



December 2021

**Determination of the Administrator of the Environmental Protection Agency
Under the Emergency Planning and Community Right-to-Know Act Section 313(b)(2)
to Apply the Requirements of EPCRA Section 313 to
Certain Contract Sterilization Facilities**

Recipients of this Determination:

1. Andersen Sterilizers, 3154 Caroline Drive, Haw River, NC 27258
2. Boston Scientific Corporation, 8 Industrial Drive, Coventry, RI 02816
3. ETO Sterilization-Plant #2, 2500 Brunswick Avenue, Linden, NJ 07036
4. Fuchs North America, 3800 Hampstead Mexico Road, Hampstead, MD 21074
5. International Sterilization Laboratory, 217 Sampey Road, Groveland, FL 34736
6. Isomedix Operations, Inc., 1435 Isomedix Place, El Paso, TX 79936
7. Isomedix Operations, Inc., 1175 Isuzu Parkway, Grand Prairie, TX 75050
8. Isomedix Operations, Inc., 435 Whitney Street, Northborough, MA 01532
9. LEMCO Ardmore, 3204 Hale Road, Ardmore, OK 73401
10. Long Island Sterilization, 175 Wireless Boulevard, Hauppauge, NY 11788
11. Medline Industries, 1160 South Northpoint Boulevard, Waukegan, IL 60085
12. Parter Medical Products Inc, 17115 Kingsview Avenue, Carson, CA 90746
13. Professional Contract Sterilization, Inc., 40 Myles Standish Boulevard, Taunton, MA 02780
14. Sterigenics U.S. LLC, 2971 Olympic Industrial Court SE, Suite 116, Atlanta, GA 30339
15. Sterigenics US, LLC, 18021 Withers Cove Park Drive, Charlotte, NC 28278
16. Sterigenics U.S. LLC, 1302 Avenue T, Grand Prairie, TX 75050
17. Sterigenics US, LLC, 687 Wanamaker Avenue, Ontario, CA 91761
18. Sterigenics US LLC, 84 Park Road, Queensbury, NY 12804
19. Sterigenics-Salt Lake City Facility, 5725 West Harold Gatty Drive, Salt Lake City, UT 84116
20. Sterigenics-Santa Teresa, NM, 2400 Airport Road, Santa Teresa, NM 88008

21. Sterigenics US, Inc., 4900 Gifford Avenue, Vernon, CA 90058
22. Sterilization Services of Tennessee, 2396 Florida Street, Memphis, TN 38109
23. STERIS Inc., 380 90th Avenue Northwest, Coon Rapids, MN 55433
24. Steris, Inc., 43425 Business Park Drive, Temecula, CA 92590
25. Steris Isomedix Services Inc, 7685 Saint Andrews Avenue, San Diego, CA 92154
26. Steris Isomedix Services Inc, 3459 S Clinton Avenue, South Plainfield, NJ 07080
27. STERIS-Isomedix Services, 2072 Southport Road, Spartanburg, SC 29306
28. Steritec, Inc., 1705 Enterprise Street, Athens, TX 75751
29. Trinity Sterile, Inc., 201 Kiley Drive, Salisbury, MD 21801

Pursuant to the Emergency Planning and Community Right-to-Know Act (EPCRA) Section 313(b)(2), the U.S. Environmental Protection Agency (EPA) is extending Toxics Release Inventory (TRI) reporting requirements to the facilities identified herein for ethylene oxide and, where specified, ethylene glycol. The requirement that the EPA is applying to these facilities requires the submission of certain chemical data if the facility manufactures, processes, or otherwise uses the chemical in amounts exceeding the respective threshold. Additional materials and information supporting this determination are available in the docket: EPA-HQ-OPPT-2021-0693.

