

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

BRIEF FOR PETITIONER

Jerome H. Heckman
Peter L. de la Cruz
Mark A. Sievers
Keller and Heckman
1150 17th Street, N.W.
Suite 1000
Washington, D.C. 20036

Counsel for Petitioner,
The Society of the Plastics
Industry, Inc.

April 27, 1990

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CERTIFICATE OF INTERESTED PARTIES

The Society of the Plastics Industry, Inc. (SPI)
certifies that this action is of direct interest only to the
following group within SPI:

Vinyl Institute
Wayne Interchange Plaza II
155 Route 46 West
Wayne, New Jersey 07470

The Vinyl Institute's members are:

Air 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.
Vista Chemical Company

Other interested persons are:

The Occupational Safety and Health
Administration and its Counsel of Record
Charles Hadden, Esq. and Barbara Werthmann, Esq.

The American Federation of Labor and Congress
of Industrial Organizations, and its Counsel
of Record, Bredhoff and Kaiser (George H. Cohen,
Jeremiah A. Collins, Martin S. Lederman) and
Laurence Gold

Counsel of Record for The Society of the Plastics
Industry, Inc., Keller and Heckman (Jerome H.
Heckman, Peter L. de la Cruz and Mark A.
Sievers)

Respectfully submitted,

Mark A. Sievers
Counsel for The Society of the
Plastics Industry, Inc.

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STATEMENT OF JURISDICTION

Jurisdiction to review this rulemaking action of the Occupational Safety and Health Administration (OSHA) is conferred upon this Court by Section 6(f) of the Occupational Safety and Health Act of 1970, 29 U.S.C. § 655(f) (19____). The Society of the Plastics Industry, Inc. originally filed a petition for review in the United States Court of Appeals for the District of Columbia Circuit, which was consolidated in this Court with several other actions challenging other provisions of the same OSHA rule by order of the Judicial Panel on Multidistrict Litigation, No. RTC-5 (Feb. 13, 1989).

STATEMENT OF ISSUES

Whether the revised permissible exposure limit (PEL) for ethylene dichloride (EDC) should be set aside because OSHA lacks substantial evidence of record to support its conclusions.

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STATEMENT OF THE CASE

I. Course of Proceedings

On June 7, 1988, OSHA issued a proposed rule to amend its standard for air contaminants in the workplace. 53 Fed. Reg. 20960 (June 7, 1988) (29 C.F.R. § 1910.1000). The Agency proposed to establish or modify the PELs for 428 substances.

OSHA provided a total of 47 days for public comment, which included a 17-day extension of the initial 30-day comment period. 53 Fed. Reg. 24956 (July 1, 1988). Immediately thereafter, OSHA held 13 days of public hearings. The Secretary of Labor established an October 7, 1989 deadline for post-hearing evidence and an October 31, 1989 deadline for post-hearing briefs. 53 Fed. Reg. 34708 (Sept. 7, 1988). These deadlines significantly shortened the period originally set by the administrative law judge for post-hearing submissions. See id. On January 19, 1989, OSHA published its final air contaminants rule which establishes new PELs or changes the existing PELs for 376 substances. 54 Fed. Reg. 2332 (Jan. 19, 1989).

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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).

II. Statement of Facts

A. The Proposed Rule on EDC

In the preamble to the proposed rule, OSHA provided only a brief overview of the health effects data on ethylene dichloride. See 53 Fed. Reg. 21052 (June 7, 1988). OSHA noted that the American Conference on Governmental Industrial Hygienists (ACGIH) had reduced its threshold limit value (TLV) for ethylene dichloride to 10 ppm as a TWA based on the hepatotoxic (liver) effects of EDC shown in animal studies. The Agency also acknowledged the decision by the National Institute on Occupational Safety and Health (NIOSH) to reduce its recommended exposure limit (REL) to a 1 ppm 10-hour TWA and a 2 ppm short-term limit over 15 minutes and to treat EDC as a potential human carcinogen based on an animal bioassay conducted by the National Cancer Institute (NCI) in 1978.

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OSHA also cited two studies from the 1950s, reports by Kozik (1957/Ex. 1-182) and Brzozowski (1954/Ex. 1-63) on workers exposed to varying levels of EDC, as evidence that exposure to EDC at the current PEL level presents a risk of hepatotoxic, hematopoietic (blood), and nervous system effects. OSHA also concluded, based on these two 30-year-old studies, that the 10 ppm TLV established by ACGIH would not provide protection from some of these effects, even though ACGIH considered these studies in establishing its TLV. See Ex. 1-3 at 252-53. With no further analysis, OSHA concluded that its proposed 1 ppm TWA and 2 ppm STEL were necessary to protect against the health risks and that the health evidence cited by OSHA provided a reasonable basis for the new PEL. OSHA concluded its discussion on EDC by promising to "establish a new limit for ethylene dichloride if the Agency determines that this limit will substantially reduce significant risk." 53 Fed. Reg. 21052 (June 7, 1988).

