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May 22, 1989

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Dear Mr. Gordon and Ms. Werthmann:

Enclosed are an original and six copies of the petition of the Society of the Plastics Industry, Inc. (SPI) for a stay and for reconsideration of the final air contaminants rule of the Occupational Safety and Health Administration (OSHA). Specifically, SPI is requesting modification of the provisions of the final rule establishing a 1 part per million permissible exposure limit (PEL) for ethylene dichloride (EDC).

We look forward to OSHA's response to our petition. If you need any additional information, or if you would like to discuss the petition further, please do not hesitate to contact me.

Very truly yours,

Peter L. de la Cruz
Peter L. de la Cruz

Enclosure

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BEFORE THE
UNITED STATES DEPARTMENT OF LABOR
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

PETITION OF
THE SOCIETY OF THE PLASTICS INDUSTRY, INC.
FOR A STAY AND FOR RECONSIDERATION OF A FINAL RULE
AMENDING THE OSHA AIR CONTAMINANTS STANDARD
FOR ETHYLENE DICHLORIDE

Docket No. H-020

May 23, 1989

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BEFORE THE
UNITED STATES DEPARTMENT OF LABOR
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

PETITION OF
THE SOCIETY OF THE PLASTICS INDUSTRY, INC.
FOR A STAY AND FOR RECONSIDERATION OF A FINAL RULE
AMENDING THE OSHA AIR CONTAMINANTS STANDARD
FOR ETHYLENE DICHLORIDE

Docket No. H-020

The Society of the Plastics Industry, Inc. (SPI) requests that the Occupational Safety and Health Administration (OSHA) of the United States Department of Labor stay its final rule amending the air contaminants standard in 29 C.F.R. § 1910.1000, 54 Fed. Reg. 2332 (Jan. 19, 1989), as it applies to ethylene dichloride (EDC). SPI further requests that OSHA reconsider the provisions of its final rule that establish a one part per million (ppm) permissible exposure limit (PEL) as an 8-hour time weighted average (TWA) and a 2 ppm short term exposure limit (STEL) for EDC. The EDC provisions of the rule are of particular concern to the Vinyl Institute, a division of SPI whose members represent the major domestic producers of EDC.^{1/}

^{1/} SPI is a 1,800 member not-for-profit corporation organized under the laws of the State of New York. The Society's members include processors and manufacturers of plastics or plastics products, suppliers of raw materials, processors and converters of plastic resins and manufacturers of accessory equipment for the plastics industry. Founded in 1937, the Society is the "voice" of the plastics industry.

The Vinyl Institute's members account for a significant percentage of ethylene dichloride production in the U.S. Th
(continued...)

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I. SUMMARY

This petition seeks a stay and reconsideration of OSHA's 1 ppm PEL and 2 ppm STEL for EDC. The former PEL was 50 ppm, with excursions permitted to 100 ppm and 200 ppm. During the air contaminants rulemaking, OSHA proposed and adopted the recommended exposure limit (REL) suggested by the National Institute for Occupational Safety and Health (NIOSH) in a criteria document on EDC.

A stay is warranted here because, contrary to OSHA's assumptions, the use of respiratory protection to meet the new standard during routine maintenance operations in the EDC production process raises significant compliance issues. These issues must be resolved prior to the effective date of the new standard so that manufacturers have a clear understanding of what types of compliance measures are permissible.

Accordingly, this petition first addresses the technological and economic feasibility issues raised by OSHA's final rule and then focuses on the deficiencies in OSHA's

1/(...continued)

members include: Air Products and Chemicals, Inc.; BFGoodrich Company; Borden Chemicals & Plastics; CertainTeed Corporation; The Dow Chemical Company; Georgia Gulf Corporation; Occidental Chemical Corporation; PPG Industries, Inc.; Shintech, Inc. and the Vista Chemical Company.

assessment of the actual risk to worker health in EDC facilities. However, we stress at the outset that the record and existing scientific literature do not support the reduction of the PEL to 1 ppm based on potential health effects.

