

ENVIRONMENTAL CANCER--A REPORT TO THE PUBLIC

October 12-13, 1977

Auditorium, School of Public Health,
University of Texas Health Science Center

6905 Bertner

Day I

9:00-9:15

Welcome

Betty Anderson, President, League of Women Voters of Texas
Brenda Gehan, President, League of Women Voters of Houston
Dr. Marcus Key, School of Public Health
Dr. Roy Gottesman, Tenneco Chemicals

I. Introduction

9:15-10:00 AM

John Weisberger, Ph.D., American Health Foundation

10:00-10:15 AM

--Questions--

10:15-10:25 AM

-Break-

II. Test Procedures

10:25-10:50 AM

Charles Shaw, M.D., M.D. Anderson Hospital and Tumor
Institute, Carcinogenesis Center, Overview

10:50-11:15 AM

B. R. Brinkley, Ph.D., Baylor College of Medicine,
Cell Transformation

11:15-11:40 AM

A. Clark Griffin, Ph.D., M.D. Anderson Hospital and Tumor
Institute, Animal Studies/Standard Assay

11:40-12:05 AM

John J. Costanzi, M.D., University of Texas Medical
Branch-Galveston, Early Detection in Man

12:05-12:20 PM

--Questions--

12:30-2:00 PM

-Lunch-

Commissioner R. David Pittle, Ph.D., U.S. Consumer Product
Safety Commission, Consumer Product Safety with Special
Attention to Products with Benzene

III. Statistics and Epidemiology

2:00-2:25 PM

Patricia Buffler, Ph.D., University of Texas Medical Branch-
Galveston, Important Statistical Considerations and
Problems in Evaluating Health Effects (emphasis on
Vinyl Chloride and Benzene)

2:25-2:50 PM

David P. Discher, M.D., San Jose Medical Clinic, Important
Epidemiological Considerations and Problems in Evaluating
Health Effects (emphasis on Vinyl Chloride and Benzene)

2:50-3:05 PM

--Questions--

3:05-3:15 PM

-Break-

IV. Cost Benefit/Risk Assessment

3:15-3:50 PM

J. Gustave Speth, LL.B., Member, Council on Environmental
Quality, An Overview from Government Perspective with
Emphasis on Risk

3:50-4:05 PM

--Questions--

4:05-4:30 PM

Charles Barden, P.E., Immediate Past Director, Texas
Air Control Board, State Government Perspective

4:30-4:55 PM

Tom Downs, Ph.D., School of Public Health, Industry
Perspective

4:55-5:20 PM

John J. Sheehan, Legislative Director, United Steelworkers,
Labor Perspective

5:20-5:30 PM

--Questions--

DINNER FOR SPEAKERS, STEERING COMMITTEE

Day II

9:00-9:10 AM Bill Stewart, P.E., M.S., Director, Texas Air Control Board, Welcome
 9:10-9:40 AM Carlo Tamburro, M.D., University of Louisville School of Medicine, Health Effects of Vinyl Chloride
 9:40-10:10 AM Susan Wyatt, M.S.P.H., Environmental Engineer, U.S. Environmental Protection Agency, Control Status of Vinyl Chloride

10:10-10:25 AM --Questions--

10:25-10:35 AM -Break-

VI. Benzene, Present Findings Concerning Health Effects

Donald Lassiter, Moderator

* 10:25-10:50 AM Joseph Wagoner, Asst. to the Secretary for OSHA, Department of Labor, Government Overview, Control Status

10:50-11:25 AM Irving R. Tabershaw, M.D., Professor Emeritus, Occupational Medicine, University of California at Berkeley, Industry Perspective

11:25-11:55 AM Sylvia Krekel, Oil, Chemical, and Atomic Workers International Union, Labor Perspective

11:55-12:15 Noon --Questions--

-Lunch-

VII. Delineation Present Regulatory Development Process (Each speaker will cover the mandate of the present legislation, research data compilation and evaluation, regulation formation, risk assessment and cost/benefit components)

1:45-2:10 PM James R. Janis, Acting Director, Standard & Regulation Division, U.S. Environmental Protection Agency

2:10-2:35 PM Roger R. Wallis, Deputy Director, Standards and Regulations Texas Air Control Board

2:35-2:50 PM --Questions--

2:50-3:00 PM -Break-

VIII. Advocacy

3:00-3:20 PM Pamela M. Giblin, Attorney, Advocacy Process in Regulation Development

3:20-3:40 PM Becky Fossdal Moon, League of Women Voters, Citizens Views and Concerns with Regard to Regulatory Process

3:40-4:00 PM Curtis W. Smith, Ph.D., Chairman of Benzene, Shell

4:00-4:15 PM --Questions--

ADJOURN

The proceedings of this Conference will be published by Texas Reports on Biology and Medicine.