B. Public Comment on the Proposal

During the comment period on the proposed rule, eight comments specifically addressed the proposed PEL for ethylene

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dichloride. Petitioner SPI, through its Vinyl Institute,^{1/} submitted substantive comments on the proposal. Ex. 3-624. The Chemical Manufacturers Association (CMA), The Dow Chemical Company, Vulcan Chemicals, and Occidental Chemical Corp. were among the other industry members submitting comments on the EDC provisions. See Exs. 3-874, 3-741, 3-677, and 3-1174.

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. Both the Vinyl Institute and CMA pointed out the severe limitations in the Kozik and Brzozowski studies. For

^{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 Chemical Company.

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example, they noted the likelihood that the actual levels of EDC to which the workers in these studies were exposed were significantly higher than the exposures indicated by the measurements included in the studies. In the Brzozowski study, the authors reported "workers breathing extremely close to barrels during pouring, spills on clothes and shoes, unchanged contaminated clothing, and the use of EDC to wash their skin." Ex. 3-624 at 3; Ex. 1-231 at 52. In the Kozik study, the authors provided no information on the nature of the sampling techniques or analytical methods used, and the study may also have involved significant dermal exposure. See Ex. 3-624, at 3-4; Ex. 3-874, at 1-2.

The comments highlighted the absence of complete information on exposure, methodology, and sampling from the studies and argued that such critical omissions limit their usefulness as support for OSHA's reduction of the PEL to 1 ppm. See, e.g., Ex. 3-624 at 4. Finally, the comments noted that only the original foreign language versions of these two studies were included in the record, suggesting that the studies themselves were never reviewed by OSHA. Id. at 3. English translations were never included in the record during the rulemaking. See Ex. 1-63; Ex. 1-182.

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The commenters also brought to OSHA's attention significant scientific information that calls into question the results of the two foreign studies and the validity of the NCI study as an indicator of the potential human carcinogenicity of EDC. Much of the evidence cited by the commenters became available after NIOSH had issued its Revised Criteria Document based on the NCI study. In particular, the commenters cited studies by Maltoni, et. al. involving long-term inhalation studies with rats and mice at concentration levels of up to 150 ppm which did not result in a carcinogenic response in exposed animals, see Ex. 3-874, at 2; Ex. 3-624 at 5, and more recently by Klaunig, et. al. indicating that route of exposure (inhalation vs. oral ingestion) was critical in determining the actual carcinogenic risk posed by EDC. See Ex. 3-624 at 5. These studies, the commenters noted, represented more recent evidence that conflicts with the results of the NCI study. See Ex. 3-624 at 5.

These newer studies were also supported by other in vivo studies of the genotoxicity of EDC via different routes of exposure, the commenters noted. In a study by Storer, et. al. involving EDC exposures via both ingestion and inhalation, the authors concluded that their "results provide additional evidence for the importance of a route of exposure effect in

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the in vivo genotoxicity and carcinogenicity of [EDC]." Ex. 3-624 at 5. The commenters cited a study by D'Souza, et. al. which identified differences in the ways that EDC is metabolized when ingested via inhalation and via oral ingestion and which strongly suggests that "the route of administration may play a role in the metabolism of EDC and in the potential carcinogenicity." Ex. 3-874 at 3. Other studies by Rannug, et. al., Boyd, et. al. and Condie were also cited by the commenters as evidence that the results of the NCI study may not be as reliable an indicator of EDC's carcinogenicity as OSHA indicated in its proposal. For example, the study by Condie showed that the corn oil used in the NCI study may have enhanced the hepatotoxicity and the carcinogenic response in that study. Ex. 3-874 at 2.

Industry commenters also observed that compliance with a 1 ppm PEL is not technologically feasible for most operations at an EDC facility through changes in work practices and engineering controls, particularly for certain intermittent operations such as maintenance, loading, and sampling. See Ex. 3-624 at 1-2; Ex. 3-874 at 3. 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

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with the standard would be more difficult using only engineering controls and work practices. See Ex. 3-874 at 3.^{2/}

C. The Final Rule

OSHA published its final air contaminants rule on January 19, 1989. 54 Fed. Reg. 2332 (Jan. 19, 1989). The Agency noted that as the "starting point" for its analysis of these substances, it 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.

Despite the evidence and arguments proffered by the commenters, OSHA's final rule retains the EDC provisions included in the proposal and establishes 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. See 54 Fed. Reg. 2479, 2484-85,

^{2/} Subsequent to the publication of the final rule, OSHA authorized the use of respirators in EDC facilities under specified conditions to meet the PEL.

