American Cyanamid Company
One Cyanamid Plaza
Wayne, NJ 07470

George J Sella Jr
Chairman of the Board
President and CEO

October 23, 1984

Mr. Ronald A. Lang
Executive Director
American Industrial Health Council
1612 K Street, NW
Washington, DC 20006

Dear Ron:

In accordance with paragraph 7.04 of the AIHC By-Laws the Sunset Committee held a meeting on October 22nd, 1984.

The Committee was pleased with progress during the year toward improvement of the effectiveness and efficiency of AIHC in fulfilling its objectives. In addition an improved system of project accounting has been developed by the Finance Committee which should ensure greater control of operating costs.

A Mission statement has been approved by the Executive Committee which clearly delineates AIHC objectives for continuing efforts toward the use of good science in government.

The Sunset Committee has concluded and recommends to the Board and the membership that there is a need for the continued existence of AIHC.

Sincerely yours,

G. J. Sella, Jr.

GJS:lg

cc: E. Blanchard
R. Leet
T. Reid
[redacted]

AMERICAN INDUSTRIAL HEALTH COUNCIL

MISSION

The mission of the American Industrial Health Council is to advocate and promote the implementation of the most advanced, sound scientific methods as a basis for the review, risk assessment, and regulation, where regulation is warranted, of substances which may pose significant chronic health risks to people without acting as an advocate for any specific substance.

The Council has the following program in support of the mission.

1. The Council will establish itself as a major informal link between scientists in industry, the academic community and Government who are addressing chronic health hazard issues involving public policy decisions.

2. The Council will work to bring together the best scientific expertise the scientific community has to offer in the chronic health area and use that expertise to assist and critique Government as it develops the scientific bases for identifying human health hazards and evaluating risks from those hazards.

3. The Council will review the scientific bases of chronic health policies developed by government, identify areas where such policies are in conflict with existing scientific knowledge and understanding and work towards their continued improvement.

4. The Council will work towards establishing within Government rules, procedures and an organizational framework which will help to insure that risk assessment is separated from risk management to the greatest degree practicable, and that regulatory decisions are based upon the best available scientific knowledge and methodologies, including appropriate peer review of the science on which such government actions are based.

5. The Council will help identify gaps in scientific knowledge and make constructive contributions to advance and strengthen sound science to reduce the basis for government to use the highest estimate of lifetime risk assessment methodologies in identifying and controlling possible hazards to human health.

6. The Council will work to become a significant information resource on chronic health policies for industry, the media, Congress and opinion leaders, providing information broadly with respect to the scientific basis of public concerns over hazards stemming from exposure to potentially toxic substances. Where appropriate, inform key professionals (e.g., journalists, social scientists, lawyers) on sound science principles, working with and through other organizations in interdisciplinary activities.

Recommended 1985 AIHC Budget

Upon the recommendation of the Finance Committee, The Board of Directors recommends approval of an expenditure budget for 1985 of $1,498,800, a 6% increase over the 1984 budget. The budget details are attached.

The dues rate of $25 per million dollars sales, the minimum dues of $250 and the maximum dues of $30,000 will remain the same in 1985 as in 1984.

Income in 1985, based on this dues structure and no major change in 1985 membership, is estimated at $1,395,500, a 2% decrease from 1984 income. The income raised will cover 93% of budgeted expenditures. The deficit will be covered by reducing the current carry-over contingency fund to an estimated $40,000.

The Finance Committee and Board believe that a contingency fund moderately higher than the estimated amount should be carried, and they will develop a proposal to achieve this.

The Board, therefore, recommends that the Membership adopt the budget as proposed.

Recommended 1985 AIHC Budget

	Counsel	Communi-cations	Expenses[1]/	Other[2]/	Personnel & Overhead	Total
Committees:						
Associations	-	-	1.2	-	7.0	8.2
Board/Executive[3]/	43.7	2.0	16.8	2.0	139.0	203.5
Legal	2.0	-	.5	-	1.0	3.5
Membership	-	.5	1.5	-	12.0	14.0
Public Affairs	10.0	2.0	3.0	-	16.0	31.0
Communications	3.0	80.0	4.0	-	108.0	195.0
Scientific & Subcommittees	160.0	5.0	10.0	5.0	160.0	340.0
Subtotal	218.7	89.5	37.0	7.0	443.0	795.2
Task Forces:						
EPA	23.0	2.0	2.0	-	48.0	75.0
OSHA	10.0	-	1.0	-	15.0	26.0
Science Policy	14.0	-	1.0	-	24.0	39.0
FDA	6.0	-	1.0	-	15.0	22.0
CPSC	5.0	-	.5	.5	11.0	17.0
State Resource Dep.	40.0	5.0	10.0	-	34.0	89.0
Subtotal	98.0	7.0	15.5	.5	147.0	268.0
Project Fund:						220.0
Operations:						
Mailing						35.3
Reproduction						27.0
Counsel Disbursements						40.0
Subtotal						102.3
Administration:						
Personnel/Overhead					44.0	44.0
Administration Expenses, including telephone						69.3
Subtotal						113.3
TOTAL	316.7	96.5	52.5	7.5	634.0	$1,498.8

1/ Staff travel, meeting rooms, dinners, luncheons, etc.
2/ Consultant expenses, honoraria, speaker expenses, etc.
3/ Includes administration of Finance, Nomination and Sunset Committees.

