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March 10, 1988

MEMORANDUM FOR THE ETHYLENE OXIDE INDUSTRY COUNCIL

Attached for your consideration is an initial draft Post-Hearing Brief in the OSHA-excursion limit proceeding. According to the schedule established by the OSHA Administrative Law Judge, post-hearing data submissions are due March 10, and post-hearing briefs must be submitted no later than March 17, 1988. We will check to see what, if any, additional data submissions are filed with OSHA on March 10.

We ~~propose to~~ send a record ~~copy of~~ the final Post-Hearing Brief to the ~~Office of~~ Management and Budget as well as to ~~OSHA~~.

Sara D. Schotland
John M. Bredehoft

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CGS&H DRAFT/4580B(S)-4597B(O)
MARCH 9, 1988
PRIVILEGED AND CONFIDENTIAL

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

POST-HEARING BRIEF OF THE ETHYLENE OXIDE INDUSTRY
COUNCIL OF THE CHEMICAL MANUFACTURERS
ASSOCIATION ON OSHA'S PROPOSED RULE
AND NOTICE OF HEARING FOR
OCCUPATIONAL EXPOSURE TO ETHYLENE OXIDE,
53 Fed. Reg. 1724 (January 21, 1988)

Proposed Rule and Notice of Hearing For	)
Occupational Exposure to Ethylene Oxide,	)
53 <u>Fed. Reg.</u> 1724 (January 21, 1988)	)

Docket No. H-200B

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March 17, 1988

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POST-HEARING BRIEF OF THE ETHYLENE OXIDE INDUSTRY
COUNCIL OF THE CHEMICAL MANUFACTURERS
ASSOCIATION ON OSHA'S PROPOSED RULE
AND NOTICE OF HEARING FOR
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INTRODUCTION

The Ethylene Oxide Industry Council ("EOIC") of the Chemical Manufacturers Association is pleased to submit this Post-Hearing Brief to the Occupational Safety and Health Administration ("OSHA") in connection with OSHA's March 3, 1988 hearing on the issue of an "excursion limit" ("EL") for ethylene oxide ("EO"). In general, EOIC notes that the comments and testimony presented at the hearing support EOIC's position that, should OSHA decide that an EL is reasonably necessary or appropriate,^{1/} an average short-term limit at the 10-ppm level would be feasible provided that respirator use was permitted for sterilizer unloading as well as other tasks for which respirators now are permitted to be used.^{2/}

^{1/} EOIC reiterates its position, expressed in EOIC's written pre-hearing comments, that no EL is warranted under the statutory standard given current exposure data and the absence of dose-rate toxicity data.

^{2/} An EL of 10 ppm makes considerably more sense than one at 5 ppm. Monitoring and accuracy and precision concerns presented by a 5 ppm EL become less of a problem at the 10 ppm level. Moreover, a 10 ppm level would more likely be economically feasible in certain industry sectors than a 5 ppm EL.

SUMMARY

To avoid duplicating EOIC's previous submissions, EOIC wishes at this stage of the proceeding to emphasize the following items of particular concern:

1. Testimony at the March 3, 1988 hearing supported EOIC's position that the product exemption and labeling provisions of the proposed EL rule are inappropriate. The proposed rule as written is inconsistent with OSHA's generic Hazard Communication Standard and expands the scope of the hazard communication provisions of the EO rule without justification or analysis.

2. Assuming arguendo that OSHA determines to impose an EL, the testimony and comments submitted provided substantial support for EOIC's position that monitoring concerns indicate the appropriateness of a 10 ppm rather than a 5 ppm EL, and a 30-minute rather than a 15-minute monitoring period.

3. Evidence presented at the hearing also supported the position of the Health Industry Manufacturers Association ("HIMA") that use of respirators for sterilizer unloading is a prerequisite for the feasibility of an EL in the sterilizer sector. EOIC endorses HIMA's position on this issue.