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2937. 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. The final rule also goes well beyond the ACGIH TLV for EDC of 10 ppm as an 8-hour TWA. Instead, the final rule adopts the NIOSH limits for EDC.

Despite the significant deficiencies in the Kozik and Brzozowski studies noted in the comments, OSHA continued to rely primarily on these studies to support its conclusions on the noncarcinogenic effects of EDC. In a discussion borrowed directly from the NIOSH Criteria Document (Ex. 1-231), OSHA cites two other studies which it did not bother to include in the record. The first, by Cetnarowicz, mostly involved measurements above 25 ppm and reported adverse effects that were limited primarily to workers exposed to concentrations of EDC well above 50 ppm. See Ex. 1-231 at 49-52. The second study, by Rosenbaum, did not include information on the methods of measuring or sampling and indicated no changes in the blood or internal organ functions of those exposed to EDC at unspecified levels below 25 ppm. See Ex. 1-231 at 54. These facts were not acknowledged by OSHA although they were apparent in the NIOSH publication from which they are taken.

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While OSHA acknowledged some of the deficiencies in the studies it relied upon, it continued to find that the studies demonstrated that "occupational exposures to EDC at levels of 10 ppm or somewhat higher (i.e., in the 14-15 ppm range) caused severe health effects in specific target organ systems" 54 Fed. Reg. 2937 (Jan. 19, 1989). OSHA concluded that the effects shown in these studies "clearly warrant a reduction in the PEL to a level substantially below the level (10 ppm) shown to cause toxic liver and other effects."

With regard to the potential carcinogenicity of EDC, OSHA restated some of the points made by the commenters but presented no additional evidence or explanation to address the claims that (1) the results of the NCI study may have been enhanced by the use of corn oil as a vehicle, (2) that route of administration is an important factor in assessing the carcinogenicity of EDC, and (3) the NCI study involving oral gavage administration may not be a reliable predictor of the carcinogenicity of EDC when inhaled, as in the workplace. Instead, OSHA again relied on the NCI oral study and another study, apparently described in a document of the Environmental Protection Agency (EPA) which again is not included in the record, involving intraperitoneal administration (i.e., via injection) of EDC.

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The EPA document also apparently describes a study involving dermal application of EDC, although this is not clear from OSHA's cursory reference to the study. The studies cited in the EPA document, which involve exposure via routes other than inhalation, do not address the industry comments regarding differences in health effects when exposure to EDC is via inhalation as opposed to other routes of exposure. Although OSHA cites comments by the AFL-CIO emphasizing EDC's carcinogenicity, the AFL-CIO stated only that it supported a finding that EDC was an occupational carcinogen but presented no scientific evidence to support this finding. Ex. 194 at A-6.

OSHA did not include a quantitative risk assessment for EDC in its final rule and made no other attempt to quantify the risk posed by EDC at the relevant levels of 50 ppm (existing OSHA standard), 10 ppm (ACGIH) and 1 ppm (NIOSH).

III. Standard of Review: "Substantial Evidence"

Under Section 6(f) of the OSH Act, the Court must ensure that OSHA's standards are supported by "substantial evidence" on the record as a whole. 29 U.S.C. § 655(f). See also National Grain and Feed Assn. v. OSHA, 858 F.2d 1019, 1030

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(5th Cir. 1988). Under this "more rigorous" standard, the Court "must take a 'harder look' at OSHA's action" than it would in applying "the more deferential arbitrary and capricious" standard that typically applies to review of an agency rule promulgated under informal rulemaking procedures. See Administrative Procedure Act, 5 U.S.C. § 706 (19__). National Grain and Feed Assn., 858 F.2d at 1030; Asbestos Information Assn. v. OSHA, 727 F.2d 415, 421 (5th Cir. 1984); Texas Independent Ginners Assn. v. Marshall, 630 F.2d 398, 405 n.24 (5th Cir. 1980).

The "substantial evidence" test applies both to the factual findings of the Agency and to its policy determinations. National Grain and Feed Assn., 858 F.2d at 1030; Texas Independent Ginners Assn., 630 F.2d at 404. Substantial evidence to support a factual finding means that the record must include "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." National Grain and Feed Assn., 858 F.2d at 1030 (quoting Universal Camera Corp. v. NLRB, 340 U.S. 474, 477 (1951)). To support a policy determination under the "substantial evidence" standard, the Agency must show that its action is "(1) consistent with the statutory language and purpose of the OSH Act and (2) reasonable under the state of the record before

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[it]." Id. at 1030-31. The "reasonableness" requirement here involves a "more rigorous" application of the judicial inquiry conducted under the "arbitrary and capricious" standard into "whether enough facts are available and have been investigated to render rational the making of a policy judgment . . ."
Texas Ind. Ginners Assn., 630 F.2d at 405 and n.24 (emphasis added).