PROXY BALLOT

(Please Return Promptly)

TO: Ms. Lydia Calvello
AIHC
1075 Central Park Avenue
Scarsdale, New York 10583

Our company does not presently plan to be represented at the November 29th Annual Meeting. Our votes with respect to the Recommendations of the AIHC Sunset Committee and proposed slate of candidates for Board of Directors, Class of 1987 are as follows:

A. Recommendation of the Sunset Committee: ____ Approve ____ Disapprove

Comments _____

_____

_____

B. Slate of Candidates for Board of Directors, Class of 1987:

____ Approve ____ Disapprove

Comments _____

_____

_____

C. Recommended 1985 Operating Budget of $1,498,800:

____ Approve ____ Disapprove

Comments _____

_____

_____

Voting Representative _____
(Designated Contact - Signature)

Company _____

Date _____

AP00036695

Panelists' Profiles

DR. WILLIAM ANLYAN was named Chancellor for Health Affairs at Duke University in May 1983. Prior to that, served as Vice President – Health Affairs for 14 years, as well as professor of surgery. He has served as a consultant to the Department of Health, Education and Welfare on medical education. He is a member of the Institutes of Medicine, the National Academy of Sciences, the American Medical Association (where he currently serves on an advisory committee on medical science), the National Library of Medicine and the American Surgical Association.

DR. ROBERT BARKER is a biochemist who has been involved in teaching, academic research and administration for the past 30 years. He is currently provost at Cornell University. Dr. Barker has an active research program with emphasis in the molecular structure of cell surfaces. He has served as Director of the Division of Biological Sciences and then as Vice President for research and advanced studies at Cornell. He has also served as Consultant to NIH, NAS/National Research Council, National Board of Medical Examiners, and other research-oriented institutions and universities.

JACKSON B. BROWNING, Corporate Director, Health, Safety & Environmental Affairs, Union Carbide Corporation; is a member of the American Institute of Chemical Engineers, on the Board of Directors and Executive Committee of the American Industrial Health Council, and chairman of its Science Policy Task Force; chairman of the Chemical Manufacturer Association Public Compensation Task Group and on the Executive Committee of the Chemical Industry Institute of Toxicology.

DOUGLAS M. COSTLE is Counsel to the law firm of Wald, Harkrader & Ross, Washington, D.C.; Counsel to the law firm of Updike, Kelly and Spellacy, P.C., Connecticut; and an Adjunct Professor, John F. Kennedy School of Government, Harvard University. He served as Administrator of the Environmental Protection Agency from 1977 to 1981. He is a member of the Board of Directors and Chairman of the Executive Committee of the Environmental Testing and Certification Corporation, New Jersey; a trustee of the Keystone Center and Member of Board of Directors, Clean Sites. He is the U.S. Chairman of the US-USSR Joint Committee on Cooperation in the Field of Environmental Protection. Mr. Costle is a graduate of Harvard University and the University of Chicago Law School.

PETER BARTON HUTT is a partner in the Washington, D.C. law firm of Covington & Burling, specializing in food and drug law and in government regulation of health and safety. From 1971 to 1975 he was Chief Counsel for the Food and Drug Administration. He presently serves on many prestigious advisory bodies and maintains directorships on boards in government, professional societies, academia, and industry. Mr. Hutt holds degrees from Yale, Harvard and New York University.

ROBERT J. MOOLENAAR, Ph.D., Project Director, Health and Environmental Sciences, the Dow Chemical Company. Prior to July 1983, he was Director of Environmental Sciences Research Lab, Health and Environmental Services at Dow. He is Chairman of the American Industrial Health Council Scientific Committee. He is a member of the U.S. Business and Industry Advisory Committee (Chemical Subcommittee) to advise the U.S. government on the OECD chemicals program; U.S. industry advisor, representing BIAC to advise EPA in matters relating to the updating of health and environmental test methods for OECD.

DR. ROBERT OLSON, M.D., Ph.D., Professor of Pharmacology and Medicine at the State University of New York at Stony Brook. Previously, he was Professor of Biochemistry and Medicine at the University of Pittsburgh School of Medicine. As a researcher, Dr. Olson has done extensive work in the fields of metabolism, endocrinology, toxicology and nutrition in both animals and man. Special emphasis in his research was on the metabolism of tumor tissue. He holds a Ph.D. in biochemistry from St. Louis University and an M.D. from the Harvard Medical School.

