1625 I Street, N.W.
Washington, D.C. 20006
202 [illegible]

Organization Resources Counselors, Inc.

May 19, 1978

Dr. Eula Bingham
Assistant Secretary of Labor
Occupational Safety and Health
Administration
U.S. Department of Labor
200 Constitution Avenue, NW.
Washington, D. C. 20210

Re: Proposed "Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk"

Dear Dr. Bingham:

We appreciate your response of May 11, 1978 to our March 31 letter on the requirements of Executive Order 12044, "Improving Government Regulations" as they relate to the proposed regulations of toxic substances posing a potential occupational carcinogenic risk.

We do not, however, agree with your conclusions of this issue as to the applicability of the Executive Order. For the reasons stated in our letter of March 31 and the follow-up letter of April 28, our view remains that the proposal does meet the requirements of Executive Order 12044. We urge you to reconsider your decision and proceed with the preparation of such analysis.

Sincerely,

J. W. Miller

WWA:shb

RECEIVED

MAY 15 1976

U.T. BARR

U.S. DEPARTMENT OF LABOR
Occupational Safety and Health Administration
WASHINGTON, D.C. 20210

OSHA

4-98E-C

MAY 5 1976

TO ALL PARTICIPANTS IN THE OSHA "CANCER POLICY" HEARING

The enclosed material is sent to you to help you be prepared for the scheduled hearing beginning May 16. Please note the "Prehearing Guidelines" because some of the procedures are newly adopted for this hearing. Due to the number of participants in this hearing and its length some new procedures were necessary. Also enclosed is a listing of the groups mentioned in the Prehearing Guidelines and a tentative order of testimony. The order of testimony is tentative and there may be changes made during the course of the hearing but we hope to be able to adhere to the prepared schedule.

If you have any questions about the hearing please contact Tom Hall or Kevin Conlon at 202-523-8024.

Sincerely,

Tom Hall

Tom Hall
Hearing Management Officer

U.S. DEPARTMENT OF LABOR
OFFICE OF ADMINISTRATIVE LAW JUDGES
Suite 700-1111 20th Street, N.W.
Washington, D.C. 20036

TO ALL PARTICIPANTS IN THE OSHA "CANCER POLICY" HEARING
RE: PREHEARING GUIDELINES

Your participation in the "Cancer Policy" hearing is both welcome and appreciated. As you may know, several hundred persons have indicated a desire to participate in this proceeding. In the interest of allowing the fullest public participation without unduly protracting this proceeding, the following prehearing rules are issued.

The hearing will begin at 9:30 a.m. on May 16 and at 9:45 a.m. on subsequent days, unless special circumstances require a change; any such change will be announced during the course of the hearing. A lunch break will be taken at a convenient point in the testimony. The hearing day will end when the scheduled testimony and questions for that day are finished.

TESTIMONY AND EVIDENCE

In the interest of due process, fairness, and the development of a complete record, OSHA has required that any participant who requests more than 15 minutes for his presentation, or who will submit documentary evidence for the hearing, submit by February 28 the written testimony and documentary evidence he intends to present at the hearing. This material has been placed in the OSHA Docket Office, Room S6212, U.S. Department of Labor, 3rd Street and Constitution Avenue, N.W., Washington, D.C. 20210, where it is available for inspection and duplication. This will afford all participants full opportunity to review the evidence and to formulate any questions they wish to ask at the hearing. Submission of testimony and other evidence in written form will assist in expediting the hearing process. In the absence of special circumstances, participants who have filed notices of intention to appear but who have not substantially complied with the requirements for the submission of written testimony and documentary evidence, will be allowed a maximum time of 15 minutes for their presentations at the hearing.

Since written evidence will be received as part of the record of this proceeding (and, of course, is entitled to the same weight as evidence presented orally) the presentation of a witness at the hearing must summarize the written submission in 15 minutes or less. Alternatively, a participant may elect not to make an oral presentation but simply to offer his written data as submitted and to make himself available for questions. It is recognized that many of the participants have busy schedules and that many are attending from distant locations at considerable expense.

QUESTIONING

A scheduled has been established which is intended to provide a reasonable opportunity for questioning, without unduly protracting the proceeding or inconveniencing the participants. In light of the number of participants in the proceeding it will not be possible to allow unlimited questioning. By the close of each hearing day, each participant who intends to question a witness scheduled to appear the next hearing day must so indicate his intention on a sign-up sheet provided by OSHA. The amount of time requested for questioning must also be indicated. Where the time available for questioning appears to be inadequate to accommodate all of those who wish to question a particular witness, time limitations and a rotation of questioners will be utilized. The time limitations will vary according to the importance of the issues, the amount of time for which a witness has been scheduled and the number of participants who wish to question the witness. The rotation of questioners will be done in as fair a way as possible. Therefore each participant has been assigned by OSHA to a group for the sole purpose of organizing the rotation for questioning. Attache hereto are those assignments. Questions from a participant in a group are not viewed as being on behalf of others in the group. Rather, the grouping of participants is merely a mechanism to provide everyone with a reasonable opportunity to ask questions of other participants.

The questioning will be done in rounds. Each group will hav one questioner per round. Thus, the questioning of the first witness will begin with a designated participant from group 1. When the questioner has used the allotted time (for example, 30 minutes), a designated participant from each of the remaining groups would be given an opportunity to ask questions for up to the allotted time. After all groups have completed the first round of questioning, the second round of questioning will begin with another participant from group 1 for an allotted time (for example 15 or 30 minutes). Another participant from each of the other groups would be given an opportunity to ask questions of that witness. Subsequent rounds of brief duration will be permitted where necessary and to the extent that time permits.

At the conclusion of the scheduled time for each witness, any participant who indicated a desire to ask questions of a particular witness and believes that he or she did not have sufficient time to ask questions on important issues and that other questioners did not deal with the issue, may, within 3 work days submit written questions on such issues to the Administrative Law Judge, to OSHA, and to the witness. The witness may, if he or she chooses, respond to these questions in writing. In appropriate circumstances, OSHA or the Administrative Law Judge may request that the witness return at a later date to respond to such questions or to submit written responses. Where the participant who submits written questions as described above has already asked questions of that witness, he or she must also demonstrate why such questions could not have been asked in the allotted time. In this regard, it is suggested that questioners commence their questioning with the most crucial issues and ask their most important questions first.

In the event that a group is unable to agree on who will question for a particular round, the Administrative Law Judge will determine who will do so. Questions should be as brief as possible, may not be repetitive and must be designed to clarify testimony or elicit relevant information within the witness's area of competence or expertise. "Questions" which are really testimony will not be permitted.

POST HEARING COMMENTS

A 15 day period after the close of the hearing will be designated for the receipt of any additional information or evidence requested from participants during the proceeding. Participants will also be afforded 35 additional days to submit written comments, summations, or briefs during an additional interval which will be designated for this purpose. At the close of the posthearing comment period the entire record of this rulemaking proceeding will be certified by the Administrative Law Judge and forwarded to the Assistant Secretary of Labor for Occupational Safety and Health for final action.

The foregoing rules are deemed consistent with orderly and fair procedures. Exceptions to the above will be allowed in appropriate circumstances, as determined by the Administrative Law Judge

J.F. Greene
Administrative Law Judge

GROUP I

Adhesive and Sealant Council, Inc.

American Coke and Coal Chemicals Institute

American Foundrymen's Society

American Industrial Health Council

American Industrial Hygiene Association

American Iron and Steel Institute

American Iron Ore Association

American Occupational Medical Association

American Paper Institute

American Petroleum Institute

American Textile Manufacturers Institute

Asbestos Information Association

Boating Industry Association

Chamber of Commerce of US

Chemical Specialities Manufacturers Association

Cleaning and Laundry Association Executives

Diesel Automobile Association

Drycleaning Industry Council

Dry Color Manufacturers Association

Dyes Environmental and Toxicology Organization

Fluor Engineers and Constructors, Inc.

Health Industry Manufacturers Association

International Fabricare Institute

Manufacturers Association of Hartford County

Manufacturing Chemists Association

Motor Vehicle Manufacturers Association

Motor Vehicle Manufacturers Association

National Agricultural Chemicals Association

National Association of Chemical Distributers

National Association of Engine and Boat Manufacturers

National Association of Printing Ink Manufacturers

National Constructors Association

National Cotton Batting Institute

National Cotton Council of America

National Cottonseed Products Association

National Electrical Manufacturers Association

Neigborhood Cleaners Association

Polyurethane Manufacturers Association

Refractories Institute

Rubber Manufacturers Association

Harvey M. Sheldon, Attorney

Society of American Wood Preserves, Inc.

Society of Plastics Engineers

Society of the Plastics Industry, Inc.

Synthetic Organic Chemical Manufacturers Association

Textile Fibers and By-Products Association

West Gulf Maritime Association

Western Wood Products Association

GROUP 2

Air Products and Chemicals

Alcoa

Allegheny - Ludlum Steel Corp.

Allied Chemical

American Color and Chemical Corp.

American Cyanamid Co.

Apollo Colors Inc.

Armstrong Cork Co.

Balchem Corp

Bethlehem Steel Corp.

BF Goodrich Company

Bristol - Myers Company

Brush Wellman, Inc.

Burlington Industries, Inc.

Chemetron Pigments, Allegheny Ludlum Industries

Chicago Molded Products Co.

Danna Molded Products

Detrex Chemical Industries, Inc.

Diamond Shamrock

Dolomite Brick Corp of America

Dow Chemical U.S.A.

E. I. du Pont

Ethyl Corp.

Exxon Corp.

Exxon Nuclear Company

Fike Chemicals, Inc.

FMC Corp.

General Electric

Georgia Pacific Corp.

