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XF: UCCP

TO: Sid Pitts

FROM: T. G. Grumbles
DATE: August 5, 1986

Interoffice
Communication

SUBJ: OSHA AND ETO

VISTA

The July 10 Federal Register contained only technical amendments and corrections. I believe there is no impact on us but have enclosed a copy fyi.

However, on July 28 the court has remanded OSHA to review it's decision to not include a STEL in the final Eto Standard. A copy of a letter describing this action is enclosed. Too soon to guess the outcome of this.



Thomas G. Grumbles

ajo/9

Enclosure

cc W. L. McClain
T. H. Huffman

VVV 000015384

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

Occupational Exposure to Ethylene Oxide

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Final rule; technical amendments and corrections.

SUMMARY: This document corrects administrative errors and incorporates clarifying language into OSHA's final rule on occupational exposure to ethylene oxide (EtO) that was published June 22, 1984 (49 FR 25734). This action is necessary to eliminate confusion with respect to the regulatory obligation imposed by the appendices to the EtO final rule. The information in EtO Appendices A, B, C, and D is not intended by itself to create any additional obligations not otherwise imposed by the standard. A statement that these appendices are non-mandatory in nature was included in paragraph 1910.1047(n) to the final EtO standard. To ensure that it is clearly understood that the EtO appendices impose no regulatory burden, however, a statement to that effect is added to the beginning of each appendix. Confusion over the appendices has also arisen by inadvertent use of the mandatory words "must" and "shall" in Appendix A. The word "should" is substituted for the words "shall" or "must" in the Appendices when specific obligation is not imposed by the standard. An incorrect reference in Appendix A to the existence of a short-term exposure limit for EtO is also deleted.

This document also corrects the amendatory language contained in the October 11, 1985 Federal Register notice on ethylene oxide dealing with labeling of EtO containers (50 FR 41491).

Language changes in that document intended to amend paragraph (j)(i)(ii) which covers labeling, instead of (j)(i)(i), which covers signs.

FOR FURTHER INFORMATION CONTACT: Mr. James Foster, OSHA-U.S. Department of Labor, Office of Public Affairs, Room N-3641, 200 Constitution Ave., NW, Washington, DC 20210. Telephone (202) 523-8151.

Signed at Washington, DC this 1st day of July.

John A. Pendergrass,
Assistant Secretary of Labor.

Accordingly, the Occupational Safety and Health Administration is amending 29 CFR 1910.1047 as follows:

1. The headings of appendices A, B, C, and D are corrected to read as follows:

§ 1910.1047 Ethylene oxide.

Appendix A—Substance Safety Data Sheet for Ethylene Oxide (Non-Mandatory)

Appendix B—Substance Technical Guidelines for Ethylene Oxide (Non-Mandatory)

Appendix C—Medical Surveillance Guidelines for Ethylene Oxide (Non-Mandatory)

Appendix D—Sampling and Analytical Methods for Ethylene Oxide (Non-Mandatory)

2. In addition, Appendices A and B are amended as follows:

A. In Appendix A, paragraph I.F. is revised to read

"F. Permissible Exposure: Exposure may not exceed 1 part EtO per million parts of air averaged over the 8-hour workday."

B. In Appendix B, paragraph III. B., the word "must" is revised to read "should".

C. In Appendix B, paragraph III. C., the word "shall" is revised to read "should".

D. In Appendix B, paragraph IV. A. 1., the word "must" is revised to read "should".

E. In Appendix B, of paragraph IV. A. 2. and paragraph IV. B. second full paragraph, the word "must" is revised to read "should" in each paragraph.

F. In Appendix B, paragraph V, first sentence, the word "shall" is revised to read "should".

G. In Appendix B, paragraph V, second paragraph, the word "must" is revised to read "should".

H. In Appendix B, paragraph VI. D., the word "shall" is revised to read "should".

3. The following corrections are made to FR Doc. 85-24844 on page 41491 in the issue of October 11, 1985:

1. On page 41491, middle column, in the paragraph "Summary", "(i)(1)(i)(A)" is corrected to read "(j)(1)(ii)(A)."

2. On page 41491, middle column, in the paragraph "Dates", "(j)(1)(i)(A)" is corrected to read "(j)(1)(ii)(A)."

3. On page 41493, third column, last paragraph, "(i)(1)(i)(A)" is corrected to read "(j)(1)(ii)(A)."

§ 1910.1047 [Corrected]

4. On page 41494, middle column, amendment paragraph 2., to § 1910.1047, "(j)(1)(i)(A)" is corrected to read "(j)(1)(ii)(A)"; and the designations in the text of § 1910.1047 are connected accordingly.

5. On page 41494, middle column, amendment paragraph 4., to § 1910.1047, in paragraph (m)(3)(i), "(j)(1)(i)(A)" is corrected to read "(j)(1)(ii)(A)".

[FR Doc. 86-15492 Filed 7-9-86; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD7 86-12]

Drawbridge Operation Regulations; Atlantic Intracoastal Waterway, SC

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: At the request of the South Carolina Department of Highways and Public Transportation the Coast Guard is changing the regulations governing the Ben Sawyer Bridge, mile 462.2 at Sullivan's Island, by permitting the number of openings to be limited during certain periods. This change is being made because of reports of vehicular congestions. This action will accommodate the needs of vehicular traffic yet still provide for the reasonable needs of navigation.