AIHC

Perspectives
on Science, Risk Assessment and Public Chronic Health Hazard Policy

Annual Meeting of
American Industrial Health Council

Thursday, November 29, 1984
8 AM-2 PM
Mayflower Hotel
1127 Connecticut Avenue, NW
Washington, DC

AIHC

AIHC's Annual Meeting for 1984 will feature presentations by individuals who will offer real-world prespectives on the chronic health hazard policy-making process. Speakers include former regulatory agency officials, prominent university scientists and key industry representatives. Ample time will be allotted in the program for audience discussion and participation.

The mission of the American Industrial Health Council is to advocate and promote the implementation of the most advanced, sound scientific methods as a basis for the review, risk assessment, and regulation (where regulation is warranted) of substances which may pose significant chronic health risks to people. AIHC does not and will not act as an advocate for any specific product or substance.

Annual Meeting Program

AIHC

(Time is scheduled for Q & A each session)

8:00 Registration

8:30 AIHC Business Meeting

- Report of the Sunset Committee and Vote
- 1984 Financial Report
- Presentation of 1985 Budget and Vote
- Report of the Nominations Committee and Election of New Members of the Board

Richard M. Leet, AIHC Chairman
Executive Vice President
Standard Oil Company (Indiana)

- Remarks by AIHC Vice Chairman
  Toy F. Reid
  Executive Vice President
  Eastman Kodak Company

9:15 Prospects for the Use of Quality Science in Regulatory Decision-Making on Chronic Health and Related Environmental Issues — An FDA and EPA Update and a Look Ahead

Moderator:
Edwin L. Behrens, Chairman
AIHC Public Affairs Committee
Associate Director, Technical Affairs
The Procter & Gamble Company

Panelists:
Peter Hutt
Covington & Burling
Former Chief Counsel, FDA

Douglas M. Costle
Wald, Harkrader & Ross
Former Administrator, EPA

10:15 The Role of Academia in the Formation of Public Science Policy

Moderator:
Carl Umland, Vice-Chairman
AIHC Scientific Committee
Environmental Health Coordinator
Exxon Chemical Americas

Panelists:
Dr. Robert Barker
Provost
Cornell University

Dr. William Anlyan
Chancellor for Health Affairs & Professor of Surgery
Duke Medical Center

Dr. Robert E. Olson
Professor of Pharmacology & Medicine
State University of New York at Stony Brook

11:15 AIHC: A Link with Scientists in Industry, Academia, and Government on Addressing Chronic Health Hazard Issues Involving Public Policy Decisions

Moderator:
Leonard J. Guarraia, Chairman
EPA Task Force
Director, Regulatory Affairs
Monsanto Company

Panelists:
Robert J. Moolenaar, Chairman
AIHC Scientific Committee
Project Director, Health & Environmental Sciences
The Dow Chemical Company

Jackson B. Browning, Chairman
AIHC Science Policy Task Force
Corporate Director — Health, Safety & Environmental Affairs
Union Carbide Corporation

12:00 Cocktail Reception

12:30 Luncheon
Alvin L. Alm, Deputy Administrator, Environmental Protection Agency
"The Role of Science in Regulatory Policy & Risk Management"

AMERICAN
INDUSTRIAL
HEALTH
COUNCIL
NEWSLETTER

AIHC ANNUAL MEETING TO FEATURE PAST EPA HEAD, FORMER FDA COUNSEL

Douglas M. Costle, Former Administrator, U.S. EPA

On November 29, Douglas M. Costle, EPA Administrator during the Carter Administration, and Peter Hutt, former FDA Counsel, will talk about current and future prospects for sound science at the EPA and FDA. They will be addressing attendees at AIHC's Annual Meeting at the Mayflower Hotel, Washington, D.C. in a session moderated by Edwin L. Behrens, AIHC's Public Affairs Committee Chairman.

Another program segment will address the role of academia in the formation of public policy. That session will be moderated by Carl Umland, Vice Chairman of AIHC's Scientific Committee. The panelists are: Dr. Robert Barker, Provost at Cornell University; Dr. William Anlyan, Chancellor for Health Affairs and Professor of Surgery at Duke Medical Center; and Dr. Robert E. Olson, Professor of Pharmacology & Medicine at the State University of New York, Stony Brook.

The final panel will discuss an integral part of AIHC's mission: how AIHC can serve as a link between scientists in industry, academia and government — describing current programs and future plans. Leonard J. Guarraia, Chairman of AIHC's EPA Task Force will moderate a panel consisting of Robert J. Moolenaar, AIHC Scientific Committee Chairman, and Jackson B. Browning, Chairman of AIHC's Science Policy Task Force.

