UNIROYAL, Inc.
Oxford Management & Research Center
Middlebury, Connecticut 06749

January 6, 1978

Docket Officer, Docket No. H090
Room S-6212
U.S. Department of Labor
3rd Street and Constitution Ave, N.W.
Washington, DC 20210

Dear Sir:

These comments are directed to the October 4, 1977 OSHA Publication (FR 42, 54148-54246) under the title "Identification, classification and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk."

Uniroyal through its Chemical Division is supporting the efforts of the American Industrial Health Council. I have seen their early drafts and am generally in agreement with their constructive approach and with the content of their statement.

From my vantage point as a member of Uniroyal's Corporate Medical Department and as a member of a number of technical committees of various trade associations and scientific societies, I make the following comments:

(1) OSHA is grossly overestimating the amount of sickness and death caused by exposure to industrial carcinogens. It is my considered opinion that OSHA can accomplish the same benefits at a small fraction of the cost which this proposal would cause.

(2) The concept that once the rule is promulgated it is "foreclosed from reconsideration in future regulating activity" is not sound.

(3) The Secretary should not determine the Category of a "carcinogen." This should be left to a committee of competent experts preferably divorced from the Labor Department.

(4) OSHA should not be locked into a fixed approach. Chemicals vary so widely in properties and nature of exposure that they must be given individual consideration. Some limited grouping may be possible.

(5) OSHA should not regulate beyond knowledge. While it may quiet certain pressure groups for the moment, it can damage American industry with no real benefit in improved health.

OSHA has succumbed to pressure from those who take for granted that a large part of the cancer problem is the result of industrial exposure to carcinogens. While this belief may be sincere it is ill-informed. There is no question but that a few chemicals have caused human cancer. However, the number of such deaths are almost infinitesimal compared with other risks which we accept such as driving cars and smoking.

As a member since 1971 of the MCA Vinyl Chloride Committee I have been intimately involved in events leading to the final vinyl chloride standard. The discussion which follows is presented to show the nature of an industrial carcinogen. Much of the thinking on carcinogens fails to recognize that industrial exposure to a given carcinogen often involves few people. Careful control at the source of exposure can often eliminate the problem at little expense. A gas such as vinyl chloride is so different from a waxy solid such as MOCA that it is unwise to cover them by the same type of regulation.

Vinyl Chloride is the best example of a large volume industrial carcinogen which was regulated by OSHA. Much of the effort which went into the regulation of this chemical should be considered a learning process. I am convinced that the problem would have been taken care of by industry once it was known that VC is a human carcinogen and the 50 ppm limit set in the original ETS would have adequately protected the worker. As it is about 2 people per year have developed angiosarcoma in the U.S. and other types of cancer have not been high in the industry as was originally feared. In fact the University of North Carolina study of Uniroyal's Painesville, Ohio plant showed all types of cancer to be about 40% of the national average. There have been no cases of angiosarcoma or of any other liver cancer among the workers in this plant. This was an ordinary well run plant, not a special showplace plant. A review of the vinyl chloride facts is, therefore, instructive.

Commercial production of vinyl chloride started in the late 30's, grew during the war years and late 40's and expanded almost exponentially thereafter to about six billion pounds by 1974.

The early plants were really pilot plants for the much larger plants built in the 50's and thereafter. As experience was gained and as economics forced more efficient operation exposure almost certainly was reduced. Discovery of VC related acroosteolysis (flattening of the end bones of the fingers) resulted in a further drop in exposure in the late 60's. With the report of angiosarcoma at Louisville by Goodrich in late January 1974, the industry made a concerted effort to reduce every source of exposure. By mid-summer of 1974 most companies had reduced exposure of vessel cleaners to below 50 ppm from probably about 1,000 in the early years. Excursions to tens of thousands of ppm must have been present

in these early years as evidenced by reports of men fainting. OSHA rapidly dropped the limit from 500 ppm to 50 ppm and later to 1 ppm. The cost to reach 50 ppm was not great but to go from 50 to 1 ppm cost the industry tens of millions of dollars. It is my considered opinion that this expense was unnecessary but is possibly excusable as a learning experience in view of the sheer size of the industry. America can ill afford many such learning experiences. It was assumed by many that because of the almost logarithmic growth in the period 1950-1970 so many people were exposed that the rate of discovery would rise astronomically. But this has not happened. In evaluating the data shown on the table which follows it is important to realize that angiosarcoma due to VC exposure has been found only among people who were very heavily exposed for a period of years.

I have reorganized NIOSH's August 1977 report of confirmed VC related cases so that they are arranged according to date of death (or date of discovery of angiosarcoma in the two men still living). Several facts stand out:

(1) Since 1967 the number of cases of angiosarcoma per year has averaged 2.1.

(2) The rate of discovery has increased only slightly if at all since 1967.

(3) The interval from first exposure to death has increased from 15 in 1961 to an average of 33 years through the first 7 months of 1977.

(4) Because of the stretched interval as exposure was reduced prior to 1974 we will probably continue to see occasional cases until

well after the year 2000.

It is my opinion that the 50 ppm standard would have been adequate and that all OSHA needed to do was make the facts available to the industry with sensible guidelines.

