

Vinylidene chloride: no trace of cancer at Dow

Dow Chemical's extensive tests with rats, and probes of employee medical records fail to support cancer link found by Italian researcher Maltoni

Dow Chemical has a problem. An Italian investigator instrumental in bringing vinyl chloride carcinogenicity to light now has implicated a closely related product—vinylidene chloride—as well. On the other hand, Dow, the major U.S. producer of the plastic monomer, has studied vinylidene chloride extensively in test animals and hasn't found any evidence of carcinogenicity. Moreover, the big Michigan-based chemical maker has checked the medical records of its workers who have made or used the chemical over the past 30 years or so and hasn't found any problems there either.

The controversy started in February when Dr. Cesare Maltoni of the University of Bologna, Italy, disclosed at a New York City press conference sponsored by the American Cancer Society that his laboratory studies showed that mice exposed to vinylidene chloride vapors for prolonged periods developed kidney tumors (C&EN, Feb. 28, page 6). Maltoni found that about 25% of the 120 male Swiss white mice exposed to 25 ppm of vinylidene chloride for life developed kidney carcinomas. Female mice exposed to the same conditions, however, did not

develop kidney tumors, and neither male nor female mice exposed to 10 ppm of vinylidene chloride developed any tumors. Maltoni also studied vinylidene chloride in rats and hamsters, but didn't find any tumors. Even so, the American Cancer Society's chief epidemiologist, Dr. E. Cuyler Hammond, says Maltoni's data are the first clear link between vinylidene chloride exposure and cancer.

The big difference between the Dow and Maltoni studies is that Dow used rats, "a more reliable animal," according to Dow chief toxicologist Perry J. Gehring. The Dow studies, started in 1974, are sponsored by the Manufacturing Chemists Association. So far they include 90-day ingestion and inhalation studies in rats; two-year ingestion and inhalation studies in rats; ingestion and inhalation teratology studies in rats and rabbits; mutagenicity studies in rats; and metabolic studies in rats. None of these tests, adds Dow toxicologist Jessie M. Norris, show any tumors.

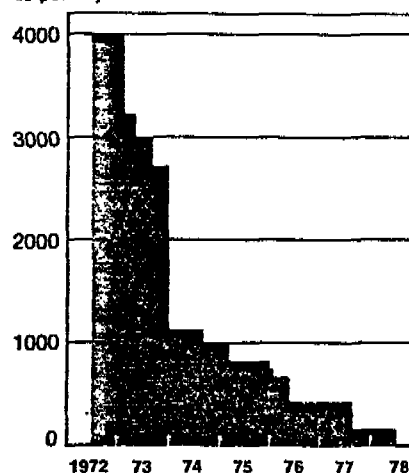
Dow inhalation studies, for example, were conducted at 25 ppm and 75 ppm in both the 90-day and two-year experiments. After 12 months of the studies, Dow toxicologists were able to find only reversible "minimal microscopic changes" in the livers of some test animals. No kidney effects were observed. All of the other studies performed by Dow failed to show any other effect of vinylidene chloride dosing.

Gehring attributes the difference in Maltoni's findings to the test animals and the high dose level. Male mice, Gehring points out, have faster metabolisms than rats or female mice, and are more sensitive to toxic materials because of this. Once an animal is suffering from chronic toxic effects in an organ, he says, the chances of its developing a tumor, particularly in a target organ such as the kidney, are much greater. Maltoni's Swiss white mice have a high incidence of spontaneous kidney disease in any event, Gehring says. "If you give sufficiently large doses to cause organ damage," Gehring affirms, "you can show something to be carcinogenic."

Meanwhile, Dow also has tried to find tumors related to vinylidene chloride among workers that make or use the material. Dow physician William A. Fishbeck says there just isn't any evidence for this, and the firm has looked back over more than 30 years. Fishbeck claims that Dow has been more than 90% successful in following up on its present and former employees who have worked with vinylidene chloride—for example, the firm pays for employee medical insurance even after the person leaves the company. PPG In-