SPI's most immediate practical concern is that a 1 ppm PEL is not technologically feasible through engineering controls and changes in work practices alone. OSHA noted that EDC production occurs in a closed system. While this is true, the nature of EDC production requires that workers periodically clean the interior of production vessels and unclog piping systems. OSHA assumed that 1 ppm could be attained for these routine maintenance operations with the use of respirators. Permitting the use of respirators, however, raises critical questions regarding the types of respirators that may be used and the conditions under which they may be employed. Workers face several physical constraints when using elaborate supplied air systems. The interiors of distillation columns do not permit the use of air lines or air packs. The work is often physically strenuous and occurs in elevated locations. For these reasons, air lines and self-contained breathing apparatus (SCBA) are, at best, cumbersome and inconvenient and, at worst, unsafe. They are not, therefore, a feasible alternative in this situation.

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In addition, air-purifying respirators, such as charcoal canister respirators, do not appear to be acceptable from a compliance standpoint. First, the 1 ppm PEL is well below the odor threshold for EDC (5-6 ppm). Under normal industrial hygiene guidelines, air-purifying respirators generally are not used when workers cannot physically sense a "breakthrough" of the contaminant should the respirator fail to function adequately. Second, NIOSH guidelines indicate that the preferred half-face cartridge respirators should not be used in atmospheric concentrations that are 10 times higher than the PEL. With a 1 ppm PEL, these half-face masks could only be used in an atmosphere where the concentration was 10 ppm or less. This leaves only full-face respirators (which would be limited to use in concentrations of 50 ppm or less) and more elaborate supplied-air systems. Although there is strong evidence that half-face respirators will work in concentrations of greater than 10 ppm, use of these respirators at such levels would appear to raise compliance issues of concern to EDC manufacturers.

Finally, but most importantly, the record in this case on the health effects of EDC and the scientific literature in general does not support the reduction of the PEL to 1 ppm. OSHA relied primarily on two 30-year-old Eastern European studies which have severe limitations. These studies involved

excessive worker exposures to EDC and working conditions that are simply not relevant in today's industrial environment. The Agency also failed to adequately consider later data which shed light on the proper interpretation of earlier epidemiologic and animal studies. These data provide strong evidence that EDC does not present a carcinogenic risk when exposure occurs through inhalation rather than through ingestion. Although OSHA adopted the NIOSH REL, it based its regulation of EDC primarily on liver toxicity, which is not the health effect for which NIOSH recommended a 1 ppm REL. OSHA's analysis of the health data in the Preamble to the final rule is not sufficient to satisfy its obligation to show that a 1 ppm PEL is necessary to reduce or eliminate a significant health risk.

Because significant problems of compliance with the PEL remain and because OSHA has not justified its PEL on the basis of the available health data, OSHA has failed to satisfy the statutory prerequisites. A stay is necessary, therefore, because EDC manufacturers are not in a position to comply with the new standard by September, 1989. For the same reasons, OSHA should reconsider its adoption of a 1 ppm PEL and 2 ppm STEL.

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II. FACTUAL STATEMENT

A. Legal Framework

Under the Occupational Safety and Health Act of 1970, 29 U.S.C. §§ 655, 657, OSHA must establish air contaminant standards that will actually reduce or eliminate significant risks of material health impairment resulting from exposures to the regulated substance. See Industrial Union Department v. American Petroleum Institute, 488 U.S. 607, 642 (1980) ("Secretary is required to make a threshold finding that a place of employment is unsafe in the sense that significant risks are present and can be eliminated or lessened by a change in practices"). In addition, OSHA must demonstrate that the standard established is technologically and economically feasible. The requirement that feasibility be considered is included in the Act itself, see § 6(b)(5), 29 U.S.C. § 655(b)(5) and has been reaffirmed by the courts. See American Textile Manufacturers Institute v. Donovan, 452 U.S. 490, 531-32 (1981).

B. Regulatory Proceedings

On June 7, 1988, OSHA issued a proposed rule to amend its standard for air contaminants in the workplace found at 29

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C.F.R. § 1910.1000. 53 Fed. Reg. 20960 (June 7, 1988). OSHA proposed to establish or modify the PELs for 428 substances. As the starting point for its analysis of these substances, OSHA used the "already published and widely accepted 1987-88 Threshold Limit Values (TLVs) published by the American Conference of Governmental Industrial Hygienists (ACGIH) and the Recommended Exposure Limits (RELs) developed by the National Institute for Occupational Safety and Health (NIOSH)." 54 Fed. Reg. 2333 (Jan. 19, 1989). OSHA proposed to adopt the NIOSH recommended limits for EDC of 1 ppm as an 8-hour TWA and a 2 ppm STEL.