Registration information for the AIHC Annual Meeting can be obtained by calling AIHC's New York office (914) 725-1492.

SCIENTIFIC WORKSHOP OFFERS CURRENT CARCINOGENICITY CRITERIA

Findings Published in Major Scientific Journal

An interdisciplinary panel on carcinogenicity concluded that "Characterization of human risk always requires interdisciplinary evaluation of the entire array of data on a case-by-case basis."

Convened at the request of the American Industrial Health Council, and chaired by Dr. Philippe Shubik of Oxford University, the panel of prestigious scientists set out to re-evaluate the criteria for assessing whether or not a substance causes cancer.

Their findings were published on August 17 in the major peer-review journal, *Science*.

The panel fulfilled a recommendation made in a 1977 report by the Committee on Environmental Carcinogenesis of the National Cancer Advisory Board, which called for continuing scientific review of the issue.

The panel reached significant conclusions regarding the value of epidemiology, long-term bioassays, and short-term tests in the overall assessment process to determine chemical carcinogenicity.

- **Epidemiological Studies.** The panel noted that human data provides the only direct evidence that a chemical produces cancer in man. Although the value of negative epidemiology is limited, since it is impossible to prove a negative, these results are useful in indicating the limits within which a specific type of exposure will not affect the incidence of cancer in man.

(See SCIENTIFIC WORKSHOP, page 2)

From the Editor

ON COMMUNICATING RISKS: HOW ARE WE DOING?

Discovering and publicizing "new" potential chronic health hazards are things our society does well. You know the litany of past "discoveries": Love Canal, nitrites, saccharin, dioxin, formaldehyde, EDB. That's not to say that these things pose zero risk. *Nothing* poses zero risk. The point is, all risks need to be evaluated and compared with known risks, known benefits, the risks and costs of regulatory controls, and uncertainties. And yes, ways must be found to compare apples with oranges.

What we have not yet learned to do well is to assess a hazard's potential for human harm with precision, and precisely convey that information in a way that is relevant to an individual who may face the consequences of exposure. And, until we know the specific mechanisms of chronic disease causation, we must do the best with what we have.

There is growing recognition that we are not doing the best that we can with what we have — the "we" being all of us involved in the science and health policy processes: industry, government, consumer groups, the news media and the scientific community. This writer's purpose is not to assess blame. Responsibility to first develop sound scientific information, and *only then* to communicate, understand, and *act* on the basis of that information, rests with all of us. Now for the good news. Organizations representing diverse interests *are* doing things to improve the flow of good information through the government-industry-scientific community-media pipeline. Some examples:

– Workshops and conferences on "Science, Health Risks and the Media" separately sponsored by Boston University, The University of North Carolina, Georgetown University, Cornell University, the Harvard School of Public Health and the Foundation for American Communication.

– NIEHS Task Force III, mandated by Congress to recommend areas of promise for research in the environmental health sciences, has included a panel for information exchange in its work.

– A major research project on "Risk Perception, Risk Acceptance and Risk Communication: Assessment of the State of Knowledge" is being conducted at the University of Southern California, funded by a grant from the National Science Foundation.

– A pilot program "to enhance the quality of reporting of environmental health issues by the media" has been proposed by the University of Massachusetts.

– The National Cancer Institute is soliciting proposals for a cancer communications system — for dissemination and interpretation of information regarding the cause, prevention, detection and treatment of cancer.

– A three year pilot project that will help students and the general public understand the uses and hazards of chemicals is under way at the University of California's Lawrence Hall of Science in Berkeley.

– A formal program in Science and Environmental Reporting is in it's third year at New York University; a Science Communications Center is taking shape at the University of Missouri.

These are only a few examples of programs to improve risk communications — evidence that the importance of the relationship between public understanding and sound chronic health hazard policy has been fully recognized. And what's more important, we are doing something about it. Perhaps, in the near future, we can point to risk communication as something else that we do well.

AIHC

SCIENTIFIC WORKSHOP, from page 1

• **Long-term Bioassays.** The panel pointed out that these tests often produce different patterns of tumor development in test animals. These patterns most likely represent different mechanisms having different significance to human risk. They should be recognized as such. Each experiment must be assessed individually and different weights of evidence accorded for purposes of extrapolation to humans.

• **Short-term Tests.** The panel stressed that these tests alone are not adequate to determine carcinogenicity. Although scientists hoped that early tissue changes would be found that would predict carcinogenicity, until now, the overall performance of short-term tests has been accurate only 50 to 70 percent of the time.