Dow has reduced vinylidene chloride emissions at Midland

Lb per day



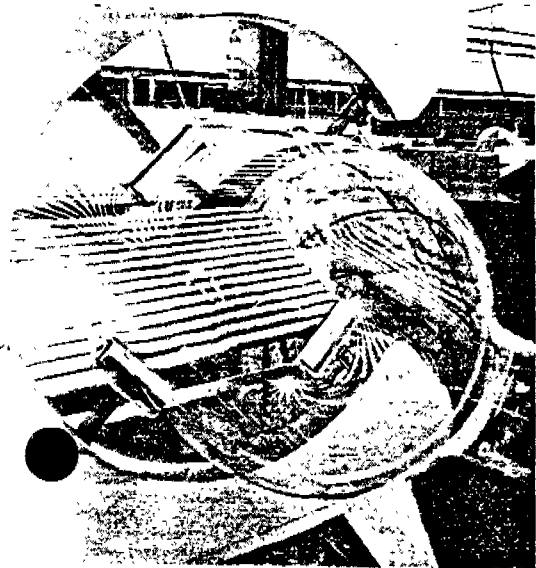
Source: Dow Chemical

dustries, the other major U.S. producer of vinylidene chloride, also has looked over its employees' medical histories and hasn't found any problems, but its studies go back only seven years.

Dow's concerns about the Maltoni data stem naturally from the fact that vinylidene chloride and products made from it are big business for the firm. Vinylidene chloride is largely used to make copolymer resins for food wraps such as the sarans, and in particular Dow's brand Saran Wrap. Fearing guilt by association, Dow is quick to point out that film products such as Saran Wrap contain no more than 10 ppm of unreacted monomer, and that within detectable limits, no more than 10 ppb could get into food even under severe conditions of use. The American Cancer Society's Hammond agrees. But the problem is that the so-called Delaney amendment to the federal Food, Drug & Cosmetic Act bars any material from food contact applications that has been shown to be a carcinogen in animals.

The federal government, however, apparently is not very excited by the Maltoni data. An FDA spokesman in Washington says that the agency has looked over the data and has decided that it need not take any action against food wraps containing vinylidene chloride.

Dow apparently isn't taking any chances with vinylidene chloride in its plants. In its Midland, Mich., saran resin polymerization plant, for example, worker exposure is monitored continuously with an elaborate system of computer-controlled gas chromatographic detectors. If



Saran Wrap produced by Dow contains less than 10 ppb unreacted monomer

vinylidene chloride or the vinyl chloride that it is polymerized with to make saran resin, escapes from a reactor vessel, lights flash and bells ring, warning workers to get out of the area.

Currently the federal workplace limit for vinylidene chloride is 10 ppm, but Dow engineers say that exposure to the monomer is rarely above 1 ppm—particularly in saran resin production, where vinyl chloride exposure must be held to 1 ppm. Many safety and environmental precautions are the same for both monomers. One way Dow production engineers are able to minimize exposure to vinylidene chloride is by vacuum stripping of reaction vessels after a polymerization run. The recovered vinylidene chloride is re-used.

Although Dow's data, the firm believes, effectively answer Maltoni's data, the last word has not been heard about vinylidene chloride safety. As Gehring notes, "It is impossible to prove that vinylidene chloride is absolutely safe. . . . You can develop masses of data [but] you can never satisfy everyone who would criticize it."

Chris Murray, C&EN Washington

NRC to study need for research instruments

Unlike high-energy physics, for example, chemistry hasn't required large cooperative facilities for research. All that may be changing. In fact, the need for very expensive, sophisticated instrumentation, although still far from the scale of particle accelerators, has generated enough concern in the chemical community that the National Research Council is setting up a committee to look into the need for such instruments.

A chairman and vice chairman have just been appointed by NRC's Assembly of Mathematical & Physical Sciences to head a committee for a Study on Major Instrumentation Needs for Research in Chemistry, Biochemistry, and Biophysics. Chairman of the group is Dr. Frank A. Bovey of Bell Telephone Laboratories. Vice chairman is Dr. Elkan R. Blout,

professor of biological chemistry at Harvard medical school.

The committee to be chosen will consist of about 15 members. NRC intends that about a third will represent broad experience in management of large industrial and governmental research organizations. The other two thirds will be made up of specialists from various subfields of chemistry, biochemistry, and biophysics who are knowledgeable in the use of instrumentation.