Finally, Section 6(b)(5) of the OSH Act requires that OSHA's factual findings be founded "on the basis of the best available evidence." 29 U.S.C. § 655(b)(5); Texas Independent Ginners Assn., 630 F.2d at 405 and 413 n. 48. OSHA must base such a standard on "research, demonstrations, experiments and such other information as may be appropriate" and must consider the "latest available scientific data in the field." Id. While not expected to establish its findings to the point of "scientific certainty," Benzene, 448 U.S. at 656, OSHA is expected to

identify relevant factual evidence, to explain the logic and the policies underlying any legislative choice, to state candidly any assumptions on which it relies, and to present its reasons for rejecting significant contrary evidence and argument.

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International Union, UAW v. Pendergrass, 878 F.2d 389, 392 (D.C. Cir. 1989); Building & Construction Trades Dept., AFL-CIO v. Brock, 838 F.2d 1258, 1264 (D.C. Cir. 1988).

SUMMARY OF ARGUMENT

OSHA has not fulfilled its legal obligation to support with substantial evidence its finding that the permissible exposure limit (PEL) for ethylene dichloride (EDC) is reasonably necessary and appropriate to reduce or eliminate a significant risk of material health impairment. See Industrial Union Dept. AFL-CIO v. American Petroleum Institute, 448 U.S. 607, 639 (1980) (plurality opinion) ("Benzene"). Despite the Agency's claim that its review of the studies on the health effects of each substance was a critical step in the rulemaking process, OSHA made no attempt to review the actual studies and data on the health effects of EDC. In fact, most of the studies cited by OSHA in support of its PEL for EDC were not even included in the record. The two studies that did appear in the record were included only in their original foreign language versions.

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In addition, OSHA did not consider "the latest available scientific data in the field." Instead, it relied principally on "Criteria Documents" on EDC published by the National Institute on Occupational Safety and Health (NIOSH) in 1976 and 1978. OSHA relies exclusively on NIOSH's 1976 discussion of two very limited studies on workers conducted in the 1950s. The public comments on OSHA's proposal explained that the results of these studies were unreliable because they lacked critical information regarding the sampling and measurement of EDC exposure and involved outdated work practices that resulted in direct contact of EDC on the workers' skin. OSHA also relied on the 1978 NIOSH discussion of a National Cancer Institute study on EDC. The applicability of the results of the NCI study to worker exposure has been called into question by more recent studies on EDC which the Agency ignored. Even when these more recent substantive studies were brought to OSHA's attention during the comment period, OSHA failed to present any reasons for its rejection of this "significant contrary evidence."

OSHA's reliance on the NIOSH documents also led OSHA to adopt the NIOSH recommended exposure limit (REL) for EDC which was established in 1978 and based on assumptions which were found to be inadequate to support a finding of "significant

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risk" in the Benzene case in 1980. By adopting the NIOSH REL, along with the assumptions made by NIOSH, OSHA has failed to support a statutory finding of "significant risk" with substantial evidence.

Finally, in its attempt to develop a more efficient and comprehensive means of revising PELs for air contaminants, OSHA failed to follow the procedural guidance provided by the Administrative Conference of the United States (ACUS). The ACUS had endorsed OSHA's comprehensive approach to PELs in cases where generally accepted consensus recommendations are available. OSHA ignored the only "generally accepted" consensus recommendation on an exposure level for EDC -- that of the American Conference of Governmental Industrial Hygienists (ACGIH). By adopting the NIOSH REL, which is not generally accepted, OSHA was unable to find adequate support for its PEL on EDC. Because OSHA has failed to meet its minimum obligations under the law in establishing this PEL, this provision of OSHA's rulemaking should be remanded for further consideration by the Agency.

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ARGUMENT

- I. **THE OSH ACT REQUIRES OSHA TO MAKE A THRESHOLD FINDING THAT ANY REVISED EDC STANDARD BE REASONABLY NECESSARY AND APPROPRIATE TO REDUCE OR ALLEVIATE A SIGNIFICANT RISK OF A MATERIAL HEALTH IMPAIRMENT FROM EDC EXPOSURES ABOVE THE EXISTING PEL**

Section 6(b)(5) of the Occupational Safety and Health Act (the Act), 29 U.S.C. § 655(b)(5) (19__), establishes the criteria that OSHA must follow in establishing standards governing toxic materials or harmful physical agents in the workplace. OSHA is obligated by this section to

set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity . . .

Id.

Under Section 3(8) of the Act, 29 U.S.C. § 652(8) (19__), an "occupational safety and health standard" must be "reasonably necessary or appropriate to provide safe or healthful employment and places of employment." When Sections 6(b)(5) and 3(8) are read together, they require OSHA "to determine that [the standard] is reasonably necessary and appropriate to remedy a significant risk of material health impairment." Industrial Union Department, AFL-CIO v. American

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Petroleum Institute, 448 U.S. 607, 639 (1980) (plurality opinion) (hereinafter cited as "Benzene").

