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## DEPARTMENT OF LABOR

### Occupational Safety and Health Administration

#### 29 CFR Part 1910

[Docket No. H-200C]

RIN 1218-AB60

#### Notice of Availability of the Regulatory Flexibility Act Review of the Occupational Health Standard for Ethylene Oxide

**AGENCY:** Occupational Safety and Health Administration, Department of Labor.

**ACTION:** Notice of availability.

**SUMMARY:** The Occupational Safety and Health Administration (OSHA) has conducted a review of its Ethylene Oxide (EtO) Standard pursuant to section 610 of the Regulatory Flexibility Act and section 5 of Executive Order 12866 on Regulatory Planning and Review. EtO is used as a chemical intermediate to produce antifreeze and as a sterilant. In 1984, OSHA promulgated a standard to lower exposure to EtO from 50 parts per million (ppm) to 1 ppm based on evidence EtO exposure was associated with cancer in animals. The regulatory review has concluded that new studies indicate that EtO is associated with cancer in humans, that employee exposures have been substantially reduced thereby lowering risk to employees, that the standard has not had a negative impact on small businesses, that EtO production has increased, and that EtO sterilizers have been developed that meet the standard and cost less than older non-compliant sterilizers. Public commenters agree that the standard should remain in effect. Based on this review, OSHA concludes the EtO standard should remain in effect, but will issue new guidance

materials in response to some commenters requests for clarification.

**ADDRESSES:** Copies of the entire report may be obtained from the OSHA Publication Office, Room N3101, 200 Constitution Avenue, NW., Washington, DC 20210, telephone (202) 693-1888, Fax (202) 693-2498. The full report, comments, and referenced documents are available for review at the OSHA Docket Office, Docket No. H-200C Room N2625, 200 Constitution Avenue, NW., Washington, DC 20210, telephone (202) 693-2350. The main text of the report will become available on the OSHA Web page at [www.OSHA.gov](http://www.OSHA.gov).

**FOR FURTHER INFORMATION CONTACT:** Joanna Dizikes Friedrich, Directorate of Evaluation and Analysis, Room N3641, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, telephone (202) 693-1939, fax (202) Direct technical inquiries about the EtO standard to Gail Brinkerhoff, telephone (202) 693-2190, or visit the OSHA Homepage at [www.OSHA.gov](http://www.OSHA.gov). Direct press inquiries to Bill Wright, Room N3647, telephone (202) 693-1999.

**SUPPLEMENTARY INFORMATION:** The Occupational Safety and Health Administration (OSHA) has completed a “look back” review of its EtO Standard, 29 CFR 1910.1047, titled “Regulatory Review of the Occupational Safety and Health Administration’s Ethylene Oxide Standard, March 2005.” This **Federal Register** document announces the availability of the Regulatory Review and briefly summarizes it. The review was undertaken pursuant to Section 610 of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) and Section 5 of Executive Order 12866 (59 FR 51739, Oct 4, 1993) and all issues raised by those provisions. The purpose of a review under section 610 of the Regulatory Flexibility Act “Shall be to determine whether such rule should be continued without change, or should be rescinded, or amended consistent with the stated objectives of applicable statutes to minimize any significant impact of the rule on a substantial number of small entities.”

“The Agency shall consider the following factors:

- (1) The continued need for the rule;
- (2) The nature of complaints or comments received concerning the rule from the public;
- (3) The complexity of the rule;

(4) The extent to which the rule overlaps, duplicates or conflicts with other Federal rules; and, to the extent feasible, with state and local governmental rules; and

(5) The length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the areas affected by the rule.”

The review requirements of Section 5 of the Executive Order 12866 require agencies:

“To reduce the regulatory burden on the American people, their families, their communities, their state, local and tribal governments, their industries to determine whether regulations promulgated by the [Agency] have become unjustified or unnecessary as a result of changed circumstances; to confirm that regulations are both compatible with each other and not duplicative or inappropriately burdensome in the aggregate; to ensure that all regulations are consistent with the President’s priorities and the principles set forth in the Executive Order, within applicable law; and to otherwise improve the effectiveness of existing regulations.”

OSHA published a **Federal Register** document requesting public comments on the EtO Standard and specifically all issues raised by those provisions, and held a public meeting on those matters (62 FR 28649, May 27, 1997). The Review summarizes the public comments and responds to them.

Ethylene Oxide is an industrial chemical that has high volume uses as an intermediate to produce other chemicals such as antifreeze. It is also used as a sterilant principally in the hospital, medical device and spice processing industries.

In 1984, principally based on evidence of carcinogenicity in animals, OSHA issued a standard (29 CFR 1910.1047) lowering exposures from 50 parts per million (ppm) to 1 ppm. That standard also included requirements for monitoring, medical surveillance, training and other provisions.