The reason for the study was stated at one point during the proceedings leading to it by Dr. Richard N. Zare, professor of chemistry at Columbia University, and Dr. John D. Roberts, professor of chemistry at California Institute of Technology. The escalating sophistication, size, and associated costs of major instrumentation, they point out, are one of the most important problems facing research in chemistry and biology today. Many models of x-ray diffraction spectrometers, mass spectrometers, NMR spectrometers, analytical electron microscopes, special chemical physics instruments, and their associated real-time computers for data acquisition and analysis have come to cost upwards of \$250,000 and soon may be at the \$1 million level.

Bovey doesn't prejudice the study's outcome beyond that assessment. It remains to be discovered, he says, what the situation is.

If the situation is as some believe, however, it well could lead to changes in the way many chemists work. The performance level of the newer instruments, Zare and Roberts explain, is often orders of magnitude ahead of their previous state-of-the-art counterparts, and they offer unusual opportunities for major breakthroughs in many areas of research. But, they say, effective use of some of this sophisticated instrumentation, let alone efficient use of instrumentation dollars, may require new institutional mechanisms—cooperative efforts and facilities for research.

The year-long NRC study will investigate a number of topics. It will, for instance, identify scientific fields in chemistry, biochemistry, and biophysics requiring new instrumentation; estimate



Bovey: chairman of instrument group

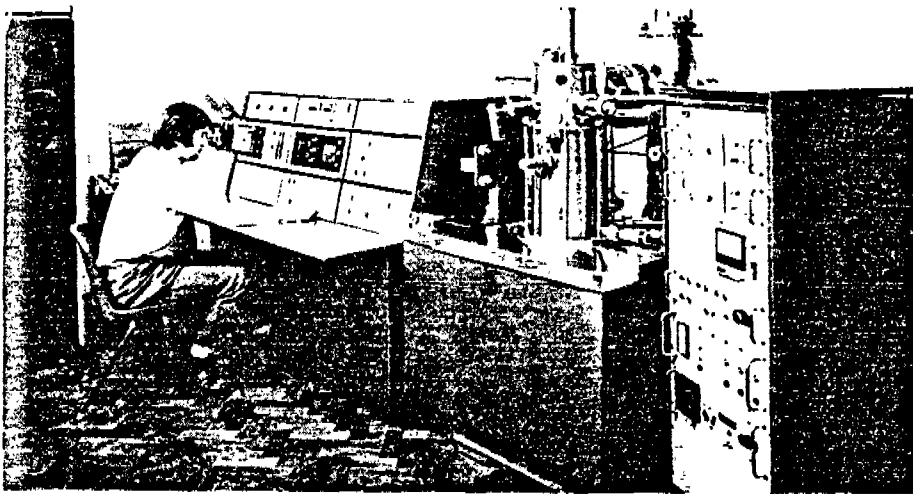
their current and needed level of instrumentation support; and estimate the size of the instrumentation "shortfall" for chemistry, biochemistry, and biophysics.

The study also will assess and document the potential impact on scientific production if instrumentation needs were more adequately fulfilled, and it will develop additional cost-benefit indicators to aid in defining an adequate level of instrumentation support.

And the study will inventory currently available major instrumentation and analyze the way it is used in university, government, industry, and national research laboratories. The aim here is to develop models for more effective utilization, maintenance, transfer, and replacement of instruments.

In addition, the study will look into what scientific areas and what kinds and levels of instrumentation require cooperative effort and facilities. For example, it will consider the question of major instruments for individual investigators versus groups of users. And it will consider whether a university consortium, regional center, or national laboratory would be the most desirable focus for instrument development and analytical services for instruments so large as to require collaborative efforts.

The original impetus for the study came last March from a workshop on high-field NMR spectroscopy, sponsored by the National Institutes of Health. A resolution was approved by the workshop calling for a study by the National Academy of Sciences into major instrumentation needs and problems in chemistry and biology. Subsequently, an ad hoc panel was convened by the Advisory Board of the Office of Chemistry & Chemical Technology. The panel met in October. After hearing presentations and related discussion, it strongly endorsed the need for an NRC study in the broader context of major instrumentation needs, as well as needs for cooperative efforts and facilities for research in chemistry, biochemistry, and biophysics. □



Cost of electron microscopes, as well as other instruments, is escalating rapidly

General Policy**REVISED OMB PROPOSAL SEEN ON POLICY COVERING OUTSIDE STANDARDS GROUPS**

A revision of proposed regulations governing the relationship of federal agencies with standards-setting organizations outside the Government is expected to be published in the Federal Register by the Office of Management and Budget in late March, an OMB official said.