Goodyear Tire and Rubber Company

Grace Chemicals Division

Hercules, Inc.

Highland Plastics

H. Kohnstamm & Co., Inc.

Hoekstra Uniform Rental Service

Hooker Chemicals and Plastics Corp.

Hughson Chemicals, Lord Corp.

Industrial Health Engineering Association, inc.

Inland Steel

Inmont Corp.

Johns - Manville

Jones & Laughlin Steel Corp.

Kaiser Steel

Kawecki Berylco Industries

Koppers Company

Major Laundry Rental Service, Inc.

Mallinckrodt, Inc.

Monsanto Company

Muskegon Chemical Co.

National Steel Corp.

Northern Petrochemical

P/A Industries, Inc.

Phillips Petroleum Company

PPG Industries

Plastics Engineering Company

Raybestos - Manhattan

Republic Steel

Reserve Mining Co.

Reynolds Aluminum Company

Shell Oil Company

Standard Oil Company of California

Stauffer Chemical Company

Styrex Industries

Sun Chemical Company

Tenneco Chemicals

Union Carbide Corp.

Uniroyal Chemical

Uniroyal Inc.

United States Steel Corp.

United Technologies

Upjohn Company

US. Borax

Vineland Chemical Co.

Virginia Chemicals

Vulcan Materials Company

Witco Chemical

GROUP 3

AFL-CIO

Amalgamated Clothing and Textile Workers Unions

IUD - AFL-CIO

International Brotherhood of Teamsters

International Chemical Workers Union

OCAW

United Electrical Radio and Machine Workers of America

United Steelworkers of America

United Steelworkers of America, AFA-CIO

United Steelworkers of America - (DuPont Comm)

United Steelworkers of America - Local Unions (7)

United Steelworkers of America - Local Unions (11)

United Steelworkers of America - (15 Locals)

United Steelworkers of America (Local 2609)

United Steelworkers of America (Local 2610)

GROUP 4

Environmental Defense Fund

National Resources Defense Council

Public Citizen

Urban Environmental Conference, Inc.

GROUP 5

All Federal Governmental Agencies.

Witnesses asked by OSHA to testify.

GROUP 6

Association of American Cancer Institutes

Cap ital Legal Foundation

Carnegie - Mellon Institute

Chemical Industry Institute of Toxicology

Harry B. Demapoulos, MD., (private)

Department of Health, State of Connecticut

A Healthy, Holistic Awareness Association

Industrial Health Foundation

Thomas H. Jukes

National Legal Center for the Public Interest

Bill Pegram

Glenn E. Schweitzer

Society of Toxicology

State of North Carolina Department of Labor

U.S. DEPARTMENT OF LABOR
Occupational Safety and Health Administration
WASHINGTON, D.C. 20210

Informal Public Hearing on Proposed Standard on the Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk

TENTATIVE SCHEDULE OF APPEARANCES

Commencing at 9:30 a.m. on May 16, 1978

Departmental Auditorium - Constitution Avenue Between 12th and 14th Streets, N.W. Washington, D.C. May 16 - 24

New Department of Labor Auditorium
New Department of Labor Building
3rd and Constitution Avenue, N.W.
Washington, D.C. 20210
May 24 - Until Conclusion

Administrative Law Judge: J.F. Greene
Hearing Management Officer: J. Thomas Hall
Hearing Management Officer: Kevin Conlon
Office of the Solicitor: Edward Klein
Office of the Solicitor: Edith Nash
Office of the Solicitor: Charles Gordon
Office of the Secretary: Anson M. Keller
Clement Associates-: Consultant to OSHA

APPEARANCE	WITNESS
	Occupational Safety and Health Administration (OSHA)
May 16 Tuesday	Grover Wrenn, Director, Directorate of Health Standards Programs, Occupational Safety and Health Administration
May 17 * Wednesday	Arthur C. Upton, Director of the National Cancer Institute
	Accompanied by Umberto Saffiotti, National Cancer Institute, and Marvin A. Sneiderman, National Cancer Institute
May 18 Thursday	David P. Rall, Director of the National Institute of Environmental Health Sciences

* Unless otherwise noted each witness for OSHA appears as an individual and not as a spokesman for his or her agency.

May 19
Friday — Donald Kennedy, U.S. Commissioner of Food and Drugs, Food and Drug Administration.

May 22
Monday — Richard R. Bates, Associate Commissioner for Science Food and Drug Administration and Harold L. Stewart, Scientist Emeritus, National Institute of Health

May 23
Tuesday — Marvin A. Sneiderman, Associate Director, Field Studies and Statistics Programs, Division of Cancer Cause and Prevention National Cancer Institute and Robert N. Hoover, Head of the Environmental Studies Section of the Environmental Epidemiology Branch, National Cancer Institute

May 24
Wednesday — Umberto Saffiotti, Chief, Experimental Pathology Branch, Carcinogenesis Research Program, Division of Cancer Cause and Prevention National Cancer Institute and Richard A. Griesemer Associate Director for Carcinogenesis Testing Program, Division of Cancer Cause and Prevention National Cancer Institute

May 25
Thrusday — William Lijinsky, Director, Chemical Carcinogenesis Program, Frederick Cancer Research Center

May 26
Friday — Samuel S. Epstein, University of Illinois. Professor of Occupational and Environmental Medicine, School of Public Health

May 27
Saturday — (Continued if Necessary)

May 30
Tuesday

Joyce McCann
University of California

Mathew S. Meselson
Thomas Dudley Cabot, Professor of the National Sciences, Harvard University

May 31
Wednesday

John W. Berg
Associate Director for Epidemiology and Statistics
Colorado Regional Cancer Center

David H. Wegman, M.D.
Associate Professor of Occupational Health, Harvard School of Public Health

June 1
Thursday

Irving Selikoff
Mount Sinai School of Medicine

William J. Nicholson
Associate Professor, Department of Community Medicine, Mount Sinai School of Medicine

Renate D. Kimbrough
Research Medical Officer, Center for Disease Control, U.S. Public Health Service

June 2
Friday

Lawrence Fishbein
Assistant to the Director for Environmental Surveillanc
National Center of Toxicological Research

Benjamin L. Van Duuren
Professor of Environmental Medicine, New York Univeristy Medical Center

M. Adrian Gross
Associate Director for Pre-clinical Investigations, U.S. Food and Drug Administration

June 5
Monday

Benjamin F. Trump, M.D.
Chairman of the Department of Pathology University of Maryland School of Medicine

June 5
Monday

Curtis C. Harris
Head, Human Tissue Studies Section, Experimental Pathology Branch, National Cancer Institute

June 6
Tuesday

David G. Hoel
Chief of the Viometry Branch and Acting Scientific Director of the National Institute of Environmental Health Sciences, Research Triangle Park

David G. Kaufman
Associate Professor of Pathology and of Biochemistry and Nutrition, North Carolina School of Medicine

June 7
Wednesday

Bernard Weinstein
Professor of Medicine and Director of the Division of Environmental Sciences, COllege of Physicians and Surgeons of Columbia University

June 8
Thursday

Nicholas A. Ashford
Senior Research Associate, Center for Policy Laternatives, Massachusetts Institute of Technology

June 9
Friday

Richard Peto
University Reader in Cancer Studies, Radcliffe Infirmary, Oxford University

June 12
Monday

Industrial Hygienists Panel
Charles W. Billings
Darrell D. Douglas
Bruce J. Held
Duncan A. Holaday
Robert D. Soule

June 13
Tuesday

National Institute for Occupational Safety and Health
Edward J. Baier, Deputy Director
Richard F. Boggs
David H. Groth
Richard W. Niemeier
Robert H. Hill

June 13
Tuesday — National Institute for Occupational Safety and Health
Robert T. Hughes
Robert H. Schutz
Richard J. Waxweiler
Howard A. Walderman

June 14, 15, 16, & 19 NO TESTIMONY SCHEDULED

June 20, 21, 22
Tuesday, Wednesday, Thursday

American Industrial Health Council
Paul Oreffice, Pre. Dow Chemical
Robert E. Olson, Consultant
Francis JC Roe, Consultant
Richard Wilson, Consultant
David Brusick, Litton Bionetics
Ronald W. Hart, Consultant
RF Crampton, Consultant
Paul Grasso, BP Occup. Health
George Claus, Consultant
AEM McLean, Consultant
Leonard Goldwater, Consultant
Johannes Clemmesen, Consultant
Bernard Oser, Consultant
Frank C. Lu, Consultant
Robert Murray, COnsultant
Ronald A. Lang, Executive Secretary
Josaph Nemec
Philip Gisser
Robert Shriner
Robert C. Barnard, Attorney
James H. Jandl, Consultant
HGS Van Raalte, Toxicologist Shell International
T. Colin Campbell, Consultant
Elwood P. Blanchard, Fred Hoerger, Alternatives
George Dominquez, Economic

June 23
Friday

BF Goodrich Company
William C. Becker, V-P Ext. Affairs
Maurice N. Johnson MD, Adm. Environ. Health
Robert K. Hinderer, Ph.D., Toxicologist
Richard Wilson, Ph.D., Prof. Physics, Harvard
Roger W. Strassburg, Ph.D., Dir., Environmental Affairs

June 23
Friday

Phillips Petroleum Company
JV LeBlanc, MD., Med. Dir.
W. B. Thomas, Vice President

Air Products and Chemicals
Richard Fleming, Exec. V-P
John T. Barr, Ass't Dir. of Research for Plastics

