

MR. JUSTICE CLARK:

This is a petition for review of the health and safety regulations for the vinyl chloride industry, 29 C.F.R. §1910.93q, promulgated by the Secretary of Labor on October 4, 1974, pursuant to the Occupational Safety and Health Act, 29 U.S.C. §651 et seq. (hereinafter OSHA). The standard and the Secretary's statement of reasons for its imposition are set forth at 39 Fed. Reg. 35890-35898. In brief, the Secretary has adopted a standard which requires that no worker is to be exposed to concentrations of vinyl chloride in excess ~~of~~ ^{one} part per million (ppm) averaged over any eight-hour period. 29 C.F.R. §1910.93q (c)(1).

Petitioners -- manufacturers of vinyl chloride and vinyl chloride products -- make five principal claims: (1) the available scientific and medical evidence does not establish that the 1 ppm exposure level adopted by the Secretary is required by health or safety considerations; (2) that the Secretary violated the requirements of 29 U.S.C. §655(b)(5) by adopting a standard which is technologically and economically infeasible for the industry to meet; (3) that the standard is so vague and uncertain in its terms that enforcement will violate the requirements of due process; (4) that there was no substantial evidence in the record to support the Secretary's conclusion that those who fabricate products out of vinyl chloride should be subject to the same requirements as those who produce vinyl chloride; and (5) that the Secretary's sign and labelling requirements unduly and hence unlawfully emphasized the carcinogenic properties of vinyl chloride. We find these contentions meritless, and the petitions for review are accordingly denied.

SCOPE OF JUDICIAL REVIEW

Before proceeding to an examination of the regulations at issue in this case, it would be wise to reemphasize the unique nature of the court's role under OSHA. Although the statute sets forth general policy objectives and a procedural framework, the formulation of specific safety and health policies is left to the Secretary, subject to review in the United States Courts of Appeals. Our mandate is contained in 29 U.S.C. § 655 (f), which states in relevant part:

The determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole.

Yet the traditional "substantial evidence" test is almost impossible of application where, as here, the Secretary's decision-making is essentially legislative in character.

The problems involved in according judicial review in such circumstances have been wisely discussed by Judge McGowan in Industrial Union Department, AFL-CIO v. Hodgson, 499 F. 2d 467 (D. C. Cir. 1974), who pointed out that, under OSHA:

[T]here are areas where explicit factual findings are not possible, and the act of decision is essentially a prediction based upon pure legislative judgment, as when a Congressman decides to vote for or against a particular bill.

[P]olicy choices of this sort are not susceptible to the same type of verification or refutation by reference to the record as are some factual questions. Consequently, the court's approach must necessarily be different no matter how the standards of review are labeled. [499 F. 2d at 474-75.]

In these circumstances, Judge McGowan concluded, the reviewing court must recognize that its task defies generalized description and go from there to achieve its paramount objective which "is to see whether the agency, given an essentially legislative task to perform, has carried it out in a manner calculated to negate the dangers of arbitrariness and irrationality in the formulation of rules for general application in the future." Automotive Parts & Accessories Assn. v. Boyd, 407 F. 2d 330, 338 (D.C. Cir. 1968).

Thus armed with these salutary remarks on our limitations and our obligations, we turn to the challenged regulations. The examination of the 4,000-page record in this case has been a prodigious task, aggravated by duplications of testimony, irrelevant exhibits and letters, almost illegible reproduction of documents, and a generally blunderbuss approach in petitioners' briefs. Given the task, however, we have performed it and conclude that the standard laid down by the Secretary is fully supported by the record and well within the requirements of Universal Camera Corp. v. NLRB, 340 U.S. 474 (1951), and Assoc. Industries of New York State, Inc. v. Department of Labor, 487 F. 2d 342 (2d Cir. 1973), as well as Industrial Union Department, AFL-CIO v. Hodgson, *supra*.

II.

BACKGROUND

There are three basic components of the vinyl chloride industry. First, there are the manufacturers of vinyl chloride itself. A gas at ambient temperatures and pressure, vinyl chloride monomer (VCM) is primarily synthesized by the oxychlorination of ethylene in a handful of

... outdoor production plants which resemble oil refineries. Shell, Dow, and Goodrich are the leading producers, accounting for some 50% of the 5.2 billion pounds annually available in the United States. Because of the high degree of automation involved in this manufacturing process, only some 1,500 workers are employed in VCM production. VCM plants are open-air facilities, primarily in the South.