The changes in the proposed OMB circular, originally announced December 8, 1976 (41 FR 53723), will reflect comments and recommendations included in more than 500 letters received by OMB on the proposal, according to David Baker, deputy assistant administrator, office of federal procurement policy, OMB.

"The thrust will be the same" in the revised version, Baker said. The circular is aimed at encouraging government agencies to rely more heavily on "commercial standards in lieu of in-house standards when they will serve the agency's purpose and are consistent with applicable laws and regulations" (Current Report, February 10, p. 1181).

Following a review by the OMB staff of comments received, Baker said the changes will cover "specific procedure criteria which the standards-setting bodies must adhere to." Other "internal mechanisms" will be addressed in the revisions and references by name to several standards groups, which were criticized as improper, will be eliminated in the new proposal, according to Baker.

Many industries wrote in support of the OMB draft circular, including E.I. du Pont de Nemours and Company. "The public is certain to benefit from increased government application of private sector standards. Participation in standards setting is the best way to assure one's interests are represented," R.L. Klausmeier, design division standards manager at Du Pont, wrote.

Public Interest Groups

The proposal was criticized by public interest groups on the grounds that the interests of the consumer, worker, and small businessman would be overshadowed by large corporation members of standards-setting organizations.

"We strongly oppose the last-minute, Nixon-Ford Administration attempt by OMB to give undue influence and status to industry-dominated commercial standards groups at the expense of public health and safety," Peter Greene, attorney for the Ralph Nader Health Research Group, wrote.

Greene argued that independent organizations and associations are not bound the way government agencies are under the Constitution to regulate commerce "in the name of the people." Outside groups "must satisfy their members, overwhelmingly large corporations," he said.

The Center for Study of Responsive Law, another Nader group, also criticized the plan and offered recommendations for improving it, such as provisions for balanced representation to cover consumer and small business interests, requiring all meetings to be open to the public, allowing for an appeals mechanism, reviewing standards every five years, and a preference for performance over specification standards.

The center, represented by Peter L. Maier, urged deletion of "an improper and unseemly endorsement of standards-setting groups such as ANSI" in the preamble of the original draft proposal. Baker agreed that the references would be removed and said they were never intended as an endorsement of any group.

Among responses from government agencies was one from a Department of Labor official — Walter C. Terry,

director, Office of Grants, Procurement, and ADP Management Policy — who said the department agreed with the OMB circular as proposed.

NIOSH Impact

John F. Finklea, director, National Institute for Occupational Safety and Health, wrote that the institute would be "heavily impacted" by the policy and submitted a number of questions.

Finklea asked if public interest groups and worker representatives were involved in the drafting and if meetings of the Interagency Committee on Standards Policy (ICSP) were open to the public. "Regarding consensus groups, are there to be constraints placed on them in terms of conflict of interest provisions, openness of meetings requirements, and Freedom of Information type access to records and correspondence," Finklea asked.

The NIOSH director continued: "Above every other consideration we must place the need for NIOSH recommendations for occupational safety and health standards to be viewed as unbiased, truly reflective of available data, and in the best interests of the health and safety of American working men and women."

Congressional reaction included a warning against favoritism for large corporations by Representative David R. Obey (D-Wis) and a suggestion from Representative John E. Moss (D-Calif) that more responsibility for standards setting be shifted from the Commerce Department to the General Services Administration.

Senator James Abourezk (D-SD) asked for a delay from OMB in adopting a policy until completion of studies on standards and standards setting bodies by the Senate Judiciary Antitrust Subcommittee and the Federal Trade Commission. He expressed concern that standards setting practices could be used against competitive market operation.

Health Hazards**STUDY DESCRIBED LINKING CANCER IN MICE WITH VINYLIDINE CHLORIDE**

Research conducted in Italy has uncovered a link between a chemical used in the United States in some plastic food wrap and kidney cancer in laboratory mice, scientists reported at the conclusion of a medical conference.

Vinylidene chloride, which is related to vinyl chloride and trichloroethylene, was shown to cause kidney cancer in 20 percent of 120 exposed mice in experiments conducted by Cesare Maltoni at the Institute of Oncology in Bologna. Three years ago research by Maltoni revealed the carcinogenic properties of vinyl chloride, another plastics chemical.

Although the complete results of Maltoni's work will not be published for several months, they were outlined by him at a meeting of scientists and health experts which ended February 21 and was sponsored by the New York Academy of Sciences and others.