EFFECTIVE DATE: These regulations become effective on July 19, 1986.

FOR FURTHER INFORMATION CONTACT: Mr. Wayne Lee, (305) 536-4103.

SUPPLEMENTARY INFORMATION: On May 5, 1986, the Coast Guard published (51 FR 16568) a proposal to revise these regulations. The proposed regulations were also published in a public notice issued by the Commander, Seventh Coast Guard District, on May 19, 1986. In each case, interested persons were given until June 19, 1986, to submit comments. This final rule is being made effective in less than 30 days after Federal Register publication because following normal rulemaking procedures would be impractical. The existing temporary rule governing this bridge expires on July 20, 1986. To avoid unnecessary traffic disruption caused by expiration of the temporary rule, we are making the final rule effective on July 19.

Drafting Information

The drafters of these regulations are Mr. Wayne Lee, Chief, Bridge Section, Aids to Navigation Branch, project officer, and Commander Ken Gray, project attorney.

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July 28, 1986

MEMORANDUM FOR THE EOIC EXECUTIVE COMMITTEE

Re: Court of Appeals Decision in
PCHRG v. Tyson.

The United States Court of Appeals for the District of Columbia Circuit has issued its opinion on the challenges in the above-captioned case to the OSHA standard for EO (copy attached). The court upheld the 1 ppm PEL, but found that OSHA's decision not to issue a STEL was not supported by substantial evidence in the record. Accordingly, the court remanded the STEL issue to OSHA for further rulemaking. Because of its decision on the STEL, the court declined to address what it called difficult constitutional questions regarding participation by OMB. The major aspects of the decision are briefly summarized below.

1. The PEL

The court held that the 1 ppm PEL was supported by substantial evidence. The cumulative evidence of carcinogenicity and reproductive effects was considered sufficient, although individual studies may be less than

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conclusive. The OSHA finding of significant risk was held to be adequately based on mathematical extrapolation from the Bushy Run study.

2. The STEL

In assessing the validity of OSHA's decision not to issue a STEL, the court upheld OSHA's conclusion that no dose-rate effects have been demonstrated for EO. The court nevertheless rejected the OSHA decision not to issue a STEL, based on what the court considered inadequate consideration of the possibility that a STEL would contribute to the reduction of cumulative exposure to EO.

The court first held that, under the OSH Act, OSHA must adopt a STEL if it would further reduce a significant health risk allowed by the PEL. Because OSHA found that the 1 ppm PEL still allows a significant risk, the court stated that "the agency must find either that a STEL would have no effect on that risk or that a STEL is not feasible." The court found the record inadequate to assess whether compliance with the PEL eliminates the need for a STEL, stating that this conclusion requires evidence that "employers will in every case reduce short-term exposures to a point at or below the 10 ppm STEL." (Emphasis in original). Accordingly, the court remanded the issue to OSHA for consideration of this question, stating:

On remand, we expect the agency to ventilate the issues on this point thoroughly and either adopt a STEL or explain why empirical or expert evidence on

exposure patterns makes a STEL irrelevant to
controlling long-term average exposures.

Eric C. Jeffrey

Attachment

Court Pressures OSHA on Limits For Ethylene Oxide

By CATHY TROST

Staff Reporter of THE WALL STREET JOURNAL

WASHINGTON — A federal appeals court ordered the Occupational Safety and Health Administration to adopt a limit for short-term exposure to ethylene oxide or to justify its refusal to do so.

The ruling by the three-judge panel here affirmed the standard the agency issued two years ago, sharply reducing the permissible exposure of workers to the chemical averaged over an eight-hour period. But the court said OSHA's subsequent

refusal to limit short exposures to intense concentrations of the chemical "is not supported by the record."

The court sent the matter back to the agency for further consideration. The agency was ordered to "either adopt" a short-term limit or "explain why empirical or expert evidence on exposure patterns" makes a short-term limit unnecessary in controlling longer exposures.

Ethylene oxide is a colorless gas used in manufacturing and as a sterilizing agent in hospitals. The chemical has been found to increase the risk of cancer, genetic damage and reproductive problems in humans.

The chemical's regulatory history is filled with controversy. After OSHA declined to issue a short-term limit, critics charged that the White House budget office improperly influenced the decision. The Public Citizen Health Research Group, which is affiliated with consumer advocate

Ralph Nader, sued the agency, arguing that the decision wasn't supported by the evidence and that the budget office's participation in that rule-making process was illegal.

Though the court said the budget office's role presents "difficult constitutional questions," it didn't rule on its legality.

According to the court record, OSHA initially believed a short-term limit was necessary. But the budget office objected, and the limit wasn't included in the standard. Instead, OSHA continued its rule-making process to determine whether such a limit were necessary. Though the agency's scientific staff supported a limit, the agency ruled finally that scientific evidence didn't support one.

OSHA officials didn't have any comment on the court decision. Officials of the Public Citizen group and the Ethylene Oxide Industry Council, which supported OSHA's refusal to issue a short-term limit, couldn't be reached for comment.