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August 1, 1989

BY TELECOPIER

Mr. Charles James
Office of the Solicitor
U.S. Department of Labor
200 Constitution Avenue, N.W.
Room S-4004
Washington, D.C. 20210

Re: Request for OSHA Clarification on Use of Respirators to Meet PEL For EDC

Dear Mr. James:

On July 17, 1989, the Acting Assistant Secretary of Labor for Occupational Safety and Health, Alan C. McMillan, formally denied the request of The Society of the Plastics Industry, Inc. (SPI)[1/] for a stay of the provisions of the

1/ SPI is a 2,000 member not-for-profit trade organization representing all segments of the plastics industry in the United States. The Society's members include processors and manufacturers of plastics and plastics products, suppliers of raw materials, processors and convertors of plastic resins and manufacturers of accessory equipment for the plastics industry. Founded in 1937, SPI is the major national trade association of the plastics industry.

The EDC provisions of the rule are of particular concern to the Vinyl Institute, a division of SPI whose members repres nt the major domestic producers of EDC. The Vinyl Institute's members account for a significant percentage of thylen dichloride production in the U.S. The members include: Air

(continued...)

Occupational Safety and Health Administration's (OSHA) final air contaminants rule governing exposures to ethylene dichloride (EDC). On July 31, 1989, SPI filed a request for a judicial stay from the Eleventh Circuit Court of Appeals in connection with SPI's lawsuit against OSHA. SPI v. OSHA, No. 89-7249. SPI's reason for seeking a stay of these provisions from OSHA and now from the Court of Appeals is the approaching September 1, 1989 deadline for achieving the PEL for EDC using only engineering controls and changes in work practices.

OSHA indicated in the preamble to its final rule that it would be likely to permit air-purifying respirators to be used after the September 1, 1989 deadline for certain intermittent operations where the PEL cannot be achieved through changes in work practices and engineering controls alone (i.e., maintenance, loading, and sampling). See 54 Fed. Reg. 2798 (Jan. 19, 1989). However, in many instances wh re these respirators would be effective in reducing EDC exposures below the 1 ppm PEL, their use would raise serious issu s as to whether such use is consistent with the policies of OSHA and the National Institute of Occupational Safety and Health (NIOSH). The basis for this concern is described more fully below and in the enclosed Memorandum of Law which accompanied SPI's request for a judicial stay.

As a means of alleviating those concerns and eliminating the need for a judicial stay of the EDC provisions pending a final decision by the Court on SPI's Petition for Review, SPI is now requesting that OSHA recognize the propri ty of using air-purifying respirators to achieve the 1 ppm PEL for EDC in conjunction with a sound respiratory protection program. If OSHA is willing to provide such a letter, SPI will withdraw its motion for a stay now pending before the Court of App als.

As described more fully on pages 21-24 of the enclosed Memorandum, NIOSH guidelines governing the use of air-purifying respirators provide that (1) air-purifying respirators should not be used to achieve a PEL for a substance when ambi nt concentrations are below the odor threshold for the substance, (2) half-facemask air-purifying respirators should not be used when ambient concentrations of a substance are greater than 10

1/(...continued)
Products and Chemicals, Inc.; BFGoodrich Company; Borden Chemicals and Plastics; CertainTeed Corporation; The Dow Chemical Corporation; Georgia Gulf Corporation; Occidental Chemical Corporation; PPG Industries, Inc.; Shintech, Inc. and the Vista Chemical Company.

times the PEL for the substance, and (3) full-facemask air-purifying respirators should not be used when ambient concentrations are greater than 50 times the PEL for th substance. See, e.g., NIOSH, Criteria for a recommended standard . . . Occupational Exposure to Ethylene Dichloride (March 1976), at 107.

Since the odor threshold for EDC is in the 8-10 ppm range, the NIOSH guidelines would normally preclude the use of air-purifying respirators when ambient concentrations of EDC are below that level. In addition, with a 1 ppm PEL for EDC, half-facemask respirators could not be used when ambi nt concentrations were above 10 ppm and full-facemask air-purifying respirators could not be used when ambient concentrations were above 50 ppm. Thus, the more practical and preferred half-facemask respirators could virtually nev r be used to reduce EDC exposures below the PEL and full-facemask respirators could only be used when ambient levels were below 50 ppm under the NIOSH guidelines.