Two of the meeting's participants, E. Cuyler Hammond of the American Cancer Society and Irving J. Selikoff of the Mt. Sinai Medical Center, called for a closer look by government and industry at the effects and use of vinylidene chloride.

An official of Dow Chemical Company, Midland, Mich., rejected the idea that the Maltoni study had proved vinylidene chloride to be carcinogenic and said that its presence in the Dow product, Saran Wrap, did not pose any threat either to employees working with the chemical or to the public.

Mice, rats, and hamsters in the Maltoni study were exposed to various levels of vinylidene chloride through inhalation beginning with 10 parts per million parts of air for up to one year, according to Hammond. Kidney cancer developed in some of the mice at an exposure level of 25 ppm but did not appear in rats and hamsters, Hammond reported. At higher doses the mice died before getting cancer.

Maltoni also exposed mice for two years without ill effects to 10 ppm of vinylidene chloride, which Perry Gehring of Dow said is more than the exposure level received by Dow employees working with the chemical now.

"If people were exposed to kidney damage, it would have come out by now; it's obviously not carcinogenic," Gehring, director of toxicology research at Dow, said. He explained that 138 employees, some of them with histories of exposure dating back to 1944 and levels up to 75 ppm of vinylidene chloride, were studied and "the tests have been negative, no health problems."

Gehring emphasized that in Maltoni's study no cancer appeared in the rats and hamsters, which, he said, agreed with results of a nearly finished Dow study that exposed rats to levels of 25 ppm and 75 ppm of vinylidene chloride "with no pathological or carcinogenic damage."

"A key factor is that the effect was seen only in mice," Gehring said. Although the Dow study does not include exposure to mice, Gehring said the company probably would wish to investigate the metabolism of vinylidene chloride in mice.

Asked about the possibility of vinylidene chloride leaching into food from plastic wrap, Gehring said testing, accurate to one-to-five parts per billion, showed a complete absence of the chemical in food packaged in plastic containing vinylidene chloride. "There is absolutely no hazard to the consumer," he said.

Recommended Actions

Selikoff, who is director of the Environmental Science Laboratory at Mt. Sinai, said the industry should take note of Maltoni's findings and look for ways to reduce contact by workers and consumers with the chemical. "I am strongly convinced that this will prove possible," Selikoff said.

To protect the worker he suggested the possibility of using closed systems in production and cited past success with vinyl chloride. As for the use of plastic wrap containing vinylidene chloride and the consumption of plastic-wrapped food, "the problem here lies with the residual monomer and whether it leaches into the food," Selikoff said. "Our experience with vinyl chloride is that this problem, too, can be solved," he added.

Lawrence Garfinkel, assistant vice president of the American Cancer Society in New York, suggested that "the next step is to get the government representatives to follow through." Representatives who attended the medical conference with Maltoni, Hammond, Selikoff, and others included officials from the National Institute for Occupational Safety and Health and the Occupational Safety and Health Administration.

Roscoe M. Moore, technical evaluation chief, NIOSH, said a full-scale epidemiological study to detect any excess mortality among workers at a polymerization plant which at one time produced vinylidene chloride will be launched by NIOSH in about three months.

The study at the BASF Wyandotte Corporation facility in South Kearny, N.J., was requested after preliminary investigations showed some liver changes in employees who worked with vinylidene chloride.

The Maltoni research was sponsored by BASF, AG of West Germany, Dow Chemical Corporation's Europe division,

Imperial Chemical Industries of Great Britain, Solvay of Belgium, and the Italian Government.

Diving Operations

ARTHUR YOUNG ARGUES PROPOSAL WILL NOT AFFECT ENERGY SUPPLY

The United States' energy supply will not be significantly affected by any price increases in commercial diving caused by the Occupational Safety and Health Administration's proposed standard for that industry, according to the post-hearing comments of Arthur Young and Company.

Arthur Young and Company filed its comments in response to criticism of the inflation impact assessment it prepared for OSHA on that agency's proposed standard for commercial diving operations (Current Report, February 17, p. 1210).

Info Works, a Louisiana consulting firm hired by the Association of Diving Contractors, said during OSHA's public hearing on the proposal in New Orleans, La., that price increases caused by the proposed standard's requirements would affect the U.S. energy supply. Commercial divers are employed in the exploration and exploitation of off-shore energy supplies.