During the comment period on the proposed rule, eight comments specifically addressed the proposed PEL for ethylene dichloride. The Vinyl Institute, the Chemical Manufacturers Association and The Dow Chemical Company were among the industry members submitting comments on EDC. The industry commenters noted the deficiencies in the scientific studies relied upon by OSHA in its assessment of the potential risk to worker health posed by EDC and urged OSHA to conduct a more thorough review of the scientific literature in this area. These comments also emphasized that there is inadequate evidence of the carcinogenic effects of EDC exposures occurring via inhalation and that the PEL should not, therefore, be established on the basis of EDC's carcinogenic potential.

Industry commenters also observed that compliance with a 1 ppm PEL is not technologically feasible for most operations at an EDC facility and particularly for certain intermittent operations such as maintenance, loading, and sampling. Some commenters stated that compliance with a 10 ppm PEL would be feasible for most routine manufacturing operations and that respirators should be permitted for those intermittent operations where compliance with the standard would be more difficult using only engineering controls and work practices.

On January 19, 1989, OSHA published its final rule which establishes or changes the PELs for 376 substances. 54 Fed. Reg. 2332 (Jan. 19, 1989). The final rule sets a PEL of 1 ppm as an 8-hour TWA and a 2 ppm STEL for EDC. These limits represent a severe reduction from the previous standard of 50 ppm as an 8-hour TWA, a 100 ppm STEL, and an acceptable peak of 200 ppm, and even go well beyond the ACGIH TLV for EDC of 10 ppm as an 8-hour TWA. Instead, the final rule adopts the NIOSH recommended limits for EDC.

On March 10, 1989, SPI filed suit in the U.S. Court of Appeals for the District of Columbia Circuit challenging OSHA's final rule for EDC. This action has since been consolidated with several other challenges to the OSHA rule in the Eleventh Circuit Court of Appeals.

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C. EDC Facilities and Operations

EDC is a clear, colorless liquid but often becomes mixed with much heavier materials, including solids, during the manufacturing process. The EDC purification process, intended to remove the heavier materials, routinely results in the pluggage of processing lines, vessels and pumps. The blockage of this processing equipment is so severe that there is no effective means of removing the pluggage other than to have workers open the equipment and physically remove the obstruction.

When equipment, such as distillation columns, become obstructed or require routine maintenance, steps are taken to purge the vessel with water, steam or other means to reduce the EDC level in the equipment. However, because blockage is normally involved, it is simply not possible to completely purge the equipment and reduce the EDC level to 1 ppm.

When workers are required to gain access to piping or to open pumps or other equipment, they wear the appropriate personal protective equipment that experience suggests for the situation at hand. When necessary, respiratory protection is worn during the initial step of equipment opening. While OSHA's 50 ppm PEL was in effect, workers would wait until they received a reasonable assurance that exposure levels were below the PEL. Full maintenance and clean-up activities were then

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performed without respiratory equipment or with air-purifying half-face respirators because the tasks could not be performed safely or effectively while the workers were encumbered with full protective suits, air lines or supplied-air equipment. In fact, because of the demanding physical conditions in EDC plants and the convoluted interiors of distillation columns, air line and air pack equipment can actually contribute to unsafe working conditions. Since engineering controls and work practices alone cannot enable EDC-producing companies to comply with the new 1 ppm standard under such conditions, companies must either keep unprotected workers from the work area until ambient levels drop below 1 ppm or provide their workers with respirators that will reduce exposure below 1 ppm.^{2/}

^{2/} Because the new 1 ppm standard effectively eliminates the option of waiting for ambient levels to fall below the PEL before allowing workers to perform maintenance operations without some form of respiratory equipment, some companies operating combined EDC/vinyl chloride plants now face another concern. A few of these plants have an internal policy of prohibiting the use of air-purifying respirators in their EDC facilities because of the possibility that workers will use the same respiratory protective equipment during the vinyl chloride operations in which they are involved. Such respirators are not considered effective in vinyl chloride operations. To avoid any potential confusion by workers, and to insure that the proper equipment is worn during vinyl chloride operations, some of these combined facilities permit only the more elaborate supplied-air systems in their plants. These supplied-air systems may be used for higher exposures during the initial stages of maintenance operations but are not appropriate for completing these lengthy operations. Thus, in addition to the guidance from OSHA requested below for other EDC facilities on air-purifying respirators, guidance from OSHA is also needed for this situation that is unique to a few facilities. This issue is distinct from the issues regarding the use of air-purifying respirators to which the remainder of this Petition is devoted.

