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August 28, 1979

MEMORANDUM FOR AIHC

Re: Status Report

This memorandum will describe briefly and indicate the status of proposed regulations, reports and pending legislation designed to identify and control substances which present a human carcinogenic risk or risk of other chronic health effects. The memo will refer to generic proposals to deal with chronic health effects as distinguished from regulation of a particular substance, e.g. saccharin.

The changes from the June status report will be identified by a line in the margin.

A. Interagency Organizations

I. Regulatory Council.

In October 1978 the President created the Regulatory Council composed of departments and agencies with regulatory functions. The purpose of the Council was to manage the regulatory process more effectively.

The first act of the Council was to publish a calendar of Federal Regulations, 44 Fed. Reg. 11388, February 28, 1979.

In June the Council announced that the President had asked the Council to develop a national policy framework for carcinogen regulation. The Council is cooperating with the IRLG

agencies in preparing that national policy, building on the IRLG Report. A status report to the President originally due July 31st has been extended with real due date unknown.

The Council is also preparing a manual for benefit analysis, emphasizing health safety and environmental regulation.

The Council is also studying cost analysis and considering whether some central source of information on governmental cost analysis should be established.

Finally, the Council will endeavor to identify alternatives to the traditional regulatory process.

II. IRLG

1. The Inter Agency Regulatory Liaison Group (IRLG) made up of OSHA, EPA, FDA, CPCS and (recently added) the Department of Agriculture. On February 6, 1979 Douglas Costle as Chairman of the Regulatory Council established by the President, released an IRLG Report which described the scientific bases for the agencies to use in determining whether a substance presents a carcinogenic risk. The report covers both the methodology for determining whether there is a qualitative cancer risk as well as the method for quantifying the risk.

Status. The IRLG Report has been submitted to the Journal of the National Cancer Institute and is expected to be published as a supplement to the July issue of the Journal when peer review is complete.

When the report was first released, three agencies (EPA, FDA and CPSC) said they would jointly or severally publish the Report in the Federal Register for comment. OSHA said it would

not join in such a publication for comment because the issues had been addressed in the hearing on the generic cancer policy. The Report was published for comment on July 6, 1979, 44 Fed. Reg. 39858. Comments are due September 30, 1979.

The AIHC Scientific/Alternatives Committees have completed a draft of comment for review on the Report. That draft comment has been circulated to members for review and has been widely distributed to association members, government agencies and scientists in academic institutions.

The IRLG Report methodology was used by EPA in proposing proposed water quality criteria for priority pollutants. CPSC has also announced its intention to use the IRLG Report.

III. Toxic Substances Strategy Group

1. The President created this group made up of the regulatory agencies and research agencies and chaired by CEQ to advise the President on strategies for control of toxic substances. One of its tasks was to develop a national cancer policy. The deadline for the publication of that national policy was December 31, 1978.

Status. Earlier this month the Council on Environmental Quality released a Report to the President by the Toxic Substances Strategy Committee on cancer policy. Comments are due September 30, 1979. The AHIC Scientific Committee is preparing comments.

B. Regulatory Agencies

IV. OSHA

1. On October 4, 1977, OSHA released its proposed generic regulation for control of exposure to substances presenting a

potential occupational carcinogenic risk. (42 Fed. Reg. 54148). That proposed regulation would establish criteria to determine whether a substance presented a carcinogenic risk and, depending on the category in which the substance was placed in the scheme, would also determine what the regulatory response would be.

Status. The hearing record closed on September 15,1978. In the calendar of regulations published by the Regulatory Council the date for publication of a final regulation was given as May 1979. Informal indications are that a draft of the regulation (and preamble) is being circulated for review within the agency. The BNA Environmental Reporter recently published a story indicating that Dr. Bingham has fixed early September as the publication date. Further checking indicates that the earliest likely date for publication is late September or October.

Related Information. In 1978 the Fifth Circuit Court of Appeals set aside the benzene standard established by OSHA. American Petroleum Institute v. OSHA, 581 F.2d 493 (1978). The Supreme Court has granted certiorari in that case and has agreed to review two questions.

(1) Whether OSHA is required to find that the costs of the regulation are reasonably justified by the benefits;

(2) Whether OSHA may rely on "old" evidence when new evidence is readily available to the agency.

The benzene case has been set down for argument in October. Decision is expected in January/February 1980.

V. FDA

1. On March 20, 1979 the Food and Drug Administration issued a proposed rule under the so-called DES Proviso to the Delaney Clause (44 Fed. Reg. 17070). The regulations establish criteria and procedures for evaluating residues from animal drugs or food additives found in meat and food products produced by animals (e.g. eggs). The preamble to the regulation describes the criteria for the determination whether the residue substance is a carcinogen under the Delaney Clause. The Commissioner also gives the reasons why he has decided to abandon the Mantel-Bryan mathematical model for extrapolation to low doses and to adopt in its place the much more conservative linear-through-zero model of extrapolation. FDA also explains why a lifetime risk of 1 in a million calculated by that model imposes no additional cancer risk to man.

