

U.S. Department of Labor

Assistant Secretary for
Occupational Safety and Health
Washington, D.C. 20210



JUL 17 1989

Peter L. de la Cruz
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Washington, D.C. 20036

Dear Mr. de la Cruz:

This letter is in response to your petition of May 23, 1989 on behalf of the Society of the Plastics Industry, Inc. (SPI), for a stay and for reconsideration of the recently revised Permissible Exposure Limit (PEL) for ethylene dichloride (EDC). You have requested the Occupational Safety and Health Administration (OSHA) to stay the PEL for EDC, set at 1 ppm as an 8-hour Time Weighted Average (TWA) and 2 ppm as a Short Term Exposure Limit (STEL), pending the outcome of judicial proceedings before the United States Court of Appeals for the Eleventh Circuit. In addition, you have requested that OSHA reconsider its PEL for EDC and establish new less protective limits that you contend are consistent with the scientific literature on EDC and economically and technologically feasible.

At the outset, I would note that the petitioner bears a heavy burden in justifying its request that OSHA stay its final standard in this matter. See United States v. Bogle, 855 F.2d 707, 708 (11th Cir. 1988). Under the Administrative Procedure Act, 5 U.S.C. 705, OSHA may delay the effectiveness of a standard pending judicial review only "when [it] finds that justice so requires." Therefore, it is incumbent upon the petitioner clearly to demonstrate that the circumstances are such that permitting the standard to take effect would be unjust, and that the "exceptional response" of granting a stay is warranted. See Garcia-Mir v. Meese, 781 F.2d 1450, 1453 (11th Cir. 1986), cert. denied, 479 U.S. 889 (1986). In determining whether a stay is justified, I consider the following factors: (1) the likelihood that the petitioner will prevail on the merits; (2) the prospect of irreparable injury to other parties if relief is withheld; (3) the possibility of harm to other parties if relief is granted; and (4) the public interest. See Bogle, 855 F.2d at 708; Garcia-Mir, 781 F.2d at 1453. Of course, I must bear in mind that the interest in conserving life and health has a special claim to government protection as compared to the petitioner's cost of complying with the standard. See, e.g., Environmental Defense Fund v. Ruckelshaus, 439 F.2d 584, 591, 592, 598 (D.C. Cir. 1971). After careful consideration of the allegations in your petition, the evidence in the record and the factors outlined above, I have concluded that a stay is not warranted. In addition, as the following discussion makes clear, there is no basis for reconsideration inasmuch as the standard is supported

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by substantial evidence and is technologically and economically feasible. I will now address the relevant factors in turn.

(1) Likelihood of Success on the Merits

The likelihood that the standard will be set aside on appeal is ordinarily the foremost factor in considering a stay. Garcia-Mir, 781 F.2d at 1453. Your petition challenges the standard on three substantive grounds: (1) no substantial evidence that EDC causes significant adverse health effects at levels up to 10 ppm; (2) technological infeasibility; and (3) economic infeasibility. For the reasons set forth below, I believe you are unlikely to prevail on these arguments on appeal.

(a) OSHA's health assessment for EDC

After review of the evidence in the record, I am confident that OSHA's health assessment for EDC will be upheld. The test formulated by the courts provides substantial leeway to the agency in assessing health risks, especially where, as here, the determination is on the frontier of scientific knowledge. OSHA's findings need not be supported "with anything like scientific certainty." Industrial Union Department, AFL-CIO v. American Petroleum Institute, 448 U.S. 607, 656 (1980). "[S]o long as they are supported by a body of reputable scientific thought, the agency is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection." Id.

OSHA's conclusion that EDC poses a significant risk of material health impairment at levels above 1 ppm meets this test. A number of case studies of industrial exposure discussed in the preamble to the final rule, 54 Fed. Reg. 2484 (January 19, 1989) (Preamble), including those of Kozik; Brzozowski, et al.; Cetnarowicz; and Rosenbaum, demonstrate EDC's hepatotoxic and gastrointestinal effects at exposure levels in the 10 to 15 ppm range. These adverse effects were confirmed both clinically and by laboratory analysis. See Health Assessment Document for 1,2 Dichloroethane (Ethylene Dichloride) EPA/ 600 /8-84/ 006F (September 1985) at 79-84. Preamble at 2485/1. Although specific exposure levels and precise industrial hygiene measurements are not available for some of these studies, OSHA concludes that the evidence as a whole is consistent, biologically plausible and convincing.

In addition, EDC has been implicated as a possible carcinogen by the National Cancer Institute (NCI). Based on NCI's 1978 gavage study and other evidence, NIOSH has recommended that EDC be controlled as an occupational carcinogen. See NIOSH Revised Recommended Standard (Ex. 1-1120).