In discussing the requirements of the Act, the Supreme Court plurality in Benzene found that every permanent health or safety standard must be predicated upon "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." 448 U.S. at 642. In addition, the Court found that assumptions regarding risk made by OSHA in establishing the benzene standard were "not a proper substitute for the findings of a significant risk of harm required by the Act." 448 U.S. at 662; see also Texas Independent Ginners Assn., 630 F.2d at 412 (unsupported assumptions that regulatory benefits will accrue or even findings supported by substantial evidence that "appreciable" benefits are "likely" are not sufficient to meet Act's requirements). Even in those limited areas where OSHA may be justified in making "assumptions in interpreting the data with respect to carcinogens," such assumptions must be "supported by a body of reputable scientific thought." Benzene, 448 U.S. at 656.

"Benzene established that the burden of proving that the subject of the proposed regulation presents a significant

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health risk remains with the agency." Public Citizen Health Research Group v. Tyson, 796 F.2d 1479, 1485-86 (D.C. Cir. 1986). OSHA exceeds its power when it attempts to impose on industry the burden of proving a safe level of exposure to a substance rather than fulfilling its "threshold responsibility of establishing the need for more stringent standards." Benzene, 448 U.S. at 659.

II. OSHA FAILED TO: SUPPORT ITS FINDING OF A "SIGNIFICANT RISK OF MATERIAL HEALTH IMPAIRMENT" WITH THE BEST AVAILABLE EVIDENCE, CONSIDER THE "LATEST AVAILABLE SCIENTIFIC DATA IN THE FIELD," OR ADEQUATELY "PRESENT ITS REASONS FOR REJECTING SIGNIFICANT CONTRARY EVIDENCE."

A. OSHA failed to include in the record critical evidence that it relied upon.

OSHA's discussion of health effects is apparently taken directly from the 1976 NIOSH Criteria Document. Compare OSHA Final Rule at 54 Fed. Reg. 2484 (Jan. 19, 1989) with Ex. 1-231 at 46-57. The studies cited by OSHA in its discussion are the same as those discussed by NIOSH, but OSHA adds little, if anything, to the NIOSH discussion. Far from being a "starting point" for OSHA's analysis, see 54 Fed. Reg. 2333 (Jan. 19, 1989), the NIOSH Criteria Documents (Ex. 1-231, Ex. 1-1120) represent the full extent of OSHA's efforts to assess the health effects of EDC. The record reflects no independent

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effort on the part of OSHA to seek out the "best available evidence" or the "latest available scientific data in the field," 29 U.S.C. § 655(b)(5), developed after the NIOSH documents were published in the mid-1970's. Nor does it reflect any effort by OSHA to ensure that "enough facts are available and have been investigated to render rational" its PEL determination. See Texas Independent Ginners Assn., 630 F.2d at 405 and n. 24.

It is likely that the absence of any analysis of the studies by OSHA is due to the fact that the Agency never reviewed the actual studies upon which its EDC rule is based. As a critical part of its approach to this rulemaking, OSHA claims in the Preamble to have

. . . reviewed the studies to see if there was substantial evidence of significant risk . . .

and to have

reviewed the studies to determine if the new PEL would lead to a substantial reduction in significant risk.

54. Fed. Reg. at 2372 (emphasis added). The two principal studies on workers relied upon by OSHA, Kozik, et al and Brzozowski, et al, were included in the record only in their foreign language version. See Ex. 1-182, Ex. 1-63. The other

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scientific evidence relied upon by the Agency (the NCI study, the EPA Assessment, and the studies by Cetnarowicz and Rosenbaum) was not even included in the record. See supra at ___, ___ [STATEMENT OF FACTS]. Although OSHA relies on the NCI study as partial justification for its PEL on EDC, and even cites to the study as "Exhibit 1-947" in the record, the NCI study is not included in the record. Exhibit 1-947 is a reference to another NCI bioassay on titanium dioxide which is wholly unrelated to EDC.

In a very literal sense, therefore, there is no "substantial evidence in the record as a whole" to support OSHA's determination of "significant risk" for EDC. See 29 U.S.C. § 655(f) (19___); National Grain and Feed Assn., 858 F.2d at 1030. See also Texas Independent Ginners Assn., 630 F.2d at 405 ("The agency record should contain the data required under the substantial evidence standard for appellate review of the reasonableness of OSHA's policy making as well as of OSHA's obedience to other statutory limitations.") The absence of such evidence in the record not only makes the court's review of the Agency's action more difficult, if not impossible, but also undermines the effectiveness of the critical public comment phase of informal rulemaking. [Cite]

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- B. The studies principally relied upon by OSHA are inadequate to support a finding of "significant risk."**

1. Evidence of Noncarcinogenic Effects

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.^{3/} 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. 54 Fed. Reg. 2484 (Jan. 19, 1989).

