



CHEMICAL REGULATION REPORTER

A weekly review of activity affecting chemical users and manufacturers

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HIGHLIGHTS

THE FIRST CHEMICALS to be considered for Environmental Protection Agency testing rules under Section 4 of the Toxic Substances Control Act will be acrylamide, chloromethane, and chlorinated benzenes, according to an EPA official. The two chemicals and the chemical group were given priority for testing by the Interagency Testing Committee (p. 1459).

ENDANGERMENT would be created as a new federal felony by a bill approved by the Senate Judiciary Committee. The term would apply if a violator of TSCA, the Federal Insecticide, Fungicide, and Rodenticide Act, or other statutes knowingly places another person "in imminent danger of death or serious bodily injury" (p. 1459).

LATE REPORTS are still being received by EPA for the TSCA inventory of existing chemicals, even though the reporting deadline ended July 1, according to an official in EPA's Office of Toxic Substances, who adds that, so far, very few reports have been submitted by processors (p. 1460).

THE REPRODUCTIVE TOXICITY of 2,4,5-T and Silvex and their dioxin contaminant TCDD justifies holding hearings on the remaining uses of the products, according to a decision approved by Steven D. Jellinek, head of EPA's Office of Pesticides and Toxic Substances. The hearings probably will be combined with ongoing hearings to cancel the major uses of the herbicides (p. 1460).

DECISIONS TO BE MADE on chemicals subject to rebuttable presumption against registration in the next three months, and the status of several sets of EPA regulations under development are outlined by agency staff members at the annual meeting of the State FIFRA Issues Research and Evaluation Group (p. 1461).

BENZENE VAPOR EXPOSURE for tankermen and ship and towboat personnel would be limited to 10 parts per million over an

eight-hour period, under interim standards adopted by the Coast Guard pending a Supreme Court decision on the Occupational Safety and Health Administration benzene standard (p. 1462).

REVIEW PROCEDURES for EPA's premanufacture notifications are refined in a letter to be sent to the EPA Administrator's Toxic Substances Advisory Committee. The draft letter says the agency intends to include more information in the public notices of PMN receipts (p. 1462).

A PETITION FOR A BAN on all consumer products containing *n*-hexane is denied by the Consumer Product Safety Commission, but the issue continues to be under study (p. 1464).

HIGH PRIORITY for carcinogenesis testing by the National Cancer Institute's chemical selection subgroup is given to three dyes and the pesticide 2,4,5-TCP (p. 1464).

A DRAFT DOCUMENT which outlines how the food, fertilizer, animal feed, and agricultural industries can examine their facilities for sources of potential polychlorinated biphenyl contamination is being reviewed by EPA prior to joint publication with the Food and Drug Administration and the Agriculture Department (p. 1464).

PRESIDENT CARTER signs legislation giving the Department of Transportation authority to regulate pipeline transportation of petroleum and other hazardous liquids (p. 1465).

SUPERFUND LEGISLATION being considered by a Senate committee may include provisions for the siting of hazardous waste facilities, according to a committee aide (p. 1466).

EPA PLANS IN 1980 to expand the list of hazardous substances designated in the Clean Water Act and to propose hazardous substance spill clean-up regulations, according to an EPA Office of Water Planning and Standards staff member (p. 1467).



Testing

FIRST SECTION 4 RULE TESTING DECISIONS TO BE MADE FOR TWO CHEMICALS, ONE GROUP

Acrylamide, chloromethane, and chlorinated benzenes are expected to be the first chemicals considered for testing rules under Section 4 of the Toxic Substances Control Act, according to an Environmental Protection Agency official.

Warren Muir, EPA's deputy assistant administrator for testing and evaluation, told an industry group December 5 that EPA's first determinations of whether or not to test substances given priority for testing by the Interagency Testing Committee (ITC) will be made on these two substances and one group.

Muir said EPA expects to propose a rule in the first quarter of 1980 which either would require testing for the substances or would give EPA's reasons for deciding not to do so (Current Report, October 26, p. 1285). Muir said the decisions on whether or not to test would only address health effects testing.

Chloromethane and chlorinated benzenes were recommended for testing by the ITC in October 1977. Acrylamide was recommended for testing in April of 1978.

EPA has been under considerable pressure to develop test rules for the ITC recommendations ever since the Natural Resources Defense Council brought suit against the agency for not developing test rules within one year after the substance was recommended for testing (May 11, p. 143).