Your criticism of some of the data supporting OSHA's determination does not demonstrate that the evidence of liver toxicity and other effects is unreliable. While interpretation of the Brzozowski study is confounded because of significant dermal contacts and high peak exposures, Brzozowski's results are consistent with other studies discussed in the preamble that do not involve these complicating factors. For example, Kozik's study of aircraft workers involved controlled exposures in the range of 10 to 15 ppm, and only limited, and likely insignificant, dermal contact. Preamble at 2484/3. Further, OSHA notes that the evidence in rabbits indicates that EDC is not readily absorbed through the skin. Preamble at 2485/1. OSHA concludes, therefore, that inhalation exposure in the range of 10 to 15 ppm is the principal cause of the adverse health effects reported by Brzozowski. Moreover, even if Brzozowski's study were discarded, substantial evidence of EDC's adverse health effects would remain. The case studies of Kozik, Cetnarowicz and Rosenbaum, discussed extensively in the preamble and in EPA's Health Assessment Document, provide ample independent evidentiary support for OSHA's position. In addition, Spreafico's toxicology study reports "significant changes in . . . liver and kidney function" in rats exposed to levels from 5 to 150 ppm of EDC. This study provides further evidence of EDC's hepatotoxic effects at levels at and above 10 ppm. Thus, I reject your argument that the evidence of EDC's liver and gastrointestinal toxicity is fatally flawed.

By the same token, the recent studies relied on by SPI do not refute OSHA's conclusion that EDC poses a possible cancer hazard. Spreafico's toxicology study cannot be considered conclusive on this issue because the animals involved were not examined for gross or histopathologic organ changes. Further, the animal bioassays by Maltoni and Klaunig, and the work of Storer, do not rule out EDC as a potential human carcinogen. While the mechanism by which EDC causes cancer in animals is not completely understood, the animal evidence is sufficient that "[i]n the absence of adequate data in humans, it is reasonable for practical purposes to regard [EDC] as if it presented a carcinogenic risk to humans." Preamble at 2485/2 (NIOSH posthearing comments). This evidence consists of the finding of multiple tumor types in oral bioassays conducted in two species of animals, suggestive evidence in other animal bioassays, evidence of reactive metabolites and formation of a DNA adduct, and evidence that EDC is a mutagen. Preamble at 2485/1.

In light of EDC's demonstrated hepatotoxic and gastrointestinal effects at levels of 10 ppm and above, and the additional risk posed by the substance's possible carcinogenicity, reduction of the PEL to a level substantially below 10 ppm is warranted. As discussed in the preamble at 2398, the use of safety factors to account, inter alia, for variations in individual human responses, and uncertainties in the available data, is common

among leading industrial hygienists. OSHA's selection of 1 ppm as a permissible TWA and 2 ppm as a STEL reflects its reasoned professional judgment as to an appropriate margin for error for EDC and is well within the range of one to three orders of magnitude commonly used for serious effects. Preamble at 2398/3. Thus, considering the evidence as a whole, OSHA's health assessment is solidly grounded in reputable scientific thought.

In sum, the weight of the evidence clearly supports OSHA's health assessment for EDC. The agency recognized the strengths and weaknesses of the data and took the latter into account in assessing the evidence. Further, the agency's position is based upon all the evidence and not upon any single study. For these reasons, OSHA's conclusion that a significant risk of material health impairment exists at levels above 1 ppm is sound and unlikely to be set aside on appeal.

(b) Technological infeasibility

As discussed in the preamble at 2485, OSHA has concluded that compliance with the PEL is feasible for all routine industry operations using readily available engineering controls and improved work practices. Industry has largely concurred in this assessment and you do not challenge it here. Rather, you contend that compliance is infeasible for certain intermittent maintenance and repair operations, for which respirators are typically permitted. Respirators are infeasible here, you argue, because NIOSH odor threshold and maximum contaminant concentration guidelines for respirator selection rule out feasible air-purifying respirators and because air-supplied respirators are infeasible for these operations. This argument is unpersuasive for the following reasons.

First, it is not necessarily true that use of air-purifying respirators is precluded. NIOSH respirator selection criteria provide general guidance concerning respirator use, but are not controlling in all circumstances. OSHA remains willing to consider special conditions applicable to EDC producers and other users, and may authorize the use of air-purifying respirators upon written request. Such authorization has been granted in the past in cases in which the odor threshold of the particular substance involved exceeded the PEL. If you believe an air-purifying respirator not yet approved by NIOSH is feasible and efficacious for the maintenance and repair operations at issue, you should write the agency and request an interpretation of the matter.