Upjohn Company
Paul F. Woolrich, Envir. Qual. Program Mgr.
jj Gernik, MD., Dir.-Occup. Health
ES Feenstra, DVM, Res, Mgr. Path Toxicology
R. A. Donia, Ph.D., Dir., Fine Chemical Production
D. H. Gregg, Ph.D., International-Administrative
J. C. Griffin, Ph.D., Dir., Pharmaceutical ... Manufacturing
R. L. Johnston, DVM, Supportive Research, Agric. Res. & Devel.
W. H. Nay, Vice President, Engineering
M. D. Welch, Attorney

PPG Industries
Zeb G. Bell, Mgr. Toxicology

June 26 & 27
Monday & Tuesday

American Petroleum Institute
Dr. Hardin B. Jones
Arthur Furst
Dr. Peter Goldman
Irving I. Kessler, MD
Howard I. Miabach, MD
Rulon W. Rawson, MD
David Scho Henfeld, MD
John Thrope, MD
Melvin First, ScD
Richard Zeckhauser, Ph.D
Daniel B. Rathbun, Vice President

June 28
Wednesday

American Iron and Steel Institute
Robert Snyder, Ph.D., Consultant
Anthony J. Triolo, Ph.D., Consultant
Carl Ackerman, Engineer
John D. Bealer, MD., Med. Dir. Bethlehem Steel
William L. Gadd, Mgr. Ind. Hyg, National Steel
Robert J. Halan, MD., J-L Steel
William C. Jones, Mgr. Environ Health - USS

June 28
Wednesday

American Iron and Steel Institute
AE Moffit, Dir - Toxicology Bethlehem Steel
John H. Stenmark, V-P Ind. Rel. AISI
Lindsley D. Van Der Verr, Mgr. Cost Planning USS
Peter C. Wright, Ph.D., Biostatistician
Neil J. King, Attorney
Arthur B. Spitzer, Attorney
Robert P. Stranahan, Jr., Attorney

Manufacturing Chemists Association
M.W. Johnson, MD, B. F. Goodrich
D.E. Ellison, Virginia Chemicals
Thomas J. McDonagh, MD, Exxon Chemical
J.M. Pardee, Eastman-Kodak
P.W. Simmons, Dow Chemical
John H. Pickering
Andrew T. W. Macdonald
Edmund B. Grost

June 29
Thursday

Johns-Manville Corporation
Paul Kotin, M.D.
Dr. Gerald R. Chase

June 30
Friday

Dow Chemical U.S.A.
Dr. Etcyl Blair, Dir. of Health & Environmental Research
Dr. Perry Gehring, Dir. of Toxicology Research
Dr. Ralph Langner, Dir. of Industrial Hygiene
Richard Olson, Mgr.-Industrial Hygiene
Cheryl Schultz, Industrial Hygiene
Roger Daniel, Environmental Health Services
Dr. Robert Bumb, Manufacturing Mgr. - Styrene Plastics
J. S. Hanson, Attorney

FMC Corp
Dr. Sherman K. Reed, V-P Chem. Tech.
Dr. Harold K. Latourette, Environ. Mgr.
Dr. Martin J. Fletcher, Mgr. Toxicology

Society of Toxicology
Harold M. Peck, M.D., President

July 5
Wednesday

E. I. duPont de Nemours Co.
Dr. Bruce Karrh, Medical Director
John A. Zapp, Toxicologist

July 5
Wednesday

E. I. duPont de Nemours Co.
Ben C. Rusche, Dir. Health & Safety
Russel S. Pease, Occup. Environ. Control
Charles F. Reinhardt, Haskell Lab.
Ned K. Walters, Mgr. Safety
William E. Fayerweather, Biostatistician
Robert R. Bonczek, Attorney
Taylor W. Hanavan, Attorney
B. Anne Gwynn, Attorney
John F. Dickey, Attorney

Fike Chemicals, Inc.
Elmer A. Fike

A Healthy, Holistic Awareness Association
Josephine A. Trevathan, Esq., President

July 6
Thursday

Reserve Mining Co.
Matthew R. Banovetz, Executive Vice President
Edward T. Fride, Attorney
George W. Wright, M.D., Consultant
Ian T. T. Higgins, M.D., Consultant
William E. Smith, M.D., Consultant
Donald D. Haase, M.D., Occupational Medical Consultant
Dr. Lawrence J. Partridge, Jr., Consultant
Raymond L. Erickson, Attorney

National Agricultural Chemicals Association
Dr. Stan D. Vessleinoritch
Dr. William H. Butler
Dr. Mitchell R. Zavon
Dr. John L. Emerson
Dr. Michael A. Gallo
Dr. TH Kakuk
Dr. Jerry M. Smith
Charles A. O'Connor, III, Attorney

July 7
Friday

New York University Medical School
Harry B. Demapoulos, M.D., (private)

Shell Oil Company
RH Coe - Mgr. OSH-Affairs
RE Joyner, Med. Dir.
HL Kusnetz - Mgr. Ind. Hyg.
ML Sagenkahn - Mgr. Business Res.
MB Slomka - Toxicologist
KR Sommer - Toxicologist

July 7
Friday

Shell Oil Company
FB Thomas - Toxicologist
CH Kline - Pres. CH. Kline Company
GL Innes - V-P CH Kline Company
DE Stevenson - Dir., Toxicology Lab.
B. F. Aurelius, Attorney

Exxon Corp.
Robert A. Scala, Dir. Toxicology
Jeremiah Lynch, Ind. Hyg.
N. J. Roberts, M.D., Medical Director

Goodyear Tire and Rubber Company
Waveland D. Davis - Mgr. Safety Compliance
William B. Hirsch - Mgr. Chem. Engineering
Dr. Lawrence K. Hunt - Health Safety Section Head
HR Wickenden - Mgr. Planning
Dale R. Martin, Attorney

Monsanto Company
John W. Hanley, Pres.
Monte C. Throdahl, Group Vice President
Environmental Policy Staff
Alexander Munn, M.D., Dir., Medicine &
Environmental Health

Polyurethane Manufacturers Association
Jack E. Peterson, Ph.D., Peterson Assoc.
Kurt C. Frisch, Ph.D.
Alphonso Chapanis, Ph.D.
Arrid A. Sather, Michael, Bert & Friedrich
George Kilbride, Mandrels, Inc.
Jay Meili, Moldea Dimensions, Inc.
William G. Stahr, Whittaker Coatings
Gene A. Huber, SWECO Inc.
Thomas M. Houghton, CONAP, Inc.

July 10
Monday

American Federation of Labor and Congress of
Industrial Organizations
A. F. Grospiron
George J. R. Taylor
Margaret Seminario
Steven Wodka
Michael Wright

July 10
Monday

Industrial Union Department of the AFL-CIO
Sheldon W. Samuels

Oil, Chemical and Atomic Workers
Steven Wodka
Jimmie Truite
Noel King

July 11
Tuesday

United Steelworkers of America
Melena Burkman
Elmer Chatak
Mary-Win O'brien
Michael J. Wright
Adolph E. Schwartz

Public Citizen
Sidney M. Wolfe, M.D., Health Research Group

American Occupational Medical Association
Robert E. Eckardt, M.D., Ph.D.
Bruce E. Douglass, M.D.

Association of American Cancer Institutes
Henery C. Pitot, M.D., Ph.D.
Edwin A. Mirand, Secretary-Treasurer

July 12
Wednesday

Urban Environment Conference Inc.
George Coling

National Resources Defense Council
Marcia J. Cleveland, Attorney

Motor Vehicle Manufacturers Association
Thomas H. Hanna, V-P
Timothy Mather, Mgr. Personnel
Thomas J. Slavin, Ind. Hyg.
V. Marla Slywynsky, Attorney
Anthony P. Massaro, Inc. Hyg. AMC
Daryl N. James, Inc. Jyg. Chrysler
Lawrence Roslinski, Toxicologist, FMC
Gene Kortsha, Hyg. GM
Gerald A. Sattelmeier, Industrial Hygiene Department

Refractories Institute
J. William Widing, Pres.
John D. Kern, V-P
John P. Holt, V-P

July 12
Wednesday

Refractories Institute
David A. Knowlton, Dir. Safety and Health
Otto L. Forchheimer, Tech. Dir.
Lawrence J. Partridge, Proj. Dir. AD Little
AM Carto, Exec. V-P

Standard Oil Company of California
ED Kane, V-P Tech.

July 13
Thursday

Chemical Industry Institute of Toxicology
Leon Golberg, Pres.

Bristol - Myers Company
Dr. Paul Medford Newberne, Consultant
Dr. Adrianne Ellefson Rogers, Consultant
William K. Hoskins, Member-Legal Staff

Society of the Plastics Industry, Inc.
Ralph L. Harding, Pres.
Stanford H. Shaw, Chmn
Lawerence,
Hadley
EL Bixby, Goodall Rubber
Len Bothe , Bird & Son
Bill Hammond, GAF Corp.
Larry S.Weaver, Plasticware Cup Co.
Clayton T. Lyons, Master Container
Robert Wood, Mobil Chemical
Paul Rothchild, Owens - Illinois Inc.
Charles Harrison, Hedwin Corp.
Paul Trow, Rexel Division
Harley Henry, Styrex Industries
Robert Cook, Plastics Industries
Michael Roby, Rubbermaid Inc.
Thomas Van Acker, Monsanto
Lloyd Dixon, Dexter corp.
Everrett Oftedahl, Expanda - Foam, Inc.
Luther Dickens, Radva Plastics Corp.
Dana Kelley, Dres. International
Fred Ford, Duval Corp.
John W. Morse, Engineering Plastics
Rodger Glander, Glastic Corp.
Ken Iseler, Budd Co.
James Smith, Rostone Corp.
E. D. Edmisten, Fibercast Co.
M. L. Christensen, Atlas Plastics CO.
Chester McCloskey, Norac Co.