The ITC has recommended 38 substances or groups of substances for testing under Section 4 of TSCA.

Legislation

SENATE PANEL APPROVES BILL MAKING ENVIRONMENTAL 'ENDANGERMENT' A FELONY

A person or corporation that places others in imminent danger in violation of federal health, safety, or environmental laws would be guilty of a felony under a bill approved by the Senate Judiciary Committee December 4.

The measure (S 1722) would create a new federal felony offense called "endangerment."

A person would be guilty of endangerment if he engages in "conduct that he knows places another person in imminent danger of death or serious bodily injury" and his conduct shows an unjustified disregard of human life.

To constitute a federal offense, however, the conduct would have to occur within an area under special federal jurisdiction or be in violation of one of the following laws:

- ▶ Toxic Substances Control Act;
- ▶ Federal Insecticide, Fungicide, and Rodenticide Act;
- ▶ Federal Water Pollution Control Act;
- ▶ Solid Waste Disposal Act;
- ▶ Clean Air Act;
- ▶ Noise Control Act;
- ▶ Occupational Safety and Health Act;
- ▶ Federal Coal Mine Safety and Health Act;
- ▶ Food, Drug, and Cosmetic Act;
- ▶ Public Health Service Act;
- ▶ Federal Hazardous Substances Act;
- ▶ Outer Continental Shelf Lands Act;
- ▶ Marine Protection Research and Sanctuaries Act; or
- ▶ Rivers and Harbors Act.

If the conduct shows "an extreme indifference to human life," the offense would be a "Class D felony," carrying a penalty of up to five years imprisonment and a fine of up to \$250,000.

If the circumstances show only "an unjustified disregard" of human life, the offense would be a "Class E felony," punishable by up to two years in prison and a fine of up to \$250,000.

If the violator is a corporation or other organization, the maximum fine would be \$1 million.

Compromise Reached

According to Judiciary Committee staff members, the endangerment provision represents a compromise among the committee, Department of Justice, and business interests represented by the Business Roundtable.

The original version of S. 1722, introduced by Senator Edward M. Kennedy (D-Mass) September 7, contained a more comprehensive endangerment provision. The initial bill would not have required a finding of "unjustified disregard" of human life for establishing the offense. It also would have applied the penalties to conduct that endangers others and violates any law "designed to protect public health and safety."

In an attempt to create a bill that would have industry support, the committee approved a narrower version of the endangerment provision. At this stage, the bill would have required a finding of "extreme indifference to human life," as a condition for establishing the offense. This version would have applied the sanctions only to conduct in violation of the Federal Coal Mine Health and Safety Act, Clean Air Act, Federal Water Pollution Control Act, Noise Control Act, or Outer Continental Shelf Lands Act.

But the Department of Justice protested the limiting of white-collar crime provisions of the bill, prompting the committee to reconsider. The final measure lists specific health and safety laws which may involve the offense of endangerment.

John Blouch, special counsel to the Business Roundtable, told Chemical Regulation Reporter that the Roundtable considered the general reference contained in the Kennedy version too vague.

Although the final version applies to most major public safety and health laws administered by federal agencies, it does not include such laws as the Consumer Product Safety Act, the Hazardous Materials Transportation Act, or the Natural Gas Pipeline Safety Act.

The inclusion of environmental laws, including TSCA and FIFRA, was done at the insistence of Senator Patrick Leahy (D-Vt). Other laws, including the Occupational Safety and Health Act and the Food, Drug, and Cosmetic Act, were included at the request of the Justice Department's Criminal Division.

According to a Criminal Division staff member, the division stressed inclusion of the statutes that have given rise to the greatest practical problems in enforcement. He said the Occupational Safety and Health Act had the highest priority for inclusion in the view of the division.

Bill Would Increase Existing Penalties

The bill also includes a section which codifies and in some cases increases penalties for criminal offenses under nine existing environmental laws.

* Dated: December 10, 1979.

Frank H. Mudden,

*AID Advisory Committee Representative,
Joint Committee on Agricultural
Development, Board for International Food
and Agricultural Development.*

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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

Occupational Exposure to Vinyl Chloride and Polyvinyl Chloride

AGENCY: Occupational Safety and health
Administration, Department of Labor.

