Anthony J. Diglio
Director
Corporate Environmental Activities
(215) 481-8339

AIR PRODUCTS

24 April 1987

F. J. Ryan

Frank:

AIHC has asked that you contact prospective AIHC members. If you wish to do so, I have drafted a letter for your signature to Nick Lynam, Union Oil and Tony D'Amato, Borden Chemical.

Please let me know if you need anything else.

A. J. Diglio

AJD:pbr
1825c

Attachments: Draft letters and attachments

[redacted]

AP00024696

Air Products and Chemicals, Inc.
Box 538
Allentown, PA 18105
Telephone (215) 481-4911

AIR PRODUCTS

24 April 1987

Mr. Nicholas E. Lynam
Senior Vice President
Union Oil Company of California (UNOCAL)
Union Chemicals Division
1900 East Golf Road
Schaumburg, IL 60195

Dear Nick,

I hope by now that you are convinced that you need to become a member of the American Industrial Health Council. In the past few months, eight companies decided to join as new members of AIHC.

There are three reasons why I believe UNOCAL should join AIHC. First, Congress and the government agencies are pushing government activism involving environment, health and safety. The public believes that deregulation went too far in these areas. In a recent Wall Street Journal/NBC News poll, 61% of those surveyed said there should be more government regulations of the environment, while only 6% said there should be less. AIHC works for the use of the best science and information in assessing risks and in developing government regulations. If federal officials pass inappropriate regulations and miscommunicate to the public, our chemical businesses could be dramatically affected financially.

Second, the Council's work on the leading edge of health issues educates member companies' environmental, medical, safety, and regulatory personnel and puts them in contact with top academians, scientists, and regulators. This added knowledge could benefit UNOCAL by preventing potential liabilities in the handling of your chemicals by your employees and customers.

Finally, if the chemical industry doesn't support organizations devoted to regulations of chemicals based on sound scientific reasons, who will?

I believe you or someone from your staff would find AIHC's May 20 Washington conference beneficial and it would present an opportunity to meet other Board and company representatives.

I look forward to seeing you or someone from your staff at the meeting and hope you will join AIHC. Please let me know what you decide.

Sincerely yours,

Frank J. Ryan

pbr

Enclosures: AIHC Membership, Conference Brochure, Literature

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WASHINGTON CONFERENCE UPDATE. Mark your calendars now! AIHC's Washington Conference, May 20 at the Vista International Hotel in Washington, D.C., will focus on a key issue: The Need For Sound Science in Shaping Public Health Policy. Experts from the Congress, federal and state government, the scientific community and the press will address the many aspects of this important topic.

Program highlights include:

8:45 a.m. Congressional Perspective

"The Importance of Science in the Shape of Legislation to Come"	A Key Legislator (to be announced)

9:45 a.m. The Changing Nature of Science in Public Health Policy

"Integrating Scientific Advances into Chronic Health Risk Assessments"	Dr. Richard A. Griesemer Director, Biology Division, Oakridge National Laboratory; Chairman, Environmental Health Committee, EPA Science Advisory Board
"Science and Policy Conflict in Risk Assessment"	Dr. Marc Roberts School of Public Health, Harvard Univ.
"Science and Media: Communicating Risk to the Public"	Ms. Abigail Trafford Editor, HEALTH, The Washington Post

11:15 a.m. State Perspective

"How the States Use Science In Implementing State Initiatives and Federal Requirements"	State Health Official (to be announced)

1:15 p.m. Federal Perspective (luncheon speech)

"Emerging Public Health Policy Issues"	Donald Newman Under Secretary Dept. of Health and Human Services

CONTACT: Helen Hall, AIHC

Beverly Lehrer, Editor, AIHC Alert

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AIHC
ALERT

ISSUE #23 APRIL 15, 1987

AIHC COMMENTS ON "DES PROVISO." AIHC urged the Food and Drug Administration (FDA) to assure that a proposed rule and guidelines for implementing the DES Proviso of the Delaney Clause have a sound scientific basis. The DES proviso authorizes FDA to approve the use of carcinogenic compounds in food producing animals.

"Guidelines should be sufficiently flexible to incorporate scientific advances and new scientific data," AIHC said in a letter to the agency.

AIHC supported the Animal Health Institute's proposal that particular procedures and methodologies to be used in risk assessment not be specified in a regulation implementing the DES proviso. The Animal Health Institute proposed instead that risk assessment procedures be placed in a guideline, to allow for incorporation of the latest available scientific data into the risk assessment process.

AIHC also urged FDA to adopt guidelines based on principles established in the Office of Science and Technology Policy report, "Chemical Carcinogens; A Review of the Science and Its Associated Principles."

"We believe this will provide a sound scientific basis for determining the safe use of products of food producing animals under the DES Proviso," the AIHC comments concluded.