Second, there are the manufacturers of polyvinyl chloride (PVC). Virtually all vinyl chloride is polymerized into thermoplastic PVC resin which serves as the basis for a wide variety of useful plastic products. Goodrich is by far the largest single producer, producing some 20% of the country's 5.4 billion pounds annually, though in total there are only 21 companies operating the 37 PVC plants. Historically, PVC production has been a "batch" or non-continuous operation carried out in relatively small (2,000-6,000 gallon) "reactors" which require frequent cleaning; the trend, however, is towards substantially larger reactors. PVC plants are not open-air facilities and are generally located in colder climates than VCM plants. They employ some 5,000 workers.

Third, and finally, there are the fabricators of products which utilize PVC resins. Innumerable firms throughout the country, employing thousands of workers, compound PVC with plasticizers, heat stabilizers, lubricants, light stabilizers, flame retardants, or impact modifiers to produce an astounding variety of wares, such as pipes and conduits for building and construction, flooring, wire and cable, furniture, phonograph records, and packaging. In fabrication, residual VCM that has been entrapped in the PVC resin escapes during the heating process, and in this way workers in the fabricating industry are also exposed to vinyl chloride.

the vinyl chloride industry are subjected to a serious health risk from VCM. Although conclusive proof of the carcinogenic and, in turn, fatal character of VCM did not emerge until early in 1974 when the deaths of three workers in Goodrich's PVC plant at Louisville were reported, strong warning signals had appeared long before. As early as 1949, when the vinyl chloride industry had barely reached its tenth anniversary, a study conducted among vinyl chloride workers in the Soviet Union found liver damage in 15 of 48 workers studied, and in 1958 and 1959, Dow Chemical scientists elicited liver irregularities in rats and rabbits at a 100 ppm concentration of VCM. Although Dow recommended a 50 ppm allowable level in 1961, the industry adhered to its previous 500 ppm standard.

We need not outline in detail the morbid "Vinyl Chloride Chronology", published by an industry spokesman, the Manufacturing Chemists Association (MCA), in a 1974 press release (Joint Appendix at 134-145) in order to illustrate the mounting evidence of VCM's carcinogenicity. Indeed, the record shows what can only be described as a course of continued procrastination on the part of the industry to protect the lives of its employees. In 1967, when the industry had not reached its thirtieth anniversary, upon receiving recurring reports of the softening of the finger tips and bone of VCM/PVC workers, the Manufacturing Chemists Association had the University of Michigan study the causes of this abnormality. Three years later, in 1970, when it was advised that research could not pinpoint the cause of the malady but recommended a VCM/PVC ceiling of 50 ppm VCM, nothing was done. And in March of the same year, Dr. F. L. Viola of the Regina Elena Institute for Cancer Research in Rome, Italy, published a report that 30,000 ppm VCM exposure for four hours per day, five days per week for a

...and cancer of the skin, lung, and bones of rats, and a few months later at the Tenth International Cancer Congress, described observations of malignant tumors in the ear canals of rats subjected to the same exposure, apparently relying on Dr. Viola's comment at the close of his abstract that: "No implications to human pathology can be extrapolated from the experimental model reported in the paper," the industry did nothing.

In 1971, MCA began to inquire by letter regarding the conduct of toxicological studies on laboratory animals with VCM and in May of 1971 heard a detailed presentation by Dr. Viola regarding his earlier studies as well as other studies then unreported. The industry began talking about raising funds for epidemiological research on VCM carcinogenicity, but not until March 30, 1972 did 17 U. S. companies agree to finance such a study. By then, the first deaths of U. S. workers due to VCM exposure were being recorded.

Months were consumed in 1972 by negotiations among the participating company representatives, and it was not until February of 1973 that a protocol was agreed upon and a research contract for animal exposure studies signed. Meanwhile, startling results from European experiments were filtering back to the industry. By January of 1973 it was discovered that European experiments with rats had not only found tumors of the ear canal (which Dr. Viola had reported as early as 1970), but also of the kidneys and liver at concentrations as low as 250 ppm VCM, but not at 50 ppm. This discovery, however, was kept confidential, and it was not even revealed to the National Institute of Occupational Safety and Health (NIOSH) until July 17, 1973.