III. ARGUMENT

A. Compliance With The EDC Exposure Limits Is Not Feasible

1. Industry Experience in Limiting Worker Exposure

OSHA has concluded that the 1 ppm limit is both technologically and economically feasible for most operations using engineering controls and improved work practices. For certain operations, such as maintenance, loading, or sampling operations, OSHA has apparently concluded that the intermittent, non-routine and varied nature of such operations should be the subject of special consideration on a case-by-case basis. Typically, in special circumstances, OSHA will permit the use of respirators to meet the PEL when it is not feasible to meet the limit using engineering or work practice controls.

Actual experience in the EDC industry, however, suggests that OSHA's findings are based more on well-intentioned but erroneous assumptions rather than a full investigation of actual conditions at EDC plants. The vast majority of companies in the EDC industry have attempted to use the ACGIH TLV of 10 ppm as a guideline. For the most part, the industry has been able to institute engineering and work

practice controls that generally achieve the 10 ppm level or less for ambient air conditions during normal operations.

As OSHA has apparently recognized, for many special operations in the EDC production process, compliance with the ACGIH 10 ppm limit using engineering and work practice controls is simply not feasible. A 1 ppm PEL during these operations is, of course, similarly unachievable through the use of such measures alone. As discussed below, without some assurance from OSHA that the use of certain respirators will be considered appropriate and in compliance with the standard, OSHA's general statement that it will permit the use of respirators to meet the 1 ppm PEL for EDC when it cannot be attained through work practice and engineering controls is not an adequate solution.

**2. Use of Supplied-Air Respirators is Not
Appropriate and May be Unsafe In
Many Circumstances**

The use of supplied-air respirators (i.e. those using air lines and air packs) is not appropriate for several reasons. First, the physical bulk of the equipment or trailing air line makes this type of equipment undesirable and unsafe for use when workers are cleaning the interior of certain vessels, such as distillation columns. Second, maintenance work will frequently occur in an elevated location. The balance and control problems presented by air packs, in

addition to the problems presented by intertwining air lines and their normal pulling effect, present a safety hazard to workers at elevated heights that is not justified in light of the minimal risk reduction such systems provide over cartridge respirators. Third, many EDC facilities are located in Texas and Louisiana which are subject to hot, humid weather. Supplied-air systems complicate matters by aggravating heat exposure.

Under these circumstances, the use of heavy, cumbersome supplied-air equipment is simply not feasible and will greatly increase the potential for workers to sustain injuries during these operations. In situations requiring more than one worker, such equipment will also reduce the ability of the workers to communicate and present the further risk of some workers becoming entangled in or interfering with other workers' equipment. Because such equipment restricts worker movement, these operations will take even longer to perform, further increasing the risk of injury arising from fatigue and heat exhaustion. Finally, it is simply not fair or reasonable to ask workers to perform these tasks under conditions of extreme discomfort.

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3. Use of Air-Purifying Respirators Raises Serious Compliance Problems Requiring OSHA Resolution

a. 1 ppm is below the odor threshold -- The use of air-purifying respirators to reach a 1 ppm PEL in EDC facilities would conflict with fundamental precepts of industrial hygiene. Air-purifying charcoal cartridges used in respirators are replaced when their purifying capabilities are depleted. This is done periodically and as soon as the worker senses a break-through of the substance through the mask.

A fundamental principle of industrial hygiene (and of OSHA's respiratory protection policy as we understand it) provides that air-purifying respirators should not be used unless the substance has adequate warning properties at or below the exposure limit. The odor of a substance is the most common warning property.

The 1 ppm PEL for EDC, however, is well below its odor threshold which NIOSH has acknowledged may be as low as 5-6 ppm.^{3/} Since the PEL is below the odor threshold, the worker will be unable to detect break-through above the 1 ppm PEL until the air-purifying cartridge is more fully depleted and a break-through in the 8-10 ppm range or higher occurs. Thus, air-purifying respirators are inappropriate for a 1 ppm PEL.