Angiosarcoma Among Vinyl Chloride
Exposed Workers in the United States

NIOSH Case No.*	Year of Death**	No. per Year	Year of First Exposure	Interval		Average Age at Death	
08	1961	1	1946	15		41	
05	1964	1	1944	20		52	
04	1968		1952	16	18.4	43	47.2
07	1968	3	1944	24		45	
10	1968		1951	17		55	
16	1969	2	1950	19		41	
12	1969		1949	20		50	
11	1970	1	1946	24	20.8	61	47.6
02	1971	1	1955	16		37	
01	1973		1948	25		49	
23	1973	3	1958	15		50	
03	1973		1945	28		58	
13	1974	2	1944	30	22.6	52	49.2
17	1974*		1955	19		43	
09	1975		1954	21		43	
19	1975*		1943	32		60	
18	1975	4	1954	21		46	
06	1975		1962	13Y	22.8	45	52.2
20	1976	2	1955	21		58	
22	1976		1949	27		52	
25	1977***		1947	30		67	
24	1977	3	1939	38	33	60	64.7
21	1977		1946	31		67	

*Cases 14 and 15 were dropped because pathologists determined they were probably not related to Vinyl Chloride.

**Year of recognition; still alive 1978.

***To August 1, 1977.

Y - This case appears out of line. The other 4 cases average 25.3 years.

The opening paragraph of the October 4th publication entitled "Summary" sets forth the concept that once this proposed rule is promulgated it is "foreclosed from reconsideration in future regulatory activity..." It would be the height of folly to cut off all possibility of reconsideration. New facts will require change. We are still at a very primitive stage in our knowledge of cancer and its causes.

Turning now to the proposed regulation Part 1990, I offer the following brief comments:

Section 1990.103 a. Provides that "Whenever the Secretary receives information submitted in writing by any interested person, concerning any toxic substance, ...he shall....within thirty (30) days publish notice of receipt in the Federal Register." While the reason - to solicit informed comment - is laudable, the overall effect may be harmful. When anyone with a special interest calls the Secretary's attention to any data, however limited or unreliable, (s)he is then bound to publish the allegation in the Federal Register. When a carcinogen is involved such an announcement will be widely cited by the news media. The public has enough real worries without being bombarded continuously by unfounded scare stories about cancer. Such data should first be given to a committee of competent scientists to decide whether the "lead" should be followed up.

b. Classification. This paragraph gives to the Secretary the responsibility of classifying the chemical. (S)He is generally not technically competent to make such a decision nor is it wise for him/her to make it. A committee of competent scientists, knowledgable in various areas of cancer research and completely independent of the Labor Department should do the classifying.

Part 1990.112 requires that if the chemical is classified as a Category I carcinogen the Secretary shall issue an Emergency Temporary Standard, which then locks OSHA into a strict time table. The problem here is that OSHA will often be taking a panic approach on a non-existent or very minor problem. Under the Toxic Substances Act EPA will have a list of all manufacturers of a given chemical. If confronted with real evidence of carcinogenicity, the chemical and allied industries will take the necessary steps if for no better reason than self-interest. Industry will run too great a risk of expensive litigation and compensation costs for "exposed" workers who get cancer whether caused by the chemical or not. The Secretary should wait for the best scientific advice. Simple notification of industry with recommended workable handling procedures will result in virtual elmination of the problem with far less expense and disruption than the procedure outlined by OSHA. A low but measurable limit should be set to enable OSHA to prosecute recalcitrant manufacturers.

OSHA should avoid trying to regulate beyond knowledge. There will never be enough inspectors to enforce unrealistic regulations. When the public does not really believe in a regulation it is virtually impossible to enforce it. It is far better to write realistic regulations only on real problems and then to enforce them even handedly.

Section 1990.113. It should be possible in any public hearing to present any data which sheds light on the subject of the hearing. The hearing officer admittedly should be allowed some freedom to cut off irrelevant information or debate.

Categories

Without going into great detail I would recommend the following general approach:

Category I. Proven human carcinogens. Regulations should be developed with the aid of those most knowledgable about processes of manufacture and use so as to achieve minimum exposure with minimum expense. This has to be done on one chemical at a time because of widely different properties, toxicity, and processes. The number of proven carcinogens is small and it is imperative that OSHA take the necessary time to set meaningful, workable standards.