At all other times when engineering controls and work practices cannot reduce the ambient levels below 50 ppm (i.e., for certain intermittent operations such as cleaning, maintenance and sampling), only the more elaborate and cumbersome supplied-air systems would be permitted. However, air-purifying respirators have been shown to be effective at much higher concentrations than would be permitted under the NIOSH guidelines. See NIOSH, Criteria for a recommended standard . . . Occupational Exposure to Ethylene Dichloride, at 108 (March 1976) (This portion was not changed by the September 1978 revisions); see also Respirator Cartridge Efficiency Studies: V. Effects of Solvent Vapors, J. Am. Ind. Hyg. Ass'n. (July 1974). Thus, the limitations on respirator use imposed by the NIOSH guidelines are impractical and unnecessary here.

SPI believes that the use of air-purifying respirators should be permitted when they will be effective in reducing exposures below the PEL and when engineering and work practices controls are inadequate by themselves to reduce the exposures below the PEL. To minimize the potential for a breakthrough of EDC through the respirator at levels below the odor threshold, a schedule for periodically changing the charcoal cartridges in the respirators should be developed to ensure that cartridges are replaced prior to the point of depletion when breakthrough could occur. Existing studies on the service life of air-purifying respirators used for EDC could be used initially as the basis for establishing an appropriate replacement schedule. See, e.g., NIOSH, Criteria for a recommended standard . . .

Occupational Exposure to Ethylene Dichloride (March 1976), at 108.

We are hopeful that we can reach a prompt resolution of this matter. If so, the immediate concerns of SPI and its members regarding the approaching September 1, 1989 deadline would be addressed and, accordingly, our motion for stay would be withdrawn.

Thank you for your assistance in clarifying the situation regarding the use of respirators to meet the PEL for EDC. We look forward to OSHA's reply.

Very truly yours,

Peter

Peter L. de la Cruz

Enclosure

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

THE SOCIETY OF THE PLASTICS INDUSTRY, INC., Petitioner, v. OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, U.S. DEPARTMENT OF LABOR, Respondent.	No. 89-7249

ON PETITION FOR REVIEW OF AN ORDER
OF THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION,
U.S. DEPARTMENT OF LABOR

PETITIONER'S MOTION FOR STAY

1. On March 10, 1989, The Society of the Plastics Industry, Inc. (SPI) timely filed a petition for review of the final rule of the Occupational Safety and Health Administration (OSHA) of the United States Department of Labor 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's petition was originally filed in the U.S. Court of Appeals for the District of Columbia Circuit and has since been consolidated in this court with other petitions seeking review of the OSHA rule by an order of the Judicial Panel on Multi-district Litigation (No. RTC-5; Feb. 13, 1989). Pursuant to Rule 18 of the Federal Rules of Appellate Procedure, SPI

respectfully moves this Court to stay enforcement of the provisions of this rule establishing exposure limits for EDC.

2. SPI is seeking a stay of the provisions of OSHA's air contaminants rule establishing permissible exposure limits (PELs) of one part per million (ppm) on an 8-hour time weighted average (TWA) and a two ppm short-term exposure limit (STEL) for EDC. The former TWA was 50 ppm, with short-term 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. See 54 Fed. Reg. 2484 (Jan. 19, 1989).

3. A stay is warranted here because the record and existing scientific literature do not support OSHA's assessment of the actual risk to worker health in EDC facilities and, consequently, do not provide adequate evidence to support the Agency's reduction of the TWA to 1 ppm based on potential health effects. 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 later data

provide strong evidence that EDC does not present a carcinogenic risk through inhalation. 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.

4. Furthermore, contrary to OSHA's assumptions, the use of respirators will not enable manufacturers to meet the new standard during routine maintenance operations in the EDC production process without raising significant questions as to whether such use complies with the Act. Without resolution of these issues, manufacturers will be forced into the dilemma of either: (1) using air-purifying respirators that do not appear to comply with OSHA guidelines for respiratory protection or (2) using overly cumbersome supplied air systems that unnecessarily increase the risk of physical injury to those workers using this heavy, bulky equipment.

5. 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 mandatory statutory prerequisites to regulation. A stay is necessary, therefore, because EDC manufacturers are not

in a position to comply with the new standard by September 1, 1989 in many common situations without the use of burdensome protective equipment that unnecessarily increases the risk of worker injury while achieving little or no reduction in the actual risk of harm from EDC exposure.

6. A stay of this provision will not leave EDC unregulated but will result in a return to a 50 ppm TWA for EDC. However, SPI member companies now use as a guideline the 10 ppm threshold limit value (TLV) for EDC established by the American Conference of Governmental Industrial Hygienists (ACGIH). We note that the vast majority of PELs adopted by OSHA in this rulemaking were the ACGIH limits. Therefore, we do not believe that workers will be subject to any health risk if this stay is granted.