Both the Kozik (Ex. 1-182) and Brzozowski (Ex. 1-63)^{4/} studies have significant weaknesses and limitations that have not been fairly or adequately considered by OSHA. Indeed, without adequate explanation or justification, OSHA ignored the

^{3/} Kozik, J.V., Problems of Industrial Hygiene Arising from the Use of Dichloroethane in the Aviation Industry. Gigiena Truda I Professionalnye Zaboлевaniia (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.

^{4/} "Ex. ____" refers to Exhibits in OSHA's rulemaking record.

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interpretations of these studies by ACGIH and NIOSH, the health authorities upon which OSHA purportedly relied. Significantly, ACGIH has known about these studies for years and cited them as part of the literature on EDC underlying its 10 ppm TLV. The TLV established by ACGIH remains at 10 ppm. Based on the same literature on EDC's noncarcinogenic effects relied upon by OSHA, NIOSH set an REL of 5 ppm. See 1-231 at 1. OSHA offers no assessment of the "significant risk" associated with these levels of EDC that would support setting the PEL for EDC below the ACGIH and NIOSH levels.

The reason that these studies do not support a revised PEL of 1 ppm were described 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. It is likely that the measured exposures reported in these studies significantly underestimated the actual levels to which workers were exposed. In the Brzozowski study, for example, 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 exposures. See Ex. 3-624 at 4, Ex. 3-874 at 1-2. Furthermore,

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the information in the NIOSH Criteria Document confirms that, with few exceptions, even the reported exposures in these studies involved levels well in excess of the 10 ppm level found by OSHA to pose a "significant risk." Ex. 1-231, at 52-56. Because of a lack of adequate information on sampling and measuring techniques, see Ex. 3-624 at 3-4, Ex. 1-231 at 52-56, Ex. 3-874 at 1, the exposure information, as a whole, is unreliable.

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. See Ex. 3-624 at 3-4; Ex. 3-874 at 2. 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. In fact, NIOSH itself concluded that skin absorption "probably was as significant a contribution to exposure as inhalation" in the Brzozowski study. Ex. 1-231, at 52. Since OSHA makes no effort to assess the impact of these dermal exposures on the health effects reported in these

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studies, or the lack of accurate information on sampling and measuring of inhalation exposure, it provides no basis for its conclusion that "airborne exposure was the predominant contributor to these effects." Id.

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 of 10 ppm and that its 1 ppm PEL is necessary to eliminate a significant risk to health posed by higher levels of EDC.

2. Evidence of Potential Carcinogenicity

As noted above, the 1976 NIOSH Criteria Document (Ex. 1-231) proposed a 5 ppm REL based on studies relating to EDC's noncarcinogenic risks. The revised NIOSH Criteria Document lowered the REL from 5 to 1 ppm predicated on its conclusion that EDC posed a potential risk of carcinogenicity. See Ex. 1-

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1120 at 1.^{5/} This conclusion was based solely upon the oral gavage study in rats and mice conducted by the National Cancer Institute (NCI) in 1978.^{6/} The study involved the forced-feeding of EDC to the animals and the applicability of its results to worker exposure to EDC have been called into question by more recent scientific evidence. Specifically, its results are not a proper indicator of the health effects of EDC exposure via inhalation. See discussion, infra, at _____. In addition, it is apparent from OSHA's preambles to both the final and proposed rule that its discussion of the health risks of EDC at 10-15 ppm is based primarily on the studies of Kozik and Brzdzowski, not the NCI bioassay. 53 Fed. Reg. 21052; 54 Fed. Reg. 2484. Yet its PEL of 1 ppm is taken from NIOSH based on the potential carcinogenic risk cited in the Revised 1978 Criteria Document. As noted below, however, the Criteria Document's reliance on a study of questionable relevance to an assessment of the health effects of EDC inhalation does not provide an adequate basis for OSHA's promulgation of a 1 ppm PEL for EDC. See discussion, infra, at _____.

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).

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C. OSHA failed to consider the most recent scientific data available in the field.

When an agency attempts to regulate "on the frontiers of scientific knowledge," [cite], it must at least attempt to ensure that its regulation is based on the most current information available. The OSH Act explicitly requires that the Agency "consider the latest available scientific data in the field." OSH Act, § 6(b)(5); 29 U.S.C. § 655(b)(5). Instead, however, OSHA relied exclusively on a 12-year-old NIOSH document to discover two 30-year-old studies on which to base its "cutting-edge" standard. It 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 in 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). See, e.g., Ex. 3-624.^{1/}

^{1/} 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

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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 (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 tend to show that the potential carcinogenic effects of EDC are 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 lower when exposure occurs through inhalation or drinking water than through forced-feeding (oral gavage), as was done in the NCI study in 1978.