I. THE PROPOSED RULE SHOULD BE REVISED IN LIGHT OF POSSIBLE IMPACTS ON DOWNSTREAM USES OF EO-DERIVED PRODUCTS

The proposed rule should be revised to take into account the unanticipated and unjustified possible effects on downstream uses of EO-derived products.

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The proposed rule, as written, would limit the availability of the exemption provided in the existing EO standard for products whose releases are below the action level, 29 C.F.R. § 1910.1047(a)(2). Where a worst-case analysis demonstrates that a product is "capable" of releasing EO in amounts above the excursion limit, that product would now be subject to the rule. This expands the reach of the current regulatory scheme, which exempts the processing, use, or handling of EO where the action level of 0.5 ppm (TWA) is not reached. The proposed rule also appears to trigger compliance with the product labeling requirements of the existing EO standard, 29 C.F.R. § 1910.1047(j)(1)(ii), in circumstances under which OSHA's generic Hazard Communication Standard would not necessarily require labeling.¹

EOIC therefore believes that the proposed rule would impose a substantial new burden, potentially imposing a labeling requirement on a host of EO-derived products and, at a minimum, imposing the obligation to test those products for EO releases, to determine whether the labeling requirement is applicable. OSHA has not evaluated the cost and other impacts of such a change, nor has it demonstrated any anticipated health benefits:

*2. 10/20/80
10/20/80 Release*

As explained below, OSHA's generic Standard imposes certain hazard communication duties with respect to products containing more than 0.1 percent of a carcinogen or when emissions exceed the PEL, as opposed to the proposed rule requiring labeling if release may occur at the EL.

° Mr. Norman Gaines of Union Carbide Corporation, testifying on behalf of EOIC, noted that the proposed rule would impose "a substantial cost and compliance burden on downstream users of ethylene oxide derived products as well as on ethylene oxide producers and users."^{4/}

° Dr. Lawrence H. Hecker, Director of the Health Instrument Manufacturers Association, testified that the "costs of doing scientific studies to determine whether downstream labeling is needed for the 10 to 20 billion items sterilized annually is not included in the Heiden or the Meridian reports. . . ." Dr. Hecker indicated that the cost of a single scientific study for one product to decide whether or not a label might cost tens of thousands of dollars.^{5/}

° Mr. Tom Grumbles of Vista Chemical testified on behalf of EOIC that it would be impossible for an EO producer or ethoxylator even to estimate, much less evaluate or test, the conditions under which a downstream customer uses an EO-derived product.^{6/}

° Indirect impacts of a "cancer" label on marketing of downstream products also need to be considered.

At the March 3, 1988 hearing, OSHA defended this expansion of the labeling required under the existing EO rule by stating that it was identical to what is required under OSHA's

^{4/} Transcript of the March 3, 1988 Informal Public Hearing on Occupational Exposure To Ethylene Oxide (hereafter "Trans."), at 149.

^{5/} Trans. at 75-6.

^{6/} Trans. at 161-3.

generic Hazard Communication Standard.^{1/} The generic Standard requires product MSDS disclosure or labeling, inter alia, where (i) a mixture contains more than 0.1 percent of a carcinogen, (ii) the OSHA PEL or ACGIH TLV is exceeded, or (iii) a "hazard" exists. Mr. Adkins' assertion that the provisions are coextensive apparently was reflecting the view that a "hazard" per se exists above the EL. Trans. at 23. However, this reading ignores the absence of evidence in the record demonstrating a dose-rate hazard, as well as OSHA's own recognition that no STEL is warranted by the ethylene oxide toxicological or hazard data. 53 Fed. Reg. 1724, at n. 1 (January 21, 1988). As Mr. Adkins testified at the hearing, OSHA previously has found that the available health data do not demonstrate the risks from ethylene oxide exposure to be dose-rate dependent. Trans. at 11-12. Thus, exposure above the EL alone does not necessarily constitute a hazard per se.