ACTION: Request for information on vinyl
chloride and polyvinyl chloride.

SUMMARY: This notice requests information on vinyl chloride (CAS No. 75-01-4) and on polyvinyl chloride (CAS No. 9002-86-2). Vinyl chloride (VC), a synthetic chemical, was once synthesized by the addition of hydrogen chloride to acetylene. Currently, the most common route of production is by the halogenation of ethylene. In this latter process, ethylene is reacted with hydrogen chloride and oxygen to give ethylene dichloride, which is subsequently cracked thermally to produce vinyl chloride and hydrogen chloride. Vinyl chloride is used primarily to produce polyvinyl chloride (PVC), a plastic resin, through conversion of the VC monomer into a polymer or copolymer form. Vinyl chloride is also used in the production of methyl chloroform and in the production of resins as a comonomer with vinylidene chloride. PVC is used in the manufacture of a variety of industrial and consumer products, such as containers, wrapping film, electrical insulation, and pipes.

In 1975, OSHA regulated vinyl chloride as a carcinogen, based primarily on evidence of excess liver angiosarcoma incidence following VC exposure (29 CFR 1910.1017). OSHA did not regulate exposure to PVC dust in the same standard. Therefore, it continues to be regulated as an inert or nuisance air contaminant (29 CFR 1910.1000, Table Z-3).

Research since 1975 has provided considerably more information concerning the carcinogenic and other toxic effects of VC and PVC exposure. OSHA is currently in the process of evaluating the available evidence pertaining to the potential occupational health hazards of VC and of PVC and, by this notice, is requesting information related to several important issues.

DATE: The information requested in this notice must be submitted in quadruplicate on or before February 10, 1980.

ADDRESS: The information requested in this notice should be submitted to the Docket Officer, Docket No. H-634, Room S6212, U.S. Department of Labor, OSHA, 200 Constitution Avenue, N.W., Washington, D.C. 20210, (202-523-7894).

FOR FURTHER INFORMATION CONTACT: Dr. Peter Infante, Office of Carcinogen Identification and Classification, Directorate of Health Standards Programs, Room N3718, U.S. Department of Labor, OSHA, 200 Constitution Avenue, N.W., Washington, D.C. 20210, (202-357-0325).

SUPPLEMENTARY INFORMATION:

Background

Vinyl chloride (C_2H_3Cl ; CAS No. 75-01-4; chloroethene) is a colorless gas at room temperature and pressure. After synthesis from VC monomer, polyvinyl chloride ($(C_2H_3Cl)_n$; CAS No. 9002-06-2; chloroethene homopolymer) is in the form of white or colorless granules. Residual vinyl chloride monomer can become trapped in the PVC particles. However, recent processing methods can reduce considerably the amount of residual VC trapped in the polymer resins.

The vinyl chloride industry can be divided into three major components: VC synthesis, VC polymerization, and PVC fabrication. It has been estimated that in the U.S., 15 plants manufacture vinyl chloride, 43 plants polymerize polyvinyl chloride, and at least 7,500 plants are engaged in the fabrication of PVC. During 1978, 3.47 million tons of VC and 2.94 million tons of PVC were produced.

The present permissible limit for occupational exposure to vinyl chloride is 1.0 ppm averaged over any 8-hour period, and 5.0 ppm averaged over any period not exceeding 15 minutes (29 CFR 1910.1017). For polyvinyl chloride dust, the standard is 15 mg/m³, averaged over any 8-hour period (29 CFR 1919.1000).

Laboratory Studies

Experimental bioassays have demonstrated the induction of cancer by VC at levels of exposure lower than those previously reported. In VC inhalation studies of rats, Maltoni (1) has induced liver angiosarcomas at 25 ppm and mammary carcinomas at one ppm. In addition, several different test systems have provided evidence for the mutagenic potential of VC, i.e., *E. coli*, *S. typhimurium*, *S. pombe*, insects, plants, and cultured mammalian cells (2). VC also has been demonstrated to have a

transplacental effect in rats. Inhalation exposure of pregnant rats to VC concentrations of 6,000 and 10,000 ppm have resulted in VC-dependent tumors in their offspring (1).

There is also evidence from animal studies that PVC may induce non-malignant respiratory disease. It has been reported that after seven months of exposure, rats and guinea pigs caged in work areas where sacks were being filled with PVC powder developed pulmonary pathological changes and granulomatous lesions containing foreign particles thought to be PVC dust (3).