7. As more fully described in the memorandum accompanying this motion, SPI is likely to succeed on the merits of its claims, SPI member companies and some of their workers will suffer irreparable injury if the final rule is enforced prior to a decision on appeal, other parties will suffer no harm if a stay is granted, and the public interest will be promoted rather than harmed by the grant of a stay.

8. Application for the relief sought by this motion was formally made to Respondent OSHA on May 23, 1989. OSHA rejected SPI's Petition For Stay and For Reconsideration in a

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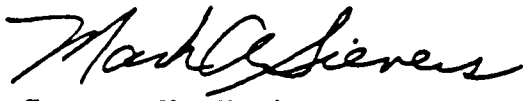
letter from the Assistant Secretary of Labor for Occupational Safety and Health dated July 17, 1989. A copy of that letter is attached to the memorandum as Appendix B.

WHEREFORE, Petitioner SPI respectfully moves this Court to enter an order staying the enforcement of the provisions of OSHA's final air contaminants rule governing EDC exposure until final determination in this Court of the issues raised by the Petition for Review.

Respectfully submitted,



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CTL027717

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

The Society of the Plastics Industry, Inc., Petitioner, v. Occupational Safety and Health Administration, U.S. Department of Labor, Respondent.	No. 89-7249

ON PETITION FOR REVIEW OF AN ORDER
OF THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION,
U.S. DEPARTMENT OF LABOR

PETITIONER'S MEMORANDUM IN SUPPORT OF MOTION FOR STAY

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July 29, 1989

CTL027718

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

THE SOCIETY OF THE PLASTICS INDUSTRY, INC., Petitioner,	
v.	No. 89-7249
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, U.S. DEPARTMENT OF LABOR, Respondent.	

ON PETITION FOR REVIEW OF AN ORDER
OF THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION,
U.S. DEPARTMENT OF LABOR

PETITIONER'S MEMORANDUM IN SUPPORT OF MOTION FOR STAY

Pursuant to Rule 18 of the Federal Rules of Appellate Procedure and for the reasons set forth below, The Society of the Plastics Industry, Inc. (SPI)[1/] respectfully requests that

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1/ SPI is a 2,000 member not-for-profit trade organization representing all segments of the plastics industry in the United States. The Society's members include processors and manufacturers of plastics and plastics products, suppliers of raw materials, processors and converters of plastic resins and manufacturers of accessory equipment for the plastics industry. Founded in 1937, SPI is the major national trade association of the plastics industry.

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

this Court stay the ethylene dichloride (EDC) provisions of the final air contaminants rule promulgated by the Occupational Safety and Health Administration (OSHA). 54 Fed. Reg. 2332 (Jan. 19, 1989). These provisions establish permissible exposure limits (PELs) for EDC of one part per million (ppm) on an 8-hour time-weighted average (TWA) and a two ppm short-term exposure limit (STEL) for EDC.

I. STATEMENT OF FACTS

A. Regulatory Proceedings

On June 7, 1988, OSHA issued a proposed rule to amend its standard for air contaminants in the workplace found at 29 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). The ACGIH TLV for EDC is 10

1/(...continued)
Chemical Company.

ppm. OSHA, however, proposed to adopt the NIOSH-recommended limits for EDC of 1 ppm as an 8-hour time-weighted average (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. See 54 Fed. Reg. 2479, 2484-85, 2937 (Jan. 19, 1989). Relevant excerpts of the preamble to the final rule are attached as Appendix A. 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 timely filed a petition for review of OSHA's final rule in the U.S. Court of Appeals for the District of Columbia Circuit. This action has since been consolidated in this Court with several other challenges to the OSHA rule pursuant to an order of the Judicial Panel on Multi-district Litigation (No. RTC-5; Feb. 13, 1989). On May 23, 1989, SPI filed with OSHA a Petition For Stay and For Reconsideration of the final rule. In a letter from the

Assistant Secretary of Labor for Occupational Safety & Health dated July 17, 1989, OSHA formally rejected SPI's petition for the relief sought in this motion. A copy of the Assistant Secretary's letter is attached as Appendix B.

B. 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 periodically open the equipment and physically remove the obstruction.

When equipment becomes obstructed or requires 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. Two types of respirators are generally used in the workplace. See Affidavit of Robert F. Adams, Appendix C, ¶ 4 (hereinafter cited as Adams Affidavit). First, air-purifying respirators are worn so as to cover the face and typically feature a charcoal canister or cartridge that filters the air inhaled by the worker. Air-purifying respirators come in both half-facemask and full-facemask models. The second type of respirator is a supplied-air system which provides air from an air source, either through an airline hooked to a separate air supply or through a self-contained "air pack" worn on the worker's back. These supplied air systems are heavier, more cumbersome, and more difficult to work in, and are, therefore, used only when concentrations are too high to permit the use of an air-purifying respirator. Adams Affidavit, ¶ 7.