Either the proposed rule imposes additional labeling and other requirements on downstream uses, or it does not. Mr. Adkins' statement seems to suggest that it does not, and the complete absence of data in the record on the economic impact of or health rationale for a change would indicate that OSHA does not intend to impose broad new requirements.

^{1/} Testimony of Charles Adkins, OSHA Directorate of Health Standard Programs, Trans. at 23.

If, however, the proposed rule merely reiterates the requirements of OSHA's generic Hazard Communication Standard, the situation would be indistinguishable from that which occurred in the formaldehyde rulemaking, where the Office of Management and Budget on February 3, 1988 disapproved a similar labeling requirement as unsupported in view of the existing generic standard. Moreover, the proposed rule (which would appear to require labeling of downstream uses) is more restrictive than the generic Standard, which allows the use of MSDSs to provide certain hazard information, and does not require every hazard to be included in the label.

EOIC's position on this issue is uncontested. No party at the hearing or in the written comments submitted for the record supported the imposition of vast new testing, monitoring, and recordkeeping requirements with respect to downstream uses of EO-derived products. The hazard communication provisions of the existing generic Standard and the existing EO-specific regulation are amply protective of worker health: Mr. Adkins did not cite any analysis to the contrary when questioned by EOIC counsel. Trans. at 21-24. OSHA should remove any ambiguity in the final rule by deleting the proposed changes to the product exemption criteria in section 1910.1047(a)(2) and the proposed changes to the labeling requirements of section 1910.1047(j)(1)(ii).

****[Should we propose as a fall-back position a better formulation of the "capable of release" test, perhaps specifying how an employer is to determine when levels in excess of the EL might result in downstream uses? Is there language we could propose that would allow limited tests of release under reasonably foreseeable conditions, that would be feasible for manufacturers and acceptable to downstream users?]**

II. OSHA SHOULD RECOGNIZE PERFORMANCE-ORIENTED MONITORING TECHNIQUES WHICH MEET ACCEPTED LEVELS OF ACCURACY

EOIC believes that the paucity of validated short-term monitoring methods and rapidly-evolving technology requires a performance-oriented standard. OSHA properly recognizes a variety of monitoring methods may be used, provided the requisite accuracy can be achieved.

EOIC strongly believes that OSHA should not degrade the accuracy that it has constantly required of sampling methods, as was suggested by one participant at the hearing. See the testimony of Mr. Grumbles, Trans. at 165. The professional industrial hygiene community has worked to develop a consensus on accuracy requirements necessary to a valid sampling method. OSHA has supported these efforts in the past and in the context of previous regulations.

The purpose of the accuracy requirements is to assure that the uncertainty associated with the measurement of expo-

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sure is relatively insignificant compared to the true variability that occurs naturally in the workplace. Relaxed accuracy requirements result in over- and under-estimation of exposure levels, encourage the use of poor analytical methods, and increase the number of samples required to make a decision regarding the significance of exposure.

Given the current undeveloped state of the art in short-term EO monitoring, should an excursion limit be imposed, EOIC contends that an EL of 10 ppm makes considerably more sense from an analytic standpoint than a 5 ppm limit.^{1/} A limit of 5 ppm is at the borderline of current monitoring methods; a 10 ppm limit would be preferable.^{2/}

****[INSERT: Discussion of any additional Clayton Report data submitted for the record by EOIC.]****

None

^{1/} EOIC notes that, in a hospital context, substantial analytical concerns arise in sampling at the 5 ppm level. See, e.g., Testimony of Clarence Daly on behalf of the American Hospital Association, Trans. at 129, 131.

^{2/} OSHA has reiterated that the proposed EL is a time-weighted average value and not an instantaneous ceiling. Testimony of Mr. Adkins, Trans. at 21.

III. OSHA SHOULD UTILIZE A 30-MINUTE SHORT-TERM SAMPLING PERIOD

The length of the monitoring period should be extended to thirty minutes, rather than remaining at fifteen minutes, to approximate more closely the actual length of tasks which produce short-term exposures in the producer/ethoxylator segments.