Roy T. Gottesman, Ph.D., Tenneco Chemicals, Inc. Current: Director, Environment and Regulatory Affairs Department, Tenneco Chemicals, Inc; Responsible for a multi-faceted program involving environmental science, occupational medicine and health, industrial hygiene, toxicology, product safety and regulatory affairs; senior member, American Chemical Society; member, Association of Research Directors; Fellow, American Institute of Chemists; Fellow, New York Academy of Science; member, Phi Beta Kappa. Previous: doctorate in Organic Chemistry, Rutgers.

John H. Weisburger, Ph.D., Vice President for Research, American Health Foundation. Current: Director, Naylor Dana Institute for Disease Prevention, AHF; Research Professor of Pathology, New York Medical College; Research on the etiology of the major human cancers: in particular, cancers in the digestive tract, the endocrine-related organs, and the respiratory tract; broad background in the area of chemical carcinogenesis, the mechanism of action and metabolism of chemical carcinogens, the bioassay of chemical carcinogens, and the interrelationships between mutagenesis and carcinogenesis.

INTRODUCTION--ENVIRONMENTAL CANCER-REPORT TO THE PUBLIC: Current data show that 80-90% of human cancers stem from environmental causes. The basis for this statement hinges on a consideration of 1) changes in incidence of specific cancers such as cancer in the lung, breast, stomach, colon, and the like, with time; 2) the incidence of these cancers in various parts of the world; and 3) the changes in incidence when people move from one area to another.

Historically, cancer was first related to environment in people exposed to specific products like soot or coal tar and, later, to chemicals, in an occupational setting. This demonstration has opened the field of environmental carcinogenesis. Thus, the public in general and even experts are under the impression that cancer in people is due to specific chemicals like those in the special case of occupational exposure.

To provide perspective, we can state that occupational exposure in industrial societies accounts for 1-5%, at most, of all cancer cases. Most of the human cancers, including those at the main sites, namely cancer lung (98,000 new cases in 1977 - American Cancer Society data), stomach (23,000 new cases in 1977), large bowel (101,000 new cases), pancreas (21,800 new cases), breast (89,000 new cases), prostate (57,000 new cases), ovary (17,000 new cases), and endometrium (27,000 new cases), in most instances, relate not to specific chemicals in the environment but to our lifestyle.

People are aware that one aspect of our lifestyle, smoking of cigarettes, leads to lung cancer and, in fact, some other cancers such as larynx, esophagus, and oral cavity (together with excessive usage of alcohol beverages) and, in part, urinary bladder. People are not aware that the other major factor leading to disease stems from the diet. Cancer of the stomach has declined here but is high in Japan, Central and Latin America, and Eastern and Northern Europe and is ascribed to specific factors, in particular, the absence of foods containing Vitamin C on a year round basis. The other cancers mentioned stem, in part, from diets containing high fat levels such as those in the Eastern world, in contrast to diets eaten in Japan, where cancer of the colon, breast, prostate, and ovary have far lower incidence than in the West.

While much more research is required to acquire full comprehension in this complicated field, it would seem that the public can help themselves in preventing or avoiding specific cancers by minor alterations in lifestyle. Thus, public action even at this time would prevent the major human avoidable cancers.

Charles R. Shaw, M. D., Professor of Biology, University of Texas
M. D. Anderson Hospital. Chaired National Academy of Sciences
Committee on Public Information in the Prevention of Occupational
Cancer, 1975-1977. Diplomate of the American Board of Psychiatry
and Neurology. Member of the Environmental Mutagen Society.
Also member of the American Society of Human Genetics.

B. R. Brinkley, Ph.D., Professor, Department of Cell Biology, Baylor College of Medicine. Previous: Professor and Director of Cell Biology, The University of Texas Medical Branch-Galveston; Assistant and Associate Biologist, M.D. Anderson Hospital and Tumor Institute.