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^{3/} NIOSH, Criteria for a Recommended Standard: Occupational Exposure to Ethylene Dichloride (1,2-dichloro-ethane). U.S. DHEW, PHS, CDC, NIOSH, p. 45 (March 1976) (Record Exh. 1-213) (hereinafter referred to as NIOSH Criteria Document).

b. 1 ppm Presents Protection Factor Problems -- To provide a "protection factor" for the use of air-purifying cartridge respirators, NIOSH has recommended that half-facemask air-purifying respirators not be used under conditions involving exposure at more than 10 times the PEL. NIOSH Criteria Document, at 107. Full-facemask respirators are not recommended for use in concentrations greater than 50 times the PEL. Id. If the PEL is 1 ppm, use of half-mask respirators would not be appropriate unless the concentration is 10 ppm or less and the use of full-mask respirators would not be appropriate in concentrations greater than 50 ppm.

The use of these cartridge respirators is certainly preferred by both workers and manufacturers to the use of more elaborate supplied-air respiratory equipment. NIOSH has itself recognized that these cartridge respirators are effective even when concentrations of EDC are as high as 1000 ppm. NIOSH Criteria Document, at 108. With the new PEL, however, their use is severely restricted to conditions involving very low EDC concentrations, i.e., under 50 ppm for full-masks and 10 ppm for half-masks. Use of these respirators at higher concentrations, even though they are effective and suitable, will raise serious compliance questions that would discourage SPI member companies from such use. Resolution of these compliance issues by OSHA is needed to make compliance with the standard more feasible.

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**B. OSHA Failed to Adequately Consider the Economic
Impact of its Decision to Reduce the EDC PEL to 1 ppm**

As a result of its misconceptions regarding compliance with the new standard at typical EDC facilities, OSHA has significantly underestimated the economic impact of its final rule on EDC manufacturers. OSHA responded to industry comments pointing out the anticipated costs of complying with the new standard by assuming that the sanctioned use of respirators or other personal protective equipment would allow compliance at much lower cost. As noted above, however, the use of such equipment is inappropriate, infeasible, and unsafe for workers if used to meet a 1 ppm PEL. Instead of using such equipment, major capital investments would be required. This situation results in added compliance costs not adequately considered by OSHA in promulgating its final rule.

Because of the problems associated with the use of respirators or more elaborate supplied-air systems, the type of engineering controls and changes in work practices that would be needed to bring exposure levels down to 1 ppm during certain critical EDC operations are either non-existent or economically prohibitive. For example, plant-wide maintenance and clean-up operations that are needed periodically require that equipment throughout the plant be opened and purged at the same time. The only currently available method of reducing the ambient levels to 1 ppm during this time, without mandating the use of

heavy personal protective equipment, would be to shut down and ventilate the plant until levels dropped to 1 ppm, at which time the workers could resume their cleaning and maintenance activities. For exposure levels to drop to 1 ppm, however, the entire plant would have to be shut down for days or weeks.

It has been estimated that these shut-down periods will result in an average sales loss of between \$20-30 million for each EDC/vinyl chloride plant and a total loss of sales for the industry of between \$320-480 million. Not only would this shut-down have a devastating economic impact on the EDC facility, but it would also result in shut-downs at downstream facilities that rely on a ready supply of EDC for their operations.

Since it is economically infeasible to rely on plant shut-downs to comply with the standard, very costly modifications would be required in plant facilities. The industry anticipates that major capital investments would be needed to supplement or modify existing facilities in the areas of tank farm vent controls, sample gathering and laboratory techniques, process sewer systems, additional employee exposure monitoring, loading/unloading operations and maintenance.

The industry estimates that these new or modified facilities will require an initial capital investment of between \$10-25 million for each plant. In addition, the added

expense of complying with the standard has been estimated to be \$4-5 million for each plant per year. When these figures are calculated on an industry-wide basis, the initial capital expense that would be necessary to bring the entire industry into compliance with the new standard is \$160-400 million and the annual operating cost to maintain industry compliance would be \$60-80 million. Even with these investments, compliance with the standard would still require lengthy and costly shut-down periods for each facility during the extensive purging and cleaning process.

It is important to note that the industry is, for the most part, now complying with the ACGIH TLV of 10 ppm for general ambient exposures during normal operating periods. Thus, these cost estimates are based not on the modifications that would be necessary to bring exposure levels down from the existing PEL of 50 ppm to 1 ppm, but rather the cost of further reducing exposure levels from what industry believes to be an already safe level of 10 ppm to the new standard of 1 ppm. In light of the fact, discussed more fully below, that OSHA lacks adequate scientific support for its conclusion that reducing the PEL to 1 ppm will eliminate or lessen a significant risk of material health impairment of the workers in the EDC industry, these combined costs of compliance are exorbitant and cannot be justified.