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I. BACKGROUND AND AUTHORITY

A. Toxics Release Inventory Reporting Requirement

EPCRA Section 313 requires owners and operators of covered facilities to submit certain data to the EPA TRI on the releases of listed toxic chemicals annually. *See* EPCRA § 313, 42 U.S.C. § 11023; 40 CFR 372. For a general overview of TRI, please visit the EPA website (<https://www.epa.gov/tri>). In

addition, the Pollution Prevention Act (PPA) of 1990 requires owners and operators of TRI-covered facilities to report on additional waste management (*i.e.*, recycling, treatment, and energy recovery) and source reduction activities for these toxic chemicals. *See* PPA § 6607, 42 U.S.C. § 13106.

Specifically, EPCRA Section 313(a) requires any facility covered by a rule or determination under EPCRA Section 313(b) to report to TRI data on chemicals that it manufactures, processes, or otherwise uses in quantities exceeding the listed chemical's respective reporting threshold. *See* EPCRA § 313(a), 42 U.S.C. § 11023(a) (“[t]he owner or operator of a facility subject to the requirements of this section shall complete a toxic chemical release form as published under [EPCRA Section 313(g)] for each toxic chemical listed under [EPCRA Section 313(c)] that was manufactured, processed, or otherwise used in quantities exceeding the toxic chemical threshold quantity established by [EPCRA Section 313(f)] during the preceding calendar year at such facility.”). Thus, the owners or operators of such facilities are required to determine, each year, whether the facility meets the reporting thresholds for TRI chemicals. The owner or operator of each facility must conduct a threshold analysis for such chemical(s) and submit a TRI reporting form for the chemical(s) should the reporting threshold be exceeded for the given chemical(s).

Pursuant to 40 CFR 372.5, if the owner and operator of a facility are different persons, only one of them needs to report under 40 CFR 372.30, or provide a notice under 40 CFR 372.45, for each toxic chemical in a mixture or trade name product distributed from the facility. However, if neither submits a report or provides notice, the EPA will hold both persons liable under EPCRA Section 325(c), except as provided in 40 CFR 372.38(e) and 372.45(g).

B. Application to Additional Facilities Under EPCRA Section 313(b)(2)

EPCRA Section 313(b)(2) provides the EPA with the authority to extend the reporting requirements of EPCRA Section 313(a) to additional facilities per the Administrator's discretion:

The Administrator, on [their] own motion . . . , may apply the requirements of [EPCRA Section 313(a)] to the owners and operators of any particular facility that manufactures, processes, or otherwise uses a toxic chemical listed under [EPCRA Section 313(c)] if the Administrator determines that such action is warranted on the basis of toxicity of the toxic chemical, proximity to other facilities that release the toxic chemical or to population centers, the history of releases of such chemical at such facility, or such other factors as the Administrator deems appropriate.

Using this authority, the EPA may subject any particular facility to TRI reporting requirements for listed chemicals if the Administrator decides that such action is warranted based on the statutory factors provided in EPCRA Section 313(b)(2). Following such a determination, the facility is then subject to the TRI reporting requirements in EPCRA Section 313(a), regardless of its industry sector or number of full-time employee equivalents. *See* EPCRA § 313(a), (b)(1)-(2), 42 U.S.C. § 11023(a), (b)(1)-(2); 40 CFR 372.

C. Entities Covered by this Determination

The EPA Administrator is issuing this determination to apply TRI requirements to the facilities listed in Table 1 for ethylene oxide (CASRN: 75-21-8) and, where noted, ethylene glycol (CASRN: 107-21-1). The EPA rationale supporting this determination for each facility is outlined in Section II and Appendix

A, below.

This determination applies to the entire facility for each facility identified in Table 1, including all establishments. A TRI reporting facility can be comprised of multiple establishments—distinct and separate economic units—located on a single site (or contiguous or adjacent sites) if those establishments are owned or operated by the same person (*e.g.*, individual, trust, firm, joint stock company, corporation).

For the purposes of this determination, please refer to the definitions in EPCRA Section 329 and 40 CFR 372.3. Specifically, a few important definitions include:

Establishment means an economic unit, generally at a single physical location, where business is conducted or where services or industrial operations are performed.