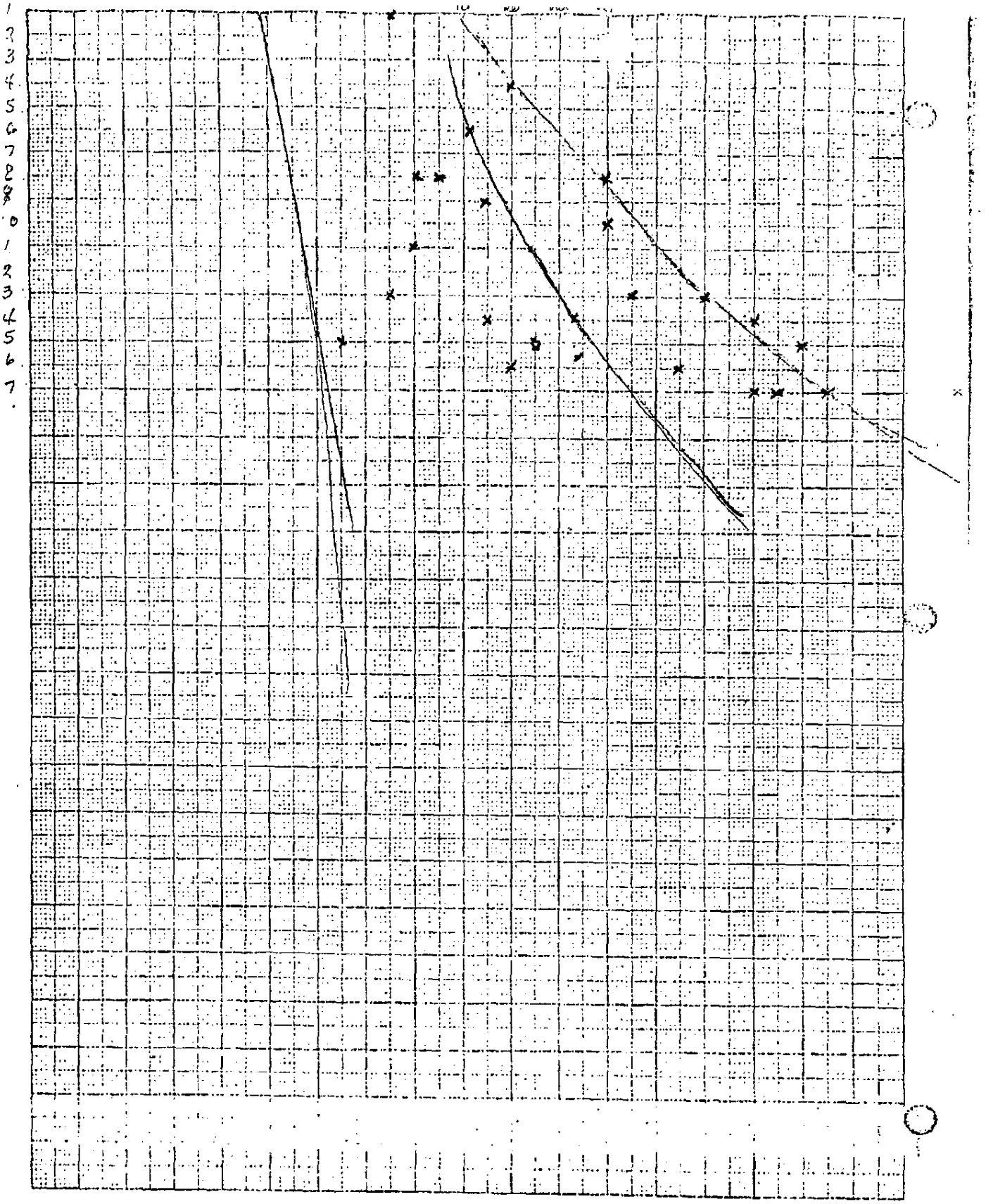
Category II. Suspect carcinogens based on animal studies or suggestive but inadequate epidemiological evidence. The known facts should be put before those handling the chemical and proper research carried out to determine as soon as possible whether it is likely to be a serious human carcinogen.

Category III. Possible carcinogens based on very limited suggestive animal data whether or not backed up by Ames or other in vitro tests. Research should be continued.

Under any circumstances provision for updating should be made as new facts emerge. We must never close the book. Even the ancient Babylonian and Persian kings had to change the "immutable laws" of the Medes and the Persians as new facts came to light.

Respectfully submitted,

Walter D. Harris, Ph.D.
Corporate Industrial Toxicologist



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11 January 1978

To: J. T. Barr
C. E. Blades
R. Fleming
R. H. Schenck
W. H. Smith

From: R. A. Gray, Jr.

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Plastics Corner

Polyurethane Manufacturers Association Enlists in Move To Influence OSHA Policy

By WILLIAM H. LANDER
Journal of Commerce Staff

The Polyurethane Manufacturers Association, based in Chicago, has enlisted in the move to try to encourage the Occupational Safety and Health Administration to adopt a rational, practical and effective policy in its regulations for the workplace.

Ellis Murphy, executive secretary, reports that the PMA is fully supporting the work of the newly created American Industrial Health Council, along with The society of the Plastics Industry and other companies and groups.

Organization of the AICH was described in **The Journal of Commerce** on Nov. 25, 1977 and the plans of the SPI and plastics manufacturers and processors to take a strong position in the Washington hearings starting April 4, 1978 were described on Dec. 22, 1977.

"We will be following the activities of the American Industrial Health Council closely and are committed to keeping our members informed and urging them to provide data when such requests come, and to contact their senators and representatives," Mr. Ellis told this newspaper.

The PMA's legal counsel, Arvid Sather of Michael, Best & Friedrich is serving on the council's legal committee, and Jay E. Meili, a past president of PMA and president of Molded Dimensions Inc., of Port Washington, Wis., will serve on the council's alternatives committee.

Mr. Ellis, along with the current PMA president — George Kilbride who is president of Mandrels, Inc., in Louisville, Ohio — and William Stahr, PMA vice president, of Dayton Coatings & Chemicals, division of Whittaker Corp., will also be following activities of the associations committee of the council.

PMA's current treasurer, Gene Huber, vice president of engineering for Sweco Inc., is following the work of the council's public relations committee.

"When the hearings start, PMA plans to be there to provide testimony and will also take along some expert witnesses. "We are very much opposed to giving OSHA the right to select 'substitute' chemicals for us. We still object strenuously to signage that includes the world 'cancer'. We also expect to challenge some aspects of the workplace regulations," Mr. Ellis added.

As readers of this column know, when MOCA and other questions affecting the interests of its members arises, the Polyurethane Manufacturers Association does not fool around, but moves in full strength to tackle the problem.