TEST PROCEDURES--TUBULIN AND ACTIN IMMUNOFLOUORESCENCE: AN ASSAY FOR CELL TRANSFORMATION IN VITRO: Cells transformed in vitro by either chemical or viral agents usually display a variety of distinct but dissociable properties, including alterations in shape, cell surface changes, loss of density-dependent growth control, loss of anchorage-dependent growth, and reduced serum requirements. In addition, increased mobility of cell surface receptors and redistribution of the receptors within the plane of the cell membrane has been described as a consistent property of many transformed cells. Recent studies in our laboratory and elsewhere have identified specific alteration in cytoskeletal elements, including cytoplasmic microtubules (Mts) and microfilaments (Mfs), that may account for several of the previously mentioned tumor cell properties. Using monospecific antibodies made against 6S bovine brain tubulin as immunofluorescent probes, we have identified an extensive cytoplasmic microtubule complex (CMTC) in a variety of nontransformed cells in vitro. The CMTC consists of a delicate network of fine fluorescent filaments that radiate out from a central focus within the cytoplasm (the centrosphere) toward the cell surface. These filaments, believed to be individual microtubules, are seen to terminate near the plasma membrane. This would be expected if they are associated with receptor complexes on the cell surface, as some studies have indicated. Colcemid and other microtubule inhibitors reversibly abolish the CMTC.

When transformed cells are examined by tubulin immunofluorescence staining, the CMTC is usually undetectable or greatly diminished. When microtubules are present, they appear as short, randomly oriented filaments. The striking differences in immunofluorescent patterns between normal and transformed cells have enabled us to correctly identify transformants in mixed cell populations containing both normal and malignant cells.

Similar alterations are observed in the structure and distribution of cytoplasmic actin-containing microfibrils (Pollack et al., Proc. Nat. Acad. Sci. USA 72:994-998, 1975). Normal fibroblasts display numerous parallel bundles of actin filaments (stress fibers) whereas transformed cells have very few stress fibers. We propose that tubulin and actin immunofluorescence patterns can be used in conjunction with other assays in short-term screening of chemical carcinogenesis.

A. Clark Griffin, Ph.D., American Cancer Society Research Professor of Biochemistry. Current: Member, Biochemistry Department, M.D. Anderson Hospital and Tumor Institute; Research in carcinogenesis, protein synthesis, nucleic acids, mechanisms of cancer induction, and cancer prevention. Previous: Faculty, Biochemistry, Stanford University School of Medicine; Chairman, Biochemistry Department, Baylor University College of Medicine; Ph.D., University of Wisconsin.

TEST PROCEDURES--ANIMAL STUDIES: A brief historical account of the involvement of chemicals in the origin of tumors in man and animals will be presented. With increasing indication that many chemicals may cause cancer in several animal species, the U.S. Public Health Service has compiled these findings into several volumes entitled: Survey of Compounds which have been Tested for Carcinogenic Activity. Factors related to the development of a standard test on assay procedure will be reviewed which will include: animal species, strain, age, sex, mode and dosage of test chemicals, time factor, pathological evaluations, data analysis, cost factor and final evaluations and recommendations. Several animal model test systems will be reviewed and problems related to the testing for chemicals in the air, water and the environment will also be considered.

John J. Costanzi, M.D., Associate Professor of Medicine, Department of Internal Medicine, The University of Texas Medical Branch-Galveston.

TEST PROCEDURES--SCREENING TESTS FOR CANCER: Unfortunately, there is no known test that will predict or detect very early cancer except the well-known Pap smear for carcinoma of the cervix in women. In general, the best screening test available is a careful survey of high risk patients. Other tests which have come into widespread use over the past four to five years have included serum test for carcino-embryonic antigen, alpha fetoprotein determinations and various other immunoserological tests. Other screening tests, such as the Makari test, are currently being investigated.

One of the known events with most patients with cancer is a depression of the immune system. It is therefore reasonable that if certain parameters of the immune system are depressed, this patient may be more prone to develop cancer. Many efforts are being examined along these lines.

This discussion will encompass all of these points and elaborate on the best methods for screening patients at risk for developing cancer.

R. David Pittle, Ph.D., Commissioner, U.S. Product Safety Commission.
Current: Member, U.S. Product Safety Commission. Previous: Assistant Professor of Electrical Engineering and Public Affairs, Carnegie-Mellon University; President, Alliance for Consumer Protection; Member, Federal Executive Board Consumer Services Committee; Member, Consumer Advisory Committee, Pennsylvania Insurance Department; Member, Consumer Relations Panel, National Association of Homebuilders, Consumer Federation of America, American Council on Consumer Interests, Consumer Standards Committee of the American Society for Testing and Materials, and the American National Standards Institute.