• **Pharmacokinetics.** The panel also said special attention must be given to the pharmacokinetics (the observance of actions of a substance in the body over a period of time) of chemical carcinogens. For example, at elevated doses, the body may be unable to clear the chemical as rapidly as administered and toxic concentrations may be reached. This and other variables in the pharmacokinetics of carcinogens limits extrapolation of metabolic data from test species to the human situation. In conclusion, no single in vitro test can exactly mimic pharmacokinetic parameters in animal tests.

• **Extrapolation from Experimental (Animal) Data.** Since animal experiments are usually conducted with higher exposure levels than those normally encountered by humans, risk must be estimated by extrapolating results from these high doses to the lower doses experienced by humans. This process is fraught with uncertainty. Therefore, pending further scientific understanding of cancer mechanisms, statistical methodologies should be developed to incorporate all the variables. This includes pharmacokinetic data and the time between exposure and tumor development, the amount of exposure and the duration of exposure and competing risks. Although some regulatory agencies emphasize a worst case or upper confidence level based on the models used, the most probable estimates should always be presented, together with the upper and lower confidence limits of the estimates.

• **Overall Assessment Process.** In the past there has been great reliance on tumor incidences in any animal study. The panel concluded that a full scientific evaluation to characterize risk must not only consider positive animal tests but must also look at evidence from short-term tests, human population studies, biometric analyses and metabolism studies, as well as any other relevant information. A single method alone cannot produce a reliable estimate of a chemical's risk to man, but together they could provide an estimate that can be given a higher degree of confidence.

AIHC

AIHC NETWORKING GENERATES PRAISE AND COMMITTMENT

Edward J. Calabrese, PhD., Professor, Environmental Health Program, University of Massachusetts

Robert E. Olson, M.D.; Professor of Pharmacology & Medicine, SUNY at Stony Brook

Scientific and governmental health hazard policy makers have praised AIHC's Communications Networking Program. Through this program, independent scientists are winning the support of "influentials" in academia and government for AIHC's position that regulation of chronic health hazards be based on sound science.

The program is a broadened version of AIHC's Media Tour Program. It featured independent scientists who were interviewed by broadcast and print journalists in selected markets. Now, the scientists participating in the program also visit their scientific peers in government and academia, as well as other government officials involved in the regulation of chronic health hazards.

Two networking efforts have taken place so far this year. In May, Dr. Edward Calabrese, (Professor in the Environmental Health Program at the University of Massachusetts at Amherst) visited San Francisco and Sacramento, California. He spoke with people like Dr. Gordon Duffy, Secretary of the California Department of Environmental Affairs and Dr. Howard Maccabee, Director of the Radiation Oncology Center in Walnut Creek, California. They both agreed with Dr. Calabrese's premise that scientists must be more involved early on in the policy-making process for chronic health hazards.

In August, Dr. Robert Olson (Professor of Pharmacology and Medicine at SUNY, Stony Brook) visited Boston and Providence. There, people like Dr. Brian MacMahon, Chairman of the Epidemiology Department at Harvard, and Dr. Peter Goldman, Director of the Food and Nutrition Laboratory at Harvard, said they would be interested in appropriate future participation in AIHC issues.

This type of scientific commitment will be extremely valuable as chronic health hazard issues arise on the national and local levels. The recent call for comments by the Office of Science and Technology Policy on its Document on Chemical Carcinogens is one example of a situation where the support of the independent scientific community would be very helpful. The need for external scientific input on the forthcoming EPA study on cancer and air pollution is another example.

A networking program is scheduled for Louisiana the week of October 22. Future networking efforts are planned for Texas and New Jersey.

BOOKS

A useful overview of developmental toxicity processes and assessment methods can be found in **Principles for Evaluating Health Risks to Progeny Associated with Exposure to Chemicals During Pregnancy.** Described as the "collective views of an international group of experts," it was published this year by the World Health Organization as number 30 in their Environmental Health criteria series.

Elements of Risk: The Chemical Industry and Its Threat to America, was written by Cathy Trost and published by N.Y. Times Books, New York City. The book is not the "expose'" that its title and pre-publication promotional materials would lead you to expect. The book begins with an objective, almost positive history of the U.S. chemical industry's development, later to be contrasted with accounts of alleged health effects and individual suffering linked to chemical exposure.

Workers at Risk by Dorothy Nelkin and Michael S. Brown, University of Chicago Press, focuses on the perceptions and concerns of people in a wide range of occupations who work with chemicals. Seventy five such individuals were interviewed. Their responses, as well as comments from spokesmen for industry, government, universities and unions, provide the basis for this book.

The Good News Is The Bad News Is Wrong by Ben Wattenberg, has been published by Simon & Schuster, New York City. As the titles implies, the book refutes the liturgies of the apocalyptics on health (and other) risks posed to our society's citizens.