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 performed without respiratory equipment or

with air-purifying half-facemask respirators because the tasks could not be performed safely or effectively while the workers were encumbered with full protective suits, air lines or air packs. 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. See Adams Affidavit, ¶ 8. As industry commenters have noted and OSHA has acknowledged, 54 Fed. Reg. 2798 (Jan. 19, 1989), engineering controls and work practices alone may not enable EDC-producing companies to comply with the new 1 ppm standard during many common operations. Thus, companies must (1) either keep unprotected workers from the work area until ambient levels drop below 1 ppm which, in some cases, could require a production shutdown for several days or longer and is impractical or (2) provide their workers with respirators that will reduce exposure below 1 ppm.

II. ARGUMENT

BECAUSE THE REQUIREMENTS FOR A STAY OF AGENCY ACTION HAVE BEEN MET, THE COURT SHOULD STAY THE EFFECTIVE DATE OF THE PROVISIONS OF THE FINAL RULE GOVERNING ETHYLENE DICHLORIDE PENDING FINAL RESOLUTION OF THE ISSUES RAISED IN SPI'S PETITION FOR REVIEW.

In deciding whether to issue a stay, the Court 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.

United States v. Bogle, 855 F.2d 707, 708 (11th Cir. 1988). 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 following discussion of each of the four factors demonstrates that each is met and that the balance of equities tips sharply in favor of granting a stay in this case.

A. Because OSHA Has Failed To Satisfy The Legal Standard For Promulgating A PEL, There Is A Significant Likelihood That SPI Will Prevail On The Merits Of Its Claim

There are serious deficiencies in OSHA's analysis of the health effects and feasibility issues involved in its decision to establish a 1 ppm PEL for EDC. The discussion below demonstrates that OSHA has failed to meet 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 the Court will find that OSHA has

not satisfied these applicable legal requirements with regard to the EDC provisions of its final rule.

Under the Occupational Safety and Health Act of 1970, 29 U.S.C. §§ 655, 657 (1982), 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 (AFL-CIO) 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) (1982), and has been reaffirmed by the courts. See American Textile Manufacturers Institute v. Donovan, 452 U.S. 490, 531-32 (1981).

1. 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

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.[2/] OSHA apparently concludes 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 (Ex. 1-182) and Brzozowski (Ex. 1-63)[3/] 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, see e.g., Ex. 3-741 at 52; Ex. 3-624 at 3-4; Ex. 3-87 at 1-2, 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 studies. OSHA attempts to dismiss the possible distorting effects of these dermal exposures in the Brzozowski study by

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2/ 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.

3/ "Ex. ___" refers to Exhibits in OSHA's rulemaking record.

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 has still not concluded that these studies provide 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 (Ex. 1-231) proposed a 5 ppm REL based on these and other studies. The revised NIOSH Criteria Document (Ex. 1-1120)[4/] lowered the REL from 5 to 1 ppm predicated on its conclusion that EDC posed a potential risk of carcinogenicity. This conclusion was based solely upon the oral gavage study in rats and mice conducted by the National Cancer Institute (NCI) in 1978.[5/] Since this study involved the forced-feeding of EDC to the animals, its results are not a proper indicator of the health effects of EDC exposure via inhalation. See discussion, infra, at pp. 15-

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

5/ 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).

17.[6/] In addition, it is apparent from OSHA's preamble discussions to both the final and proposed rule that its 1 ppm PEL for EDC is based primarily on the studies of Kozik and Brzozowski, not the NCI bioassay. Thus, the 1978 NIOSH Criteria Document, and its reliance on a study of questionable relevance to an assessment of the health effects of EDC inhalation, do not provide an adequate basis for OSHA's promulgation of a 1 ppm PEL for EDC.

OSHA provides no adequate explanation why, after a brief 7-month rulemaking involving 427 other substances, it concludes 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 throughout most the rulemaking contained, and may still contain, only the foreign language versions of the two studies principally relied upon. 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.

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

More importantly, OSHA either misinterpreted or ignored more recent studies on the health effects of EDC that were brought to OSHA's attention during the public comment period. See, e.g., Ex. 3-624 at 4-5; Ex. 3-741 at 52-53; Ex. 3-677 at 5-6. For example, the commenters pointed out that a study on EDC inhalation by mice and rats conducted by Spreafico, et al[7/] 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). See, e.g., Ex. 3-624. The commenters similarly noted that other studies evaluating the toxicology of EDC show, at most, that EDC is a weak carcinogen presenting a very low potential risk of cancer. See, e.g., Ex. 3-624 at 5. These studies include those of Maltoni, et al

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7/ Spreafico, F., Zuccato, E., Marcucci, F., Sironi, M., Paglialunga, S., Madonna, M., and Mussini, E., 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 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.