Arthur Young stated that "the demand for commercial diving is relatively inelastic, particularly in the energy supply sector." The company argued that "the user industries would not diminish their use of the services as the price increased."

Underwater Welding

Chicago Bridge and Iron Company, Houston, Tex., declared "a strong objection" to any prohibition of AC underwater welding. The proposed standards do not include such a prohibition, but, according to this company, "interested parties are now proposing to prohibit AC welding underwater."

Miller Electric Manufacturing Company, Appleton, Mass., also argued against prohibiting AC welding underwater. The company's vice president wrote that "to infer that DC is safe and AC is lethal is a gross oversimplification." The company manufactures equipment used in AC underwater welding.

Shallow Water Diving

Several companies submitted comments similar to the statement of Northwest Divers Supply, Inc., Coos Bay, Ore., which said, "As admitted by OSHA, compliance with the proposed safety standard will force some shallow water diving companies out of business. Because of this we are asking that shallow water diving companies with less than 10 full- or part-time shallow water (less than 120 feet depth and 30 minutes ascent time) divers be excluded from the safety standard."

OSHA has said that it expects to issue the final standard around mid-year 1977. The period for submitting post-hearing comments closed February 28.

Asbestos

FIBERS MAY BE RELEASED IN PROCESS OF EXFOLIATION OF VERMICULITE ORE

Inspections of exfoliation processing of vermiculite ore will include evaluating worker exposure to asbestos, the Occupational Safety and Health Administration said after receiving data on asbestos content in the ore.

not technically or economically feasible in a split decision by the Occupational Safety and Health Review Commission.

The ruling of the three-member tribunal came April 18 in *West Point Pepperell, Inc.* (No. 8255), modifying a report by Review Commission Judge Erwin L. Stuller.

The employer was cited for a violation of 29 CFR 1910.95(b)(1) for failure to use feasible engineering or administrative controls to reduce noise levels in two weaving rooms of its Lindale, Ga., plant. At work stations in weaving room #2, which contained 112 Draper shuttleless looms, a steady noise level of 97 dBA was recorded, and in weaving room #3, with 1,178 Draper fly shuttle looms, 103 dBA was measured. Since employees in both rooms worked about 7 1/2 hours per day, the noise exposure considerably exceeded the permissible level of 90 dBA for an eight-hour day.

Judge Stuller credited the testimony of the Labor Department's expert witness, J. Ronald Bailey, that noise reduction kits were available from the manufacturer for the looms in room #2 and could be expected to reduce the noise there by about 8 dBA. The judge rejected contrary testimony by the employer's witnesses as unpersuasive. With regard to room #3, Judge Stuller held that the secretary had failed to prove that feasible controls would bring the noise level down to 90 dBA. Accordingly, the judge affirmed the citation as to room #2, but found no violation with respect to room #3.

Majority Opinion

On review, Commissioner Robert D. Moran, joined by Chairman Frank R. Barnako, vacated the citation in its entirety. Moran found the testimony of Bailey too speculative to be relied on, noting that the suggested controls for room #2 had never been tested in an operating mill. According to Moran, Bailey, "by his own admission, had absolutely no practical knowledge of the feasibility of noise attenuation devices in a textile mill."

Commissioner Moran also rejected a recommended administrative control method, rotation of exposed employees on a four-hour shift, as excessively costly. Moran accepted the employer's estimates that the rotation and cross-training of 380 employees would cost nearly \$5.4 million during the first year and over \$2.6 million per year thereafter.

Cleary Dissents

Commissioner Timothy F. Cleary took strong exception to the majority's treatment of Bailey's testimony and its findings and conclusions. Cleary called Moran's discussion of Bailey's qualifications "incredibly misleading," noting that Bailey is a leading expert on noise problems in the textile industry and has done experimental noise reduction research on the type of looms in question. In contrast, according to Cleary, the employer's experts were not trained in acoustical engineering.

The majority also erred, Cleary contended, in disregarding Bailey's testimony that the suggested controls could be installed for about \$20 per loom and that the necessary techniques and materials had been available for many years. The employer's responsibilities under the standard "include at least the adaptation and application of existing technologies to reduce excessive noise in the workplace. . . . The employer cannot sit idly by in the face of such knowledge and wait for others to develop for the marketplace engineering control methods that are adaptable to his particular worksite," Cleary added.