AIHC

LEGAL DECISIONS: FETUS PROTECTION POLICY

In 1982, the Fourth Circuit Court of Appeals in the *Olin* case (697 F. 2d 1172) held that plaintiffs had made a prima facie case of sex discrimination under Title VII of the Civil Rights Act by the fetus protection policy and sent the case back to the trial court to determine whether there was scientific/medical support for the policy that would justify the policy under the business necessity rule. The trial court held the policy justified (585 F. Supp. 1447) and, in a confused procedural posture, the case has been appealed back to the Fourth Circuit.

On August 24, 1984 the Federal Court of Appeals for the District of Columbia Circuit ruled that the American Cyanamid policy was not in violation of the OSH Act. A fetal protection policy, the court ruled, is not a "hazard" of employment under the general duty clause. The Title VII discrimination issue was settled and the court did not address that issue. *Oil, Chemical and Atomic Workers International Union v. American Cyanamid Company*, #81-1687, August 24, 1984.

NEW AIHC PROJECTS APPROVED

AIHC is an effective organization, but its resources are limited. Setting priorities for the use of AIHC's resources is an important function of the AIHC Executive Committee. Before a project is submitted to the Executive Committee for consideration, a series of questions must be addressed in the proposal:

What is the project's objective? What will it achieve? How does this project and what it will achieve relate to AIHC's mission? Why is AIHC undertaking this project rather than another organization? How much will it cost? What priority is placed on the project by the proposing committee?

The following projects withstood the scrutiny of the AIHC Executive Committee, and were approved on August 29.

Project #071: Scientific Outreach Program

Submitted by the AIHC Scientific Committee; Robert J. Moolenaar, Chairman, Oral presentation by Carl Umland, Vice-Chairman.

OBJECTIVE: Establish effective, regular contact with a broad spectrum of influential scientists for exchange of views on chronic health hazard public policy issues. This is an effort to convince them to become involved in dialogues with government and the media to promote sound science as the basis for government decisions.

Project #073: Animal-to-Man Extrapolation Workshop

Submitted by the AIHC Risk Assessment Subcommittee; Donald Hughes, Chairman.

OBJECTIVE: Reassess the scientific basis for extrapolation of animal carcinogenicity data to humans, both qualitatively and quantitatively.

Project #042.1: Epidemiology - Risk Assessment Symposium

Submitted by the Epidemiology Subcommittee; Martin J. Reape, Chairman

OBJECTIVE: Define and promote the role and valid application of epidemiology in the conduct of human health risk assessment.

Project #045.1: Continued Promotion and Distribution of "Cancer, Pollution and the Workplace" booklet.

Submitted by the Communications Committee; Phillip H.L. Schneider, Chairman.

OBJECTIVE: Continue promotion and distribution of a well-written, well-received booklet which, in lay language, puts in perspective what is known about industrially-linked causes of cancer.

AIHC

SIX MONTH AIR TOXICS STUDY

Late in July the press carried stories about a new study of air toxics completed in six months, hence the name. The draft study contained an estimate of 2,010 cases of cancer due to air pollution. AIHC has reviewed the draft study and expects a public briefing and release in the near future, after peer review. The study uses Cancer Assessment Group upper confidence limits unit risks and depends on population exposure estimates. The draft study recognizes that the data are not such as to support a scientifically sound estimate. EPA has indicated that it does not intend to use the study for regulatory purposes but to develop a policy on "air toxics" as part of the "fast track" program to review alleged toxic air pollutants. A new policy staff has been appointed with instructions to report by year end. The study has already had some practical results. NRDC is suing EPA for the decision (49 *Fed. Reg.* 31680) not to regulate polycyclic organic matter (POM) under §112 of the Clean Air Act; NRDC has cited the draft study as indicating that POM may be the cause of more than 800 cancer cases.

EPA has reissued the draft study with a disclaimer and a cover memorandum pointing out some of the limitations of the study. EPA also has solicited informal peer review. Notwithstanding these developments, the findings of the study continue to be cited in EPA-sponsored publications without qualification, including in the September issues of the *EPA Journal* and *Air Toxics*.

AIHC

NTP BLUE RIBBON PANEL REPORT FILED

The blue ribbon scientific committee reviewing the NTP program filed its report with the NTP Board of Scientific Counselors on August 17, 1984. The panel report did not recommend basic changes in the NTP program. The report did recommend that the technical reports indicate both the quality of the data and the possible relevance to human risk assessment. The report pointed out that because of potentially "immense economic and public health importance of the results", it is important that good laboratory practices be followed and studies be evaluated for quality assurance. (The AIHC quality assurance subcommittee has strongly urged that NTP strengthen the quality assurance audit program.) Since the predictive value of a study depends on the quality of the study design and the conduct and interpretation of the results, the report recommends NTP re-evaluate selected "old" bioassays that serve as a basis for regulatory decisions. The report also urges animal tests of known human carcinogens as an additional method of ensuring the integrity and credibility of the program.