Facility means all buildings, equipment, structures, and other stationary items which are located on a single site or on contiguous or adjacent sites and which are owned or operated by the same person (or by any person which controls, is controlled by, or under common control with such person). A facility may contain more than one establishment.

Person means any individual, trust, firm, joint stock company, corporation (including a government corporation), partnership, association, State, municipality, commission, political subdivision of a State, or interstate body.

A TRI reporting facility can be comprised of multiple establishments—distinct and separate economic units—located on a single site (or contiguous or adjacent sites) if those establishments are owned or operated by the same person (*e.g.*, individual, trust, firm, joint stock company, corporation). This determination applies to the entire facility for each facility identified in Table 1, including all establishments.

II. DETERMINATION TO APPLY TRI REPORTING REQUIREMENTS TO PARTICULAR FACILITIES UNDER 313(b)(2)

EPCRA Section 313(b)(2) provides that the EPA may subject a facility to the TRI reporting requirements of EPCRA Section 313(a) “if the Administrator determines that such action is warranted on the basis of toxicity of the toxic chemical, proximity to other facilities that release the toxic chemical or to population centers, the history of releases of such chemical at such facility, or such other factors as the Administrator deems appropriate.”

The purpose of TRI is to provide governments and the public, including residents of communities surrounding covered facilities, with information on the releases and other waste management activities of listed toxic chemicals. After considering the factors for each facility as presented in Appendix A—including the toxicity of the chemicals, the facility’s proximity to population centers (including the number of schools and children under the age of five), the facility’s history of releases (as determined through past TRI reporting), and other factors the EPA Administrator deems appropriate (including concerns for facility workers and potential environmental justice concerns), and the EPA estimates for

potential ethylene oxide quantities manufactured, processed, or otherwise used on-site¹—the EPA has determined that applying TRI reporting requirements to the facilities in Table 1 for ethylene oxide (and ethylene glycol, when noted) is warranted under EPCRA Section 313(b)(2). The EPA believes the public would benefit from increased information disclosure related to releases of these chemicals at these facilities. Therefore, pursuant to the EPA Administrator’s authority under EPCRA Section 313(b), the EPA hereby determines that it is appropriate to apply the requirements of EPCRA 313 to the facilities in Table 1 to the TRI reporting requirements for ethylene oxide (and ethylene glycol, when noted).

TABLE 1. Facilities to whom this determination applies.

Facility Name	Street Address	City	State	ZIP Code	Chemical(s)
Andersen Sterilizers	3154 Caroline Drive	Haw River	NC	27258	• Ethylene oxide (CASRN: 75-21-8)
Boston Scientific Corporation	8 Industrial Drive	Coventry	RI	02816	• Ethylene oxide (CASRN: 75-21-8) • Ethylene glycol (CASRN: 107-21-1)
ETO Sterilization-Plant #2	2500 Brunswick Avenue	Linden	NJ	07036	• Ethylene oxide (CASRN: 75-21-8) • Ethylene glycol (CASRN: 107-21-1)
Fuchs North America	3800 Hampstead Mexico Road	Hampstead	MD	21074	• Ethylene oxide (CASRN: 75-21-8)
International Sterilization Laboratory	217 Sampey Road	Groveland	FL	34736	• Ethylene oxide (CASRN: 75-21-8)
Isomedix Operations, Inc.	1435 Isomedix Place	El Paso	TX	79936	• Ethylene oxide (CASRN: 75-21-8)
Isomedix Operations, Inc.	1175 Isuzu Parkway	Grand Prairie	TX	75050	• Ethylene oxide (CASRN: 75-21-8) • Ethylene glycol (CASRN: 107-21-1)
Isomedix Operations, Inc.	435 Whitney Street	Northborough	MA	01532	• Ethylene oxide (CASRN: 75-21-8)
LEMCO Ardmore	3204 Hale Road	Ardmore	OK	73401	• Ethylene oxide (CASRN: 75-21-8)

¹ EPA does not believe that EPCRA Section 313(b)(2) requires that a facility currently meet the TRI reporting thresholds for this determination to be warranted. However, EPA does believe that considering the quantity of ethylene oxide or ethylene glycol potentially manufactured, processed, or otherwise used on-site is appropriate in determining whether this action is warranted.