4-988-L-C

OSHA Proposes New Approach to Setting Standards for Suspected Carcinogens

by Jim Foster

While thousands of hazardous substances are being used in the workplace with more being introduced every year, OSHA has completed regulatory activity for only 17. In an effort to escape the slow "substance-by-substance" approach to setting standards, OSHA has proposed a system that would permit standardized responses, in regulatory terms, for suspected carcinogens.

Secretary of Labor Ray Marshall and Assistant Secretary Eula Bingham, head of the Occupational Safety and Health Administration, have announced the first comprehensive proposal for regulating cancer-causing substances. The proposed cancer policy will establish a procedure for identification, classification, and regulation of potential carcinogens in American workplaces. At the outset, OSHA recognizes that 1,500 to 2,000 agents have been identified by NIOSH as being "suspect carcinogens" (HEW Publication No. (NIOSH) 77-149). Yet OSHA has completed regulatory action on only 17.

OSHA recognizes that in regulating occupational carcinogens, many gaps remain in the knowledge of cancer, its causes, prevention, and cure. However, to wait for years to resolve these issues scientifically without some consistent and workable system for the regulation of toxic substances, for which there is evidence of carcinogenic potential to humans, would be inconsistent with OSHA's statutory obligations and unacceptable to all concerned.

The new OSHA proposal and broad rulemaking proceeding which will accompany it are intended to establish:

- New procedures and regulatory framework for regulating worker exposures to potential occupational carcinogens.
- Scientifically-based policies to identify and classify such substances.
- Three model standards for use in specific rulemaking involving such substances.

Secretary Marshall noted that "this comprehensive cancer policy represents a major breakthrough for OSHA. Trying to control carcinogenic substances on a case-by-case basis is like trying to put out a forest fire one tree at a time. Instead, we are proposing a systematic way of determining which toxic substances require emergency attention by OSHA.

"This new policy will allow OSHA to respond to threats to worker health with much greater speed and efficiency. This represents another step in our continuing efforts to make OSHA a model regulatory agency. Eula Bingham and her staff are to be commended for their efforts in developing such an important policy." Dr. Bingham pointed to the proposed cancer policy as another indication of OSHA's renewed commitment to protecting American workers from health hazards.

"The sad fact is that more than 1,000 Americans die every day from cancer—370,000 a year. Leading cancer researchers have attributed more than 60 percent of these cancer cases to environmental factors.

"I believe the time has come to implement a comprehensive program to prevent cancer in the workplace."

Dr. Bingham noted that as a result of the proposed rule, OSHA will develop three model standards, incorporating OSHA's views on which protective provisions are generally the most appropriate for different categories of substances. Thus, in a later rulemaking for a specific substance, the only major issues to be resolved would be selection of an appropriate exposure limit and determination of whether OSHA has appropriately classified the substances.

Classifying substances

In classifying each toxic substance encountered, OSHA will rely on evidence from human epidemiological studies, adequately designed and conducted animal studies, or both. The degree of conclusiveness of such data would determine whether the toxic substance in question should be regulated as a Category I or Category II substance. Alternatively, a designation of Category III may be assigned (for a substance requiring further data development) or Category IV (for substances OSHA believes are not found in American workplaces, but otherwise would be regulated).

The proposed rules and system would permit any "interested person" or OSHA itself to present

information to the Secretary of Labor for the classification of any toxic substance. After receipt of such information, the Secretary would publish a notice for public comment giving the contents and source of such information. Generally a 30-day public comment period would be provided following which the secretary would, within 30 additional days, publish a notice classifying the substance as Category I, II, III or IV, and explaining his decision.

OSHA proposes to classify as Category I those substances whose carcinogenicity has been established in humans, or in two mammalian species of test animals, or in one species if those results have been replicated. Category II substances would be those whose carcinogenicity has been reported but the evidence is only suggestive, or is positive in only one species and not yet replicated.

Classification of a substance in Category I would trigger the immediate issuance of the model emergency temporary standard. This would be quickly followed by rulemaking—using the model for proposed permanent standards for Category I substances. At the conclusion of the rulemaking, if the Secretary of Labor determines the substance should more correctly have been classified as Category II, the model for that standard would be followed in issuing the permanent rule.

Under these procedures, rulemaking would be significantly streamlined and speeded because the issues for rulemaking in dealing with Category I substances would be limited to: whether the Secretary correctly classified the substance as Category I; whether he was correct in the determination that the Category I classification should not be rebutted; whether the lowest feasible exposure level was selected or whether there are suitable less hazardous substitutes; whether the substance has unique properties that make provisions of the model inappropriate; and the environmental impact arising from regulation of the substance.

Similarly, an initial classification of a toxic substance in Category II would initiate rulemaking following the model for permanent standards for such substances.

The three model standards to be developed include an emergency temporary standard to be issued, in general, if the toxic substance meets the criteria for a Category I substance; a proposed permanent standard for such substances; and a proposed permanent standard for those substances that meet the criteria only for a Category II designation.

In discussing its proposed system for classifying substances as Category I, II, III, or IV, OSHA notes in the proposal (which appeared October 4 in the *Federal Register*) that there is general agreement among scientific experts on: the practical and ethical difficulties in relying on epidemiological studies in man as the sole basis for establishing the carcinogenic potential of a substance; the validity of studies in experimental animals to establish the carcinogenic potential of a substance; the minimal and optimal experimental conditions for carcinogenic testing; and, the kinds of statistically significant changes in tumor incidence that can be observed in experimental animals and used to characterize carcinogenic potential.