Chairman Doull, speaking of the report, said that regulatory decision-making was not part of the responsibility of the NTP or the blue ribbon committee. Discussion on regulatory aspects of toxicity testing was dropped in the final report.

AIHC SPEAKS

October 4 – *U.S. Operating Committee of Ecological and Toxicological Association of the Dyestuffs Manufacturing Industry* - E. Behrens and R. Moolenaar provided USOC with an overview and discussion of AIHC activities.

October 11 – *State and Territorial Air Pollution Program Administrators Association of Local Air Pollution Control Officials.* F. Hoerger will offer an AIHC perspective on the framework for risk assessment and risk management for hazardous air pollutants.

November 13 – *New York University* J. Browning and R. Lang join N.Y.U. pathologist Dr. Harry Demopoulos in a full day's discussion of the role of journalists in public health policy development. The participating audience will be graduate students in N.Y.U.'s Science and Environmental Reporting Program.

IN BRIEF:
SCIENCE AND POLICY DEVELOPMENTS

Interagency Risk Management Council

Peer review and public participation. AIHC has written to Dr. Henney (NCI) and Dr. Miller (FDA) co-chairpersons of the IRMC subcommittee on cancer risk assessment guidelines with proposals for public participation in the work of the subcommittee through informal peer review of drafts and a scientific workshop.

AIHC has written a similar letter to Dr. Anderson (EPA) chairperson of the IRMC subcommittee on reproductive effects risk assessment. The work plan of the subcommittee includes preparation of a background paper by a contractor. AIHC has proposed an opportunity for public comment in that process. AIHC has also suggested a scientific consensus workshop on reproductive effects.

Toxic Torts/Causation Issues

NCL Position. On July 26th the National Conference of State Legislatures adopted a resolution on hazardous waste and victims' compensation. The resolution calls upon the federal government to determine health effects from exposure. The resolution urges that federal health effects studies be designed to be admissible in victims' compensation cases. It also calls for review of state laws on victims' compensation.

As part of the study of health effects, NCSL urges the federal government to seek independent scientific review of the federal research efforts. "An active peer review approach should characterize all such research in order to establish a consensus to the greatest extent possible."

OSHA

New deputies. Robert Rowland, the new OSHA Administrator, has announced some changes in the administrative structure. Pat Tyson will be deputy assistant secretary for federal and state operations, technical support, and health and safety standards. Michel Korbey will be deputy assistant secretary for public affairs, administration policy development, legislative affairs and regulatory analysis. Jane A. Matheson will be deputy assistant secretary for field operations. Korbey and Matheson came from the Occupational Safety and Health Review Commission which Rowland chaired before coming to OSHA.

UAREP Study. The scientific study by UAREP (commissioned by industrial groups) of injury to members of the puplic from exposure to waste dumps is expected to be released in November. The report was prepared by the Executive Scientific Panel on Health Aspects of Disposal of Selected Waste Chemicals formed by the Universities Associated for Research and Education in Pathology. AIHC is a non-contributing sponsor of the study.

EPA

SAB Nominations. EPA has requested nominations to fill 10–15 positions on the Science Advisory Board in the next year. Nominations are to have been submitted by September 28th, 49 *Fed. Reg.* 33169.

Risk assessment guidelines. EPA has announced a program of publishing six risk assessment guidelines by November 1st. A number of the draft guidelines are now out for informal peer review (carcinogenicity, mutagenicity, exposure) and EPA expects to be on schedule for all six. AIHC has nominated scientists as informal peer reviewers.

AIHC

CORNELL SPONSORS FORUM ON "TOXIC CHEMICALS AND THE MEDIA"

The tremendous increase in information on toxic chemicals transmitted to the public through the media has had a profound impact on the public's perception of risk. In view of this, the Cornell University Institute for Comparative and Environmental Toxicology (ICET) recently hosted a 1½ day symposium, "Toxic Chemicals and the Media."

Led by ICET director, Christoher F. Wilkinson, seminar participants from the scientific community, government, industry and public interest groups evaluated the complexities of the risk communication process.

Dr. Charles Powers, President of Clean Sites, Inc., Washington, D.C. noted in his plenary address the public's sense of panic about toxic waste. He said that language is the key to understanding and interpreting fact from fiction and that reporters must "sift through the muck for clarity."

John Frawley, General Manager, Health and Environment, Hercules, Inc., emphasized that science is not absolute, and that oftentimes it consists of judgements rather than facts. He also said that there is a bias in the media which falls somewhere between informing and influencing the public.