July 13
Thursday

Society of the Plastics Industry, Inc.
Douglas I. Hanson, Hanson Pattern & Mold
Lloyd Gottesman, Tenneco Chemicals
Robert Hay, Firestone Foam Products
Ernest McClelland, Plast-O-Meric, Inc.
Society of the Plastics Industry, Inc.
Al. Haas, Eastman Chemical
Dr. Kenneth L. Burgess, Dow Chemical
H. Donald Fenney, Borg-Warner Chemical
D. C. Neuchterlein, Dow Chemical
James V. Hardman, Hardman Inc.
Jim Hornberg, Hysol Corp.
Chester McClosky, Norac Co.
Daniel Hidding, Dana Molded Products
Paul Thomas, Chicago Molded
Jerry Formo, Plastics, Inc.
Richard McKibben, Modern Plastics
Adolphe J. de Matteo, Thieley Plastics
William F. Mericle,Cincinnati Milacron Inc.
James McWilliam, Ivanhoe Tool & Die
Harry B. Ussery, Southeatern-Kusan, Inc.
Fritz Backscheider, Recto Molded Products
Robert A. Hoffer, Hoffer Plastics
Bryon Anderson, Northern Petrochemical
Norbert Finke General Molded
Ken Dahl, JS Plastics
Paul Tiez, Tiez-Bauer Plastics
Lawerence R. Bauer, Reed Prentice Division
Robert Poet, Vistron Corp.
Gerald Kessler, Kessler Products Co.
Gordon J. Naff, Highland Plastics

Union Carbide Corp.
Jackson B. Browning, Dir. Health & Safety
Thomas W. Carmody, Dir. Occp. Health
Carl U. Dernahl, MD, Medical Director
Carrol S. Weil, Toxicologist
John W. Whittlesey, Attorney

July 14
Friday

Stauffer Chemical Company
Wayne C. Jaeschke, Dir. - Environ. Services
Ralph I. Freudenthal, Dir. Toxicology
John T. Ronan, III, Attorney

Carnegie - Mellon Institute
Raymond S. E. Yang, Toxicology

July 17
Monday

Industrial Health Envineering Associates, Inc.
Knowlton J. Caplan - (private)

National Constructors Association
Delano F. English
V Sherwood Kelly
James E. Pakenham
Richard E. Peterson

Kawecki Berylco Industries
Tyson W. Coughlin, Attorney

Economic Analysis Division, EPA
Bill Pegram

West Gulf Maritime Assoc.
Hal Draper, Safety Director

National Steel Corp.
William M. SMith, Dir. - Environ. Control
William L. Gadd, Dir. - Ind. Hyg.
Dr. E. L. Tertick - Medical Director
Carl H. Hellerstedt, Jr., Attorney
Roger M. Golden, Attorney

Health Industry Manufacturers Association
G. Briggs Phillips, Ph. D.

American Cyanamid Co.
C. Boyd Shaffer, Dir. - Toxicology
Nolan B. Sommer, Senior Vice President

American Coke and Coal Chemicals Institute
Lucian M. Ferguson, Exec. V-P

American Paper Institute
Julian M. Kien, DIrector, Employee Relations

United Technologies
W. F. Patton - Supr. Health & Safety Engineering
J. A. Martin - Dir. - Ind. Hyg.

Western Wood Products Association
K. L. Patrick

Ethyl Corp.
Gary Ter. Haar

July 17
Monday

Armstrong Cork Co.
L. J. Bibri, V-P

National Association of Chemical Distributers
James K. Coyne, Gor. Rel.
Vernon Lowe, Exc. Sec.
Philip B. Bowman, Attorney

Allegheny - Ludlum Steel Corp.
W. R. Deem, V-P Manufacturing
A. S. Odasso, Director, Environmental Control
Glenn E. Schweitzer

National Association of Printing Ink Manufacturers
james E. Renson, Exec. Dir.

July 18
Tuesday

Highland Plastics
Gordon J. Naff

Hooker Chemicals and Plastics Corp.
John Janous, Ind. Hyg.
Paul Nees, Toxicologist
Fred Olotka, Mgr. Safety and Health
Neil WOodworth, Supr-Environ Services
Robert Luss, Attorney

Muskegon Chemical Co.
John R. Yost

Dana Molded Products
Daniel P. Hidding

Environmental Defense Fund
Leslie Dach

Raybestos - Manhattan
Hilton C. Lewinsohn, Corp. Med. Dir.

Jones E. Laughlin Steel Corp.
Dr. R. J. Halen, Med. Dir.
J. H. Kirkwood, Vice President, Industrial Relations
Robert C. Gombar, Attorney

Diesel Automobile Association
Robert A. Gibbons, President

Chicago Molded Products Co.
Paul M. Thomas, Executive Vice President

July 18
Tuesday

Uniroyal Inc.
Walter D. Harris, Ph.D., Ind. Toxicologist

American Iron Ore Association
RM Neil, Chemical Safety Commission

Mallinckrodt, Inc.
Noble Robinson, Dir.-Env. Affairs
Roger A. Keller, Attorney

Witco Chemical
George F. Polzer, Exec. V-P

Kaiser Steel
J. S. Hazen, Dir. - Labor Rel.
E. H. Given, Mgr - Medical Services
D. A. Kandel, Industrial Hygiene Administrator

Plastics Engineering Company
Ralph T. Brotz, President

Tenneco Chemcials
Dr. Roy T. Gottesman

Exxon Nuclear Company
Warren S. Nechadom, Mgr. Licensing
Roy Nilson, Manager, Licensing

Hercules, Inc.
Emil Christafano, Ind. Hyg.

July 19
Wednesday

Crane Packing Company
Harvey M. Sheldon, Attorney

National Cottonseed Products Assoc.
Garlon A. Harper, Dir. - Res. and Educ.
Fred E. Husbands, Executive Vice President

National Cotton Batting Institute
Dr. P. J. Wakelyn, Mgr. Evniron. Safety
Arthur Grehan, Executive Secretary

Balchem Corp.
Herbert D. Weiss, Pres.
Ursula T. Berube, Administrative Assistant

July 19
Wednesday

Reynolds Aluminum Company
E. Claiborne Irby, MD., Med. Dir.
Harry L. Skalsky, Ph.D., Toxicology MCV
Joseph F. Borzelleca, Ph.D., Toxicology MCV
John R. Amos, Attorney

National Association of Manufacturers
Richard Gallagher
Randolph M. Hale
W. Scott Railton
William Blasier
Robert R. Siegel
Edward Singer

Grace Chemicals Division
Peter M. Matonis, Ph.D. Dir-Environ. Affairs

P/A Industries, Inc.
Robert G. Hauser, Pres.

American Color and Chemical Corp.
Garrett A. Sullivan, Pres.

Dolomite Brick Corp of America
OL Forchheimer, V-P
Eric Charlton, Executive Vice President

Asbestos Information association
Harrison B. Rhodes, Dr. Eng.
R. H. Mereness, Executive Director

Diamond Shamrock
Donald W. Hillman, MD., Med. Dir.

Society of American Wood Preserves, Inc.
George K. Eliades, Pres.

Dyes Environmental and Toxicology Organization
Samuel N. Boyd, El DuPont
Chmn. Rd-DETO

Koppers Company
Alonzo W. Lawrence, Ph.D., V-P Occup. Health

Sun Chemical Company
Dr. Hugh M. Smith - Mgr. R & D
Michael Lewis - Dir. Engineering

July 19
Wednesday

Rubber Manufacturers Association
Frank T. Ryan, Dir. Environ. Health Affairs

Hughson Chemicals, Lord Corp.
John J. Szwarc, Safety Engineer

Dry Color Manufacturers Association
George Koehler, Mgr. Safety American Cyanamid
John Dickenson, Pub. Affairs, Harshaw Chemical Company
J. Lawrence Robinson, Executive Director

July 20
Thursday

Society of Plastics Engineers
Lawrence J. Broutman, Ph.D., Pres.
Joseph E. Hadley, Jr., Attorney

National Legal Center for the Public Interest
Miro M. Todoovich - Chmn. Academic Council
Alexander Von Graevenitz
George E. Moore
Barth X. de Rosa

Capital Legal Foundation
James R. Richards, Legal Dir.

General Electric
Thomas R. Casey MD, Med. Director
Jerome T. Coe, Environ. Qual. Task Force

Adhesive and Sealant Council, Inc.
Julie Rapp, Exec. Sec.

Georgia Pacific Corp.
TM Hahn, Pres.

Textile Fibers and By-Products Association
Dr. P J Wakelyn
Don A. Bryant, President

Alcoa
Bertram D. Dinman, Med. Director

Fluor Engineers and Constructors, Inc.
James E. Owens, Dir., Quality Assurance,
Marvin Marcus

July 20
Thursday

Vineland Chemical Co.
Arthur Schwerdtle
E. George Pazianos, Attorney

Chemical Specialties Manufacturers Association
Dan R. Harlow, JD, Ph.D., Dir. Scientific Affairs

Dept. of Health, State of Connecticut
Douglas S. Lloyd, MD, MPH, Commissioner

National Electrical Manufacturers Association
Bernard H. Falk, Pres.
Dale R. Schmidt, Coordinator of Government Activities

American Textile Manufacturers Institute
Joseph L. Lanier, Chmn Health & Safety
Raymond P. Boylston, Dir., Safety and Health Division

Neigborhood Cleaners Association
William Seitz, Exec. Dir.

