to be completed at the end of 1982 because AIHC has advocated and recommended the creation of an independent central body for judging the merits and quality of scientific evidence to be used in regulatory decision.

The major purposes of the Committee Study are 1) to assess the merits of separation of the scientific function of risk assessments from the regulatory decision process; 2) to consider the feasibility of unifying risk assessment functions; 3) to consider the feasibility of developing coherent risk assessment guidelines; and 4) to address relevant procedural and institutional issues concerning risk assessment and the regulatory process.

Reconsideration of OSHA's Generic Cancer Regulation

- To insure that OSHA's generic cancer regulation is amended so as to insure that the identification of carcinogens is based on good science and that the control measures recommended are both effective from a health view point and the least burdensome in terms of economics.

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AIHC Assistance to State Industry Organizations Concerned with Chronic Health Hazard Issues

- State legislative and regulatory activities on chronic health hazard issues has been increasing in a number of states. Most state industry organizations do not have the experience or scientific background to adequately address these issues. The project is to assist state industry organizations in dealing with chronic hazard issues at the state level which AIHC has worked on at the federal level.

Cooperative Epidemiological Research Study with American Petroleum Institute - "Comparison of Standardized Mortality Ratio (SMR) and Proportional Mortality Ratio (PMR) in a Cohort of 35,000 Union Members"

- To determine the concordance (or lack of it) between cause-specific SMRs and several types of PMRs based on complete death ascertainment as well as on deaths known to the union only to evaluate the validity of using PMRs in risk assessment based on incomplete death information.

The Scientific Committee believes that the study subject deals with a very real problem for the industrial community. Access to such a well-defined cohort and union records is unique. The proposal offers potential for an important contribution to the knowledge base for assigning proper perspective to epidemiological PMR studies as they become known.

Epidemiological State-of-the-Art Position Paper

- To promote the fundamental importance of sound epidemiology as a disciplined science to gain understanding of the critical factors which influence chronic disease in human populations. Epidemiology provides the only real link available for relating hazards and potential risks identified in laboratory studies to evaluations of actual risk to humans from exposures to those hazards.

Quantitative Risk Assessment: State-of-the-Art for Carcinogenesis Document

- A critical evaluation of the use of statistical models in carcinogenic risk assessment is made in this document with emphasis on the strengths and weaknesses of current practice. The objective is to bring together information from the fields of toxicology and statistics to develop a sound scientific basis for making risk decisions. It is emphasized that risk assessment is a complex, multifaceted process that is not easily quantified and, at present, must be based on qualitative as well as quantitative information. It is evident that dose-response modeling of tumor incidence data from animal studies is of limited value in estimating human risk associated with low-dose chemical exposures. The models take into account only one part of the complex process and have no accepted basis in biology. The key decision points, qualitative factors, and quantitative considerations are identified and discussed and a risk assessment framework that incorporates these inputs is presented for consideration. It is concluded that much work needs to be done before a completely quantitative approach to risk assessment is to be useful; in particular pharmacokinetic modeling should be pursued more aggressively. The document, prepared by the AIHC Subcommittee on Quantitative Risk Assessment, was peer reviewed at the Tox Forum in Aspen, Colorado, in July 1982 and will be published in the Fundamental and Applied Toxicology Journal.

PUBLIC RELATIONS PROJECTS IN SUPPORT OF AIHC OBJECTIVES

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Media Tour Program

- Positive public opinion is essential to the achievement of AIHC's goals. The purpose of the media tour is to communicate the views of independent scientists on AIHC issues to targeted geographic segments of the American public. No one media tour will turn public opinion, but the pattern of appearances across the country -- and the need to get, and recycle, favorable media coverage -- makes the media tour a central element in the AIHC communications program.

Refutation of HEW's 20 - 38% "Cancer Estimates Paper"

- To correct the public record on the much-quoted, yet scientifically refuted 20 - 38% "Cancer Estimates Paper" issued in 1978 by HEW. This requires a multi-faceted effort aimed at the public, the media and government administrators, legislators and regulators. The project produced the booklet "Cancer, Pollution and the Workplace." Over 60,000 booklets have been distributed to date to the media, the Congress, Government agencies, employees and other groups.

Employee Communications Program

- To help member companies inform employees in the very difficult area of chronic health hazard issues.