Patricia A. Buffler, Ph.D., Assistant Professor of Epidemiology,
The University of Texas Medical Branch-Galveston. Current: Assistant
Professor, University of Texas at Houston School of Public Health;
Co-Investigator, Development of a Model Cancer Control Program for
Employees in the Chemical Industry; Member, Medical Advisory Panel,
Texas Air Quality Control Board. Previous: Principal Investigator,
Genetic Risks of Vinyl Chloride; Principal Investigator, Epidemiology
of Primary Liver Cancer in Selected Texas Counties; Member, International
Who's Who in Asian Studies, Sigma Xi, Galveston Chapter; Participant,
documentary film, "Occupational Carcinogenesis."

IMPORTANT STATISTICAL AND EPIDEMIOLOGICAL CONSIDERATIONS AND PROBLEMS
IN EVALUATING HEALTH EFFECTS--Outline:

- I. Cancer increase - apparent vs. real increase
effect of population changes (aging and growth of
population)
- II. How much of cancer incidence is due to environmental factors? (60-90%) -
how these estimates derived
known environmental etiologies
evidence for environmental causes of cancer (geographic
comparisons)
- III. What to measure? - what health effects are important? (premature
death, morbidity, reproductive outcomes, effects on
offspring-childhood-malignancies)
- IV. Identifying health effects - three basic approaches used in
epidemiologic studies -
descriptive (cross-sectional or ecologic)--examples:
chemical industry countries and cancer
what type of information obtained--interpretation
limitations
case-control (retrospective)--example: primary
liver cancer in selected Texas counties
what type of information obtained--interpretation
limitations
cohort or mortality followup studies (prospectives)--
example: mortality followup
study of VCM exposed cohorts
what type of information obtained--interpretation
limitations

David P. Discher, M.D., Director, Department of Industrial and Environmental Medicine, San Jose Medical Clinic. Current: Specialist in occupational medicine; Responsible for the development of health service programs for industry; Research in occupational health problems.

Gus Speth, LL.B., Member, Council on Environmental Quality, Co-founder and Staff Attorney, Natural Resources Defense Council. Previous: Law Clerk, Justice Hugo L. Black, U.S. Supreme Court; Yale Law Journal; Rhodes Scholar; Author of numerous articles; Witness before Congressional Committees on environmental issues.

Charles R. Barden, P.E. Current: Manager of Air Quality Control, Engineering Science, Inc.; Member, Texas Society of Professional Engineers, Texas Public Health Association, Air Pollution Control Association, American Industrial Hygiene Association. Previous: Executive Director, Texas Air Control Board.

Thomas D. Downs, Ph.D., Professor of Biometry, University of Texas School of Public Health. Current: Adjunct Professor of Mathematical Sciences, Rice University. Previous: Faculty, Biometry Department, Case Western Reserve University; Ph.D. from the University of Michigan.

John J. Sheehan, United Steelworkers. Current: Legislative Director, United Steelworkers.

Bill Stewart, P.E., Texas Air Control Board. Current: Executive Director, Texas Air Control Board. Previous: Texas State Department of Health; General Portland, Inc.; M.S., Environmental Health Engineering, University of Texas.

Carlo H. Tamburro, M.D., Professor of Medicine, University of Louisville School of Medicine. Current: Chief, Digestive Diseases and Nutrition Section; Director, Vinyl Chloride Project; Member, International Association for the Study of the Liver, American Association for the Study of Liver Disease, American Federation for Clinical Research, and American Association of Human Genetics; author of more than 40 publications and contributions to books. Previous: Professor of Medicine/Associate in Oncology/Associate in Pediatrics, University of Louisville.