International Fabricare Institute
William E. Fisher, Adm. Research

UC - Berkley
Thomas H. Jukes (private)

Vulcan Materials Company
Thomas A. Robinson, Ph.D., Dir. - Environ Affairs

Organization Resources Counselors, Inc.
B. K. Kwon
D. K. Mattheis

July 21
Friday

Major Laundry Rental Service, Inc.
Sol Schwartz, Owner

Northern Petrochemical
B. J. Anderson, V-P

Drycleaning Industry Council
Philip W. Croen, Chmn

Cleaning and Laundry Association Executives
Philip W. Croen, Pres.

Hoekstra Univorm Rental Service
Herman C. Hoekstra, Owner

July 21
Friday

Department of Defense
George Marienthal, Dept. Ass. Sect. Energy, Environ, Safety

Styrex Industries
Harley D. Henry, Pres.

Manufacturers Association of Hartford County
Richard C. Noyes, Pres.

Chemetron Pigments, ALlegany Ludlum Industries
Blaine C. Mays, Consultant Gov. Affairs
Robert R. Mueller, Prod. Mgr.
Rene A. Willis, Gov. Affairs

Bethlehem Steel Corp.
AE Moffitl, Dir. Environ. Toxicology
Carl Ackerman, Staff Engineer
David M. Anderson, Manager of Environmental Quality Control

Inmost Corp.
Alfred S. Kidwell, Dir. Gov. Affairs

Virginia Chemicals
Donald E. Ellison, Mgr. Gov. Relations

Uniroyal Chemical
Edward J. Sowinski, Industrial Toxicologist

United States Steel corp.
W. C. Janes, Mgr. Environ Health
Dr. Merle Bundy, Med. Director
Dr. D. J. Smith - Ass't Med. Dir.
L. D. Van Der Veer, Mgr. - Cost Planning
W. L. White, Attorney
J. L. Boucher, Attorney

Inland steel
Richard G. Phelps, Mgr. - Primary Tech.
James J. Romanek, Attorney

Boating Industry Association
National Association of Engine and Boat Manufacturers
Clifton Peter Rose, Attorney

American Foundrymen's Society
Gary E. Mosher, Industrial Hygienist

July 21
Friday

American Foundrymen's Society
H. Kohnstamm & Co., Inc.
Paul L. Kohnstamm, Chairman & Chief Executive Officer

Apollo Colors Inc.
Warren Norton

July 24
Monday

Industrial Health Foundation, Inc.
Paul Gross, M.D.

Chamber of Commerce of the United States
Christine M. Waisanen

National Cotton COunsil of America
Earl W. Sears

U.S. Borax and Chemical Corp.
H. Steinberg

Council on Wage and Price Stability
Roy A. Nierenberg

July 25
Tuesday

Brush Wellman, Inc.
John M. Newman, Jr.

American Industrial Hygiene Association
Paul F. Woolrich

Synthetic Organic Chemical Manufacturers Association
Ronald A. Lang

Allied Chemical
John T. Estes

3. NIOSH believes that scientifically sound judgments can be made only by review of all data. NIOSH offers to lead in setting up a government review panel made up of experts from NIC, FDA, EPA, CPSC and NIEHS.

4. NIOSH believes that "lowest feasible level" should be based on health risk and if engineering, etc. controls cannot bring exposure doses below concentrations which cause cancer in animals, no exposure should be permitted.

Vinyl chloride cited as case where industry said control impossible, but control achieved.

5. Model Standards. NIOSH favors more flexibility in certain parts of model standards: prevention of dermal and eye exposures; protective clothing and equipment; hygiene facilities and lunchroom facilities. Suggests approach comparable to the standards completion project.

Emergency notification requirements in standards burdensome and OSHA should consider whether such extensive reporting required.

NIOSH favors warning signs when there are process control failures and periodic measurements to assure effectiveness of ventilation and control devices.

Controls must be evaluated when there is a process change and the standard should deal with protection to repairmen.

NIOSH favors quantitative fit for respirators.

No smoking should be permitted where carcinogens may be released into the work place air.

NIOSH favors extending medical exam in certain way.

OSHA submitted 32 questions to NIOSH some of which are answered in Appendix C. NIOSH's answers cover:

1. Animal studies are appropriate to identify potential human carcinogens. Species should be those consistently positive when tested with human carcinogens. Rodents fit this criteria.

NIOSH rejects the criticism of mice as test animals.

2. Don't know how valid 1-5% estimate for occupational cancers. The dose relationship shown by carcinogens lead to expectation of fewer cases at low doses.

OSHA is directed by its statute to determine socially acceptable value of risk and the establishment of absolute risk, not relative risk.

3(a). OSHA sets out tables showing agents identified as occupational hazards by epidemiology and confirmed and suspect carcinogens by target organ (6 pages).

(b). No one study can provide all needed health information. Epidemiological studies have potential to determining effect of long-term low level exposure, but difficult to determine past exposure and dose-response. Animal data present problem of extrapolation. Both studies should be used.

(c). Epidemiology uncovered smoking risk, benzene and arsenic.

More weight must be given to positive epidemiological studies than negative.

(d). Efforts should be made to identify high risk individuals in epidemiological studies.

4. Animal data can be relied on in the absence of human data. Inhalation and percentaneous routes of exposure are satisfactory. Oral route also satisfactory.

Inhalation preferred route; topical applications also give useful information.

Injection site sarcomas by themselves probably do not indicate carcinogenicity.

Support MTD.

5. Present information is not sufficient for development of a consistent basis for decisions on additive and synergistic effects.

6. Not clear whether cancer caused by first exposure or repeated exposure. Latency is an imprecise term.

7. Short term tests which are being validated should be used as originally intended as screening device. They cannot be substituted for long term animal studies.

8. Discussion of various factors involving extrapolation:

(a) failure of rodent tumors to metastasize not critical.

(b) differences in target organ not critical.

(c) route of administration important for health purposes.

(d) OSHA should also consider physical agents - ultraviolet and infra red.

8 May 1978

OSHA Carcinogens

File No. 4-988-L

R. Fleming — Executive

R. H. Schenck — Law

cc: J. T. Barr

Attachdd is Appendix C containing NIOSH's responses to OSHA's questions.

R. H. Schenck

RHS:rgs

ATTACHMENT

APPENDIX C

The following are responses to some of those questions received from OSHA. Responses to some questions have not been furnished in this appendix either because they have been discussed in the prepared statement or because of the complexity of the issues and the short amount of time available to gather and evaluate the data, prepare an appropriate response and meet the April 4, 1978 due date for submissions to the OSHA Docket Office.

Questions 1, 2 & 21

The proposal recommends that animal studies be used to identify potential human carcinogens. This is quite appropriate. In fact, the purpose of the Proposal is to decrease human experimentation, i.e., decrease occupational exposures to carcinogens. Although there might not be 100% correlation between the effects of chemicals on animals and humans, that is not surprising nor should it discourage us from pursuing our goal. It should be noted that of the chemicals and/or classes of chemicals that have been found to cause cancer in humans, including: benzidine; 2-naphthylamine; bischloromethylether; chloromethyl methyl ether; 4-aminodiphenyl; N,N-bis(2-chloroethyl)2-naphthylamine; chrysotile; crocidolite; amosite; cadmium compounds; chromium compounds; nickel compounds; arsenic compounds; beryllium compounds; benzene; auramine; diethylstilboestrol; and vinyl chloride, all except possibly benzene have been found to cause tumors in animals (Tomatis, 1976; Newberne, 1975; Bayliss and Wagoner, 1977; Infante, et al., 1977; Oswald and Goerttler, 1971). Thousands of workers have developed cancer as a result of exposures to these agents. They have unwittingly provided scientists with the information needed to make the correlation between animal and human responses to carcinogens.

Another important consideration is the animal species and strain that should be used in the test systems. The degree of correlation between each species and humans as well as the relative cost in performing the studies must be considered before recommendations can be made. Obviously, those species which have been consistently positive when tested with known human

carcinogens are acceptable. Of the human carcinogens mentioned above, almost all have been shown to be positive in rats and several of them are positive in mice. Fortunately, these are the mammalian species which are least costly to process, and, therefore, their use can be recommended with very few or no qualifications.

Some scientists believe, however, that the mouse is too sensitive to carcinogens, and, therefore, the rat is a better model. Implied in this opinion is that mice will respond to lower doses of carcinogens than will humans. Since quantitative data on carcinogen exposures to humans is almost non-existent, that comparison is impossible to make. The fact that the mouse is slightly more sensitive to carcinogens than the rat is well-known (Tomatis, 1973), however, the model should be designed to protect humans, not rats. Another argument that has been frequently used to exclude mice is that they have a high frequency of spontaneous tumors which might be induced by hormones and/or viruses, and that tumor promotion, but not induction, is measured when that model is used. What the proponents of that argument fail to recognize is that whatever variables are present in mice might also be present in humans. Human tumors might also be induced by yet unrecognized viruses, and hormones certainly play a role in human carcinogenesis (Furth, 1975). It is not unreasonable to expect that the mechanisms of carcinogenesis operative in mice might be identical to those in humans, for example, humans have no zymbal gland. It is certainly possible that many carcinogens in humans are in fact co-carcinogens. There is no method to determine this with any degree of certainty in humans.

Question 4

It has been estimated that occupational cancer represents about one to five percent of the cancer cases reported annually in the United States. We don't know how valid the estimates are of the total incidence of occupational cancer. We know that there are a significant number of occupational cancer cases e.g., from 2-naphthylamine, asbestos, arsenic, vinyl chloride and this alone justifies vigorous preventive action.