Furthermore, Cleary argued, the majority's approach places an impossible burden of proof on the Labor Department, requiring it to "undertake extensive independent research and development of noise reduction techniques for each industry . . . [and] to enter each worksite to conduct

further testing in order to determine how to apply such techniques in a particular work environment." The secretary "was never intended to shoulder such a burden as it would result in a complete frustration" of the purposes of the Occupational Safety and Health Act, Cleary continued. Since the evidence indicates "a strong probability that the suggested engineering methods would substantially attenuate" noise levels in both weave rooms, the citation should be affirmed in its entirety, Cleary concluded.

This ruling will appear in a future Decisions supplement.

General Policy

RESEARCH DATA FAIL TO INDICATE CARCINOGENICITY IN VINYLIDENE CHLORIDE

Results of recent animal tests involving vinylidene chloride fail to provide any solid evidence that the substance is carcinogenic or teratogenic, according to presentations at an April 22 forum on vinylidene chloride sponsored by the National Institute for Occupational Safety and Health.

Lawrence Rampy, group leader, Dow Chemical U.S.A., stated that preliminary results of an ingestion study conducted by Dow and sponsored by the Manufacturing Chemists Association indicated that the incidence of tumors in rats given doses of VDC in drinking water was not significantly higher than that of unexposed rats.

Three groups of rats showed a "slight increase" in male mortality early in the study, but female mortality was comparable to that of the control group, Rampy reported. Body weights and organ weights for the exposed rats also were comparable to those of the unexposed animals.

No clinical signs of vinylidene chloride toxicity were found in an inhalation study involving exposure to levels of 10, 40, and 75 parts per million, Rampy added. Cumulative mortality data showed little difference in death rates of exposed and unexposed rats, except for a "slight increase" late in the study among rats exposed to the 75 ppm level. Test results indicated "minimal" liver injury in exposed rats, and no increased tumor incidence, according to Rampy.

Results of an Environmental Protection Agency study seem to indicate that vinylidene chloride is a "weak" teratogen in mice, according to William Marcus, chief of testing, EPA office of toxic substances. There is "no doubt" that the effect is real, but the researchers "do not know how to attribute it to VDC," according to Marcus.

"Dose-related" hydrocephalus and hydronephrosis of the small kidney were found in the fetuses of mice exposed to 15, 41, and 54 ppm of vinylidene chloride, Marcus reported. No discernible dose-response effects were noted in rat fetuses, except for changes in fetal weight, he added.

F. J. Murray, Dow senior research toxicologist, told the meeting that Dow inhalation and ingestion studies involving rats and rabbits showed no teratologic effects at any of the levels tested (20, 80, and 160 ppm for rats and 80 and 160 ppm for rabbits). He added that VDC appeared to be embryotoxic at levels that also were toxic to the mother.

Less vinylidene chloride is metabolized at high doses than at low doses, according to Michael McKenna, Dow research toxicologist. In a study sponsored by MCA and conducted by Dow, fed rats exposed to 10 ppm of VDC retained 4.75 percent of the substance in their bodies, while fed and unfed rats exposed to 200 ppm retained 6.18 percent and 10.52 percent, respectively.

BASF Wyandotte Study

NIOSH is "not ready" to make an association between vinylidene chloride exposure and liver impairment found

among workers at a BASF Wyandotte plant in South Kearny, N.J., according to Bobby F. Craft, director, NIOSH division of surveillance, hazard evaluations, and field studies.

Craft noted that NIOSH came into the plant in 1976 after company blood tests indicated abnormalities among VDC-exposed workers. Some 45 employees were tested by the company, of whom 31 percent were found to be normal, 56 percent to have moderate liver abnormality, and 13 percent to have severe liver impairment.

Some 256 of the 292 workers employed at the plant were given five liver tests by NIOSH, according to Craft. The "vast majority" of the workers had only one abnormal reading, and no one had as many as five.

The results of the BASF tests are comparable to those of liver tests conducted at other plants, Craft reported. He added that test results in the BASF dispersion operation, the area of the plant where VDC exposure occurred, were similar to those in other parts of the plant.

NIOSH does not know at this point "what all of this means," Craft conceded, adding that the institute still is doing research at the plant and will recommend that the company develop a careful medical surveillance program for its employees. He noted that some 300 substances are used in the plant, some of which are described in medical literature as capable of causing liver damage.