7/ (...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.

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.

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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 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. None of these studies are included in the record and OSHA's preamble discussion of EDC's health risks indicates that they were never considered, as required by Section 6(b)(5). See 29 U.S.C. § 655(b)(5); Texas Independent Ginners Assn., 630 F.2d at 405 and 413 n. 48.

D. OSHA failed to "present its reasons for rejecting significant contrary evidence and argument."

Even after this more recent substantive and conflicting scientific evidence was brought to the Agency's attention, OSHA

^{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.

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provided no reasonable explanation as to why these more recent studies were not given greater weight in its health assessment of EDC. Apparently intent on not getting "caught up in the details" of these risks for reasons of "administrative efficiency," see generally 54 Fed. Reg. 2362-63, OSHA made no effort to obtain or review the information brought to light in the public comment. The Agency instead simply reasserted, without further explanation, its reliance on the two deficient 30-year-old foreign studies and the 1978 NCI study, the significance of which was directly challenged by the new evidence.

OSHA did not explain its reasons for dismissing the study by Spreafico on EDC inhalation in rats and mice that showed no evidence of any chronic changes in adolescent animals exposed to EDC at levels up to 150 ppm. It did not explain its reasons for ignoring the more recent studies by Maltoni, Klaunig, and Storer which were conducted after publication of the NIOSH Criteria Document and which raise serious issues regarding the significance of route-of-exposure in the health effects of EDC. In fact, with the exception of a brief general reference to the Maltoni study, OSHA did not bother to comment upon, or even acknowledge the existence of these studies. While OSHA is entitled to some deference in this area, it has

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ignored its established legal duty "to present its reasons for rejecting any significant contrary evidence and argument."

International Union, UAW, 878 F.2d at 392; Building and Construction Trades Dept., AFL-CIO, 838 F.2d at 1264; Public Citizen, 796 F.2d at 1485.

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 revised PEL for EDC. The Agency's action is substantially different than adopting the ACGIH TLV of 10 ppm. OSHA has failed to demonstrate that a reduction of the PEL below 10 ppm to 1 ppm will eliminate a significant risk of a material health impairment.

III. OSHA HAS BASED ITS PEL FOR EDC SOLELY ON A 1978 RECOMMENDATION BY NIOSH, RATHER THAN FULFILLING ITS LEGAL DUTY TO MAKE ITS OWN ASSESSMENT OF SIGNIFICANT RISK BASED ON SUBSTANTIAL EVIDENCE IN THE RECORD.

1. By blindly adopting the NIOSH REL, OSHA also adopted certain unsupported assumptions employed by NIOSH which cannot serve as a basis for a finding of significant risk" under the Benzene case.

In its revised Criteria Document (Ex. 1-1120), NIOSH offers as its Recommended Exposure Limit (REL) for EDC a 1 ppm

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TWA and a 2 ppm STEL. The 1 ppm REL was reduced to its current level from the 5 ppm level that was recommended in the 1976 NIOSH Criteria Document (Ex. 1-231). The reduction was based solely on the positive results of an animal bioassay of EDC administered via gastric intubation (i.e., an oral gavage study) by the National Cancer Institute (hereinafter "NCI study"). See Exhibit 1-1120, at 4. Again, the absence of this study from the record strongly suggests that it was never actually reviewed by OSHA during the rulemaking.

Moreover, NIOSH explicitly acknowledged in its revised Criteria Document that, based on information on other studies of ethylene dichloride administered via inhalation and dermal application, NIOSH considered the carcinogenic potential of ethylene dichloride via these exposure routes as "inconclusive," (via inhalation) and "undetermined" (dermal). See Exhibit 1-1120, at 5-6. While NIOSH continued to urge regulation of EDC as an occupational carcinogen in its comments on this rulemaking, it offered no evidence or argument that it had changed its view on the state of the evidence on EDC's carcinogenicity via inhalation.

Finally, the NIOSH REL was established not on the basis of a finding that exposure to EDC poses a "significant risk of

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a material health impairment" at a higher level, as required by Benzene, 448 U.S. at 639, but rather on the NIOSH view that "it is not possible at present to establish a safe exposure level for a carcinogen." See Exhibit 1-1120 at 2. Instead of setting its REL at a level "reasonably necessary" to reduce significant risk, NIOSH simply established its REL at a level "that can be reliably measured in the workplace" based only on the view that exposure to EDC should "be kept as low as feasible." See Exhibit 1-1120, at 2, 8 (emphasis added). Obviously, the 1978 NIOSH document could not have been informed by the Supreme Court's later guidance in the Benzene decision. This is understandable. However, this does not excuse OSHA from meeting its statutory obligations some 12 years later.

By simply adopting the NIOSH recommended REL without conducting its own review and analysis of the scientific evidence (or even making an effort to include the evidence relied upon in the record), OSHA has failed to fulfill its threshold legal duty to find the level at which ethylene dichloride presents a "significant risk" and establishing a PEL in accordance with that finding. Benzene, 448 U.S. at 642. Instead, it simply incorporates the NIOSH REL and the considerations on which it is based: feasibility and an assumption that there is no "safe exposure level for a

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carcinogen." Exhibit 1-1120 at 2. This same unsupported assumption regarding the absence of a safe level for the regulated substance was firmly rejected in the Benzene case because it imposes "the burden on industry of proving the existence of a safe level of exposure, thereby avoiding [OSHA's] threshold responsibility of establishing the need for more stringent standards." Benzene, 448 U.S. at 659.

It must be noted that OSHA was precluded from making such an assumption in the Benzene case for a known human carcinogen. See 448 U.S. at 634. The carcinogenicity data cited by OSHA is not sufficient to establish EDC as a carcinogen nor has OSHA attempted to regulate it as a carcinogen. See 54 Fed. Reg. 2484 (NIOSH considers EDC a potential human carcinogen) and 54 Fed. Reg. 2669-2695 (regulations for carcinogens). Thus, OSHA has in effect adopted the unsupported assumption made by NIOSH that there is no safe level for EDC, even though it has not found that EDC is a human carcinogen. This is contrary to OSHA's obligation to first evaluate the "significance" of the risk posed by a substance at particular levels before setting a PEL. See Benzene, 448 U.S. at 634.

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OSHA may not do through NIOSH that which it is not legally permitted to do itself. If there is some basis for OSHA's establishment of a 1 ppm PEL for EDC other than those cited in the NIOSH Criteria Documents, OSHA made no attempt to explain that basis in its final rule.

IV. BY DISREGARDING THE PROCEDURAL GUIDANCE OF THE ADMINISTRATIVE CONFERENCE OF THE UNITED STATES, OSHA EMPHASIZED ITS FAILURE TO ADEQUATELY CONSIDER THE EVIDENCE BEFORE IT OR RESPOND TO PUBLIC COMMENT

This rulemaking is an effort by OSHA to overcome its frustration in revising PELs for many substances in an efficient manner. "OSHA has issued only 24 substance-specific health regulations since its creation" some 20 years ago, and the Agency believes that by "[u]sing past approaches and practices," OSHA could only regulate a small number of high priority substances and never revise or add standards for the large number of chemicals in the workplace. 53 Fed. Reg. 20963 (June 7, 1988).

In searching for procedural alternatives, OSHA turned to the Administrative Conference of the United States (ACUS) for guidance. ACUS made two sets of recommendations. 52 Fed. Reg. 23629 and 40147 (1987). Of particular relevance here is

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ACUS' suggestion that OSHA update the air contaminants rule on a generic basis, that is, including multiple standards in one proceeding. 53 Fed. Reg. 20964 (1989). However, ACUS carefully limited its endorsement of such an approach to cases where

consensus recommendations are available, which are generally accepted by employers and workers in the affected industries

Id.

The ACGIH TLVs are "generally accepted by employers" in the ethylene dichloride industry as providing reasonable guidelines in assessing appropriate controls on worker exposure, although there is obviously a distinct difference between following a voluntary guideline and meeting a regulatory mandate. In contrast, the NIOSH REL, upon which the revised PEL for EDC was purportedly based, is not "generally accepted by employers" and, therefore, not within the ACUS recommendation.

Under the circumstances of this rulemaking, it is easy to understand how OSHA could overlook important information and comments that would help inform its decision on an appropriate PEL for EDC. OSHA's misunderstanding of the NIOSH Criteria Document for EDC, its failure to actually review the studies

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upon which ACGIH and NIOSH based their proposals, and its disregard for new scientific data generated over the last decade are all reflective of the inadequacies of the present rulemaking for adopting a revised PEL that is not based on generally accepted consensus standards. Ultimately, in disregarding ACUS' carefully limited recommendation, OSHA failed to meet its statutory obligations.

CONCLUSION

Based on the foregoing, Petitioner SPI requests that this Court vacate the provisions of OSHA's final rule establishing a 1 ppm PEL for EDC and remand this action to OSHA for further consideration.

Respectfully submitted,

Jerome H. Heckman
Peter L. de la Cruz
Mark A. Sievers
Keller and Heckman
1150 17th Street, N.W.
Washington, D.C. 20036
(202) 956-5600

Counsel for The Society of the
Plastics Industry, Inc.

Date:

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