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C. The Exposure Limits for EDC are Contrary to Law Because the Reduction to 1 ppm is Not Necessary to Eliminate a Significant Risk of a Material Health Impairment

1. Deficiencies in Primary Studies OSHA Cites

In attempting to meet its obligation under the Act to demonstrate that its standard is necessary to alleviate a significant risk of a material health impairment, OSHA relies primarily on two foreign studies on workers that were conducted more than thirty years ago.^{4/} OSHA has apparently concluded that these two studies provide adequate scientific evidence linking EDC with hepatotoxicity, effects on the nervous system, and changes in the blood of workers at 10-15 ppm.

Both the Kozik and Brzozowski studies have significant weaknesses and limitations that have not been fairly or adequately considered by OSHA. First, as was pointed out in the public comments on the proposed rule, both of these studies involved worker exposures well in excess of 10-15 ppm. In addition, both of these studies involved not only exposure by inhalation but also dermal exposures that may have significantly affected the results and findings of these

^{4/} Kozik, J.V., Problems of Industrial Hygiene Arising from the Use of Dichloroethane in the Aviation Industry. Gigiena Truda I Professionalnye Zabolevaniia (MOSKVA) 1 (1957):31-38.

Brzozowski, J., Czajka, J., Dutkiewica, T. et al, Higiena Pracy I Stan Zdrowia Zatrudnionych Przy Zwalczaniu Stonki Ziemniaczanej Heksachlorocykloheksanem, Dwuchloroetanem, Medycyna Pracy Dwumiesiecznik 5 (1954):89-98.

studies. OSHA attempts to dismiss the possible distorting effects of these dermal exposures in the Brzozowski study by citing studies on rabbits that suggest "EDC is not readily absorbed through the skin in toxic quantities." 54 Fed. Reg. 2485. The Agency admits, however, that dermal exposure "undoubtedly contributed somewhat to the toxic effects seen in the workers in the Brzozowski study." Id. Since OSHA makes no effort to assess the impact of these dermal exposures on the health effects reported in these studies, it provides no basis for its conclusion that "airborne exposure was the predominant contributor to these effects." Id.

Nor did OSHA adequately address the impact of the unusually high inhalation exposure levels that occurred during these studies. The authors noted that workers were seen breathing very near barrels during pouring and that workers often spilled EDC on themselves, presumably causing them to breath vapors from contaminated clothing in addition to absorbing the substance through direct dermal exposure. Thus, the reported concentrations in the study are not reflective of actual inhalation exposures. Because of the deficiencies in these accounts of chronic EDC exposure in humans, these two studies fall far short of the scientific evidence needed by OSHA to satisfy its statutory burden. OSHA has failed to demonstrate, on the basis of these studies alone, that EDC causes chronic toxic effects in humans at levels above 1 ppm

and that its 1 ppm PEL is necessary to eliminate a significant risk to health posed by higher levels of EDC.

Significantly, while ACGIH has known about these studies for years, it was unable to conclude during this time that these studies provided a sufficient basis for lowering their recommended limits of exposure below 10 ppm. The TLV established by ACGIH remains at 10 ppm.

The 1976 NIOSH Criteria Document (Record Ex. 1-231) proposed a 5 ppm REL based on these and other studies. The revised NIOSH Criteria Document (Record Ex. 1-1120)^{5/} lowered the REL from 5 to 1 ppm predicated on its conclusion that EDC posed a potential risk of carcinogenicity based upon the oral gavage study in rats and mice conducted by the National Cancer Institute (NCI) in 1978.^{6/} It is apparent from OSHA's preamble discussions to both the final and proposed rule, however, that its 1 ppm PEL for EDC is based primarily on the studies of Kozik and Brzozowski, not the NCI bioassay. Thus, the NIOSH

5/ NIOSH, Revised Recommended Standard: Occupational Exposure to Ethylene Dichloride (1,2 Dichloroethane). U.S. DHEW, PHS, CDC, NIOSH (Sept. 1978).

6/ NCI Bioassay of 1,2-Dichloroethane for Possible Carcinogenicity. NCI Carcinogenesis Technical Report Series No. 55, DHEW Publication No. (NIH) 78-1361 GPO, Washington, D.C. (1978).