OSHA has reviewed the studies, information and public comments about the standard. Based on those, it has reached the following conclusions pursuant to the section 610 review discussed in greater length in the full report.

There is a continued need for the rule. Workers exposed to EtO in a range of

industries would continue to be at risk of cancer, genetic changes and other adverse health effects, without the standard. Since the standard was developed, the International Agency for Research on Cancer reclassified EtO as a known human carcinogen and the National Toxicology program reclassified EtO as a one "known to be a human carcinogen." Based on the significant scientific information, OSHA finds that the potential carcinogenicity of EtO and the risk posed to workers continues to justify the need for the Standard.

Comprehensive studies, compliance information, and public comments indicate that the Standard has been effective in reducing exposure to EtO thereby achieving the predicted health benefits. The public comments evidenced widespread support for continuance of the EtO Standard and endorsed its effectiveness. No commenter argued that the standard should be rescinded.

The evidence indicates that the EtO Standard has not had a negative economic impact on the industries affected by the standard, generally, or on small businesses in those industries. Production of EtO has increased from 6.2 billion pounds to 8 billion pounds since the standard was issued. Most of the small businesses affected by the EtO Standard are hospitals, medical device manufacturers, and spice manufacturers. There are no indications that the regulation of occupational exposure to EtO has impaired the economic well being of businesses in any of these sectors or has disproportionately affected small businesses.

The rule is not unduly or unreasonably complex. Although most commenters did not directly address the issue of whether the standard was considered to be unduly or unreasonably complex, a few comments at the public meeting and comments submitted to the Docket requested clarification of a few requirements of the standard. OSHA intends to issue compliance assistance and outreach materials to aid employers' and employees' understanding of the standard.

The EtO Standard does not overlap with other regulations. Four major federal regulatory entities in addition to OSHA currently regulate various aspects of EtO use and transport. The only potential regulatory conflict raised by one commenter during this lookback review involved an Environmental Protection Agency standard under the Clean Air Act for EtO using commercial sterilization and fumigation operations.

Commercial sterilization and fumigation operations using one ton or more of EtO per year are required to use emission control technology to comply with EPA standards. The two agencies' rules do not actually conflict and no employers have stated that they have not been able to comply with both.

Technological improvements have improved worker safety. OSHA's independent research, comments received, and the technical literature indicate that significant technological developments have occurred since the promulgation of the standard.

Improvements in sterilizer technology, the growth in number and use of alternative sterilants and sterilizing processes, and use of contract sterilizers to perform EtO sterilization have contributed to an observed reduction in occupational exposure to EtO. None of the comments received by OSHA indicated that technology feasibility problems prevented affected businesses from complying with the EtO Standard.

The Standard encouraged the development of improved sterilizers, which achieved compliance with the standard and cost less than other sterilizers. The newer equipment costs about half the cost of the older equipment with add-on controls. This reduced costs for all employers including small businesses.

A 1995 Congressional Office of Technology Assessment study completed after the standard took effect concluded that the Feasibility Study, which OSHA performed before issuance of the standard, was accurate and well done.

The agency has also reviewed the record and standard pursuant to E.O. 12866. Pursuant to that review it has reached the following conclusions:

The EtO Standard remains both justified and necessary. As discussed in OSHA's Section 610 analysis, EtO poses significant health and safety risks to workers exposed to the substance. While the standard has resulted in dramatic reductions in occupational exposures to EtO, OSHA continues to document overexposures and non-compliance in the workplace. A study of Massachusetts hospitals demonstrated that enforcement actions were necessary before they came into compliance with the standard.

The EtO Standard is compatible with other OSHA standards and is not inappropriately burdensome in the aggregate. No public comment questioned the compatibility of the EtO standard with Federal OSHA or state standards.

The EtO Standard is compatible with E.O. 12866. The Executive Order

essentially provides for a regulatory system that efficiently and effectively protects health and safety without imposing unacceptable or unreasonable costs on society. The regulations that are produced must be consistent, sensible, and understandable. This lookback review has received many comments supporting the standard's effectiveness in reducing occupational exposures to EtO. In addition, the industries that use EtO appear to be familiar with the standard and have adopted improved technology, use of substitutes, and other methods to improve efficiency. No evidence was submitted to the Docket or identified by OSHA in the course of this lookback review to suggest that the standard was imposing either a significant impact on a substantial number of small entities or that it was causing an excessive compliance burden. The EtO Standard is effective in achieving its mission. Uniform support for retaining the EtO standard is in the public record for this lookback review.

Therefore, based on the comments and testimony of participants in this lookback review process and the studies and other evidence submitted to the public docket, OSHA concludes, as discussed in depth in "Regulatory Review of the Occupational Safety and Health Administration's Ethylene Oxide Standard" March 2005, that the Agency's Standard should be continued without change. The evidence also demonstrates that the Standard does not need to be rescinded or substantially amended to minimize significant impacts on a substantial number of small entities.