HEALTH EFFECTS OF VINYL CHLORIDE: Vinyl chloride has been used as an anesthetic agent as well as a basic chemical for plastics manufacturing. Vinyl chloride's previously unknown carcinogenic capability appears to be related to the body's ability to convert it from a non-toxic or minimally toxic chemical to a toxic and, with prolonged exposure, cancer-forming agent. Early exposure in animals causes body cells to make adaptive changes which may prepare them for malignant transformation and which appear to precede evidence of morphological injury. These findings appear to occur before a low-grade chemical injury occurs. Vinyl chloride chemical injury in man appears to follow the same pattern. Present clinical data in humans now demonstrate evidence of pre-cancer injury and cancer transformation of various types of cells in different organs of the body. Manifestations of pre-cancerous injury to organs other than the liver (such as the lung, heart, spleen, brain, and lymphatic system) may also be occurring and require further investigation.

Early detection of these pre-cancerous chemical injuries requires a prospective on-going system of surveillance and the development of diagnostic methods which can identify specific caustic agents in the presence of non-specific injury. Such a systematic approach has been developed and is now in operation. Its initial achievements appear to be the foundation for future success in controlling the health effects of industrial chemicals.

Susan Wyatt, M.S.P.H., Environmental Engineer. Current: U.S. Environmental Protection Agency; development of standards for atmospheric emissions of vinyl chloride. Previous: M.S.P.H. from the Environmental Sciences and Engineering Department, School of Public Health, University of North Carolina.

CONTROL STATUS OF VINYL CHLORIDE: The Environmental Protection Agency (EPA) listed vinyl chloride as a hazardous air pollutant in December, 1975, and promulgated a national emission standard for it under the authority of section 112 of the Clean Air Act on October 21, 1976. On November 19, 1976, the Environmental Defense Fund (EDF) petitioned the United States Court of Appeals for review of the standard. On March 24, 1977, EDF and EPA moved to dismiss the court proceedings in view of a settlement agreement requiring EPA to propose certain amendments to the standard. These amendments to the standard were proposed on June 2, 1977. Since that time EPA has received numerous and adverse comments from the industry on the proposal.

The main issue involved is how carcinogens should be regulated under section 112 of the Clean Air Act. Section 112 of the Act requires that emission standards be set "at the level which in the judgment of the Administrator provides an ample margin of safety to protect the public health from such hazardous air pollutants." This requirement appears to assume that each pollutant regulated will have a threshold level of effects below which no health effects will occur. It has not been possible to determine if there is a threshold level of effects for vinyl chloride and it is not certain that such a threshold may be determined in the near future. In the absence of strong evidence to the contrary, then, the only level of vinyl chloride which would appear to be absolutely protective of health is zero, which may be achievable only by banning vinyl chloride emissions completely. That, in turn, would require closing the entire industry. EPA has decided that the costs of eliminating the industry are too high and has instead developed standards which require emission reduction to the lowest level achievable using technological means.

Donald V. Lassiter, Ph.D., Environmental Health Associates. Current: Development of cancer control monographs for NCI. Previous: Staff assignments with NIOSH and OSHA; Represented the U.S. as member, U.N. Committee on Occupational Cancer; Initiated and directed Occupational Cancer Control Program for OSHA.

Joseph Wagoner, S.D.Hyg., Special Assistant for occupational carcinogenesis in the Office of the Assistant Secretary of Labor, Occupational Safety and Health Administration (OSHA). Current: President, Society for Occupational and Environmental Health. Previous: Epidemiology Branch, National Cancer Institute; National Institute for Occupational Safety and Health; doctorate from the Harvard School of Public Health.

Irving R. Tabershaw, M.D., Consultant. Current: Editor, Journal of Occupational Medicine; Consultant in occupational medicine. Previous: Professor, Occupational Medicine, University of California, Berkeley; Service in government, industry, insurance, and academia.

BENZENE--PROTECTION FROM ADVERSE HEALTH EFFECTS OF BENZENE: Acute exposures to high levels of benzene produce central nervous system symptoms. Chronic benzene poisoning, that is, exposure to low levels over a long period of time, has a myelotoxic effect with a diminution in the red and white blood cells and platelets. In severe chronic exposures aplastic anemia may result, with death as the ultimate consequence.

The issue from the regulatory standpoint is whether or not benzene will induce leukemia (cancer of the blood). OSHA's policy is to make a standard as low as possible if a chemical is demonstrated to be a carcinogen. However, no clear-cut evidence exists to conclude that benzene in lower doses by itself is leukemogenic. This conclusion is based on three kinds of evidence: animal experimentation, clinical experience, and epidemiologic studies. The only conclusion permitted from this evidence is that benzene may be considered a suspect leukemogen at high doses.