Areas of agreement

In particular, there appears to be general agreement on several major issues on which OSHA is relying in proposing these regulations:

- OSHA relies, in general, only upon results found in testing of mammalian species, especially the rat and mouse, because they are directly relevant to man in carcinogenicity testing.
- Positive results in any mammalian species will, as a general rule, supersede negative findings in another species, and positive animal data generally should supersede human data because of frequent defects in human studies.
- Testing of substances at constant high exposure levels is required to overcome the statistical insensitivity of laboratory bioassays conducted with the limited number of animals than can be practicably handled in laboratories.
- The size of groups of test animals must be sufficiently large to permit statistical evaluation for significance.

OSHA notes that while there is substantial agreement on these five issues which are key to OSHA's classification system, there are six other areas where scientific experts are less fully in agreement. OSHA hopes the rulemaking will lead to full and comprehensive debate on all eleven of the classification factors to permit development of a sound classification system. In the remaining six issues, OSHA proposes:

- To place as much weight on an experiment in which only benign tumors are observed, as when both benign and malignant tumors are induced.
- To interpret the results of experiments

showing increased incidence of tumors in treated animals as evidence of carcinogenicity, regardless of spontaneous cancer incidence, provided that the experiments are sufficiently well-controlled and an increase in incidence is statistically significant.

- To consider development of tumors from dermal, inhalation, injection (with tumors at distant sites) and oral exposures as directly relevant to occupational exposure; conversely, tumors at the site of injection or implantation shall generally be regarded as irrelevant to occupational exposure.
- To place much greater weight on positive results that have been replicated in another study than on a single unconfirmed result.
- That in regulating a Category I toxic substance, the level of exposure to be set will not be a "healthful," "safe," or "no-effect" level, but a feasibility level to be determined by OSHA.
- That although the agency is of the view that "no-effect" levels cannot be set for a carcinogen, there are some who believe it may be desirable to quantify the degree of risk for the purpose of evaluating the expense and level of control considered feasible. Thus, the agency seeks comments on whether such an estimation should be attempted, and if so, the methods to be employed.

In discussing the three proposed model standards, OSHA notes its intention that, apart from the unique substance-specific aspects of these standards as future rulemakings are undertaken, the provisions of the models, as determined in this rulemaking, will not be an issue.

Model comparison

In the notice of proposed rulemaking, OSHA provides a side-by-side comparison of the three models. Each follows a standard format; but, to distinguish between emergency rules and proposed permanent rules for Category I and Category II chemicals, there are some significant differences.

Among the differences are:

- Permissible exposure limits in the emergency temporary rule and in the proposed permanent rule for Category I substances would be set at the lowest level feasible; for Category II substances, exposure levels would be those currently prescribed in OSHA's table of permissible exposure levels, or at lower levels if appropriate; or where no prescribed levels exist, they would be set at an appropriate level based on acute or chronic effects other than carcinogenicity. Also, where the record indicates that suitable substitute substances exist; OSHA can propose to prohibit the use of a Category I substance.
- Only the model for proposed permanent standards for Category I toxic substances requires establishment of a regulated area (access to which must be limited by the employer to "authorized" personnel).
- In prescribing methods of compliance, the most significant difference between the model emergency rule and the proposed permanent rule for Category I substances is that the emergency rule would permit greater reliance on respirators to reduce exposures; the permanent rule would require substantial reliance on engineering and work practice controls to reduce exposures—with respirators permitted only as an interim means of protection.
- Requirements for protective clothing and equipment would be essentially the same except that the proposed emergency rule would not require clothes-changing rooms.
- Requirements for hygiene facilities and practices are essentially the same for all three model proposals except that the emergency rule for any substance not previously regulated by OSHA would not require compliance with the requirements for lunch rooms, shower rooms, and the like.
- The three model standards require the use of signs and labels with the two models for Category I substances requiring the warning of "cancer hazard."
- Recordkeeping requirements are essentially the same except that the model emergency rule would prescribe shorter time periods for retention and would not require a transfer to NIOSH of medical records if the employer ceases to do business.

Other sections of the three models which will be essentially the same include those covering: scope, definitions, exposure monitoring and measuring, housekeeping, waste disposal, medical surveillance (with substance-specific protocols to be filled in for each new substance dealt with), employee information and training, observation of monitoring, effective dates, and appendices. All three models call for three appendices: a substance safety data sheet, substance technical guidelines, and medical surveillance guidelines.

OSHA is seeking full discussion of all of the issues raised by the proposed classification system, the agency's rationale for classifying, the model standards, procedures to be followed, and any other relevant issues raised by the proposed regulation. Comments, data, and views of interested persons are being sought. OSHA has scheduled a public hearing to begin at 9:30 a.m., March 14, 1978, in the Department of Labor Auditorium. Those who wish to present testimony should submit requests to appear, postmarked no later than January 30, 1978, to the OSHA Division of Consumer Affairs, Room N3633, U.S. Department of Labor, Third St. and Constitution Ave., NW, Washington, D.C. 20210.

Requests to appear at the hearing must contain the following: name, address and phone number of each person to appear; the capacity in which the person will appear; approximate time required; specific issue(s) raised by the proposal that will be addressed; a detailed statement of the position to be taken on each such issue; and whether documentary evidence will be submitted, and if so, a brief summary of that evidence.