Mortality Study

NIOSH intends to carry through with its plans to conduct a retrospective mortality study of VDC workers during fiscal 1977, but is having difficulty finding a suitable cohort for study, according to Cynthia Robinson, epidemiologist with the NIOSH industry-wide studies branch, division of surveillance, hazard evaluations, and field studies.

To determine whether there is any association between vinylidene chloride exposure and subsequent employee deaths, Robinson told the meeting, NIOSH first must locate a group of workers who have had sufficient exposure to the substance. There also must be an adequate latency period (preferably one of 15 to 20 years following onset of exposure), and a large enough group of subjects to produce significant results. In addition, there must be careful monitoring to determine whether there has been exposure to any other substances, and personnel records must be available.

Robinson noted that VDC-exposed workers at the BASF Wyandotte plant mentioned by Craft were not a suitable group for study, for these reasons:

- ▶ The latency period was not long enough (only 10 years).
- ▶ The group of exposed workers was too small, comprising only 25 to 30 workers in all.
- ▶ The workforce was not stable, having worked at plants other than the BASF Wyandotte facility.

Other plants have been considered for the study, and have been rejected for the same reasons, Robinson noted. She reported that the search for a cohort is continuing.

Mine Safety

SENATE SUBCOMMITTEE APPROVES BILL GIVING AUTHORITY TO LABOR DEPARTMENT

A bill that would make all miners subject to most of the standards of the 1969 Federal Coal Mine Safety and Health Act and transfer the responsibility for that law from the Interior Department to the Labor Department was favorably reported April 20 by the Labor Subcommittee of the Senate Human Resources Committee.

The full committee plans to consider the bill (S 717) May 3. Similar legislation (HR 4287) was approved by a House Education and Labor subcommittee April 5. The House committee intends to mark up the bill May 4 (Current Report, April 7, p. 1390).

During its markup session, the Senate subcommittee agreed to an amendment proposed by Senator Richard Schweiker (R-Pa), which provides that the Labor Department may issue a civil penalty closure order if a mine operator has a history of repeated violations that could have resulted in serious physical harm or death.

Under the original language of the bill, the Labor Department would have to show gross and willful negligence. Schweiker explained that his amendment has a "tighter, more stringent definition of unwarranted failure" and therefore places an "easier burden of proof on the Government."

Senator Jacob Javits (R-NY) suggested that Schweiker's amendment refer to a pattern of violations, rather than a history of violations, because "pattern" has been used in various laws and has a history of court interpretation.

The subcommittee decided to accept Schweiker's amendment in principle and to allow its staff to work out the amendment's final language, which would be considered by the full committee.

Changes in S 717

The committee print of S 717 Federal Mine Safety and Health Amendments Act of 1977 which was approved by the subcommittee included certain changes to the bill which were made since its introduction. Following are the changes made to S 717 by the subcommittee:

▶ Following the request of the Interior and Labor Departments, some of the time limitations for the steps in standards making were increased. In addition, a requirement that hearings begin within 60 days of the announcement of a request for a public hearing on a proposed rule was added. With this addition, a time limit was established for each step in the rulemaking process.

A new Section 102 (a) (4) dealing with the final promulgation of standards is patterned after a provision of the Coal Act (Reference File, 71:8501).

Section 102 (a) (5) (B) was amended to reduce from 36 to 18 months the period for compilation by the National Institute for Occupational Safety and Health of a list of toxic materials found in mines. Additional language clarifies the intent that NIOSH develop proposed standards dealing with these substances separately instead of as a part of making the list.

▶ The provisions on limited noncompliance orders and variances have been deleted. A new, general variance provision (Section 102 (e)), patterned on Section 301 (c) of the Coal Act was substituted.

▶ The provision establishing inspection procedures was eliminated and a new Section 104 (a), patterned on the procedures contained in Section 103 (a), (b) (1), and (b) (2), of the Coal Act, was substituted.

The minimum number of inspections (Section 104 (a)) was changed from four per year for all mines to four for underground mines and two for surface mines. Authority also was provided for the Labor Department to establish minimum inspections based on observed hazards. The Administration proposed an annual minimum of four inspections for underground mines and no minimum for surface mines.

▶ The right of miners' representatives to accompany inspectors (Section 104 (e)) was expanded to include the right