Status. There was a hearing on June 21 and 22, 1979 which consisted of four panels to discuss particular scientific subjects. AIHC was represented on three of the panels.

The Society of the Plastics Industry, Inc. and the Animal Health Institute were also participants at the hearing.

On August 4 there was an informal hearing at which Dr. Robert A. Neal of Vanderbilt testified as a witness offered by AIHC (Dr. Neal had been unable to appear at the June hearing).

Comments on the proposed regulation are due September 4, 1979. Draft AIHC comments have been circulated to the Board, the Scientific Committee and the Legal Committee.

Additional Information. On March 20, 1979, FDA announced the availability of a "Draft Guideline Describing Decision-making Criteria used by the Bureau of Drugs When a Member of a Class of Drugs Used in Humans is Determined to be a Known or Possible Carcinogen in Humans or Animals."

In an interlocutory decision in the cyclamate case Commissioner Donald Kennedy on June 26, 1979 (his last day in office) sent the case back to the law judge to consider the criteria for determining whether an animal test was positive or negative. He suggested the law judge consider dual criteria: 99% confidence level for a negative test and 90% confidence level for a positive result. Copies of this interlocutory decision have been sent to the Board, the Scientific Committee and the Legal Committee.

VI. EPA

1. §304 of the Federal Clean Water Act. On March 15, 1979, EPA published for comment 27 proposed water quality criteria under §304. The criteria cover 27 of the substances identified as "priority" pollutants in the decree entered into by EPA in the NRDC case. The criteria will be used by the States in fixing water quality criteria (or by EPA if the States fail to act). Water quality criteria when effective supplant permit limits.

The proposed criteria cover both risk to acquatic life and human health risk. The preamble sets out methodology for determining human health risk qualitatively and quantitatively. The IRLG methodology was used.

Status. Comments were due June 13, 1979. (44 Fed. Reg. 23570, April 20, 1979). AIHC filed comments on June 13, 1979.

Since June additional criteria have been issues. CMA is taking the lead in reviewing and commenting on these criteria.

2. §112 of the Clean Air Act. For over a year EPA has been working on regulations to identify and control hazardous pollutants under §112. In July EPA released a prepublication draft of its plan for control of substances presenting a carcinogenic hazard. EPA's regulatory plan includes the following three elements:

(1) The Interim Procedures and Guidelines for Determining Health Risk of Suspected Carcinogent. 41 Fed. Reg. 21402, May 25, 1976.

(2) A Proposed Regulation establishing the criteria and EPA's Proposed Procedure for Identifying and Listing a Substance Presenting a Potential Cancer Risk as a Hazardous Substance Under §112.

(3) An advanced notice of proposed rulemaking setting forth a Generic Work Practices Standard Applicable to Volatile Organics for Control of Fugitive Leaks and Spills. This generic work practice would be proposed as a rule whenever a substance is listed under §112.

EPA is under a court order in a suit brought by EDF to publish these regulatons and the deadline has passed. EPA earlier released the generic work practices standard and AIHC has testified on that subject.

Status. By letter dated August 6, 1979 AIHC objected to the proposed regulation and requesting a meeting with Administrator Costle. A meeting with officials from RTP has been arranged for September. No date has yet been fixed for a meeting with Costle.

Publication of the proposed regulation is uncertain and appears unlikely in the next 60 days.

EDF in an effort to speed the regulation has sent a letter to EPA announcing its dissatisfaction with the delay on the cancer policy and its intention to reopen the suit to compel a decision on new vinyl regulatons.

These regulations are expected to be very important and AIHC will take a very active role.

3. Testing Guidelines. On August 22, 1978, EPA published proposed test guidelines for registering pesticides under FIFRA, including guidelines for mutagenicity tests. 43 Fed. Reg. 37336. On May 9, 1979, EPA published proposed Good Laboratory Practice Standards for Health Effects under TSCA rules. 44 Fed. Reg. 27334. On July 26, 1979, EPA published proposed Health Effect Test Standards for TSCA Test Rules, including standards for mutagenicity. 44 Fed. Reg. 44054.

Status. In the July 1979 publication EPA in effect solicited comments on all three documents. Comments are due October 16, 1979. A public "meeting" will be held in Chicago on October 15th and 16th.

CMA is taking the lead in commenting on the test standards and G.L.P. standards. The AIHC Mutagenicity Task Group is preparing comments on mutagenicity test standards which will be incorporated in the CMA comments.