Second, you have failed to rebut our conclusion that air-supplied respirators are generally feasible for use in EDC plants. You argue that air-supplied respirators are inappropriate because (1) the physical bulk of the equipment precludes its use in confined locations such as distillation columns, (2) balance and control

problems associated with air lines constitute a greater safety hazard, and (3) prevailing hot, humid weather conditions aggravate the risk of heat exposure. OSHA's experience, however, is that air-supplied air-line respirators are well suited to the temporary operations you have described. Initially, OSHA notes that air-line equipment is not bulky and is routinely utilized in confined spaces. Moreover, air-line equipment offers several advantages over comparable canister type equipment. Air-line devices are simple to use, and are ideal for strenuous work because they offer no respiratory resistance and deliver a greater volume of air when the user's breathing rate and volume increase. Air-line respirators are also well suited to hot environments because the supplied air is blown across the worker's breathing zone and may, if necessary, be cooled. While you argue that air hoses create a tripping hazard, OSHA notes that lines supplying the pneumatic tools used to clean the interiors of the columns are already present and that workers are already required to observe caution to avoid entanglement. An additional air line will not substantially increase this danger. Finally, the agency finds that distillation columns are configured so as to permit scaffolding, life lines and air lines for other equipment and will clearly accommodate use of air-line respirators. For these reasons, I reject your contention that the standard is infeasible for maintenance and repair operations.

(c) Economic feasibility

Your challenge to the economic feasibility of the standard is premised entirely upon the assumption that no feasible respirator is available to EDC producers and that engineering controls will be required for all industry operations without exception. Thus, you argue that OSHA has failed to account for the costs of major modifications in plant facilities necessary to control emissions in intermittent maintenance and repair operations in which respirators were formerly used. For the reasons discussed above, however, OSHA rejects this contention and concludes that respirators remain a viable, low-cost compliance alternative for operations in which engineering and work practice controls alone cannot reduce exposures to the new PEL. Preamble at 27981/1. As the preamble notes, "a showing by a particular industry that compliance requires respirators in certain operations . . . does not make a standard infeasible." Accordingly, OSHA has adequately accounted for all reasonable compliance costs and its assessment of the economic feasibility of the standard will not be disturbed on appeal.

(2) Irreparable Harm

Because a stay is an extraordinary remedy, a showing of irreparable harm is a prerequisite to obtaining relief. Parks v. Dunlap, 517 F.2d 787 (5th Cir. 1976). To be irreparable, the injury must be certain to occur; "bare allegations as to what is

likely to occur or of no value." Wisconsin Gas Co. v. FERC, 738 F.2d 669, 672 (D.C. Cir. 1985). In addition, the harm suffered must be truly irreparable, not "merely substantial or serious." A.O. Smith Corp. v. FTC, 530 F.2d 515, 525 (3rd Cir. 1976). The harm you anticipate does not approach these dimensions.

You contend, initially, that industry will suffer irreparable harm as a result of enforcement citations for use of air-purifying respirators that are not NIOSH approved. For reasons previously discussed, you have failed to demonstrate that the use of air-purifying respirators need be unauthorized. Accordingly, this argument fails because the alleged harm is not certain to occur.

Alternatively, you contend that member producers who opt for air-supplied respirators will subject workers to the risk of irreparable physical harm. Your arguments on this issue have been carefully considered in the discussion of technological feasibility. OSHA has concluded, for the reasons set out there, that air-supplied respirators do not pose a significant risk to worker safety and, in fact, incorporate features which lessen the prospect of physical injury to users. Accordingly, your claim of irreparable harm is entirely unsupported in fact and law and provides no basis to grant extraordinary relief.

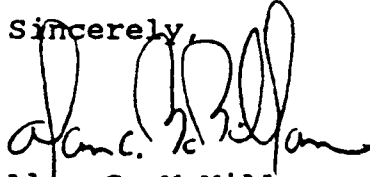
(3) and (4) Effect on Other Interested Parties and The Public Interest

Finally, I must consider the effect of a stay on other interested parties and the public interest before granting relief.

You maintain that a balancing of the equities favors a stay because a 1 ppm PEL exposes industry to irreparable harm while failing to accord significant needed protection to workers. OSHA concludes, however, that levels above 1 ppm pose a significant risk of material health impairment to exposed workers. OSHA has estimated that the number of workers routinely exposed to EDC in the plastics industry may exceed 28,000. Supplement II. These workers are the primary beneficiaries of the standard, and their interests in health and safety ordinarily take precedence over purely economic concerns. Environmental Defense Fund v. Ruckelshaus, 439 F.2d at 591-92. Moreover, you have failed to demonstrate that industry will be irreparably harmed if the standard remains in effect. Accordingly, a balancing of the equities and the public interest in safe and healthful employment militate against a stay.

I believe that the foregoing discussion has addressed the major concerns expressed in your petition. While I am unable to grant a stay of the standard, my staff and I remain willing to discuss, and hopefully to clarify, any questions you or your clients may have as to its application to EDC producers.

Sincerely,

A handwritten signature in black ink, appearing to read "Alan C. McMillan". The signature is fluid and cursive, with the first name "Alan" being more prominent.

Alan C. McMillan
Acting Assistant Secretary