(1980) and, more recently, Klaunig, et al (1986).[8/] 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. See, e.g., Ex. 3-741 at 52-53; Ex. 3-677 at 5-6. 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 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

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8/ 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.

inhalation route.[9/] 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. See Ex. 3-624.

OSHA provides no reasonable explanation as to why these more recent studies brought to light in the public comments 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, SPI believes that workers are not in jeopardy when exposed to EDC at levels up to 10 ppm. OSHA has failed to demonstrate that a further reduction of the PEL below 10 ppm to

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9/ 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.

1 ppm will eliminate a significant risk of a material health impairment.

2. Compliance With The EDC Exposure Limits Is Not Feasible

a. 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 may require 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 than on 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.

For many special operations in the EDC production process, compliance with the ACGIH 10 ppm limit using only 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. See discussion at 54 Fed. Reg. 2798 (Jan. 19, 1989).

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 compliance questions regarding the types of respirators that may be used and the conditions under which they may be employed.

b. 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, this type of equipment is undesirable and unsafe for use in the interiors of certain vessels, such as distillation columns, where movement is already restricted and made more difficult by the physical bulk of the equipment or trailing air line. See Adams Affidavit, ¶ 4. 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. See Adams Affidavit, ¶ 8. 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. See Adams Affidavit, ¶ 8. 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. For these reasons, use of supplied-air respirators is not favored except when necessary for the adequate protection of the worker from exposures. As noted below, however, use of the preferred alternative, air-purifying respirators, raises compliance issues of its own, even in situations where they provide effective worker protection.

c. Use of Air-Purifying Respirators Raises Compliance Problems

i. 1 ppm is below the odor threshold -- The use of air-purifying respirators to effectively reduce EDC exposures below the 1 ppm PEL would conflict with current regulatory guidelines on respiratory protection. Adams Affidavit, ¶ 5. 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 NIOSH'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. Adams Affidavit, ¶ 5. 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,[10/] but is more likely in the 6-10 ppm range. See Adams Affidavit, ¶ 5. 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. See Adams Affidavit, ¶ 5.

ii. 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; Adams Affidavit, ¶ 6. Full-facemask

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10/ 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 Ex. 1-213) (hereinafter referred to as NIOSH Criteria Document).

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. See Adams Affidavit, ¶ 5. Furthermore, 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 air-purifying 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. Adams Affidavit, ¶ 7. Without a change in the PEL or additional guidance from OSHA, manufacturers will be forced to use the more cumbersome supplied-air systems while ambient levels are at these more common lower levels and thereby increase the risk of worker

injuries resulting from use of this equipment. Adams Affidavit, ¶ 7-8.

3. 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. In response to industry comments on the anticipated costs of complying with the new standard, OSHA assumed 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. See Ex. 3-624 at 1. 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. See Ex. 3-624, at 1-2.

The industry estimates that these new or modified facilities will require an initial capital investment of between $10-25 million for each plant. Id. In addition, the added expense of complying with the standard has been estimated to be $4-5 million for each plant per year. Id. 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. Id. 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 that OSHA lacks adequate scientific support for its conclusion that reducing the PEL to 1 ppm instead of 10 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.

For the reasons stated above, SPI is likely to prevail on the merits of its claim that OSHA has not met its statutory obligations in promulgating the PEL for EDC.

B. If A Stay Is Not Granted, SPI's Member Companies And Some Of Their Workers Will 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 face the possibility of being cited for inappropriate use of such equipment for the reasons discussed above. 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 will lead to additional worker injuries. See id., ¶ 8. 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.

C. If A Stay Is Granted, No Other Parties Will Be Harmed During The Time The Stay Is In Effect

SPI member companies will continue to use the ACGIH recommended TLV of 10 ppm for EDC as a guideline, with actual ambient levels for most operations being safely below 10 ppm. The fact that a higher number of worker injuries are likely to result from industry efforts to comply with the 1 ppm PEL pending the outcome of this litigation also suggests that the public interest weighs in favor of granting a stay in this case.

III. CONCLUSION

Based on the foregoing, Petitioner SPI requests that this Court stay the effective date of the provisions of OSHA's final rule establishing a 1 ppm PEL for EDC.

Respectfully submitted,

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