CONTACT: David Sandler, AIHC

GOVERNMENT AFFAIRS COMMITTEE MEETS. AIHC's new Government Affairs Committee held its first meeting in March. The committee plans to work with the Scientific Committee's Air Toxics Work Group on issues related to the Clean Air Act, and with the Scientific Committee to monitor ground water issues.

CONTACT: Gaylen Millard, AIHC

PAPER WILL EXAMINE SHORT-TERM TEST USES. The Mutagenicity Subcommittee will prepare a paper reviewing the accuracy of short-term tests for predicting carcinogenicity, and the independent value of obtaining genotoxicity data as relevant to a variety of possible human health effects. The paper will be transmitted to EPA and distributed within AIHC.

CONTACT: David Sandler, AIHC

AIHC A special report on AIHC actions, chronic health issues, sound science, risk assessment, and public policy published by American Industrial Health Council, 1330 Connecticut Avenue, NW, Washington, DC 20036 • 202-659-0060

AP00024699

(e) Hazard Communication. John Bowser (OTS) is reported to be developing a hazard communication program under TSCA relating to substances not covered by the OSHA Hazard Communication Standard. The program is expected to be carried out under proposed regulations relating to significant new uses of existing chemicals. The program would include labeling and training programs analogous to those required by OSHA.

(f) Toxic Chemical Release Inventory. EPA has announced a public meeting to be held April 20th to discuss the development of a data base on the some 300 listed toxic substances that must be reported under Title III of SARA. 52 Fed. Reg. 10135. Inventory forms will be released by EPA in June and the first reports are due July 1, 1988 for calendar 1987.

(g) Science Advisory Board

- The Executive Committee will meet April 9-10 to discuss a SAB exposure assessment concept paper and EPA's comparative risk study (52 Fed. Reg. 8959).

- The SAB has released a report of the Indoor Air Quality Research Review Panel. The report, dated November 5, 1986, reported that while EPA's research was of high quality, the research as a whole did not constitute a program in indoor air quality.

7. California Proposition 65.

On March 1st the Governor published the initial list required by the Safe Drinking Water and Toxic Enforcement Act adopted by initiative. The initial list covered 27 substances known to cause cancer - all the known human carcinogens listed by IARC. The list also included 3 reproductive toxins. The Governor announced the formation of a panel of scientific experts to provide advice on listing and a "Candidate" list of substances classified by IARC and NTP as suspect carcinogens. The Science Panel had its first meeting on March 31st. The Panel reviewed "protocols" or criteria that will be used to screen the candidate substances. The next meeting in May will work on the protocols and review some two dozen candidate substances

The environmentalists have charged that the Governor's list does not comply with the law and have brought suit to seek a court order requiring the Governor to list the substances on the candidate list.

The National Food Processors Association has urged FDA to pre-empt, with reference to food, the labeling and safety requirements under Prop. 65.

AP00024700

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April 2, 1987

MEMORANDUM FOR AIHC

March Monthly Report

1. Administration

(a) Competitiveness. We are awaiting the President's Executive Order implementing the Stevenson/Wydler bill and the technology development/technology transfer segment of the President's program. A copy of the draft Executive Order was published in Inside the Administration. The Order reputedly is being held up because of DOD resistance to transfer defense developed technology to industry. Resolution is expected soon.

2. High Risk Notification bills.

Hearings are now complete on the Metzenbaum bill (S. 79), the Quayle bill (S. 638) and the Gaydos bill (HR 162). As a result of negotiations with the American Electronics Association and the AFL/CIO, Senators Metzenbaum (D. Ohio) and Senator Stafford (R. Vt.) have agreed to changes in S. 79. A new draft of S. 79 will be presented for mark-up on April 9th. One of the principal changes is to limit the trigger for notification to human data from epidemiologic and clinical studies (supported by other biological data). This was the major thrust of AIHC's testimony on March 9th. AIHC is planning to write to the Subcommittee to suggest some additional changes in the revised draft to strengthen the scientific basis for a notification program.

Mark-up on HR 122 is not expected until after the Easter recess.

At the House hearings on March 17th Secretary Bowen (HHS) stated the Administration's support for the concept of notification, but specified a number of points to which the Administration would object in any notification bill: a quota specifying a minimum number of workers to be notified; a burdensome requirement for monitoring and counseling; a requirement that the government notify workers other than those involved in a government study; and expansion of the OSHA Hazard Communication Standard outside the regular rule making process.

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3. HHS

(a) NTP: Fifth Annual Report on Carcinogens. NTP will hold a public meeting on April 21 in Washington to receive public comments on the Fifth ARC (52 Fed. Reg. 7223). AIHC has submitted written comments and expects to participate in the public meeting.