Problems inherent in science reporting were addressed by Gannett News Service reporter Rae Tyson. Lack of consensus among scientists, advocacy science, lack of accessibility to experts, scientists' failure to appreciate deadlines, and the lack of understanding of these issues among his own peers were specifically cited.

Other seminar participants included: Michael Gruber, Branch Chief, Integrated Environmental Management Division, EPA, Dr. Fred Pehme, President of the Society of Toxicology and Ruth Norris, Senior Editor of *Audubon*.

Recommendations to improve the flow of information between the scientific community included: background sessions with scientific experts in the scientific arena, wider sharing of current information on issues, better access to scientists and scientists' understanding of reporter's deadlines.

AIHC
ANNUAL MEETING
NOVEMBER 29, 1984

MAYFLOWER HOTEL
WASHINGTON, D.C.

CONFERENCES, SEMINARS, AND SYMPOSIA

October 23 – 25	**Advances in Health Risk Assessment for Systemic Toxicants and Chemical Mixtures.** Presented by the U.S. EPA Environmental Criteria and Assessment Office, Cincinnati, Ohio. Will present results of EPA-sponsored research. Contact Ms. Jo Ann Duchene, ICAIR, Life Systems, Inc., Cleveland, Ohio (216) 464-3291.
October 28 – 29	**Seventh ORNL Life Sciences Symposium: Indoor Air and Human Health.** Hosted by the Oak Ridge National Laboratory, sponsored by U.S. Department of Energy, EPA and Tennessee Valley Authority. Will focus on the health implications of the major categories of airborne pollutants in indoor environments. Contact Lois Szluha at the Oak Ridge National Laboratory (615) 576-2109.
November 12 – 14	**Principles and Mechanisms of Neurotoxicity.** Sponsored by and held at The Johns Hopkins University School of Hygiene and Public Health, Baltimore, Maryland. Contact Dr. J. Corn at Johns Hopkins (301) 955-2609.
November 13 – 16	**Third International Conference: Safety Evaluation and Regulation of Chemicals.** Sponsored by the American College of Toxicology and the U.S. EPA Office of Toxic Substances, organized by The Boston University School of Medicine. To be held at the Nova Park Hotel, Zurich, Switzerland. Contact F. Homburger at The Bio-Research Institute, Inc., Cambridge, MA (617) 864-8735.
November 15 – 16	**Conference on Health Effects of Acid Precipitation.** Sponsored by NIEHS and U.S. EPA, to be held at NIEHS facility at Research Triangle Park, North Carolina. Contact Mary Hogan at NIEHS (919) 541-7620.
December 4 – 5	**Risk Assessment and Alternatives to Animal Testing.** To be held in Montreal, Canada. Contact Dr. Gordon Krip, Society of Toxicology, PO Box 517, Beaconsfield, PQ H9W 5V1. (514) 695-7920 ext. 431.
December 7 – 8	**Second Annual Recent Advances in Occupational Cancer.** San Francisco, California. Contact Extension Programs in Medical Education, Room 569-U, University of California, San Francisco, CA (415) 661-4251.

EPA/SAB ON QUANTITATIVE RISK ASSESSMENT MODELS

In a detailed written opinion dated August 17th, a Special Committee of the Science Advisory Board concluded the EPA report did not provide adequate scientific support for regulatory decisions on radionuclides. In reviewing the EPA cancer risk estimation the SAB concluded that use of a single generally recognized-as-conservative model (the linear non-threshold model) was "scientifically inappropriate." The "preferred approach" would be to present a range of models so the risk manager would be more fully informed.

In a strongly worded letter, the National Resources Defense Council has urged EPA to issue emissions standards for radionuclides despite the SAB's criticism of EPA's risk assessment. NRDC accused the SAB of overstepping its proper functions by making policy comments. Should NRDC seek to enforce the court-ordered October 23 deadline, the case could involve important issues as to the SAB's role and EPA's risk estimation methods.

EPA is also looking at different approaches for substance-specific quantitative risk assessment. For example, EPA and OMB are reported to be in discussions to evaluate methods of risk assessment for coke oven emissions less conservative than the 95% upper confidence limit, using the linear multistage model.

One more item: Dr. Elizabeth Anderson (Director of EPA's Office of Health and Environmental Risk Assessment) published an article in Risk Analysis (Vol. 3, No. 4, 1983) "Quantitative Approaches in Use to Assess Cancer Risk". The article is an explanation of, and argument for, EPA's current methodology.

AIHC

The American Industrial Health Council is a coalition of industrial firms and trade associations concerned with ensuring that the best available science is used as a basis for the regulation of substances which pose significant chronic health risks to people. We believe that reliance upon sound science throughout the regulatory process results in effective and reasonable regulation, when regulation is warranted.

Comments and inquiries may be addressed to The Editor in care of the New York office.

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