



TO Distribution

DATE April 22, 1974

FROM R. P. Lynch

SUBJECT VCM Tank Car Safety Meeting

A review of the rulings and company reactions to these rulings was made in Philadelphia at the VCM tank car safety meeting. I was most impressed with the change in attitudes of most of the VC Poly people. They are doing most of the things that were impossible in February (by their words).

The most important item was the mouse failure. A table of results shows this:

	Mortality (M/F)		
	<u>Mice</u>	<u>Rates</u>	<u>Hamsters</u>
Control Group	15/5	4/4	13/22
50 ppm VC*	31/9	10/8	20/20
200 ppm VC	7/13	6/9	22/29
2500 ppm VC	8/13	5/7	27/27

*The VC was administered for 7 hours/day for 5 days/week. The rodents were not fed anything and 100 of each sex were used.

	Results of Autopsies			
	<u>Tumors</u>	<u>Lung</u>	<u>Angio</u>	<u>Skin</u>
Control	-	-	-	-
50 ppm	4	2	2	2
200 ppm	6	3	4	2
2500 ppm	19	17	17	3

As may be readily seen these results will lead to some severe restrictions on VC. The existing temporary standard will probably not stand. It is hoped that 10 ppm will be tried. The mice test is equivalent to approximately 20 to 25 years for a human when the first angios were found. Molteni is also finding tumors at low levels but his work is not released yet. (Most of the mortalities are from eating one another because of hunger.) BFG now has approximately ten cases. Only two or three died of angio but the others are reasonably real. Most of them had slides of biopsies that were checked for angio. Some of the deaths are back to 1969.

Another important item was the new 10 minute test. This has been very confusing. OSHA and NIOSH have both given and are using different times 1 - 3 hours. Basically they do not care about

(c) The Deputy Administrator, Veterinary Services, upon request to him, may approve other identification systems in specific cases and under such conditions as he may prescribe if he determines that such systems provide the necessary information to allow for trace-back of the swine to their herd of origin.

Any person who wishes to submit written data, views or arguments concerning the proposed amendment may do so by filing them with Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Hyattsville, Maryland 20782 before August 12, 1974.

All written submissions made pursuant to this notice will be made available for public inspection at the Federal Building, 6505 Belcrest Road, Room 870, Hyattsville, Maryland 20782, during regular hours of business (8 a.m. to 4:30 p.m., Monday to Friday, except holidays) in a manner convenient to the public business (7 CFR 1.27(b)).

Comments submitted should bear a reference to the date and page number of this issue in the FEDERAL REGISTER.

Done at Washington, D.C., this 7th day of May 1974.

PIERRE A. CHALOUX,
Acting Deputy Administrator,
Veterinary Services, Animal
and Plant Health Inspection
Service.

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DEPARTMENT OF LABOR

Occupational Safety and Health
Administration

[29 CFR Part 1910]

[Docket OSH-38]

VINYL CHLORIDE

Proposed Standards

1. **Background.** Vinyl chloride (chloroethene) Chemical Abstracts Service Registry No. 75015, is a synthetic chemical made by oxychlorination of ethylene or by hydrochlorination of acetylene. It is the parent compound of a series of thermoplastic resin polymers and copolymers which are widely used for containers, wrapping film, electrical insulation, pipe, conduit, and a variety of other products. Vinyl chloride has been made commercially in this country since 1939 and present production is in excess of seven billion pounds per year.

Vinyl chloride (VC) is a gas at ambient temperature and pressure and is a chlorinated hydrocarbon which has moderate liver toxicity. The previous standard set a ceiling value of 500 parts per million (ppm) (29 CFR 1910.93, Table G-1).