4. OSHA

(a) Reconsideration of the OSHA Cancer Policy. OSHA's recommendations for action on the reconsideration are still pending before the Departmental Policy Board chaired by M. Baroody, Assistant Secretary for Policy. In view of the Court order conditionally dismissing the petitions to review the 1980 cancer policy, AIHC is urging prompt action by OSHA.

(b) Hazard Communication Standard expansion. In response to the Court's order, OSHA in November 1985 issued a NPR to expand the standard beyond the manufacturing industry. Last year the USWA and Public Citizens requested the Third Circuit Court of Appeals to hold OSHA in civil contempt for the delay. OSHA has requested a dismissal of the petition pointing out that additional economic data were necessary and that OSHA expects to issue a final expanded standard early in 1988.

5. FDA

(a) Delaney Clause. On March 23rd the U.S. Court of Appeals for the District of Columbia Circuit heard argument on the validity of provisional listing of colors for which there is experimental evidence of carcinogenic activity. The Court also heard argument on the validity of the use of de minimis by FDA in approval of the final listing of D&C Orange 17 and Red 19. A decision is not expected before June.

(b) SOM. The Animal Health Institute requested that FDA defer action on the SOM proposed regulation until after the decision on de minimis. AHI wrote to FDA supporting the AHI position that details of the risk assessment procedure should be published in guidelines rather than in a regulation in order to facilitate updating the risk assessment the process to incorporate scientific advances.

(c) Generic threshold on regulation of indirect additives. In a speech commenting on the recommendations of the Toxicology Committee of the National Conference on Food Protection R. Scheuplein (FDA), said that any generic rule would consider factors such as migration and potency. The NCFP recommendations included availability of "most probable risk estimates" as well as upper bounds; formation of a Blue Ribbon Science Panel to provide leadership on risk assessment

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Risk Assessment

In the past 25 years, scientists have developed a wealth of data on chronic health hazards, particularly potential human cancer risks. These data reveal some potential for cancer risk in virtually every aspect of life, including diet, personal habits and exposure to chemicals at work or in the environment.

The challenge facing scientists and regulators is to develop techniques for evaluating the vast amounts of available data and make the necessary decisions that effectively protect human health.

Risk assessment, when applied to chemicals, is the process of evaluating a substance to determine its potential to harm human health. It is widely used by regulatory agencies to determine the possible cancer risk associated with exposure to a specific chemical or compound.

Steps in Assessing Risk

The National Academy of Sciences has broken the process into four steps:

- Hazard identification, which includes the analysis of data from human experience, animal studies and other scientific sources;
- Dose response assessment, which is the process of estimating the relationship between the dose of the chemical and potential harmful effects;
- Exposure assessment, which examines the potential amount and routes of human exposure to a chemical, and
- Risk characterization, or the multi-disciplinary evaluation of the available data to develop an estimation of the risk to humans.

The Office of Science and Technology Policy has published a state-of-the-science document containing principles based on the science. Some state and federal regulatory groups have published risk assessment guidelines.

However, uncertainty is an inherent part of the scientific process. Faced with rapidly changing knowledge, scientists conducting risk assessments analyze the full range of possible results associated with exposure to a substance, then use their expertise to make judgements about the most likely outcome. AIHC believes that a scientific risk estimate, particularly an estimate based on experimental animal data, is probabilistic in character and results in a range of values. A range of values, appropriately interpreted by scientific experts in the risk characterization process, can provide valuable information for use in a regulatory decision.

Risk Estimates

Lacking certainty, regulatory agencies such as the Environmental Protection Agency and Food and Drug Administration have often used "worst case" estimates of risk to set exposure limits or otherwise regulate drugs, food additives, household chemicals and other substances. These estimates start from very conservative worst case assumptions such as these: animal carcinogens are always likely to be human carcinogens; the most sensitive animal species is the most appropriate test surrogate for man; exposure will continue for a lifetime, and the relationship between the dose of a substance and the response of the test animal to it is linear.

Another widely-held assumption is that statistically-based estimates of the upper limits of risk, which are generated by statistical models to extrapolate tumor incidences from the high exposures used in animal tests to the low doses relevant to human exposure, provide the most appropriate measure of human risk. These "upper bound" estimates are not a prediction of actual risk; rather the upper bound estimate indicates at the 95 percent confidence level that the actual risk is no greater, and may be a great deal lower, than the calculated upper bound value.

In fact, there is no scientific basis for assuming that these methods correctly forecast low-exposure risk. Most scientists believe that the upper bound values exaggerate risk.

The American Industrial Health Council (AIHC) believes that a full scientific evaluation of all relevant data is needed to protect human health.

Factors to Consider

Factors that should be considered in risk assessment include:

- evidence of toxicity and an altered physiological

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