4. RCRA. On December 18,1978, EPA published Proposed Guidelines and Regulations dealing with hazardous wastes under the Solid Waste Disposal law. (43 Fed. Reg. 58946). This far

reaching regulation establishes criteria for identifying hazardous wastes, a licensing plan for generators, transporters and disposers of the wastes. The regulation would create an intricate system of record keeping, supervision of waste disposal, and financial responsibility of owners of disposal facilities.

This regulation if adopted in its present form could be one of the most expensive and disruptive regulations issued by EPA.

Status. One part of the EPA proposal is an advanced notice of rule making under §3001 of the statute on the criteria for designating a substance as a hazardous waste. One of the criteria is toxicity of the waste and the substances identified relate to drinking water quality criteria.

The comment period expired July 1, 1979. However, EPA received a large number of comments and opened the comment period for comment on the comments. The comments have not been published and must be inspected at EPA. AIHC has not yet decided to submit a comment on the comments.

VII. CPSC

1. On June 13, 1978, Consumer Products Safety Commission published its proposed statement of policy and procedure for evaluating and regulating carcinogens in consumer products. (43 Fed. Reg. 25658). The proposal was a scheme with categorization of potential carcinogens patterned on the OSHA proposal.

Status. The CPSC proposal was enjoined by the District Court. The appeal by CPSC (Dow Chemical v. Consumer Products Safety Commission, 459 F.Supp. 378 (W.D.La. 1978), appeal docketed

No. 78-1166 (5th Cir. Nov. 24, 1978).) has been dismissed.

On April 23, 1979 CPSC withdrew its policy statement and announced that it will join with EPA and FDA in publishing the IRLG Risk Assessment paper for comment.

C. Proposed Legislation

VIII. The Wampler bill, H.R. 2982.

There are a number of bills pending on specific substances alleged to be carcinogenic, e.g. nitrites and saccharin. One bill, however, deals more generally with carcinogenesis. Last term Congressman Wampler introduced a bill which would have directed the NAS to undertake to prepare a state-of-the-art statement defining and determining human carcinogenic risk. The bill has been re-introduced and hearings are expected.

IX. Regulatory Reform.

There are a large number of bills on regulatory reform, includsing one proposed by the President (S. 755). Hearings have been held by the Senate Governmental Affairs Committee on regulatory reform. Jackson Browning, representing AIHC, testified before the Governmental Affairs Committee and the Senate Judiciary Subcommittee.

The main points covered in the AIHC testimony are:

(1) Should the regulatory analysis guide agency rulemaking. AIHC supports the view that the statute requires that the costs of the rule be reasonably related to the benefits it will produce.

(2) Should there be review of the agency's compliance with regulatory analysis requirements, AIHC favors executive review and limited judicial review.

(3) AIHC proposes that the bill distinguish between the scientific function of risk assessment and the regulatory function of deciding what regulation, if any, is required. AIHC will recommend the formation of an independent scientific panel to perform the scientific risk assessment.

AIHC's testimony underscored also the need for a national cancer policy.

The Government Affairs Committee and the Judiciary Committee have joint jurisdiction over regulatory reform proposals. Both Committees are expected to reach mark-up after Labor Day and both Committees are targeting to finish by October 1st. Dates for Senate action are not fixed. Senate floor action on regulatory reform this year is considered to be likely. The House is not very far along in its consideration of regulatory reform and no forecast of dates of House action is possible at this time.

Robert C. Barnard

REPLY FORM

TO: Mr. Ronald A. Lang
Executive Director
American Industrial Health Council
1075 Central Park Avenue
Scarsdale, New York 10583

Our Company hereby applies for membership in the American Industrial Health Council based on the dues schedule of $25 per million dollars of corporate sales (minimum dues $250 and maximum dues $25,000). Our total corporate sales (for dues purposes) in our last complete fiscal year were $_____ - million. (It is not necessary to report less than $10-million or more than $1-billion.) Our annual dues will be $_____. Please send us an invoice for this amount. Our designated contact to AIHC will be _____

_____at_____

_____

_____

/____/Please send him copies of the following documents:

_____ AIHC By-Laws

_____ Draft of Comments to Inter-Agency Regulatory Liaison Group

_____ Legal Brief re OSHA Proposed Cancer Policy

_____ Analysis and Memorandum to EPA re Proposed Generic Air Emissions Cancer Policy

_____ Testimony re Work Practices Section of EPA Proposed Generic Air Emissions Cancer Policy

_____ Testimony, Background re AIHC Work on Regulatory Reform Legislation

_____ Latest AIHC Newsletter

_____ AIHC Recommended Framework for Identifying and Regulating Carcinogens

_____ Position Paper re Need for Independent Scientific Panel

/____/We are considering AIHC membership but need additional information. Please have someone contact the undersigned to discuss this. In the meantime, please send copies of the materials I have checked above.

NAME_____

TITLE_____

COMPANY_____ ____

_____ _____

DATE TELEPHONE