EOIC recognizes that both the benzene and formaldehyde proceedings imposed a 15-minute STEL. However, in neither of those proceedings was there substantial evidence on the record -- as there is in this proceeding -- that the average length of the relevant task was approximately thirty minutes.

EOIC notes that HIMA also supports this change in the proposed rule, and has submitted data demonstrating its appropriateness in the health industry sectors. Moreover, Kem Medical Products recommended, for monitoring accuracy considerations, imposition of a short term monitoring period greater than fifteen minutes.^{10/} No participant at the hearing or in written comments opposed making the short-term monitoring period more appropriate to the actual patterns of short-term exposure in the industry. The fifteen-minute period originated with ACGIH as a minimum period (not specific to any

^{10/} Testimony of Douglas A. Kruger, on behalf of Kem Medical Products Corp., Trans. at 185.

substance) for analytical accuracy.^{11/} OSHA should not automatically apply the 15-minute sampling period where data are presented that a different period is more appropriate.

IV. THERE IS NO SUPPORT IN THE RECORD FOR A 3-PPM STANDARD

One witness appearing at the hearing suggested OSHA impose a 3-ppm short-term limit. See testimony of Mr. Jordan Barab, American Federation of State, County, and Municipal Employees, Trans. at 175. This suggestion was utterly unsupported. There is no evidence in the record that such a standard would be feasible, from a monitoring or any other standpoint. OSHA's contractor, Meridian Research, explicitly declined to state that a 3 ppm limit would be feasible based on their research. Trans. at 41-46. Similarly, no dose-rate health effects evidence has been adduced.

V. RESPIRATORS SHOULD BE PERMITTED FOR STERILIZER OPERATIONS

EOIC supports the position of HIMA that the use of respirators in the unloading of sterilizers is a prerequisite to the feasibility of the standard in those sectors. HIMA's cost estimates are based on the relatively comprehensive Heiden

^{11/} EOIC believes the initial use of the 15-minute period was derived from the ACGIH STEL; that time-period is not, however, adapted to specific substance exposures (as the current proposed rule is), and was originally adopted due to monitoring considerations rather than health-based or industrial hygiene considerations.

Reports submitted for the record with HIMA's testimony.^{12/}

In contrast, OSHA's contractor Meridian Research sampled only approximately four percent of the probable universe,^{13/} and as Meridian Research itself recognized developed only "site-specific costs of compliance."^{14/}

VI. OSHA SHOULD NOT MANDATE THE FREQUENCY
OF COMPLIANCE MONITORING

EOIC suggests that the frequency of compliance monitoring be left to the sound professional judgment of a qualified industrial hygienist, working within the constraints of a written compliance monitoring strategy. Tasks where short-term monitoring may be necessary (i.e., maintenance, product shipments, and the like), do not occur at regular predetermined intervals and therefore a rigid schedule is not appropriate. OSHA recognized this concern in both the benzene and formaldehyde standards and did not specify monitoring frequency. In the EOIC-sponsored Heiden report, company industrial hygienists identified the need for approximately 60 to 90 short-term samples per location. Industrial hygiene professionals recognize

^{12/} See Trans. at 75 and Appendix A and Appendix B to Ex. 210.

^{13/} Trans. at 47.

^{14/} Testimony of Marthe Kent, President, Meridian Research, Inc., Trans. at 38. Kem Medical Products characterized conclusions drawn on the basis of Meridian's small sample as "dangerous." Trans. at 184.

the need for sampling, but an arbitrary schedule is not appropriate and could possibly be counterproductive.

****[POSSIBLE INSERT]

[VII. ADDITIONAL DATA ON HEALTH EFFECTS PRESENTED IN THIS PROCEEDING ARE OF DUBIOUS RELEVANCE

Rebuttal to data or comments submitted by Dr. Beliles for the record on March 10, 1988. If none are submitted, respond to Dr. Beliles in a letter to EPA.]****

CONCLUSION

[To be added after comments are complete.]