Since numerous studies (vinyl chloride - B(a)P, Maltoni and Lefemine, 1975; Bingham and Falk, 1969) etc., have proven that a dose-response relationship is evident in the area of carcinogenesis just as in other areas of toxicology, it is readily apparent that positive results obtained at high doses indicate that lower risks are to be expected at lower doses. The specific limitations in estimating the lower risk factors are inherent in the specific limitations of the data gathering system. Such factors as animal numbers, number of dose levels, confidence limits and other factors must be considered in properly evaluating the dose-response relationship. In addition to a socially acceptable value of risk, the establishment of an absolute value of risk, rather than a relative value of risk (Subcommittee on Environmental Mutagenesis, 1977) is mandated by the OSHAct in regard to occupational carcinogenesis.

Question 5

a. The first direct connection between an occupational exposure and risk of a specific cancer was that of chimney sweeping and cancer of the scrotum pointed out by Pott in 1775. He recognized this association because he saw several affected chimney sweeps but little or none of the disease in persons with other occupations. The disease was exceedingly rare in the general population, and the risk ratio for chimney sweeps was quite high.

About 1880 Hirting and Hesse showed that "mountain disease" was a lung neoplasm. This condition was recognized as an entity in the Middle Ages because of its frequent occurrence among young miners despite the rarity in the general population. In 1895 the German surgeon, Rehn, published on the hazard of bladder cancer among dye workers. Rehn's association was based not on an exceedingly high risk ratio but rather on the absolute high frequency of the disease among exposed persons.

During the past several decades instances of occupational carcinogens have continued to be recognized both on the basis of an extremely high risk ratio and a high incidence rate among exposed persons.

The following tables show various agents which have been identified as occupational carcinogens on the basis of epidemiologic studies and confirmed and suspected carcinogens by target organ.

* TABLE 1
Classification of Occupational Carcinogens

A. Organic agents

1. Aromatic hydrocarbons

Agents	Affected organ(s)	Incubation period (years)	Risk ratio	Occupation
Coal soot Coal tar Other products of coal combustion	Lung, larynx, skin, scrotum, urinary bladder	9-23	2-6	Gashouse workers, stokers, and producers; asphalt, coal tar, and pitch workers; coke-oven workers; miners; still cleaners; chimney sweeps
Petroleum Petroleum coke Wax Creosote Anthracene Paraffin Shale Mineral oils	Nasal cavity, larynx, lung, skin, scrotum	12-30	2-4	Contact with lubricating, cooling, paraffin or wax fuel oils, or coke; rubber fillers; retortmen; textile weavers; diesel jet tarmen
Benzene	Bone marrow (leukemia)	6-14	2-3	Explosives, benzene, or rubber cement workers; distillers; dye users; painters;

* Philip Cole and Marlene Goldman, Chapter 8-0

"Persons at High Risk of Cancer", edited by J. Fraumenic, National Cancer Institute

A. Organic agents (continued)

1. Aromatic hydrocarbons (continued)

Agents	Affected organ(s)	Incubation period (years)	Risk ratio	Occupation
Auramine Benzidine α-naphthylamine β-naphthylamine Magenta 4-aminodiphenyl 4-nitrodiphenyl	Urinary bladder	13–30	2–90	Dyestuffs manufacturers and users; rubber workers (pressmen, filtermen, laborers); textile dyers; paint manufacturers

2. Alkylating agents

Mustard gas	Larynx, lung trachea, bronchi	10–25	2–36	Mustard gas workers

3. Others

Isopropyl oil	Nasal cavity	10+	21	Producers
Vinyl chloride	Liver (angiosarcoma), brain	20–30	200 (liver) 4 (brain)	Plastic workers

A. Organic agents (continued)

3. Others (continued)

Agents	Affected organ(s)	Incubation period (years)	Risk ratio	Occupation
Bis(chloromethyl) ether Chloromethyl methyl ether	Lung (oat cell carcinoma)	5+	7–45	Chemical workers

B. Inorganic agents

1. Metals

Arsenic	Skin, lung, liver	10+	3–8	Miners; smelters; insecticide makers and sprayers; tanners; chemical workers; oil refiners; vintners
Chromium	Nasal cavity and sinuses, lung, larynx	15–25	3–40	Producers, processors, and users; acetylene and aniline workers; bleachers; glass, pottery and linoleum workers; battery makers

B. *Inorganic agents (continued)*

1. Metals (continued)

Agents	Affected organ(s)	Incubation period (years)	Risk ratio	Occupation
Iron oxide	Lung, larynx	—	2–5	Iron ore (hematite) miners; metal grinders and polishers; silver finishers; iron foundry workers
Nickel	Nasal sinuses, lung	3–30	5–10 (lung) 100+ (nasal sinuses)	Nickel smelters, mixers, and roasters; electrolysis workers

2. Fibers

Asbestos	Lung, pleural and peritoneal mesothelioma	4–50	1.5–12	Miners; millers; textile, insulation, and shipyard workers

3. Dusts

Wood	Nasal cavity and sinuses	30–40	—	Woodworkers
Leather	Nasal cavity and sinuses, urinary bladder	40–50	50 (nasal sinuses) 2.5 (bladder)	Leather and shoe workers

C. Physical agents

1. Nonionizing radiation

Agents	Affected organ(s)	Incubation period (years)	Risk ratio	Occupation
Ultraviolet rays	Skin	varies with skin pigment and texture	—	Farmers; sailors

2. Ionizing radiation

X-rays	Skin, bone marrow (leukemia)	10–25	3–9	Radiologists; medical personnel
Uranium Radon Radium Mesothorium	Skin, lung, bone, bone marrow (leukemia)	10–15	3–10	Radiologists; miners; radium dial painters; radium chemists

3. Other

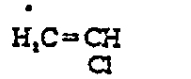
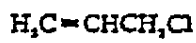
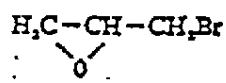
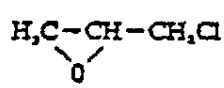
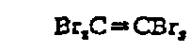
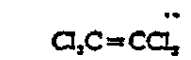
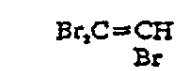
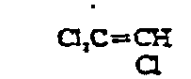
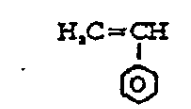
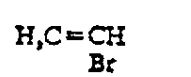
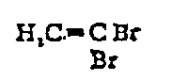
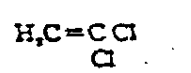
Hypoxia	Bone	—	—	Caisson workers

Table 2 Confirmed and suspected occupational carcinogens* by target organ.

Target Organ/Tissue	Occupational Carcinogen	
	Confirmed	Suspected
Bone		Beryllium
Brain	Vinyl Chloride	
Gastroenteric Tract	Asbestos	
Hematopoietic Tissue (leukemia)	Benzene Styrene Butadiene and other Rubber Manufacture Substances	
Kidney	Coke Oven Emissions	Lead
Larynx	Asbestos, Chromium	
Liver	Vinyl Chloride	Aldrin Carbon Tetrachloride Chloroform DDT Dieldrin Heptachlor PCB's Trichloroethylene
Lung	Arsenic Asbestos Bis (chloromethyl) ether Chloromethyl methyl ether Chromates Coke Oven Emissions Mustard Gas Nickel Soots and Tars Uranium Vinyl Chloride	Beryllium Cadmium Chloroprene Lead
Lymphatic Tissue		Arsenic Benzene
Nasal Cavity	Chromium, Isopropyl Oil, Nickel, Wood Dusts	
Pancreas		Benzidine PCB's
Pleural Cavity	Asbestos	
Prostate		Cadmium
Scrotum	Soots and Tars	
Skin	Arsenic Coke Oven Emissions Cutting Oils Soots and Tars	Chloroprene
Urinary Bladder	4-Aminobiphenyl Benzidine B-Naphthylamine	Auramine 4-Nitrodiphenyl Magenta

*Occupational Diseases - A Guide to their Recognition - U.S. Department of Health, Education and Welfare - NIOSH

Table 3 Suspected carcinogens based upon structural similarity to vinyl chloride.

Suspected Carcinogen	Structure
Vinyl Chloride	
Bromoprene	
Chloroprene	
Epibromohydrin	
Epichlorohydrin	
Perbromoethylene	
Perchloroethylene	
Tribromoethylene	
Trichloroethylene	
Styrene (Vinyl Benzene)	
Vinyl Bromide	
Vinylidene Bromide	
Vinylidene Chloride	

b. No one study approach can provide all or even most of the needed health information. While epidemiologic studies in the occupational setting have the potential to determine effects of long term low level exposures, the difficulty in making quantitative estimates of present exposures and the even greater problem in determining past exposures makes it hard to obtain accurate dose response data. On the other hand, while more accurate dose response data can be derived from toxicological studies using experimental animals, one is always faced with the difficulty of extrapolating results from experimental animals to humans and often with the additional problem of extrapolating from observed higher dose levels to lower dose levels. However, when the two study approaches are utilized in a coordinated way, benefits of each approach can be maintained and many of the individual methodological weaknesses can be overcome.

The following table shows these strengths and weaknesses.

Table 4*

DISCIPLINARY APPROACHES TO HEALTH EFFECTS OF AIR POLLUTION

Discipline	Population studied	Strengths	Weaknesses
Epidemiology	Communities Diseased groups	Natural exposures Observation in man No extrapolations Vulnerable groups included Long term, low-level effects evaluated Study many people	Quantifying exposure difficult Many covariates Minimal dose response data Association vs. causation Can only make few health measurements Long latent periods for disease a problem
Toxicology	Animals Biochemical systems Cells	Easy to obtain dose-response data Rapid data-acquisition Cause-effect more definite Mechanisms of response Predict shapes of dose response curves Administer toxic materials Study acute and chronic effects	Realistic models of human disease? Extrapolation from animals to man. Threshold of human response? Artificial exposures

*Dr. Carl Shy, "Strengths and Weaknesses of Epidemiological, Clinical and Toxicological Study Approaches," Chemist/Meteorologist Workshop 1975, U.S. Energy Research and Development Administration

c. The impact of epidemiologic studies in cancer research, such as the studies on cigarette smoking and lung cancer, prompted a recent Nobel Laureate to proclaim these studies as the major scientific finding of the 20th century.