Epidemiologic Studies

Several investigations of employee populations have indicated that VC/PVC exposure is associated with an increased carcinogenic risk to several organ sites in addition to the liver. A NIOSH retrospective cohort study of workers from four VC polymerization plant showed an excess number of deaths due to cancer of the liver, lung, lympho-hematopoietic system, and central nervous system (4).

Of further concern is the finding that the carcinogenic risk may extend to industries fabricating polyvinyl chloride. A proportionate mortality study of plastic workers in Great Britain, which included PVC fabricators, demonstrated a statistically significant excess of stomach cancer (5). Also, an excess of mortality from digestive system cancer among PVC fabricators of both sexes was found by Chiazze et al. in the U.S. (6). Among white females in the study, observed deaths from breast and urinary tract cancers were also greater than expected. Waxweiler et al. performed a detailed study of the excess lung cancer risk previously observed at a synthetic plastics and rubber plant (7). Analysis of lung cancer cases by cell type demonstrated a greater frequency of adenocarcinomas (Type 3) and large cell undifferentiated (Type 4) cancer. Neither cell type is believed to be strongly associated with cigarette smoking. Of 12 chemicals analyzed, only PVC dust exposure proved to be statistically significant. The authors suggested that the excess of Type 3 and 4 lung cancer cases in this plant was related to PVC dust exposure.

A recent epidemiologic study suggests that PVC may be related to pneumoconiosis (8). Employees of a polyvinyl chloride production factory in Italy were submitted to chest X-ray examination. Twenty subjects were diagnosed as having pneumoconiosis. All of these cases had worked five or more years in departments with demonstrated PVC dust pollution. No

pneumoconiosis was observed in subjects who worked in areas free of PVC dust. These findings are consistent with earlier case reports of pneumoconiosis among workers exposed to PVC dust (9,10). The Institute of Oncology and Tumor Center in Bologna, Italy has demonstrated a higher frequency of cytologically abnormal sputum cells among the workers employed in the VC/PVC industry in contrast either to workers in the general chemical industry or to individuals who are heavy smokers (11).

Epidemiologic studies also exist which demonstrate the mutagenicity of VC in humans. Chromosomal aberrations in lymphocytes of male workers, in excess of the number observed in non-exposed workers, have been reported in several studies (2). Moreover, a study of miscarriages among the wives of men occupationally exposed to VC detected a significant excess in fetal mortality following the husband's exposure to VC (12).

Information requested on vinyl chloride and polyvinyl chloride

The data recently received by OSHA suggest that a reassessment of the known health effects of vinyl chloride and polyvinyl chloride is appropriate at this time. Additional information in several areas is needed before a reassessment can be completed. The requested information includes, but is not limited to, the following:

(1) Experimental test results for carcinogenicity of vinyl chloride at atmospheric exposures of less than 50 ppm.

(2) Studies of transplacental carcinogenic and teratogenic effects in humans or animals at any level of exposure to vinyl chloride.

(3) Experimental studies of carcinogenicity and other toxic manifestations for any level of polyvinyl chloride exposure. These effects should include, but are not limited to, mutagenicity, teratogenicity, embryotoxicity, and other transplacental effects, as well as cytotoxic and cytogenetic effects on sperm cells. To the greatest extent possible, complete information concerning the industrial source of the polyvinyl chloride, the size and characteristics of the particles, and exposure levels or concentrations of PVC and residual VC should be included for each study.

(4) Epidemiologic studies of either vinyl chloride or of polyvinyl chloride (i.e. cohort, cross-sectional, or case-control).

(5) Case reports and case series of brain, lympho-hematopoietic, lung, and

liver cancers by facility and relevant demographic variables, such as age, sex, race, date of diagnosis, date of death, date of first exposure, and length of exposure for either vinyl chloride or polyvinyl chloride.

(6) Mutagenicity study results of vinyl chloride or polyvinyl chloride as measured by the analysis of human body fluids, e.g., direct mutagenic testing with peripheral blood lymphocytes, non-disjunction in humans with YFF sperm test, and *in vivo* cytogenetics.

(7) Body burden measurements of vinyl chloride in humans.