"Internal" audiences are often as important as "external" audiences. First, employees "are us." They deserve to know the truth about chronic health hazards. Second, employees can have positive or negative effects on public opinion in plant communities and elsewhere. Employees, therefore, require special communications attention. This program includes distribution of AIHC video tape and slide presentation, articles for employee publications and an employee communications kit.

The material developed by AIHC for this program emphasizes AIHC's commitment to sound science. It reports on the work and opinions of leading scientific experts -- i.e., Higginson, Lederberg, Thomas and others. This complements employee communications material developed by member companies.

Selling Industry on the Value of AIHC Membership and Participation

- To create, within the business community, an awareness and understanding of AIHC's goals, scope and achievements, emphasize AIHC accomplishments, (e.g., where would OSHA's generic cancer regulation be today if AIHC did not exist?), and anticipate and concretely address questions about the value of AIHC membership from existing and potential members.

Overview Brochure Plus Supplementary Inserts

- To update and reprint the comprehensive brochure on AIHC and to develop supplementary inserts which list AIHC's objectives, members, leadership and committees. The booklet serves as a primary communications tool in all AIHC public relations and membership recruitment/retention programs.

AIHC Annual Report for 1982

- To develop and publish an attractive, concise review of the organizations' actions and achievements during 1982.

AIHC PROJECT REQUEST

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Project Title: Establishment of a State Resource Deployment Task Force

Objective: To provide appropriate AIHC assistance to state industry organizations concerned with chronic health hazard issues. (This proposal is a modified version of Project Request #034, approved May 11, 1982 and funded for 1982 at the level of \$30,000. \$6,657 has been expended through October 1982.)

Strategy: Legislative and regulatory activities involving chronic health hazard issues have been increasing in a number of states. Actions and decisions on some of these will have an important precedent impact throughout the country. This Task Force will help coordinate the technical and scientific resources from industry to better address the chronic health policy issues at the state and local levels.

The new Task Force would greatly facilitate availability and management of industry's scientific resources in the chronic health hazard area. Its function would be to form ad hoc groups of representatives from companies with interests in the states where chronic health policies are being developed.

The Task Force would identify key issues and assist in the coordination where assistance may be needed. The necessary inter-company liaison and detailed management of a particular issue would be handled by company representatives with direct interests in that state. AIHC's scientific resources and experience in dealing with chronic health hazard issues would be used to assist and support these ad hoc company activities with the criterion of selecting the issues being consideration for national policy implications.

The Task Force would work through and with other organizations operating at the state level, such as CIC or COC. It would coordinate its activities with national organizations including CMA, SPI and API, to avoid duplication or overlap of activities. It would work with state and local groups in the following ways:

- 1) Make available all relevant AIHC materials developed for addressing chronic health hazard issues, such as the "Framework Document", comments on the OSHA cancer policy and the scientific aspects of air pollution.

- 2) Provide advice to help local organizations manage these issues.
- 3) Assist in the development of industry resources to help local organizations manage these issues.
- 4) Provide names and promote contact of scientific experts from industry and academia who could be called upon by the ad hoc group or state organization to participate in public meetings and hearings where these issues are addressed.
- 5) Provide assistance and advice on dealing with the media.
- 6) Provide limited legal advice in relation to the above policies.
- 7) Provide for advice and assistance in reviewing or helping prepare scientific papers and statements which could be used at hearings, public meetings, etc.

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Funding
Requirements:

(Dec. 1982 -
Dec. 1983)

\$100,000 (\$23,343 of this from project #034)

General Support	\$20,000
Legal	50,000
Public Relations	10,000
Consultants, etc.	20,000

General Support: Covers meetings and general expenses for the new Task Force, air fare and travel expenses where necessary for staff to consult with state organizations and corporate ad hoc groups.

Legal: Provides for legal participation in Task Force activities, limited assistance in terms of telephone advice to state groups and help in reviewing some of the issue papers which may be needed at the state or local level. Counsel will be used as a resource to the Task Force in its adaptation of AIHC material for issues of generic concern.

Public Relations: Out-of-pocket expenses involved with providing PR advice and assistance, including some travel, in connection with state problems.

Consultants, etc.: Provides limited emergency funds where it may be desirable for AIHC to pay some expenses for a scientific consultant either in preparing a paper or appearing at a hearing. No witnesses will be provided to a state industry group in a state or local hearing unless there was prior clearance from the Task Force, and every attempt will be made to have state groups be financially independent. Also provides some reserve funds for unanticipated activities which may arise as this project develops.

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Executive Committee