Copies of all written submissions and requests to appear will be available for inspection and copying in the offices noted above.

In addition to the above requirements, any person intending to testify for more than 15 minutes at the public hearing must submit not later than January 30, 1978, four copies of the full text and all documents to the OSHA Division of Consumer Affairs. Such submissions also will be available for inspection and copying, but at the OSHA Docket Office.

The Environmental Protection Agency

Earlier this year, Douglas M. Costle, EPA Administrator, delineated his agency's approach to dealing with cancer hazards.

The essence of the Toxic Substances Control Act is expressed in three policy statements which appear at the beginning of the Act, Costle said. The first statement is that "adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures." In defining this policy, Congress placed the burden for developing toxic substance information squarely upon the producers of chemical products. Congress intended that the manufacturers and producers take corrective action themselves. It was not written simply to provide a means for EPA to obtain data to support regulatory actions. EPA, of course, will use information developed by manufacturers to back up regulatory actions when necessary. "But if EPA thought its job was to protect human health and the environment solely through the imposition of a wholesale series of individual regulations applicable to individual chemicals and in individual situations, then the real thrust and meaning of this first policy statement would be lost," Costle said.

The second policy statement says "adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment and to take action with respect to chemical substances and mixtures which are imminent hazards." The burden is upon EPA to use its legal authority aggressively in the protection of health and the environment. However, EPA should use that authority only after it has evaluated the facts and determined that an "unreasonable risk" exists. To make this decision, the agency has to understand the toxicity of the chemical substance in question, the population exposed to the chemical, the degree of exposure, and the costs and problems associated with eliminating or limiting that exposure.

The third policy says that "authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation." Again, the burden is on EPA. The Congress intends that EPA exercise judgment in the regulation of chemical substances. It does not intend for EPA to ask for more information than it really needs.

All of the actions which EPA has taken, and will take, are consistent with the three basic policies set down by Congress. "We will see to it that adequate data are developed with respect to the effect of chemical substances and mixtures on health and the environment. We will regulate chemical substances and mixtures which present an unreasonable risk. And we will exercise our authority in a manner so as not to impede unduly or create unnecessary economic barriers," Costle said.

Jim Foster is OSHA chief of news media services.

Common Occupational Carcinogens

AGENT	ORGAN AFFECTED	OCCUPATION
Wood	Nasal cavity and sinuses	Woodworkers
Leather	Nasal cavity and sinuses; urinary bladder	Leather and shoe workers
Iron oxide	Lung; larynx	Iron ore miners; metal grinders and polishers; silver finishers; iron foundry workers
Nickel	Nasal sinuses; lung	Nickel smelters, mixers, and roasters; electrolysis workers
Arsenic	Skin; lung; liver	Miners; smelters; insecticide makers and sprayers; tanners; chemical workers; oil refiners; vintners
Chromium	Nasal cavity and sinuses; lung; larynx	Chromium producers, processors, and users; acetylene and aniline workers; bleachers; glass, pottery, and linoleum workers; battery makers
Asbestos	Lung (pleural and peritoneal mesothelioma)	Miners; millers; textile, insulation, and shipyard workers
Petroleum, petroleum coke, wax, creosote, anthracene, paraffin, shale, and mineral oils	Nasal cavity; larynx; lung; skin; scrotum	Contact with lubricating, cooling, paraffin or wax fuel oils or coke; rubber fillers; retort workers; textile weavers; diesel jet testers
Mustard gas	Larynx; lung; trachea; bronchi	Mustard gas workers
Vinyl chloride	Liver; brain	Plastic workers
Bis-chloromethyl ether, chloromethyl ether	Lung	Chemical workers
Isopropyl oil	Nasal cavity	Isopropyl oil producers
Coal soot, coal tar, other products of coal combustion	Lung; larynx; skin; scrotum; urinary bladder	Gashouse workers, stokers, and producers; asphalt, coal tar, and pitch workers; coke oven workers; miners; still cleaners
Benzene	Bone marrow	Explosives, benzene, or rubber cement workers; distillers; dye users; painters; shoemakers
Auramine, benzidine, alpha-Naphthylamine, beta-Napthylamine, magenta, 4-Aminodiphenyl, 4-Nitrodiphenyl	Urinary bladder	Dyestuffs manufacturers and users; rubber workers (pressmen, filtermen, laborers); textile dyers; paint manufacturers

Source: National Cancer Institute

Labor Secretary Ray Marshall

"It was not too long ago that Dr. Bingham and I announced a redirection of the resources of OSHA. With limited resources we felt that we had to focus on the most serious threats to the health and safety of workers. We announced that we were going after the whales instead of the minnows.

"We are today announcing a new policy that I believe will provide the broad net we need to catch some of the biggest whales—cancer causing substances. For too long OSHA has had to approach each toxic chemical on a substance by substance basis. Trying to control carcinogenic substances on a case by case basis is like trying to put out a forest fire one tree at a time.

"Instead we are proposing a systematic way of determining which toxic substances require emergency attention by OSHA. I believe this comprehensive cancer policy represents a major breakthrough for OSHA—it will allow us to respond to threats to worker health with much greater speed and efficiency.

"This represents another step in our continuing efforts to make OSHA a model regulatory agency. Eula Bingham and her staff are to be commended for their efforts in developing such an important policy."