OSHA also finds that the EtO Standard is necessary to protect employee health, is compatible with other OSHA standards, is not duplicative or in conflict with other Federal, state, or local government rules, is not inappropriately burdensome, and is consistent with the President's priorities and the principles of E.O. 12866. Further, no changes have occurred in technological, economic, or other factors that would warrant revision of the Standard at this time. No commenters recommended that the standard be repealed or made less protective.

As a result of this lookback review and the comments received from participants, OSHA will enhance some of its compliance assistance materials. The enhancements may cover emergency requirements, medical surveillance and other areas.

Signed at Washington, DC, this 12th day of April, 2005.

**Jonathan L. Snare,**

*Acting Assistant Secretary of Labor.*

[FR Doc. 05-8080 Filed 4-21-05; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[CGD09-05-009]

RIN 1625-AA00

#### Safety Zone; Chicago Sanitary and Ship Canal, Chicago, IL

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a safety zone around the tank barge EMC423 during salvage operations. This safety zone is necessary to ensure the safety of workers and divers during salvage operations of the tank barge EMC423. The temporary safety zone prohibits persons or vessels from entering the zone unless authorized by the Captain of the Port Chicago or the designated on-scene representative.

**DATES:** This rule is effective from 5 p.m. on April 5, 2005, until 5 p.m. on May 31, 2005.

**ADDRESSES:** Documents indicated in this preamble as being available in the docket are part of the docket (CGD09-05-009), and are available for inspection or copying at Commanding Officer, U.S. Coast Guard Marine Safety Office Chicago, 215 W. 83rd Street Suite D, Burr Ridge, IL 60527, between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** LTJG Cameron Land, U.S. Coast Guard Marine Safety Office Chicago, at (630) 986-2155.

#### SUPPLEMENTARY INFORMATION:

##### Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. This safety zone is temporary in nature and limited time existed for an NPRM. Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying this rule would be

impracticable and contrary to public interest as boating season is resuming and immediate action is necessary to clear the barge from the canal and perform clean up of the surrounding area; further, immediate action is necessary to ensure the safety of persons and vessels during the salvage operations and to prevent possible loss of life or property. During the enforcement of this safety zone, comments will be accepted and reviewed and may result in a modification to the rule.

##### Background and Purpose

On January 19, 2005, the tank barge EMC423 was involved in a marine casualty on the Chicago Sanitary and Ship Canal (CSSC) at Mile Marker 317.5. The barge sustained an explosion and partially sank with a full load of clarified slurry oil on board. Salvage and recovery operations are underway. With the change in weather and increase in recreational vessel traffic in the area, the Captain of the Port Chicago finds it necessary to implement operational restrictions and control vessel traffic through the area to protect response workers, vessels transiting the zone, and to maintain the integrity of the site.

##### Discussion of Rule

This rule establishes a safety zone from bank-to-bank beginning at the Cicero Avenue Bridge at Mile Marker 317.3 and ending at the Belt Railroad Bridge at Mile Marker 317.5 on the Chicago Sanitary and Ship Canal.

Vessels will not be allowed to enter the safety zone, without the express permission of the Captain of the Port Chicago or the designated on-scene representative. It is anticipated that controlled passage of vessels will be possible on a case-by-case basis.

Barges transiting the area will be limited to dry cargo, 35 foot wide with drafts not exceeding 9-feet. Up bound tows are limited to one barge. Down bound tows are limited to one loaded barge or two empty barges. All down bound tows require a bow assist boat.

All commercial and recreational vessels must contact the Coast Guard Forward Command Post via VHF-FM Channel 19 or land line at 630-336-0291 to request permission to transit through the safety zone.

##### Regulatory Evaluation

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that

Order. The Office of Management and Budget has not reviewed it under that Order. It is not "significant" under the regulatory policies and procedures of the Department of Homeland Security (DHS).

We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS is unnecessary.

This finding is based on the relatively small percentage of vessels that would fall within the applicability of the regulation, the relatively small size of the limited access area around the EMC423 tank barge, the minimal amount of time that vessels will be restricted when the zone is being enforced. In addition, vessels that will need to enter the zone may request permission on a case-by-case basis from the Captain of the Port or the designated on-scene representatives.

##### Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule affects the following entities, some of which might be small entities: The owners or operators of vessels intending to transit through the safety zone in and around the sunken barge.

This rule would not have a significant impact on a substantial number of small entities because the restrictions affect only a limited area for a brief amount of time as this safety zone is effective only when salvage operations on the tank barge EMC423 is underway. Further, transit through the zone may be permitted with proper authorization from the Captain of the Port Chicago or his designated representative. Additionally, the opportunity to engage in recreational activities outside the limits of the safety zone will not be disrupted.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (*see*