It is doubtful that the impact of smoking on lung cancer incidence would have been known if research had been limited solely to cellular and whole animal studies. Although agents contained in cigarette smoke have been shown to induce cancer in laboratory animals, the sum of the carcinogenic effects of the known agents does not equal that of the cigarette smoke condensate. Particular difficulty has been encountered in inhalation studies of cigarette smoke on laboratory animals because the animals, particularly smaller species such as the rat, frequently die from the acute toxic effects of the nicotine and carbon monoxide in tobacco smoke. Another problem stems from the fact that the upper respiratory tract of experimental animals, particularly the nose, is much different from analogous human structures resulting in a more efficient filtration of smoke in the upper respiratory tract of these animals.

There is mounting epidemiologic evidence from a series of occupational health studies incriminating benzene as a possible leukemogenic agent. Thus far, no animal studies have been able to demonstrate this effect. Similarly, the carcinogenic activity of

arsenic has been demonstrated through epidemiologic but not by toxicologic studies. If reliance were placed solely on cellular and animal tests, then the importance of benzene and arsenic as carcinogenic agents would presently be unrecognized.

According to Sir Austin Bradford Hill, more weight must be given to positive as opposed to negative studies. Negative epidemiologic studies, particularly in cancer, cannot be construed as providing firm evidence of safety. This is because of the problems of latency and the small number of people often observed in epidemiologic carcinogenic studies which often preclude demonstration of statistically significant differences.

d. If the appropriate steps are used in epidemiologic research, then descriptive studies have the potential to identify unusual clusters and high risk individuals for subsequent study which should then limit the number of negative studies.

Question 6

It has been customary to rely upon animal studies in the absence of human evidence for a carcinogenic assessment of chemicals. An examination of the literature and of the experience in this method of approach reveals that animal data can be satisfactorily used as a predictor of human response.

The development of the vinyl chloride study, the coal tar/coke oven emission studies and various other examples illustrate the predictive value of animal bioassay methods.

In addition, the correlation between species with certain carcinogens such as benzo(a)pyrene, bischloromethylether, aminodiphenyl, benzidine, vinyl chloride, etc., have been in excellent agreement, even though the target tissue may differ among the species tested. In the case of benzo(a)pyrene, nine species of animals have been tested and all found to respond to this widely tested ubiquitous carcinogen. (Survey of Compounds Which Have Been Tested for Carcinogenic Activity - NCI).

If the responses of animals to known human carcinogens are examined it becomes obvious that all human carcinogenic chemicals, with the possible exception of arsenic and benzene, are also carcinogenic for animals.

The inhalation and percutaneous routes of exposure are the obvious routes of choice in experimental carcinogenesis studies when considering occupational exposure to chemical carcinogens. These routes are also the

choice when considering experimental design of studies to investigate other toxic agents. However, it is well known that clearance from both the upper airways and the deep lung involves the mucociliary escalator in which materials are cleansed from these areas and usually find their way into the alimentary tract, in lieu of expectoration. Therefore, the oral route of administration via either stomach intubation, for purposes of exact quantitation of dose, or through consumption of food or water containing contaminants, is a perfectly adequate route of administration to test the carcinogencity of chemicals and complex mixtures found in the occupational environment.

Inhalation is usually the preferred route of a adminstration in animal studies for judging the carcinogenicity of airborne substances. Because of the expense of this type of study and methodologic difficulties, other routes, especially per oral, are used. In the usual case, this route gives valid, extrapolatable information, but each case has to be considered individually. Similarly, other routes, e.g., topical application, give useful information. Injection site sarcomas by themselves, probably do not indicate carcinogenicity by other exposure routes. They may indicate specific hazards in the event of accidental implantation of the substances.

The validity of using the maximum tolerated dose in rodent bioassays has been discussed and debated for a number of years. It is appropriate to mention that the National Cancer Institute as well as other agencies such as NIOSH, FDA and EPA continue to consider this as an appropriate approach in experimental bioassays. The reasons for this choice are obvious when considering economics and the probability of response.

Question 10

Present knowledge does not permit development of a consistent and rational basis for decisions on additive and synergistic effects. Complicating this problem is the question of promoting agents and co-carcinogens, widely and variously used terms without the same meanings to everyone.

Additive effects should be assumed when two agents cause cancer at the same site, especially when the two agents also have chemical similaries, such as PN's or aromatic amines. Synergistic effects should be assumed only when there are data or principles suggesting in the specific case that potentiation is likely. Similarly, co-carcinogenicity and promotion should not be assumed except in a specific case where there are data or principles that apply. In clearcut areas involving personal habits such as smoking, counseling of workers should be called for. Other areas of personal habits, such as diet or lifestyle, should not be considered in this proposed standard, at least until the issues are clearer.

Questions 15 & 16

Questions 15 and 16 are closely related and will be answered together. The problem of additive and synergistic effects is extremely difficult to assess with available scientific methodologies, either toxicology or epidemiology. To date, the scientific community has not adequately dealt with this problem. Toxicology and epidemiology both provide valuable information about carcinogenic risk. The problems of additive (or antagonistic) and synergistic effects do not make dose-response data in test animals irrelevant. Epidemiology and toxicology have both strengths and weaknesses. However, by combining two methodologies, in this case toxicology and epidemiology, it is often possible to overcome some of the weaknesses of each individual methodology, yet retaining their strengths. From this point of view, corroborating data on carcinogenic risk from both epidemiology and toxicology provides the most defensible data as to carcinogenic risk. Most toxicology studies assess effects of single exposures. It is virtually impossible to artificially generate an exact replica of the complex workplace environment in any toxicologic experiment. One of the greatest strengths of the epidemiology approach is to observe the effects of this complex environment directly in man. However, unless the possible synergistic or additive effect is specifically tested either epidemiologically or toxicologically, it is impossible to assess the importance of such interactions. In the final analysis, though, health may still be protected even if precise information on interactions is not available. This is because a given compound in a complex mixture may often serve as an index, which when controlled, will also result in decreased exposure to all compounds in the complex mixture. The situation with coke oven emissions is an excellent example in this regard.

Question 19

Latency refers to the long period of cancer induction. Because of the uncertainties in identifying the specific time or event in the genesis of the cancer and the uncertainties in identifying the cancer itself, the term latency is not precise. It usually is taken to be that interval between the first known exposure to the cancer-causing substance and the first evidence of the consequent cancer, which is often at autopsy.

Whether the cancer process is initiated by the first exposure is not known; it is generally thought that the process is initiated by the effect of repeated exposures, but there are rational bases for suggesting that any one of these repeated exposures may have been the initiating event. It is conceivable that both ideas are correct, for example, it might be that the cancer is initiated by one exposure and is enhanced sufficiently by subsequent exposures to progress to enough overt cases to constitute a statistically significant excess (whether in an epidemiologic survey or an experimental animal investigation). However, this speculation should not obscure the point that latency is an imprecise term referring to the many years required for the development of most cancers to the point they are observed and is defined more precisely in specific investigations or surveys for the purpose of that study.

Question 28

According to a report from the DHEW Subcommittee on Environmental Mutagenesis (1977), mutagenesis (short-term or in vitro) testing, in addition to providing valuable information on the risk to future generations, can provide valuable information regarding other toxicological manifestations. Examples are cited stating that there is an "apparent relationship between carcinogenicity and mutagenicity" (McCann, et al., 1975; McCann and Ames, 1976). However, the predictive value of short-term mutagenicity tests for carcinogenicity is currently under investigation, involving numerous efforts to assess the use of short-term mutagenicity tests.

The Subcommittee Report goes on further to state that the utility of mutagenicity test procedures for screening of chemicals for somatic effect, for example, carcinogenicity is not predicated on the assumption that the effect is due to mutations in somatic cells; but "the empirical demonstration of a high correlation between mutagenicity and the effect of concern (carcinogenesis) is a sufficient basis for establishing a role for mutagenicity testing as a predictive tool regardless of the mechanism involved."

There is widespread belief among investigators in the cancer area that DNA damage is involved in the induction of cancer. This is the basis for the supposition that carcinogens might be detected by the consequences of DNA damage in simple systems (Bridges, 1976).

Short term or *in vitro* tests that have had some testing for validation purposes included those referenced by Bridges (1976). Many other validation tests are ongoing (DeSerres, 1977; Dunkel, 1978). Reports are available commenting on the state of the art status of *in vitro* testing for carcinogenesis (Casto, 1977; Kouri and Schechtman, 1977; Conservation Foundation, 1977).

For scientific purposes, justification of the use of short-term tests for the purpose of screening thousands of chemicals for their suspected carcinogenic activity and for the purpose of prioritizing these chemicals for long-term animal bioassay, appears to be adequate. However, the original intent for utilization of these tests was only for these two objectives and not for use as a confirmational test for long-term animal bioassay.

It is inappropriate at this time to attempt to substitute a short-term test for a long-term animal bioassay for at least two reasons:

(1) Validation procedures are not complete and correlations between the test systems have not been adequately performed; and

(2) The outcome of the short-term tests as compared to the long-term bioassay are not biological equivalents. In one case the end point is mutagenesis, in the other case, carcinogenesis. However, one (mutagenesis) may often cause the other (carcinogenesis).

It has also been observed that a carcinogen does not always produce tumors in the same organs in all species. The mouse liver responds more readily than most other tissues with most of the carcinogens that have been tested. Yet it is still predictive for cancer at other sites in other species, including man (Tomatis, 1973; Newberne, 1975).