Dr. Eula Bingham, head of OSHA

"It is particularly significant that OSHA is taking the lead among government agencies in attempting to set comprehensive policies to deal with the problems of cancer. Ours has been the agency chosen by many as the example of bureaucratic nit-picking. But we have pledged our efforts to attack the more serious hazards. There can be no doubt that cancer is among those serious hazards. Moreover, many of the chemicals which we now regard as cancer-causing have first been recognized from the tragic consequences of cancer in the workplace.

"The sad fact is that more than 1,000 Americans die every day from cancer—370,000 per year. Leading cancer researchers have attributed more than 60 percent of those cancer cases to environmental factors.

"So the message is clear. I believe the time has come to implement a comprehensive program to prevent cancer in the workplace.

"Under this new cancer policy, we would classify a substance in one of four categories and then take specific action depending on the classification. A major purpose of the rulemaking is to settle once and for all, the policy issues that will guide OSHA in its future regulation of occupational carcinogens. In the past a great deal of time and energy has been expended in debate over scientific and medical questions about the extent to which available data could be considered as evidence of cancer hazard in man. This prudent public health policy will end the need for such exhaustive debate as we deal with each new substance.

"Also, in the past we have as an agency expended horrendous amounts of time and energy in developing each separate section of the job health standards on a substance-by-substance basis. Through this rulemaking we will develop standard formats and content for the regulations needed to deal with Category I and II substances. So we are proposing model emergency temporary standards for all substances later classified as Category I. That model would be the vehicle for promptly issuing an emergency

rule as soon as the substance involved is classified as Category I or a confirmed carcinogen.

"Another model standard would be used in developing a permanent standard for Category I substances and a third model would be used to develop a permanent rule for the Category II suspect carcinogens.

"While there are a number of differences among the three models, the most significant are in the extent to which worker exposure must be limited.

"The emergency and permanent rules we would issue for Category I substances would reduce worker exposure to the lowest level feasible, while the Category II exposure level set would be sufficiently low to prevent acute or chronic toxic effects in exposed workers.

"Our proposed system, then, will enable us to quickly react to new evidence of carcinogenicity, to properly classify a substance and deal with it in an appropriate regulatory fashion with most of the issues involved settled beforehand. This will, we are confident, markedly speed up our capability to deal with carcinogens and greatly enhance our ability to protect workers.

Grover Wrenn, OSHA health standards chief

"In general, those substances for which there exists an overwhelming consensus based on human and animal data would be placed in Category I. This would include such substances as arsenic, coke oven emissions, benzene, beryllium, chromates, and pesticides such as Dibromochloropropane and kepone. Category II would be for those substances for which there is some "strongly suggestive evidence" like those currently being tested by the National Cancer Institute. Tests of Category II substances would show some positive results that were not conclusive such as evidence in one species but not in another, or evidence in one sex but not the other. Examples would be recently-tested chlorinated hydrocarbon solvents such as perchloroethylene and trichloroethylene.

"Because this proposal does not, in itself, regulate exposure to any specific substance, an economic impact statement would be meaningless. As standards are developed under the new system, impact statements will be prepared. This is not quite a "fill-in-the-blank" proposal, but it will reduce discussion to those unique areas that relate to each substance. This proposal would make a big difference in the time needed for OSHA to respond to newly-discovered health hazards. It would remove all doubt about the method of OSHA's response.

"A preliminary review of the NIOSH list of suspected carcinogens indicates about 100 would belong to Category I. Another 3-400 would belong to Category II, and the remainder would be in Category III or IV.

Occupational Cancer and Workers' Compensation

By
Peter S. Barth

Cancer will kill some 370,000 Americans this year. While cardiovascular diseases will kill perhaps 2.5 times as many persons as cancer, the latter appears to inspire far more fear in the minds of the public. Perhaps this can be explained by the suddenness with which cancer may appear in persons of all ages

as compared to the very gradual deterioration that so frequently precedes death from cardiovascular illnesses. The fear may also be traced to the very high death rates, particularly in earlier years, in persons diagnosed as having cancer. Ultimately, however, the root of the attitude is probably the absolute ignorance of the causes of the disease. Simply put, in the vast majority of cases the cause of cancer is unknown. Further, even in those instances where the disease may be traced to a specific carcinogen, it is not known why the agent induces the disease in some persons and not in others. Thus, for example, it remains a mystery why some persons will develop cancer subsequent to very limited exposure to asbestos, while others necessarily exposed for sufficiently prolonged periods to large amounts of the substance may develop (the potentially deadly) asbestosis but do not develop cancer.

Occupational or industrial cancer occurs where the cause of the disease is largely to be found at the workplace. This definition, regrettably, yields little insight into the magnitude of the problem. Many substances to which one is exposed at the workplace may routinely be found in the environment. At the extreme, prolonged and substantial exposure to sunlight is understood to be hazardous, thus imperiling workers in outdoors activities (sailors, farmers, recreation persons) as well as sun-worshipping non-workers. The carcinogens asbestos, nickel, arsenic, etc. are often found as air pollutants, jeopardizing workers and others indiscriminately, though the extent of exposure will typically be far higher at workplaces. It is only the rarest of situations such as occurred in the case of vinyl chloride where a relatively unusual type of cancer is found and can be unambiguously traced to the workplace.

Since the causes of cancer in most cases have not been established, the extent to which the workplace is responsible for causing the disease cannot be established currently. Compounding the problems of attributing causality is the long latency period of the disease. Thus, persons developing the disease today may have been in contact with the causal agent(s) perhaps 20 or even 30 years ago. This phenomenon also contributes to the enormity of the task of putting the responsibility at the workplace in a legal proceeding.