Experience to date demonstrates that the present standard of 10 ppm provides adequate protection for the worker from acute and chronic effects. Hence, OSHA's proposal to reduce this standard to 1 ppm is unjustified. However, OSHA's proposal to include monitoring provisions will afford a further measure of protection since benzene-induced effects on the blood are reversible and will provide data upon which re-evaluation of the standard can be based in the future.

Sylvia Krekel, Oil, Chemical, and Atomic Workers International Union.
Current: Occupational Health Specialist for OCAW; Active in drive
to gain a strict standard on benzene exposure.

James R. Janis, Acting Director, Standards and Regulations Evaluation
Division, U.S. Environmental Protection Agency. Current: Chairman,
Regulation Development Work Group for OSHA, EPA, FDA, and Consumer
Product Safety Commission.

Roger R. Wallis, Deputy Director for Standards and Regulations Program,
Texas Air Control Board. Current: Member, National Governors Conference
Clean Air Task Force, Air Pollution Control Association. Previous:
Texas State Department of Health.

Pamela M. Ciblin, Attorney-at-law. Current: Attorney, McGinnis, Lochridge and Kilgore; Member, Board of Directors of State Bar Environmental Law Section. Previous: Chief Counsel, Texas Air Control Board; J.D., University of Texas Law School.

Becky Fossdal Moon, League of Women Voters. Current: Member, U.S. Environmental Protection Agency Advisory Committee for Toxic Substances; Member, League of Women Voters-U.S. Environmental Quality Committee. Previous: Air Quality Chairman, League of Women Voters of Houston; Member, Board of Directors, League of Women Voters of Houston; Chairman, Air Quality, League of Women Voters of Texas.

C. W. Smith, Ph.D., Shell Oil Company. Current: Consultant, Health, Safety and Environment, Shell Oil Company. Previous: Worked with the trade associations developing reactions to OSHA standards, especially with the MCA on benzene; Represented the MCA in meetings with the Environmental Protection Agency to develop regulations under the Toxic Substances Control Act; doctorate in Organic Chemistry from the University of Illinois.

SYNOPSIS

Responsible industry as represented by the Manufacturing Chemists Association (MCA) accepts the need for regulation and is prepared to work with others in its development. For workable, cost-effective regulation, there needs to be effective interaction between the regulatory agency, industry, and the public. Examples are cited where these three groups have worked together, but at arm's length, productively and where problems have developed when regulations are written without an understanding of the industry to be regulated. This need for input by industry is acute because there are very few people with industrial background in the agencies and because, in general, the agencies have inadequate technical strength. Mr. John Quarles, former Environmental Protection Agency (EPA) Assistant Administrator over the Toxic Substances Control Act (TOSCA), pointed out the need for greater technical strength in the Office of Toxic Substances (OTS) in his talk during the first public hearing on regulations under TOSCA. Mort Corn pointed out the same need in Occupational Safety & Health Administration (OSHA) in his review at the end of his term as Administrator of OSHA.

From personal experience, the author presents the picture that we are faced with a tremendous task of testing and regulating existing and new chemicals, and that industry is prepared to do whatever is reasonable to protect health and the environment. In particular, industry accepts the need for rational regulation and welcomes the opportunity to work with governmental agencies and the public in its development. Furthermore, because industry has the knowledge of what is involved and will be responsible for implementing the testing and regulations, it has a unique contribution to make. By the examples cited, he hopes to have convinced you that arm's-length cooperation has been productive and that to attempt to develop regulation without their effective participation results in waste motion.

Summary: C.W. Smith, Consultant
Health, Safety & Environment
Shell Oil Company

On October 7 Dr. Joseph Wagoner of OSHA, due to freeze on travel by the Department of Labor, informed us that he will not be able to attend the Conference. Dr. Peter F. Infante of NIOSH has agreed to attend in his place for the October 13 presentation. Day II, Section VI--10:35 am.

Peter F. Infante, D.D.S.--Dr. Public Health in Epidemiology from the University of Michigan School of Public Health.
Current: Epidemiologist engaged in research with Industry-wide Studies Branch NIOSH Cincinnati Ohio.

Version
10/10/27

PROPOSED AMENDMENTS TO THE NATIONAL EMISSION STANDARDS
FOR VINYL CHLORIDE

The national emission standards for vinyl chloride promulgated in October of 1976 evolved from early and open discussions between EPA, the public and industry.