Another consideration in evaluating a predictive model for human carcinogens is the route of administration. Although the route of administration might not be important in determining whether or not an agent is carcinogenic for research purposes, it is important from a preventive health standpoint. To properly evaluate carcinogenicity, the suspect agents should be administered to animals by the same routes as humans are exposed, namely, via the lungs, gastrointestinal tract, dermally and in some cases intramuscularly, intradermally and subcutaneously. The latter conditions would apply, for example, to those agents such as metal fragments that might become embedded in skin or muscles. In industrial exposures to particulates, oral exposures are frequently as important as pulmonary exposures in as much as the particulates that are trapped in the upper respiratory tract are usually swallowed.

Although in the above discussions chemicals have been given primary consideration as carcinogens, some consideration should also be given to physical agents, e.g., ultraviolet and infrared irradiation and heat. To exclude physical agents from consideration in the regulatory process is unwarranted. To exclude any agent on the basis of its proposed mechanism of action is also unwarranted, since the mechanism is not being regulated, but instead the agent. It is, therefore, recommended that paragraph (1) in section 1990.111 be deleted from the Proposal.

Question 31

In the attempts to develop models for predicting human carcinogens prolonged debates have centered around the type of lesion in animals that must be induced before a chemical can be called a carcinogen. Particular attention has been given to the mouse hepatoma (Butler and Newberne, 1975). Some scientists believe that most mouse hepatomas are not cancers because they do not metastasize, and imply that the mouse hepatoma is, therefore, not predictive. This argument is illogical. In the first place, not all hepatocellular carcinomas metastasize in any species studied, yet they are frequently responsible for the death of the hosts. Of 33 mice that died subsequent to chronic exposures to 4-dimethylaminoazobenzene, 71% died as a result of hepatocellular carcinoma (with ascites and/or anemia) yet pulmonary metastases were infrequently observed (Gellatly, 1975). Metastases are observed in humans in only approximately one-half of patients with hepatocellular carcinomas (Robbins, 1975). In the second place, even the spontaneous hepatocellular carcinomas in mice seldom metastasize. In fact, very few of any of the spontaneous neoplasms in mice or rats ever metastasize. In this way, rodents are more resistant than humans and possibly are not sensitive enough to the induction of cancer as we know it in humans. The reasons for that might also be explained on various factors that modify the ability of tumors to metastasize (Fidler, 1975). Thirdly, for predictive purposes there is no reason why the rodent tumors need metastasize. There need only be a correlation between cancer in man and a neoplasm in animals, and this has already been demonstrated many times.

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He concluded, "We have repeatedly asserted our recognition of the seriousness of any question regarding possible carcinogenicity, and the necessity for careful consideration. It would appear, however, that if the results of the single study under question are so inconclusive as to require such extensive deliberation, even the most extreme estimate of potential hazard to humans under the proposed conditions of use would be extremely minute, if in fact extant."

His letter further concluded that if the mouse study had been repeated after early review of the original study, the results would be available about now.

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EPA COMMENTS ON OSHA CANCER POLICY STRESS AGENCY'S EXPERIENCE WITH FIFRA

Citing extensive experience under FIFRA in regulating carcinogens, the Environmental Protection Agency has expressed its approval of the general thrust of the Occupationa Safety and Health Administration (OSHA)'s Proposed Regulations for the Identification Classification and Regulation of Toxic Substances Posing a Potential Carcinogenic Risk.

However, EPA pointed to what it saw as some serious problems with several aspects of the proposal, particularly OSHA's lack of attention to such factors as exposure level and potency of chemicals and OSHA's decision to require replication of animal tests.

EPA's comments on the OSHA proposal were filed after the deadline for comment, however, OSHA has over a month until its May 16 hearing on the proposal to evaluate the EPA statement (See Feb. 16, Page 18).

EPA's comments noted the Agency's belief that OSHA has taken a valuable step forward and has established a useful approach to dealing with the "grave problems posed by carcinogenic chemicals." While pointing to general support for the way that OSHA dealt with generic issues in its proposal, EPA pointed out that one area where EPA and OSHA policies may be perceived as differing is in the treatment of factors such as the amount of exposure to a chemical and the potential potency of the chemical as a carcinogen.

The agency observed that although OSHA may plan to use estimates of exposure and potency in setting regulation priorities, the proposal does not make clear whether OSHA will do so. EPA explained that its policy, developed largely during its regulatory efforts on pesticides, is to "consider the degree of public exposure and the potency of a potential carcinogen, as well as the reliability of the relevant data, in determining whether to regulate a substance as well as the degree of regulation required." The agency comment admitted, however, that these differences in approach may be due not to disagreement on the underlying issues, but rather to the differences in the missions assigned to EPA and OSHA, adding "for example, it may be that OSHA's classification system is based, in part, on the assumption that exposure to workers is nearly always significant in industrial situations."

Discussing its support of the key regulatory concept embodied in the proposed OSHA regulation -- disposition of important generic issues in this general rulemaking rather than in rulemakings involving individual chemicals or hazards -- EPA elaborated:

"There can be no question that the strategy of foreclosing repetitive debate about such issues is a sound one that serves the public interests, and the courts have recognized the appropriateness of rulemaking to effectuate that strategy. EPA experience in regulating carcinogens, particularly under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) established that immense amounts of time can be consumed in regulatory proceedings concerning an individual chemical relitigating these generic issues. The constant repetition of these extended debates increases the size of the record but does not improve the quality of the deliberations. Fairness and due process are served by ventilation of these issues once. Repetition serves only to delay regulatory efforts and consume resources which may be urgently needed elsewhere. Of course, it is obvious that some opportunity must always be available to raise genuinely new matters or to present substantial new evidence, but EPA agrees that generic issues may otherwise properly be excluded from regulatory proceedings which concern individual chemicals if they are confronted in a general rulemaking."

Serious Agency concern was expressed about the fact that the proposed regulations provide that animal test results generally cannot be relied upon as a sufficient basis for stringent regulatory action unless replicated or supported by short term studies. EPA added:

> "Although the proposal allows use of unreplicated animal tests if 'exceptionally well conducted,' we believe that this may be too great a qualification. EPA policy is that an unreplicated test can be an entirely adequate basis for concluding that a chemical must be regulated as a carcinogenic risk. Such tests can often be extremely persuasive evidence that a hazard exists. Moreover, the delay involved in waiting for replication of tests may often be quite substantial, thereby increasing human risk."

EPA also suggested that OSHA should direct additional attention to the matter of setting priorities for controlling hazardous chemicals. The agency said that given the very large number of potentially carcinogenic substances, EPA believes that thought should be given to developing some form of hazard ranking mechanism for the setting of priorities.

In addition, EPA observed that the deadline for OSHA action contained in the proposal may be too ambitious, adding, "based on our experience we fear that OSHA may be putting unrealistic demands on itself." EPA said:

> "Our experience under FIFRA also indicates to us that public input at a very early stage in the process, for example, after a tentative classification decision, could be useful and merits consideration. We are concerned as well, that by basing standards for Category II substances, which have been identified as possible carcinogens, on noncarcinogenic effects, OSHA introduces an illogical element into its system."

Addressing the amount of discretion OSHA intends to use in categorizing chemicals, EPA recommended that if the exercise of this discretion is expected to be very rare, this should be indicated.

In its elaboration on its recommendation that OSHA establish a scheme for setting priorities, EPA said:

"In the preamble to the Proposal, OSHA acknowledges that NIOSH has supplied it with a large list of potential occupational carcinogens, and that some systems will have to be developed to prioritize this list, so that the chemicals on it can be processed over a several year period in an orderly manner. However, without modifying the procedural scheme in the Proposal to expressly provide for prioritization, OSHA runs the risk of having outside groups dictate how it will attack this list -- and the order in which it will consider other potential occupational carcinogens -- by the simple expedient of filing written petitions. The way the system is currently set up, the failure to respond to such a petition by setting the regulatory machinery set out in the Proposal in motion could result in litigation, and a court order requiring OSHA to honor its commitment. Responsiveness to petitions from outside groups is of course a necessary and important function of government. However, the prerogative to decide when a problem is going to be looked at must be retained by the regulatory agency. Otherwise it will inevitably find itself expending its limited resources attempting to solve a set of problems which the agency may well find to be less important than other problems that it is aware of."

EPA suggested that the only sound solution to this problem is to create an additional step in the procedural scheme, in which OSHA considers a "candidate" toxic substance, and makes a decision concerning when it will commence processing the chemical through the system set up by the proposal.

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"RULEMAKING" PROCEDURES MAY REPLACE ADVERSARY PLEADINGS FOR RPAR APPEALS

Cross examination would be discouraged and public comment encouraged in procedures the Environmental Protection Agency may propose for handling challenges of its decisions under the rebuttable presumption against registration (RPAR) process.

A new draft of the procedures in EPA's Office of General Counsel provides for doing away for the most part with "trial type" procedures, as well as with the "alternative" procedures spelled out in an earlier draft (See Dec. 21, Page 15).

The new draft procedures would rely more on the traditional methods of rulemaking -- scientific experts on the EPA staff proposing and public comment disposing -- rather than on traditional adversary trial procedures.

EPA pledges in the draft that "the public will know what (RPAR) decisions are based on and will be able to question them." A second major intent of the draft regulations would be to: "... Establish a mechanism for shortening hearings by making policy decisions, and decisions resting on factual premises that are not legitimately in dispute, at the beginning of the formal hearing process where they can be relied on subsequently, rather than at the end of the process after a lot of time and effort have been wasted."

A preamble to the new draft outlines the steps for registration and appeal as a five-step process: