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

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Industry, Inc.

April 27, 1990

CERTIFICATE OF INTERESTED PERSONS

The Society of the Plastics Industry, Inc. (SPI) certifies that this action is of direct interest only to th 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 known to SPI and its attorneys ar

Attorneys 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)

Respondent Occupational Safety and Health Administration and its Attorneys of Record, Steven Mandel, Ann Rosenthal, Elizabeth Hopkins

and the following Intervenors:

The American Federation of Labor and Congress of Industrial Organizations, and its Attorn ys of Record, Bredhoff & Kaiser (George H. Cohen, Jerem A. Collins and Martin S. Lederman)

The American Petroleum Institute, and its Attorne of Record, G. William Frick, Valerie J. Ughetta a Kirkland & Ellis (Arthur F. Sampson)

The Chemical Manufacturers Association and its Attorneys of Record, David F. Zoll, Marilyn D. Browning and Wilmer, Cutler & Pickering (Neil J. King)

The Chlorine Institute and its Attorneys of Record, LaRoe, Winn, Moerman & Donovan (Paul M. Donovan, Gerald L. Richman and Maureen Quinn)

The American Iron and Steel Institute and its Attorneys of Record, Barton C. Green and Crowell & Moring (Dana C. Contratton, Richard E. Schwartz and Nancy S. Bryson)

The Corn Refiners' Association, Archer Daniels Midland Company and AE Staley Manufacturing Company, and their Attorneys of Record, Covington & Burling (Clausen Ely, Jr. and Michael G. Michaelson)

The National Grain and Feed Association, and its Attorneys of Record, Arent, Fox, Kintner, Plotkin and Kahn (Marc L. Fleischaker and V. Daniel Palumbo)

The Inter-Industry Committee on Carbon Disulfide and its Attorneys of Record, Gibson, Dunn, & Crutcher (Joseph H. Price, Baruch A. Fellner and Theodore J. Boutrous, Jr.)

Courtaulds Fibers, Inc. and its Attorneys of Record, Fox, Weinberg & Bennett (Lynn L. Bergeson and Kurt J. Olson)

The International Fabricare Institute and Texas Laundry and Drycleaning Association, and its Attorneys of Record, Patton, Boggs & Blow (Timothy A. Vanderver, Paul A.J. Wilson, David J. Farber and Duane A. Siler)

Respectfully submitted,

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

April 27, 1990

STATEMENT REGARDING ORAL ARGUMENT

The extensive amount of technical and scientific information involved in this review proceeding may tend to obscure the important legal questions that the Petitioners have raised. Petitioner SPI believes that oral argument will help to isolate and sharpen the legal issues under review. Should the court conclude that its review of these consolidated cases will be aided by oral argument, Petitioner SPI respectfully requests that it be given an opportunity to present its case when argument is heard.

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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) (1982). 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.

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 (1988)(to be codified at 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 (1988). Immediately thereafter, OSHA held 13 days of public hearings. The Secretary of Labor established an October 7, 1988 deadline for post-hearing evidence and an October 31, 1988 deadline for post-hearing briefs. 53 Fed. Reg. 34708 (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 (1989).

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 its June 7, 1988 proposed rule, OSHA proposed to establish a new PEL for ethylene dichloride (EDC) of 1 part per million (ppm) as an eight-hour time-weighted average (TWA) and of 2 ppm as a 15-minute short-term exposure limit (STEL). In the preamble to the proposed rule, OSHA provided only a brief overview of the health effects data on EDC. See 53 Fed. Reg. 21052 (1988). OSHA recognized that the American Conference of Governmental Industrial Hygienists (ACGIH) had reduced its threshold limit value (TLV) for ethylene dichloride to 10 ppm as a time-weighted average 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. See Ex.[1/] 1-1120.[2/] OSHA also noted NIOSH's treatment of EDC as a potential human carcinogen based on an animal bioassay conducted by the National Cancer Institute (NCI) in 1978.[3/]

OSHA cited two studies from the 1950s as evidence that exposure to EDC at the current PEL level presents a risk of hepatotoxic, hematopoietic (blood), and nervous system effects. See Ex. 1-182; Ex. 1-63. These dated studies were reports by Kozik (1957/Ex. 1-182)[4/] and Brzozowski, et al. (1954/Ex. 1-63)[5/] on workers exposed to varying levels of EDC. Based on these 30-year-old studies, OSHA concluded that the 10 ppm TLV

1/ "Ex. ___" refers to Exhibits in OSHA's rulemaking record. All cited Exhibits are included in the Certified Extracts of the Record.

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

3/ 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).

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

5/ 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 (hereinafter cited as Brzozowski).

established by ACGIH would not provide protection from some of these effects, 53 Fed. Reg. 21052 (1988), even though ACGIH considered these studies in establishing its TLV. See Ex. 3-677, at 5; 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 of EDC inhalation and that the health evidence it cited 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 (1988).

B. Public Comment on the Proposal

During the comment period on the proposed rule, eight comments specifically addressed the proposed PEL for ethylene dichloride. Petitioner SPI, through its Vinyl Institute,[6/]

6/ 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 ethylen dichloride production in the U.S. The members

(continued...)

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. See Ex. 3-624, at 3; Ex. 3-741, at 53. The Vinyl Institute, CMA and others pointed out the severe limitations in the Kozik and Brzozowski studies. See Ex. 3-624, at 3-4; Ex. 3-874, at 1-2. For 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 indicat d 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. Kozik

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6/(...continued)
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.

provided no information on the nature of the sampling techniques or analytical methods used. In addition, the study may have also involved significant dermal exposure. See Ex. 3-624, at 3-4; Ex. 3-874, at 1-2.

The commenters argued that the absence of complete information in such critical areas as exposure, methodology, and sampling limit the usefulness of these two studies 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. Se Ex. 1-63; Ex. 1-182.

The commenters also brought to OSHA's attention significant scientific information which called into question the results of the two foreign studies, as well as the validity of the NCI study as an indicator of the potential human carcinogenicity of EDC. Much of the evidence cited by th commenters became available after NIOSH had issued its Revis d Criteria Document based on the NCI study. In particular, the

commenters cited studies by Maltoni, et al.[7/] 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.[8/] 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. Another study cited in the comments, conducted by Spreafico, et al.,[9/] showed that EDC inhalation by adolescent rats and mice at levels of up to 150 ppm for most of their

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7/ 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.

8/ 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.

9/ 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 serum glutamic-oxalacetic transaminase (SGOT) levels was noted in older rats exposed to such levels of EDC for 12 months, the comments pointed out that 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 respons 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.

lifespan produced no chronic changes. See Ex. 3-624, at 4. These studies, the commenters noted, represent more recent scientific evidence that conflicts with the results of the NCI study. See Ex. 3-624, at 5.

These newer studies were supported by other in vivo studies of the genotoxicity of EDC via different routes of exposure, the commenters noted. A study by Storer, et al.,[10/] involving EDC exposures via both oral ingestion and inhalation, concluded that the "results provide additional evidence for the importance of a route of exposure effect in the in vivo genotoxicity and carcinogenicity of [EDC]." Ex. 3-624, at 5. The commenters cited a study by D'Souza, et al.,[11/] which identifies 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. Studies by Rannug, et al.,

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10/ Storer, R.D., Jackson, N.M., and Connolly, R.B., 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 (1984).

11/ D'Souza, R.W., Francis, W.R., Bruce, R.D., Anderson, M.E., Physiology Based Pharmacokinetic Model for Ethylene Dichloride and its Application and Risk Assessment, Pharmacokinetic and Risk Assessment - Drinking Water and Health, Volume 8, National Academy Press, Washington, D.C. pp. 286-301 (1987).

Boyd, et al.[12/] and Condie[13/] 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. See e.g., Ex. 3-624, at 4-6. For example, the study by Condie showed that the corn oil used in the NCI study may have enhanced the hepatotoxicity as well as the carcinogenic response. See Ex. 3-874, at 2.

Industry commenters 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 but noted 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. See Ex. 3-874, at

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12/ Boyd, S.C., Susame, H.A., and Boyd, M.R., High concentrations of glutathione in glandular stomach: possible implications for carcinogenesis. Science 20:1010-1012 (1979).

13/ Condie, L.W., Target organ toxicity of halocarbons commonly found contaminating drinking water. Report, EPA/600/D-85/172, pp. 1-14 (1985).

3.[14/] OSHA was urged to adopt the ACGIH level of 10 ppm. See, e.g., Ex. 3-677, at 6; Ex. 3-741, at 53.

C. The Final Rule

OSHA published its final air contaminants rule on January 19, 1989. 54 Fed. Reg. 2332 (1989). The Agency noted that as the "starting point" for its analysis of these substances, it used the "already published and widely accept d 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 which 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. See 54 Fed. Reg. 2479, 2484-85, 2937. These limits represent a severe reduction from the

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

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 on these studies to support its conclusions on the noncarcinogenic effects of EDC. 54 Fed. Reg. 2484 (1989). 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 the discussion is taken.

Despite OSHA's own acknowledgement of the deficiencies in the studies relied upon to set the new standard, 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. 2484 (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." Id.

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 specific claims that (1) the results of the NCI study may hav been skewed 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 involving intraperitoneal administration (i.e., via injection) of EDC, apparently described in a document of th Environmental Protection Agency (EPA) which again is not included in the record. 54 Fed. Reg. 2485 (1989). 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. Id.

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 American Federation of Labor and Congress of Industrial Organizations (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). See 54 Fed. Reg. 2484-85 (1989).

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) (1982).

See also National Grain and Feed Assn. v. OSHA, 858 F.2d 1019, 1030 (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 (1982); 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

[it]." Id. at 1030-31 (citing Texas Independent Ginners Assn., 630 F.2d at 404). 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 Independent 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) (1982); see also 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." 29 U.S.C. § 655(b)(5) (1982). While not expected to establish its findings to the point of "scientific certainty," see Industrial Union Dept. AFL-CIO v. American Petroleum Institute, 448 U.S. 607, 656 (1980) (plurality opinion), 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.

International Union, UAW v. Pendergrass, 878 F.2d 389, 392 (D.C. Cir. 1989), (quoting 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)[15/] 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) (hereinafter cited as 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 included in the record. The two studies that did appear were included in the record only in their original foreign language versions.

15/ Since OSHA's short-term exposure limit (STEL) of 2 ppm for EDC is based on the same evidence as the 1 ppm TWA, SPI is also challenging the 2 ppm STEL. For ease of reference, we refer in the text either to the PEL generally or the 1 ppm TWA. All arguments in this brief, however, are intended to apply equally to the 2 ppm STEL.

In addition, OSHA did not consider "the latest available scientific data in the field." Instead, it relied on "Criteria Documents" on EDC published by the National Institute on Occupational Safety and Health (NIOSH) in 1976 and 1978. OSHA relied principally 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 mor 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 made no attempt to quantify the risk of exposure to EDC at the existing PEL, at the new PEL, or at other relevant levels. Although it used the ACGIH TLVs as a starting point and adopted these levels for most other substances covered by the rule, OSHA failed to articulate its reasons for

choosing the 1 ppm PEL over the ACGIH TLV or other intermediate alternatives.

OSHA's reliance on the NIOSH documents also led th Agency to adopt the NIOSH recommended exposure limit (REL) for EDC which was established in 1978 based on assumptions which were found to be inadequate to support a finding of "significant risk" in the Benzene case in 1980. By blindly adopting the NIOSH REL, along with the inappropriate 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.

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 NEW PEL

Section 6(b)(5) of the Occupational Safety and Health Act (the Act) 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 . . .

29 U.S.C. § 655(b)(5) (1982).

Under Section 3(8) of the Act, an "occupational safety and health standard" must be "reasonably necessary or appropriate to provide safe or healthful employment and places of employment." 29 U.S.C. § 652(8) (1982). When Sections 6(b)(5) and 3(8) of the Act 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." Benzene, 448 U.S. at 639.

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 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: 1) SUPPORT ITS FINDING OF A SIGNIFICANT RISK OF MATERIAL HEALTH IMPAIRMENT WITH THE BEST AVAILABLE EVIDENCE, 2) CONSIDER THE LATEST AVAILABLE SCIENTIFIC DATA IN THE FIELD, OR 3) ADEQUATELY PRESENT ITS REASONS FOR REJECTING SIGNIFICANT CONTRARY EVIDENCE.

A. OSHA Failed to Include in the Record Critical Evidence Upon Which It Relied.

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 (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 (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 effort on the part of OSHA to satisfy its statutory mandate to seek out the "best available evidence" or the "latest available scientific data in

the field," 29 U.S.C. § 655(b)(5) (1982), 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 (emphasis added).

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. 2372 (emphasis added). The two principal studies on workers relied upon by OSHA, Kozik and Brzozowski were included in the record only in their foreign language versions. See Ex. 1-182, Ex. 1-63. The other 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 discussion supra at 12-14. Although OSHA

relies on the NCI study as partial justification for its PEL on EDC, and even cites to the study as "Ex. 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. See Ex. 1-947.

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) (1982); 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. See, e.g., U.S. Lines v. Federal Maritime Commission, 584 F.2d 519, 534-35 (D.C. Cir. 1978). "The failure to include the information relied upon by the agency in the administrative record, even if later disclosed to the court, is . . . inconsistent with the Administrative Procedure Act's requirement that review take place on 'the whole record.'" Id. at 534 n.43.

B. The Studies Principally Relied Upon By OSHA Ar 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. 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. 54 Fed. Reg. 2484 (1989). The inadequacies of the studies described below are reflected in OSHA's inability to make a clear and definitive finding as to the level of EDC exposure it believes poses a significant risk of adverse health effects. See id. ("at levels of 10 ppm or somewhat higher (i.e., in the 14- to 15-ppm range)") (emphasis added).

Both the Kozik (Ex. 1-182) and Brzozowski (Ex. 1-63) 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 interpretations of these studies by ACGIH and NIOSH, the h alth 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 a REL of 5 ppm in 1976. See Ex. 1-231, at 101. 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 reasons why 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. 3-874, at 1-2. Because of the outdated work practices employed at the time, it is likely that the measured exposur s 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, 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 "or somewhat higher" 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 hav 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 th se 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 (1989). Th 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.

OSHA makes no effort to assess the impact of thes dermal exposures on the health effects reported in these studies, or the lack of accurate information on sampling and

measuring of inhalation exposure. By failing to address these issues, OSHA provides no basis for its conclusion that "airborne exposure was the predominant contributor to these [health] effects." 54 Fed. Reg. 2485 (1989).

Because of the deficiencies in these accounts of chronic EDC exposure in humans, the Kozik and Brzozowski 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 proposed a 5 ppm REL based on studies relating to EDC's noncarcinogenic risks. See Ex. 1-231, at 101. 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. 1-1120, at 1. This conclusion was based solely upon the oral gavage study in rats and mice conducted by the National Cancer Institute (NCI) in 1978. Because the study involved the forced-feeding of EDC to the

animals, 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 30-32.

In addition, it is apparent from OSHA's preambles to both the final and proposed rule that its indecisive "finding" of "significant risk" at 10-15 ppm is based primarily on the studies of Kozik and Brzozowski, 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, because the Criteria Document relies on inappropriate assumptions and a study of questionable relevance to an assessment of the health effects of EDC inhalation, it is not an adequate basis for OSHA's promulgation of a 1 ppm PEL for EDC. See discussion, infra, at 36-39.

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," Benzene, 448 U.S. at 656, 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." 29 U.S.C. § 655(b)(5) (1982). 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 the Spreafico study, see supra note 9, on EDC inhalation in mice and rats 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 3 to 21 months). See, e.g., Ex. 3-624, at 4.

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. The inhalation study of Maltoni, see supra note 7, and the drinking water study of Klaunig, see supra note 8, 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.

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. 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) (1982); Texas Independent Ginners Assn., 630 F.2d at 405 and 413 n.48.

D. OSHA Failed To "Present Its Reasons For Rej cting Significant Contrary Evidence And Argument."

Even after this more recent substantive and conflicting scientific evidence was brought to the Agency's attention, OSHA provided no reasonable explanation as to why these more recent studies were not given greater w ight in its health ass ssment

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 (explaining OSHA's streamlined approach to the rulemaking), 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. OSHA 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 Documents. Those studies 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. See 54 Fed. Reg. 2484-85 (1989). While OSHA is entitled to some deference in this area, it has 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. Th 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.

E. OSHA's Failure To Apply Quantitative Risk Assessment Procedures Or To Otherwise Quantify Th Risk Of EDC Exposure Provided The Agency With N Articulated Basis For Selecting A 1 ppm PEL Over Other Alternative Levels.

The Act requires that OSHA establish an exposure standard that is "reasonably necessary and appropriate to remove a significant risk of harm." Benzene, 448 U.S. at 662. Implicit in this statutory requirement is OSHA's duty to evaluate and quantify the risk posed by a substance not only at the existing level of exposure but also at various levels below the existing PEL so that it can select an appropriate new

level. To rationally determine what exposure limit is necessary to reduce or eliminate a health risk to a point where it is no longer significant, OSHA must at least evaluate the risk at the new level. In United Steelworkers of America v. Marshall, the court provided the following analysis of this issue:

> In mentioning this second aspect of the threshold requirement - whether the significant harm at the current level can be eliminated or lessened by a change in the PEL - the [Benzene] plurality implies that § 3(8) requires OSHA to prove by specific evidence the level of risk at the new PEL, as well as the current PEL. The plurality leaves this point somewhat unclear, but in any event a requirement of such proof would seem to follow from the second statutory provision governing OSHA's toxic agent standards, § 6(b)(5).

647 F.2d 1189, 1246 n.85 (D.C. Cir. 1980) (emphasis in original). In other PEL rulemakings, OSHA has undertaken to quantify the risk posed by various substances at the new level and the courts have considered that additional step as critical to their review of the Agency's action. See, e.g., International Union, UAW, 878 F.2d at 392 ("OSHA necessarily seeks to quantify the risk posed by each toxic threat," but did not adequately do so for formaldehyde exposure) (emphasis added); Public Citizen, 796 F.2d at 1502-03 (OSHA's use of quantitative risk assessment procedures for old and new PELs for ethylene oxide satisfied Agency obligation to estimate

actual risk); Building and Construction Trades Dept., AFL-CIO, 838 F.2d at 1264 (applying risk assessment model to determine specific risk at old and new exposure level for asbestos). In this rulemaking, OSHA's evaluation of EDC involves no such quantification of the risk at the relevant exposure levels.

OSHA gets off to a bad start by hedging on its selection of a level at which it believes a significant risk from EDC exposure exists. See 54 Fed. Reg. 2484 (1989) ("at levels of 10 ppm or somewhat higher (i.e., in the 14- to 15-ppm range)"). The Agency then makes no attempt to quantify the risk at these different levels. In addition, since OSHA established the ACGIH list of TLVs as one of its "starting points," it should have evaluated the risk at the ACGIH TLV for EDC of 10 ppm. In selecting a 1 ppm PEL without making any attempt to quantify the risk posed at this or other relevant levels that may provide equal protection against the risks posed (e.g. 5 ppm), OSHA has failed in its duty to identify in some detail its "reasons for choosing between competing alternatives," Building and Construction Trades Dept., AFL-CIO, 838 F.2d at 1266; or "the considerations it . . . found relevant in reaching each of its conclusions." Public Citizen, 796 F.2d at 1503.

When the Agency chooses a PEL from among legitimate alternatives l vels, the court must "look for some articulation

of reasons for those choices." International Union, UAW, 878 F.2d at 392. Here, OSHA was obligated to provide some articulation of its reasons and considerations for choosing a 1 ppm PEL, and such an articulation should have started with quantitative information about the risks posed by EDC at this and other relevant levels. Instead, as demonstrated in the following section, OSHA made inappropriate assumptions regarding the risk of EDC in selecting the new PEL.

III. BY BLINDLY ADOPTING THE 1978 NIOSH REL AS ITS PEL FOR EDC, OSHA ALSO ADOPTED CERTAIN UNSUPPORTED ASSUMPTIONS EMPLOYED BY NIOSH WHICH CANNOT SERVE AS A BASIS FOR A FINDING OF "SIGNIFICANT RISK" UNDER THE BENZENE DECISION.

In its revised Criteria Document, NIOSH offers as its Recommended Exposure Limit (REL) for EDC a 1 ppm TWA and a 2 ppm STEL. See Ex. 1-1120. 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 Ex. 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 Ex. 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. See, e.g., Ex. 8-47, App. A.

Finally, the NIOSH REL was established not on the basis of a finding that exposure to EDC poses a "significant risk of 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 Ex. 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 vi w that exposure to EDC should "be kept as low as feasible." See Ex. 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. However, this do s 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 improper considerations on which it is based: feasibility of measurement and an assumption that there is no "safe exposure level for a carcinogen." Ex. 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. Such an unfounded assumption 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.

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 FAILED 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 (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. As part of its recommendations, ACUS advised OSHA to update the air contaminants rule on a generic basis by including multiple standards in one proceeding. See 53 Fed. Reg. 20964 (1988). 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 TLV for EDC is "generally accepted by employers" in the ethylene dichloride industry as providing reasonable guidelines for assessing appropriate controls on worker exposure. See, e.g., Ex. 3-677, at 6; Ex. 3-741, at 53 (urging OSHA adoption of ACGIH level as PEL). In contrast, the NIOSH REL, upon which OSHA based the revised PEL for EDC, is

not "generally accepted by employers." Thus, by using the NIOSH REL and NIOSH Criteria Documents as the sole basis for the revised PEL, OSHA has ignored the ACUS recommendation that only consensus industry exposure limits be used in this generic rulemaking.

In light of the enormous number of substances considered in this rulemaking and the unusually short period of time that elapsed prior to its final promulgation, 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 upon which ACGIH and NIOSH based their proposals, and its disregard for new scientific data generated over the last decade demonstrate that this present rulemaking was not an adequate or appropriate vehicle for adopting a revised PEL that is not soundly based on a generally accepted consensus standard. Ultimately, in disregarding ACUS' carefully limited recommendation, OSHA failed to develop sufficient evidenc in the record 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 PELs for EDC of 1 ppm as a TWA and of 2 ppm as a STEL and remand this action to OSHA for further consideration.

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