October 1, 1974,
Following promulgation of the OSHA standard of 1 part per million to protect workers from vinyl chloride and after extensive discussions with industry and others, EPA produced five reports¹⁾ relating to prospective vinyl chloride air quality standards. During evolution of these reports, EPA offered industry and others opportunity to discuss and comment on the reports. Following further intensive study and interaction with technical people from industry and other interested parties, EPA proposed a standard for vinyl chloride emissions on December 24, 1975, (40 FR 59532). Open public hearings were then held. Clearly an open process was followed in arriving at the existing standard, although there

was considerable dispute as to the need and justification for the stringency of its provisions. Differing views within government also were expressed and available to the public. For example, in a letter to EPA dated March 4, 1976, the Deputy Assistant Secretary for Environmental Affairs, Department of Commerce stated in commenting on the EPA's draft environmental impact statement:

- "that the need for such stringent requirements contained in the statement have not been justified"
- "when the results of available studies have been examined, it is apparent that no concrete adverse human effects outside the plant boundary can be or have been related to present emissions of vinyl chloride"
- "there is no evidence to support that there is a substantial risk and that severe illness or death will occur among populations in areas adjoining vinyl chloride plants".

Despite the dispute as to required stringency, a workable standard was evolved which was cost effective in several respects. Despite the dispute, industry pledged to meet this technology-stretching standard going so far as to urgently commit substantial capital and personnel to the task in the interest of getting on with the job of decreasing emissions.

Didn't require
oxygen substitution

extensive in standard development over a ~~one~~^{two year} period and
Surprisingly, this open and interactive process involving all parties
at interest was followed in only six months by proposed amendments which:

- were advanced before measures required by the existing standard have been fully implemented or their effectiveness measured,
- were not justified by any new toxicologic or medical evidence showing need for change,
- are not cost effective,
- excluded open participation by all parties at interest during their evolution.

In advancing the existing standard, EPA calculated that the exposure of the 4.6 million people living within a 5 mile radius of VCM and PVC plants would be decreased from 17 parts per billion in air to less than 2 parts per billion. By June of 1975, EPA had completed extensive surveys of vinyl chloride concentrations in air surrounding three different plant complexes. Findings were that concentrations beyond only 1000 meters averaged less than 5 parts

per billion. This was more than a year before the standard was promulgated! Around Shell Chemical Company's Norco plant, air concentrations beyond 1000 meters averaged only 1.3 parts per billion; ninety percent of the measurements were below 1.6 parts per billion. It is apparent from this data that levels were below those contemplated by EPA before implementation of the controls required by the existing standard. Considering this, it would seem unconscionable to propose tighter standards without a showing of need before the existing standard was fully implemented and its effectiveness measured. In a memo to the Administrator dated May 23, 1977, the Assistant Administrator for Research and Development commented "The amendment states the effects of reducing total vinyl chloride emissions is less than one percent." "The basis for these calculations is unclear and should be made explicit." "If this statement is true, the net benefit of this amendment is questionable."

Recent regulatory proceedings on vinyl chloride contrast vividly with the extensive, open and interactive process followed in developing the standard. On November 19, 1976, EDJ filed a Petition for Review of the Standard. The SP9 and two companies filed motions to intervene December 9, 1976. Surprisingly EPA opposed these routine motions to intervene as a matter of right. The court approved the interventions January 18, 1977. Starting early in January 1977, EPA began private negotiations with EDJ to dispose of the Petition for Review. These negotiations excluded all other parties despite the court approved motions to intervene and repeated requests to be included. The closed negotiations continued through mid February and ended in a formal agreement between EPA and EDJ. The court dismissed the proceedings between EDJ, EPA and SP9 as an intervenor March 24, 1977 without SP9 having participated despite its court approved right to do so. against unsupported charges

Incredibly, EPA abandoned its obligation to publicly defend ~~the~~ publicly promulgated standard as an expedient to settle with EDJ. Moreover, EPA agreed in the settlement to incorporate explicit privately negotiated terms in amendments to be proposed no later than June 1, 1977. The settlement provided also that if final action by EPA departed significantly from the terms set out, EDJ reserved the right to petition the court for review of that action. In effect EDJ, with EPA's concurrence, promulgated proposed amendments to a publicly developed standard yet to be fully implemented without participation by the affected public and industry without a showing of need.