Not only are there these problems in determining how many cases of cancer are occupational in origin, we cannot even effectively look ahead to see how the problem will develop in occupations where workers are, or have been, exposed to presently known carcinogens. First, data on the number of workers exposed to such agents is extremely crude and sketchy. For example, no distinction is typically made among workers who face occasional or extremely limited exposures, and those routinely exposed, or others who periodically must face substantial doses. Secondly, data are presented, generally, as a stock of workers exposed at a point in time, rather than taking into account labor turnover and, therefore, reporting the number of workers who have been exposed over a time period. Since inter-industry turnover rates vary substantially, the problem is especially tricky. Overall, the task is difficult but until such data are developed we will not be able to gauge accurately the potential scope of the occupational cancer problem.

Finally, it should be noted that our growing ability to treat medically individuals with cancer will partly undermine efforts to identify the extent of the problems of the workplace. A large share of the knowledge linking cancer to specific occupations, industries and/or hazards is the product of epidemiological research, much of which depends upon fatality data and death records. In summary, resolving the issue of the extent to which the workplace contributes to cancer will not be simple, cheap or quick.

Environmental causes

There appears to be wide agreement that perhaps 60-90 percent of cancer is environmentally caused. Breaking this down into its components, e.g., air pollution, diet, cigarettes, drinking-water contaminants, the workplace, etc., yields little agreement, however. That estimates of the extent to which work is responsible vary so widely is due to the problems enumerated above. While it will certainly offend parties on all sides of the debate, it seems reasonable to the author to describe as conservative, an estimate of 1 or 2 percent of the cases as caused by the workplace. Using such an estimate, based on the predicted total of 370,000 cancer fatalities for 1977, some 3,800-7,600 persons will have died from occupational cancer. The author does not believe that these numbers represent the "true" number of cases, but instead are only a very safe, lower estimate on the extent of the problem as measured by fatalities.

There exists an enormous disparity between

the numbers cited above and the extent to which occupational cancer is seen by state workers' compensation systems. Data have been compiled by the author on the extent to which occupational disease claims are paid under state workers' compensation laws. It has been found that a very small number of claims involving occupational diseases generally are seen and processed by state agencies. Data from the states in this area are incomplete and generally difficult to aggregate. Data sources examined included annual reports of state agencies, separate mail and telephone surveys of these agencies, a mail survey of insurers, and data from the National Council on Compensation Insurance, the body that assists insurance carriers in setting rates. Piecing these all together it appears safe to conclude that perhaps fewer than 100 fatality cases a year due to cancer are being compensated. Since the data on non-fatal claims are even more difficult to sort through, e.g., some skin cancer claims may be identified only as "skin disorders," it is far more speculative to guess the extent to which such cases are compensated. Nevertheless, it is absolutely certain that as in the case of fatalities, there is a large gap between claims compensated and any "conservative" estimate of the number of new cases of occupationally-related cancer each year.

The disparity between the incidence of occupational cancer and of cases compensated is likely attributable to a variety of sources. Probably foremost among these is the problem of ignorance. The physician may not know that his patient has been exposed to carcinogens at the workplace, employees may not know even what substances they handle and, moreover, they may not be aware of their potential rights to workers' compensation. The personal agony that individuals and their families suffer when confronted with such a disease can explain why many seek to avoid the extended controversy that is almost inevitable in compensation proceedings.

A second set of problems is that a variety of provisions in various state laws effectively preclude receiving compensation in many cases. For example, some statutes of limitation provisions that may bar claims based on earlier exposures may be reasonable in cases of most occupational diseases, but are not where the latency period is as long as in cancer.

A third factor tending to reduce claims is the enormity of the task of proving that the disease is work-connected. In workers' compensation proceedings the burden of proof rests with the claimant who may have been exposed to the carcinogenic agent decades earlier, and possibly while engaged in a different occupation and/or industry. Simply because a cancer victim has at one time or another been occupationally exposed to such a hazard will hardly suffice in most instances to assure that workers' compensation will be paid. Rather, claimants or their survivors must persuade the authorities that the disease was caused by a hazardous exposure that may have occurred years ago. Such issues frequently lead to physicians testifying for either litigant about the possible source of a disease that is still not basically understood.

Adversary procedures

Another problem that tends to discourage the filing of claims is the very lengthy and contentious procedure that typically precedes the resolution of a case involving occupational disease. Where a worker incurs a serious occupational disease, it typically takes well over a year from the time a claim is first filed until a first payment is made—in cases where indemnity benefits are eventually paid.

The lengthiness of workers' compensation proceedings together with the adversary process may well discourage some physicians from ever willingly becoming involved in such cases. Consequently, it is likely that they will not raise the matter of workers' compensation where patients are found to have cancer.

The system of workers' compensation in the U.S. is basically adversarial, and the resolution of a controversy regarding the source of a person's illness or death can involve substantial sums of money. Nevertheless, it is clear that the fundamental problems are scientific and technological. If the problem was primarily the way we adjudicate claims one should expect to find a far larger number of cases involving cancer in other countries that are using very different approaches to workers' compensation. Instead, it appears that the volume of claims for occupational cancer in most western European nations is quite small and not far out of line with the U.S. experience. In those countries, however, information about occupational cancer increasingly is being brought to the public's and workers' attention and a surge in claims may well result. A similar type of development in the United States should also be anticipated.