Earlier, on September 27, 1971, a patient of Dr. J. L. Creech, Jr., plant physician of the B. F. Goodrich Chemical Company in Louisville, Kentucky, died. The patient had been employed for 15 years as a helper and operator in Goodrich's Louisville PVC plant. When first

how, utilized, a tentative diagnosis was made of a bleeding duodenal ulcer, but upon re-admittance and after an exploratory laparotomy and biopsy was carried out, he was found to have angiosarcoma of the liver, an exceptionally rare and irreversible cancer which strikes only 1 person in some 50,000, no more than 20-30 persons a year. Eighteen months later, on March 3, 1973, another former employee of the Louisville plant died, and a third died on December 19, 1973, again of angiosarcoma of the liver. Recognizing the rarity of the tumor and learning that all three had worked in the Goodrich PVC plant, Dr. Creech brought the matter to the attention of Goodrich, and then on January 22, 1974, to the attention of the National Institute of Occupational Safety and Health (NIOSH).

News of other deaths followed swiftly. On January 29, 1974, Goodrich reported the death of a fourth former employee from angiosarcoma; a report of the death of a fifth employee followed on February 15th. Six days later, Union Carbide advised NIOSH of the death of one of its PVC workers from liver angiosarcoma. Goodyear Tire and Rubber Company announced a vinyl chloride worker fatality from liver angiosarcoma on March 1, 1974, and reported two more such deaths from the same cause on March 22nd. Goodrich reported cases of liver angiosarcoma in two of its living employees. On April 16, 1974, Firestone Plastics announced the death of one of its employees from the same disease. Finally, on May 10, 1974, the National Cancer Institute diagnosed another Union Carbide VCM worker as a victim of the same disease. In all, the deaths of 13 workers in the PVC and fabricating industries were reported.

Two days after Goodrich made its report to NIOSH of its first three VCM worker deaths, an inspection of its plant by NIOSH indicated considerable exposure of workers to VCM, and control procedures as well as precautionary monitoring were recommended. NIOSH alerted other federal agencies and after additional investigation soon concluded that VCM was the suspect agent for a new occupational cancer. On April 5, 1974, the Assistant Secretary of Labor, acting on behalf of the Secretary, held a hearing and promulgated an emergency temporary standard of 50 ppm TWA^{/1} in lieu of the prevailing 500 ppm one. At the hearing, industry itself showed concern, and evidence was presented that both VCM and PVC plants could reduce concentrations below 50 ppm TWA. As in the past, Dow Chemical spoke out for worker safety and urged that industry exposure be reduced to 50 ppm TWA by operational and engineering changes and that appropriate respiratory protection be given where such level was not attainable. The Assistant Secretary concluded that the evidence demonstrated VCM to be carcinogenic for man. See 39 Fed. Reg. 12342. Monitoring and housekeeping requirements were also imposed, and a requirement was included that, if the 50 ppm level was breached, appropriate respirators equipment be furnished workers. The emergency order was limited to six months "during which time the whole question of possible exposure of humans to VC would be reconsidered more fully and in the light of more information, including experiments which are underway at the time."

notified MCA that its preliminary findings in their animal exposure study showed that angiosarcoma of the liver was produced in mice at a level of 50 ppm of vinyl chloride, and MCA so informed the federal government. On May 10, 1974, the Assistant Secretary again acted. Issuing a notice of proposed permanent rulemaking, he drew attention to the MCA study results and noted that: "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."

39 Fed. Reg. 16986. In the interim, he concluded, it was necessary to abandon the 50 ppm emergency temporary standard and to establish it at as low a level as can be detected using methodologies sensitive to 1 ppm plus-or-minus 50%, i.e., the so-called "no-detectable" level. This level was to be reached through the "institution of engineering controls and work practices as soon as feasible," but respiratory protection was to be afforded where the goal could not otherwise be achieved.

On May 24, 1974, notice of a hearing on the proposed standard to be held before an Administrative Law Judge was given. Eight days of hearings were held during June and July of 1974, and additional materials were received from interested parties until September 25th. In addition, the record of the previous hearing on February 25, 1974, was ordered to be included.

On October 1, 1974, the final standard was promulgated, effective January 1, 1975.¹² See 39 Fed. Reg. 35890. The main provisions are as follows: