

ENVIRONMENTAL PROTECTION AGENCY
40 CFR Part 63

[AD-FRL-5933-6]
RIN 2060-AC28

National Emission Standards for Hazardous Air Pollutants for
Ethylene Oxide Commercial Sterilization and Fumigation
Operations.

AGENCY: Environmental Protection Agency (EPA).

ACTION: Interim final rule.

SUMMARY: Today's action suspends, on an interim final basis, the National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization and Fumigation Operations (EO NESHAP). The suspension allows affected sources subject to the EO NESHAP to defer compliance with the NESHAP for one year until December 6, 1998. This action does not change the level of the standards or the intent of the NESHAP promulgated in 1994.

DATES: This action is effective December 4, 1997.

Under section 307(b)(1) of the Clean Air Act (Act), judicial review of this final action is available only by filing a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit within 60 days of today's publication of this interim final rule. Under section 307(b)(2) of the Act, the requirements that are the subject of today's document may not be challenged later in civil or criminal proceedings brought by the EPA to enforce these requirements.

ADDRESSES: Docket. Docket No. A-88-03, category VIII Amendments, containing information considered by the EPA in developing this

rule, is available for public inspection and copying between 8:00 a.m. and 5:30 p.m., Monday through Friday, except for Federal holidays, at the EPA's Air and Radiation Docket and Information Center, room M1500, U.S. EPA, 401 M Street, SW, Washington, DC 20460; telephone (202) 260-7548. A reasonable fee may be charged for copying. This docket also contains information considered by the EPA in proposing and promulgating the original EO NESHAP.

FOR FURTHER INFORMATION CONTACT: For information concerning applicability and rule determinations, contact the appropriate EPA regional or Office of Enforcement and Compliance Assurance (OECA) representative:

Region I: Greg Roscoe, Air Programs Enforcement Office Chief, U.S. EPA, Region I, JFK Federal Building (SEA), Boston, MA 02203, Telephone number (617) 565-3221

Region II: Kenneth Eng, Air Compliance Branch Chief, U.S. EPA, Region II, 290 Broadway, New York, NY 10007, Telephone number (212) 637-4080, Fax number (212) 637-3998

Region III: Walter K. Wilkie, U.S. EPA, Region III (3AT12), 841 Chestnut Building, Philadelphia, PA 19107, Telephone number (215) 566-2150, Fax number (215) 566-2114

Region IV: Lee Page, U.S. EPA, Region IV (AR-4), 100 Alabama Street, SW, Atlanta, GA 30303-3104, Telephone number (404) 562-9131, Fax number (404) 562-9095

Region V: Howard Caine (AE-17J), U.S. EPA, Region V, 77 W. Jackson Blvd., Chicago, IL 60604, Telephone number (312) 353-9685, Fax number (312) 353-8289

Region VI: Sandra A. Cotter (6EN-AT), U.S. EPA, Region VI (6PD-R), 1445 Ross Avenue, Dallas, TX 75202-2733, Telephone number (214) 665-7347, Fax number (214) 665-7446

Region VII: Bill Peterson, U.S. EPA, Region VII, 726 Minnesota Avenue, Kansas City, KS 66101, Telephone number (913) 551-7881

Region VIII: Heather Rooney, U.S. EPA, Region VIII (8ART-AP), 999 18th Street, Suite 500, Denver, CO 80202-2405, Telephone number (303) 312-6971, Fax number (303) 312-6826

Region IX: Christine Vineyard, U.S. EPA, Region IX (Air-4), 75 Hawthorne Street, San Francisco, CA 94105, Telephone number (415) 744-1197

Region X: Chris Hall, Office of Air Quality (OAQ-107), U.S. EPA, Region X, 1200 Sixth Avenue, Seattle, WA 98101-9797, Telephone number (206) 553-1949 or (800) 424-4372 x1949

OECA: Julie Tankersley, U.S. EPA, OECA (2223A), 401 M Street, SW, Washington, DC 20460, Telephone number (202) 564-7002, Fax number (202) 564-0050.

For information concerning the analyses performed in developing this interim final rule, contact Mr. David Markwordt, Policy, Planning and Standards Group, Emission Standards Division (MD-13), Office of Air Quality Planning and Standards, U.S. EPA,

Research Triangle Park, NC 27711, telephone number (919) 541-0837 or fax number (919) 541-0942. For information concerning the accident investigations, contact Mr. Craig Matthiessen, Chemical Emergency Preparedness and Prevention Office (5101), Office of Solid Waste and Emergency Response, U.S. EPA, 401 M Street, SW, Washington, DC 20460, telephone number (202) 260-9781.

SUPPLEMENTARY INFORMATION: An electronic version of this rule is available for download from the EPA Technology Transfer Network (TTN), a network of electronic bulletin boards developed and operated by the Office of Air Quality Planning and Standards. The TTN provides information and technology exchange in various areas of air pollution control. The service is free, except for the cost of a phone call. Dial (919)541-5742 for data transfer of up to 14,400 bits per second. If more information on the operation of the TTN is needed, contact the systems operator at (919) 541-5384. The TTN is also available on the Internet (access: <http://ttnwww.rtpnc.epa.gov>).

The information presented in this preamble is organized as follows:

- I. BACKGROUND AND SUMMARY OF ACTION
- II. SUMMARY OF AND RATIONALE FOR SUSPENSION OF THE RULE
- III. ADMINISTRATIVE REQUIREMENTS
 - A. Paperwork Reduction Act

- B. Analyses Under Executive Order 12866, the Unfunded Mandates Reform Act, and the Regulatory Flexibility Act
- C. Submission to Congress and the Comptroller General

I. BACKGROUND AND SUMMARY OF ACTION

On December 6, 1994 (59 FR 64303), the EPA promulgated the EO NESHAP which regulates emissions of ethylene oxide from new and existing commercial sterilization and fumigation operations using 1 ton or more of EO per year. The regulated category and entities affected by today's action are the sources described in 40 CFR 63.360. That provision includes commercial operations using ethylene oxide as a sterilant and fumigant in the production of medical equipment and supplies, and in miscellaneous sterilization and fumigation operations at both major and area sources. Note that this description is not intended to be exhaustive but, rather, to provide a guide for readers interested in this compliance extension. To determine whether your facility is affected by today's action, you should carefully examine the applicability criteria in 40 CFR 63.360. If you have questions about the applicability of today's action to a particular entity, consult the appropriate person listed in the preceding FOR FURTHER INFORMATION CONTACT section.

In July 1997, the Agency learned of reports of explosions at ethylene oxide sterilization and fumigation facilities. EPA does

not want matters associated with the December 1997 compliance date to possibly compromise safety. Therefore, the Agency is suspending the EO NESHAP for one year until December 6, 1998.

II. SUMMARY OF AND RATIONALE FOR SUSPENSION OF THE RULE

As noted above, in July 1997, the Agency learned of reports of explosions at ethylene oxide facilities. Several of these explosions occurred at facilities subject to the EO NESHAP. The precise cause of the explosions is still uncertain at this time. The Agency, however, wishes to adopt a cautious approach in order to assure public and worker safety and, consequently, immediately began conducting a preliminary investigation to determine if the emission control equipment mandated by 40 CFR part 63, subpart O was in any way associated with the cause of the problems at these facilities.

In a July 18, 1997 memorandum, the director of EPA's Office of Air Quality Planning and Standards (OAQPS) asked all Regional Air Division Directors and Regional Air Toxics Coordinators to inform all ethylene oxide facilities of the recent incidents and the potential safety problem. Because subpart O's December 1997 compliance date had not yet been triggered, this memorandum also recommended that, if the owners or operators of the facilities had any safety concern, they should disconnect the control units until the matter could be examined further.

EPA does not know the extent to which the explosions that have occurred to date were related to the installation of control equipment to comply with the EO NESHAP. However, the Agency wishes to err, if at all, on the side of safety. Accordingly, the Agency is today suspending the EO NESHAP for one year, until December 6, 1998 pursuant to the authority inherent to EPA's general rulemaking authority under CAA section 301(a), 42 U.S.C. 7601(a).

CAA section 301(a) grants the Administrator of the EPA the authority "to prescribe such regulations as are necessary to carry out his functions under this Act." Given the unique circumstances and uncertainty surrounding the EO NESHAP, as described in this notice, EPA believes that it is necessary to suspend this rule for the safety of the public and workers in and around EO facilities. This action is consistent with the objectives of the Clean Air Act as stated in section 101(b), 42 U.S.C. § 7401(b), "The purposes of this subchapter are . . . to promote the public health and welfare and the productive capacity of its population"

The original EO NESHAP and today's action suspending that rule are promulgated pursuant to CAA section 307(d), 42 U.S.C. § 7607(d), which requires that any rule subject to that section be issued only after the public has received notice of, and an opportunity to comment on, the rule. However, section 307(d)(1) exempts from those requirements any rule for which the Agency

finds under the Administrative Procedure Act, 5 U.S.C. § 553(b), that providing prior notice-and-comment would be impracticable, unnecessary or contrary to the public interest.

EPA believes the circumstances presented here provide good cause to take this action without prior notice-and-comment. EPA finds that providing prior notice-and-comment would be impracticable and contrary to the public interest based on the potential ongoing danger to public and worker safety posed by the recent incidents at ethylene oxide facilities. There is simply not enough time to provide notice-and-comment procedures before the current compliance date of December 6, 1997 arrives, and until the compliance date is extended, sources are faced with having to install control equipment in time to meet the current compliance date. Only by omitting notice-and-comment from this action can EPA provide sources affected by the EO NESHAP with timely legal relief from the current compliance date, while EPA investigates the situation. Consequently, this action is being promulgated without prior notice-and-comment as provided for in CAA section 307(b)(1) and is immediately effective as provided for in CAA section 112(d)(10).

Nonetheless, EPA is providing 30 days for submission of public comments. EPA will consider all written comments submitted in the allotted time period to determine if any change to this action is necessary.

In addition, the OAQPS Director has requested that the appropriate Regional Offices, in cooperation with the Office of Solid Waste and Emergency Response's Chemical Emergency Preparedness and Prevention Office (CEPPO), and the Regional CEPPO program offices, visit the facilities where the incidents have occurred to gather all relevant information. In suspending the EO NESHAP and directing this investigation effort, the Administrator wishes to remind the public and the regulated community that the role of the EPA has been and continues to be protection of public health and the environment in a way that is consistent with safety concerns.

As mentioned above, EPA has been investigating and will continue to investigate the cause of these incidents. During the one year suspension period, the Agency will provide the public with the results of the investigation. At the conclusion of the one year period, EPA expects to have addressed any safety concerns with the EO NESHAP requirements. If the Agency finds that changes to the EO NESHAP are necessary to address safety concerns, EPA will conduct a rulemaking to promulgate a revised standard and sources will be given adequate opportunity to comply with the revised rule. If, however, EPA concludes that no changes are necessary, EO facilities will be expected to be in compliance with the EO NESHAP by December 6, 1998.

III. ADMINISTRATIVE REQUIREMENTS

A. Paperwork Reduction Act

The information collection requirements of the EO NESHAP were submitted to and approved by the Office of Management and Budget (OMB). A copy of this Information Collection Request (ICR) document (OMB control number 2060-0283) may be obtained from Ms. Sandy Farmer, Information Policy Branch (2136); U.S. EPA; 401 M Street, SW, Washington, DC 20460, or by calling (202) 260-2740.

Today's action has no impact on the information collection burden estimates made previously. Today's action merely suspends the EO NESHAP for one year. This change does not impose new requirements. Consequently, the ICR has not been revised.

B. Executive Order 12866, Unfunded Mandates Reform Act, and Regulatory Flexibility Act

Today's action serves to reduce the burden on certain sources by temporarily suspending the EO NESHAP. Consequently, under Executive Order 12866, this action is not a "significant regulatory action" and is therefore not subject to review by the Office of Management and Budget. Since this action is not

subject to notice-and-comment rulemaking requirements under the APA or any other law, it is also not subject to sections 202, 204 or 205 of the Unfunded Mandates Reform Act (UMRA). In addition, since this action does not impose annual costs of \$100 million or more and will not significantly or uniquely affect small governments, the Agency has no obligations under section 203 of UMRA. Moreover, since this action is not subject to notice-and-comment requirements under the APA or any other statute as discussed above, it is not subject to section 603 or 604 of the Regulatory Flexibility Act.

C. Submission to Congress and the Comptroller General

EPA submitted a report containing this action and other information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication in today's Federal Register. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule is effective immediately pursuant to 5 U.S.C. 808(2) because the EPA for good cause finds that notice and comment is impracticable, unnecessary, or contrary to the public interest, for the reasons stated previously.

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Ethylene oxide sterilization, Hazardous substances, Reporting and recordkeeping requirements.

Dated: December 4, 1997.

Carol M. Browner,
Administrator.

~~For the reasons set out in the preamble, Title 40, Part 63,~~
Subpart O of the Code of Federal Regulations, is hereby suspended until December 6, 1998.

BILLING CODE 6560-50-P