(8) For operations involving polyvinyl chloride, the types of resin in use, the concentration of vinyl chloride trapped in the resin, and the concentration of VC and PVC dust in the atmosphere where individuals are working. This information should include estimates of the particles sizes and concentrations of particles that fall within the respirable range.

(9) In PVC bagging and milling operations, atmospheric levels of PVC and VC, monitoring devices used to detect VC, and the type of respirator protection program for individuals working in these operations. This should include the sensitivity and validity of analytic techniques in use.

(10) Types of occupations, job classifications, and industries where exposure to either VC or PVC at any level may occur, and the numbers of employees involved in each vinyl chloride and polyvinyl chloride exposure situation, separated by sex and race.

(11) Appropriate engineering controls, work practices, and personal protective equipment available to reduce levels of exposure to VC or PVC below the current standards, or to the lowest levels feasible.

SUBMITTALS OF INFORMATION REQUESTED

Interested persons are invited to submit written data, views, and comments with respect to the issues described above. All communications should be submitted in quadruplicate, by February 10, 1980, to the Docket Officer, Docket H-034, Room S6212, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210 (202-523-7894).

References

The following documents, referred to in this notice, are available for inspection and copying at the OSHA Technical Data Center, Room S6212, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

1. Maltoni, C. Vinyl chloride carcinogenicity: An experimental model for carcinogenesis studies. *Origins of Human Cancer*, Cold Spring Harbor Laboratory, 1977, pp. 119-146.

2. Wagoner, J. K., and P. F. Infante. Vinyl chloride: A case for the use of laboratory bioassay in the regulatory control procedure. *Origins of Human Cancer*, Cold Spring Harbor Laboratory, 1977, pp. 1797-1805.

3. Frongia, N., A. Spinazzola and A. Bucarelli. Lesioni polmonari sperimentali da inalazione prolungata di polveri di PVC in ambiente di lavoro: (Experimental lung damage from prolonged inhalation of airborne PVC dust). *La Medicina del Lavoro*, 65: 321-342, 1974.

4. Waxweiler, R. J., W. Stringer, J. K. Wagoner, J. Jones, H. Falk, and C. Carter. Neoplastic risk among workers exposed to vinyl chloride. *Annals of the New York Academy of Sciences*, 271: 40-48, 1976.

5. Baxter, P. J. and A. J. Fox. Angiosarcoma of the liver in PVC fabricators. *Lancet*, 1: 245-246, 1976.

6. Chiazze, L., W. E. Nichols, and O. Wang. Mortality among employees of PVC fabricators. *Journal of Occupational Medicine*, 19: 623-628, 1977.

7. Waxweiler, R. J., A. H. Smith, H. A. Tyroler, and H. Falk. An epidemiologic investigation of an excess lung cancer risk in a synthetic chemicals plant. Presented at the XIX International Congress on Occupational Health, Dubrovnik Yugoslavia, 25-30 September 1978.

8. Mastroangelo, G., M. Manno, G. Marier, C. B. Battolucci, C. Cemignani, G. Saladino, L. Simonato, and B. Soia. Polyvinyl chloride pneumoconiosis: Epidemiological study of exposed workers. *Journal of Occupational Medicine*, 21: 540-542, 1979.

9. Szende, B., K. Lepis, A. Nemes, and A. Pinter. Pneumoconiosis caused by the inhalation of polyvinyl chloride dust. *La Medicina del Lavoro*, 61: 433-436, 1970.

10. Amaud, A., P. Pommier de Santi, L. Garbe, H. Payan, and J. Charpin. Polyvinyl chloride pneumoconiosis. *Thorax*, 33: 19-25, 1978.

11. Maltoni, C. Precursor lesions in exposed populations as indicators of occupational cancer risk. *Annals of the New York Academy of Sciences*, 271: 444-447, 1976.

12. Infante, P. F., J. K. Wagoner, A. J. McMichael, R. J. Waxweiler, and H. Falk. Genetic risks of vinyl chloride. *Lancet*, 1: 734-735, 1976.

Signed at Washington, D.C. this 12th day of December 1979.

Eula Bingham,

Assistant Secretary of Labor.

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BILLING CODE 4510-26-M

Pension and Welfare Benefit Programs

(Prohibited Transaction Exemption 79-79; Exemption Application No. D-837)

Exemption from the Prohibitions for Certain Transactions Involving College Retirement Equities Fund

AGENCY: Department of Labor.