1978 Criteria Document does not fully support OSHA's rationale for regulation.^{7/}

We continue to be puzzled why, after a 7-month rulemaking involving 427 other substances, OSHA believes that two 30-year-old studies now suddenly provide an adequate basis for reducing its PEL from 50 to 1 ppm. It does not appear that OSHA discovered any new data to support its position. Indeed, the OSHA docket contains only the foreign language versions of these studies. This suggests that OSHA did not undertake the required critical review of these studies that may have revealed new information on which to base its unprecedented conclusion.

More importantly, OSHA chose to ignore more recent studies on the health effects of EDC. For example, a study on EDC inhalation by mice and rats conducted by Spreafico, et al showed no evidence of any chronic changes in adolescent animals exposed to EDC at levels of up to 150 ppm for most of their lifespan (from age 3 to 21 months).^{8/} Other studies evaluating

^{7/} While EDC's potential carcinogenicity is not at issue here, we note that ACGIH does not designate EDC as a carcinogen.

^{8/} Spreafico, F., Zuccato, E., Marcucci, F., Sironi, M., Paglialunga, S., Madonna, M., and Mussini, E. (1980). Pharmacokinetics of ethylene dichloride in rats treated by different routes and its long-term inhalation toxicity. Banbury Report 5 Ethylene Dichloride: A Potential Health Risk? (1980), pp. 107-133. Although an elevation of SGOT levels was noted in older rats exposed to such levels of EDC for 12 months, the significance of this finding is called into

(continued...)

the toxicology of EDC show, at most, that EDC is a weak carcinogen presenting a very low potential risk of cancer. These studies include those of Maltoni, et al (1980) and, more recently, Klaunig, et al (1986).^{9/} The inhalation study of Maltoni and the drinking water study of Klaunig are particularly important because they show that the potential carcinogenic effects of EDC are highly dependent on the route of exposure. Significantly, the actual risk posed by EDC is much lower when exposure occurs through inhalation or drinking water than through forced-feeding (oral gavage), as was done in the NCI study in 1978.

In vivo studies examining the genotoxicity of EDC when administered through different routes of exposure provide additional support for the conclusion that route of exposure is the critical factor in assessing the health risks of EDC. For

8/ (...continued)

question by the fact that these animals were exposed during the later part of their lifespan. Even if the response by the older animals was related to the exposure to EDC, the results from the younger groups of animals provide a better basis for assessing the effects on workers since these younger animals were exposed from their early life to the point in their lifespan that is roughly equivalent to the human age of 65.

9/ Maltoni, C., Valgimigli, L., and Scarnato, C. Long-term carcinogenicity bioassays on ethylene dichloride administered by inhalation to rats and mice. Banbury Report 5 Ethylene Dichloride: A Potential Health Risk? (1980), pp. 3-29.

Klaunig, J.E., Ruck, R.J., and Pereira, M.A. Carcinogenicity of chlorinated methane and ethane compounds administered in drinking water to mice. Environmental Health Perspectives, 69 (1986):89-95.

example, Storer, et al (1984) found that EDC caused hepatic DNA damage in mice exposed to EDC through oral administration but that such damage did not occur in animals exposed via the inhalation route.^{10/} The authors concluded that their "results provide additional evidence for the importance of a route of exposure effect in the in vivo genotoxicity and carcinogenicity" of EDC.

OSHA provides no explanation as to why these more recent studies were not given greater weight in its health assessment of EDC. The Agency instead chose to rely primarily on (1) 30-year old studies on workers that involved glaring deficiencies and (2) the 1978 NCI study that involved an exposure route which would undermine its significance as an indicator of the health effects of EDC when inhaled in the workplace. The very limited scientific evidence upon which OSHA has relied in concluding that a 1 ppm PEL is needed to eliminate a "significant risk of material health impairment" is legally inadequate to support OSHA's PEL for EDC. Based on all the available scientific evidence, we do not believe that workers are in jeopardy when exposed to EDC at levels up to 10 ppm.

^{10/} Storer, R.D., Jackson, N.M., and Connolly, R.B. (1984) In vivo genotoxicity and acute hepatotoxicity of 1, 2-dichloroethane in mice: comparison of oral, intraperitoneal, and inhalation routes of exposure. Cancer Research, 44(10):4267-4271.