Also incredible was the apparent lack of involvement of the Assistant Administrator and Administrator in so important an issue before the settlement had been agreed. A memo from the Office of Enforcement to the Administrator dated May 18, 1977 contains the astounding first paragraph:

"Because the Agency has already been committed to the subject Proposed Amendments by a court stipulation in the form of a "Joint Motion to Dismiss" the petition for review of this Agency's promulgation of the National Emission Standard for Vinyl Chloride (EDJ v. Train, C.A.D.C. No. 76-2045) the circulation of this package for concurrence at this point appears to be only a pro forma exercise. This "Joint Motion" was signed by Counsel and filed March 24, 1977, without formal review and concurrence at the Assistant Administrator level."

Recent developments in vinyl chloride regulation must certainly be contrary to positions taken publicly by the Administrator and Deputy Administrator. In the Administrator's

remarks
to the National Wildlife Federation and to the National Association of Manufacturers on March 25, 1977, for example, the Administrator stated:

"During my tenure as Administrator, I intend to do all in my power to improve the performance of this agency. I want the agency's work to be marked by balance and judgment, scrupulous credibility, thorough assessment, and tough but fair enforcement. Our decisions may not always please everyone, but no one will be able to say that we are arbitrary; that we discourage diversity of opinion; and that we do not do our homework."
(Pp. 1-2.)

In that same speech, he also referred specifically to the chemical industry, and to EPA's tasks in regulating certain types of chemicals.

"The fact that evidence exists that a particular chemical may cause harm is not -- in and of itself -- sufficient to warrant a total ban. In the complex technological society in which we live, judgments on risks and benefits must be carefully made. It is essential that EPA approach this regulatory task with objectivity and openness and with scrupulous regard for the facts." (P.8.)

EPA's Deputy Administrator, in her remarks to the Chamber of Commerce of the United States on May 3, 1977, pledged that EPA would embrace "the following simple procedures":

"First, we will sincerely take a long, hard look at every potential regulatory move and ask ourselves whether it is really needed. Second, if we conclude that it is, we will do our best to write it in clear and concise English. Third, we will see to it that public participation and involvement take place from the very start of the regulatory development process. No surprises. Fourth, we will consider economic and social impacts. Fifth, we will favor economic approaches whenever these would seem to work as well or better than regulatory approaches."

Available time and the interests of this audience probably make it inadvisable for me to discuss all of the proposed amendments to the vinyl chloride standard. Our position is that, despite projections and speculations to the contrary by EPA and others, the public was and is not at risk to exposure to vinyl chloride by operatory conditions prevailing at plants even before implementation of the existing standard. No adverse human health effects in communities adjacent to such operations have been found which are related in any concrete way to vinyl chloride exposure. There is solid evidence which has been disregarded by regulators and others to show that there is a no-effect level applicable to vinyl chloride air concentrations and that concentrations to which the public may be exposed are several thousand times lower than these concentrations.

There are, however, at least three provisions of the proposed amendments that you may wish to know about.

(1) It is proposed that an ultimate goal of zero emissions be established. This is neither possible nor necessary. Since there is a limitation to society's resources, it makes no sense to spend these resources where there is no established need and when there are other problems begging attention where spending of resources would bring great benefits.

(2) It is proposed that no new source of vinyl chloride be constructed within 8 kilometers of an existing source, unless emissions of the existing source are reduced so there is no net increase in total emissions. This is an extraordinarily costly proposal having anti-competitive effects as well. Costs of increased capacity will be sizeable, debottlenecking expansions at existing facilities which have been so helpful in past to keep American Industry competitive in world markets may be excluded. There will be a tendency to

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overbuild new capacity to avoid future restraints and smaller companies will be comparatively disadvantaged. Emission/air concentration modeling studies have shown this proposal would cause but a 0.1 part per billion change in air concentrations within the 8 kilometer circle. Considering the public is not now at risk, such a proposal simply is not responsible.

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(3) It is proposed that new plants and, after three years, existing plants limit vinyl chloride concentrations in vents to 5 ppm rather than 10 as required by the existing standard. It is not reasonable to expect that plant systems designed to perform to the 10 ppm limit can be expected to perform to the lower limit with equal reliability. Therefore, this proposal would require further expenditures which are not reasonable considering EPA themselves have stated this "will have the effect of reducing total emissions by less than one percent."

Considering the foregoing, we have recommended to the EPA that the proposed rules be withdrawn in their entirety.