On January 22, 1974, the Occupational Safety and Health Administration (OSHA) was informed by the National Institute for Occupational Safety and Health (NIOSH) that the B. F. Goodrich Chemical Company reported that deaths of several of its employees from a rare liver cancer (angiosarcoma) may

have been occupationally related. As a result of this notification and after consultation with the National Institute for Occupational Safety and Health (NIOSH), and a joint inspection of the plant by OSHA, NIOSH, and the Kentucky Department of Labor, a fact-finding hearing on possible hazards involved with the manufacture and use of VC was announced on January 30, 1974 (39 FR 3374) and held on February 15, 1974.

2. **Carcinogenicity of VC.** Information produced at this hearing demonstrated that exposure of laboratory animals (mostly Sprague-Dawley rats) to VC by inhalation at and below the then current OSHA standard of 500 ppm induced tumors, including angiosarcomas of the liver. Professor Cesare Maltoni, of the Instituto di Oncologia, Bologna, Italy, reported on a series of experiments on the effect of exposure of rats, mice, and hamsters to VC at concentrations of 10,000; 6,000; 2,500; 500; 250; and 50 ppm for varying periods of time (TR-43-63). Some of the experiments have been concluded, and others are still ongoing. The experimental results reported were that tumors have been observed in groups of animals exposed to VC at concentrations as low as 250 ppm. No tumors were observed in the group of animals exposed to VC at a concentration of 50 ppm. It also appears that the total number of tumors, as well as the numbers of angiosarcomas of the liver, decreased as the concentrations of VC were reduced to 250 ppm. Another experiment by Professor Maltoni was reported underway involving the exposure of 300 animals to VC at concentrations of 50 ppm, in order to assess in a more definitive way whether that level of exposure produces tumors in animals. Data reported by Torkelson, Oyer and Rowe (American Industrial Hygiene Association J 22: 254-361 (1961)) indicate that exposure to VC at concentrations of 50 ppm failed to induce tumors in rats, hamsters, rabbits, and dogs.

The employees of the B. F. Goodrich Chemical Company who died from angiosarcoma of the liver had an average exposure of approximately 19 years to vinyl chloride, at unknown concentrations, and variable exposures to other volatile chemicals (TR 93). Some employees of Union Carbide, Firestone Tire and Rubber, and Goodyear were also reported in post-hearing comments to have had exposure to vinyl chloride and to have died from angiosarcoma of the liver. Finally, autopsies of four deceased employees revealed their liver angiosarcoma tumors were histologically indistinguishable from the angiosarcoma tumors observed in Professor Maltoni's experimental animals.

3. **The Emergency Temporary Standard.** On the basis of all information available at that time, and the fact that employees were being exposed at levels around the experimentally observed effect level of 250 ppm, an Emergency Temporary Standard (ETS) was promulgated on April 5, 1974 (39 FR 12342) as 29 CFR 1910.93c. This standard reduced

the level from a ceiling of 500 ppm to 50 ppm ceiling. It was expressly recognized that this standard limiting exposures to a 50 ppm level was intended to be a tentative, interim standard, to be in effect no longer than six months, during which time the whole question of possible safe exposure to VC would be reconsidered more fully and in the light of more information, especially results of experiments which were known to be underway at that time.

4. **Additional information.** On April 15, 1974, information and data were presented to representatives of OSHA, NIOSH and the EPA by the Industrial Bio-Test Laboratories, Northbrook, Illinois, concerning results of animal exposure studies with VC, sponsored by the Manufacturing Chemists Association (MCA). Although only preliminary in nature, these results revealed that 2 out of 200 mice exposed to VC concentrations of 50 ppm for 7 hours a day, five days a week, for approximately 2 months, developed angiosarcomas of the liver.

The Industrial Bio-Test Lab data indicate that exposure to VC at 50 ppm may well constitute a serious health hazard to employees. Also, the question of a safe level of exposure for humans cannot be determined at this time, and may continue as a matter for scientific deliberation for many years. We therefore conclude that it is now necessary to propose to change the 50 ppm level established in the ETS to as low a level as can be detected using methodologies outlined in this proposal.