IV. REQUEST FOR STAY AND FOR RECONSIDERATION

Because the requirements for a stay of agency action have been met, OSHA should stay the effective date of the final rule pending its reconsideration of the issues raised in this petition or a final decision by the Court of Appeals. OSHA has clear authority to stay its own actions pending review. 5 U.S.C. § 705. In deciding whether to issue a stay, OSHA must consider four factors:

1. The likelihood that the party seeking the stay will prevail on the merits of the appeal;
2. The likelihood that the moving party will be irreparably harmed absent a stay;
3. The prospect that others will be harmed if the court grants the stay; and
4. The public interest in granting the stay.

Wisconsin Gas Company v. FERC, 758 F.2d 669, 673-74 (D.C. Cir. 1985) (citing Virginia Petroleum Jobbers Association v. FPC, 259 F.2d 921, 925 (D.C. Cir. 1958)). These factors are not to be applied in accordance with some precise mathematical formula, but rather should be considered together in arriving at a "balance of equities." Washington Metro Area Transit

Commission v. Holiday Tours, Inc., 559 F.2d 841, 844 (D.C. Cir. 1977).

In its discussion of the balancing approach to interim injunctive relief, the court in Holiday Tours described the function and purpose of a stay pending appeal:

Generally, such relief is preventative, or protective; it seeks to maintain the status quo pending a final determination of the merits of the suit. An order maintaining the status quo is appropriate when a serious legal question is presented, when little if any harm will befall other interested persons or the public, and when denial of the order would inflict irreparable injury on the movant.

559 F.2d at 854. The court also endorsed an earlier approach taken by the Second Circuit in Charlie's Girls, Inc. v. Revlon, Inc., 483 F.2d 953, 954 (2d Cir. 1973) (per curiam), namely, that a party seeking preliminary injunctive relief could prevail by demonstrating that the case raised serious legal issues and that the balance of equities favored the parties seeking relief. Id. Thus, OSHA may decide to grant a stay based on an evaluation of the four factors cited in Virginia Petroleum Jobbers and an overall balancing of the equities.

The following discussion of each of the four factors

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demonstrates that each is met and that the balance of equities tips sharply in favor of granting a stay in this case.

The discussion above has highlighted the deficiencies in OSHA's analysis of the health effects and feasibility issues involved in its decision to establish a 1 ppm PEL for EDC. Based on this discussion, SPI strongly believes that OSHA has not satisfactorily met its obligation under the law of demonstrating that its PEL (1) is necessary to substantially reduce or alleviate a significant risk of a material health impairment and (2) is technologically and economically feasible. Accordingly, SPI believes there is a significant likelihood that OSHA will find it necessary to amend the provisions of its final rule on EDC.

Furthermore, if a stay is not granted, SPI's member companies are likely to suffer irreparable harm. Since compliance with a 1 ppm PEL is not feasible for specific operations at EDC facilities, especially for cleaning, maintenance, sampling, and loading/unloading operations, these companies will be subject to citation by OSHA inspectors after the effective date of September 1, 1989. If cartridge respirators are used to meet the new standard, these companies also face the possibility of being cited for inappropriate use of such equipment for the reasons discussed previously. If the heavier and more cumbersome personal protective equipment is required to be worn, the use of such equipment for extended

periods of time and under very difficult working conditions is likely to lead to additional worker injuries. Such irreparable physical harm to workers should not be permitted to occur when the rule is likely to be amended in a manner that would eliminate the cause of such harm.

If a stay is granted, on the other hand, no other parties will be harmed during the time the stay is in effect. SPI member companies will continue their efforts to comply with the ACGIH recommended TLV of 10 ppm for EDC, with actual ambient levels for most operations being safely below 10 ppm. In addition, in light of all the health data and the deficiencies in the studies relied upon by OSHA in its health effects assessment, SPI believes that the 10 ppm exposure limit will provide more than adequate protection for the workers of its member companies. Finally, the fact that a higher number of worker injuries are likely to result from industry efforts to comply with the 1 ppm PEL suggests that the public interest weighs in favor of granting a stay in this case pending the agency's reconsideration and amendment of its PEL for EDC.

V. CONCLUSION

Based on the foregoing, petitioners request that OSHA stay the effective date of the provisions of its final rule establishing a 1 ppm PEL for EDC. Petitioners further request that OSHA reconsider its rule on EDC and establish exposure

limits that are consistent with the scientific literature on EDC and are economically and technologically feasible. We would be happy to discuss these matters in more detail or to provide any additional information you might require.

Respectfully submitted,



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