Long Island Sterilization	175 Wireless Boulevard	Hauppauge	NY	11788	<ul style="list-style-type: none"> Ethylene oxide (CASRN: 75-21-8)
Medline Industries	1160 South Northpoint Boulevard	Waukegan	IL	60085	<ul style="list-style-type: none"> Ethylene oxide (CASRN: 75-21-8) Ethylene glycol (CASRN: 107-21-1)
Parter Medical Products Inc	17115 Kingsview Avenue	Carson	CA	90746	<ul style="list-style-type: none"> Ethylene oxide (CASRN: 75-21-8)
Professional Contract Sterilization, Inc.	40 Myles Standish Boulevard	Taunton	MA	02780	<ul style="list-style-type: none"> Ethylene oxide (CASRN: 75-21-8) Ethylene glycol (CASRN: 107-21-1)
Sterigenics U.S. LLC	2971 Olympic Industrial Court SE, Suite 116	Atlanta	GA	30339	<ul style="list-style-type: none"> Ethylene oxide (CASRN: 75-21-8) Ethylene glycol (CASRN: 107-21-1)
Sterigenics US, LLC	18021 Withers Cove Park Drive	Charlotte	NC	28278	<ul style="list-style-type: none"> Ethylene oxide (CASRN: 75-21-8) Ethylene glycol (CASRN: 107-21-1)
Sterigenics U.S. LLC	1302 Avenue T	Grand Prairie	TX	75050	<ul style="list-style-type: none"> Ethylene oxide (CASRN: 75-21-8) Ethylene glycol (CASRN: 107-21-1)
Sterigenics US, LLC	687 Wanamaker Avenue	Ontario	CA	91761	<ul style="list-style-type: none"> Ethylene oxide (CASRN: 75-21-8) Ethylene glycol (CASRN: 107-21-1)
Sterigenics US LLC	84 Park Road	Queensbury	NY	12804	<ul style="list-style-type: none"> Ethylene oxide (CASRN: 75-21-8) Ethylene glycol (CASRN: 107-21-1)
Sterigenics - Salt Lake City Facility	5725 West Harold Gatty Drive	Salt Lake City	UT	84116	<ul style="list-style-type: none"> Ethylene oxide (CASRN: 75-21-8) Ethylene glycol (CASRN: 107-21-1)

Sterigenics-Santa Teresa, NM	2400 Airport Road	Santa Teresa	NM	88008	<ul style="list-style-type: none"> Ethylene oxide (CASRN: 75-21-8) Ethylene glycol (CASRN: 107-21-1)
Sterigenics US, Inc.	4900 Gifford Avenue	Vernon	CA	90058	<ul style="list-style-type: none"> Ethylene oxide (CASRN: 75-21-8) Ethylene glycol (CASRN: 107-21-1)
Sterilization Services of Tennessee	2396 Florida Street	Memphis	TN	38109	<ul style="list-style-type: none"> Ethylene oxide (CASRN: 75-21-8) Ethylene glycol (CASRN: 107-21-1)
STERIS Inc.	380 90th Avenue Northwest	Coon Rapids	MN	55433	<ul style="list-style-type: none"> Ethylene oxide (CASRN: 75-21-8)
Steris, Inc.	43425 Business Park Drive	Temecula	CA	92590	<ul style="list-style-type: none"> Ethylene oxide (CASRN: 75-21-8)
Steris Isomedix Services Inc	7685 Saint Andrews Avenue	San Diego	CA	92154	<ul style="list-style-type: none"> Ethylene oxide (CASRN: 75-21-8) Ethylene glycol (CASRN: 107-21-1)
Steris Isomedix Services Inc	3459 S Clinton Avenue	South Plainfield	NJ	07080	<ul style="list-style-type: none"> Ethylene oxide (CASRN: 75-21-8) Ethylene glycol (CASRN: 107-21-1)
STERIS-Isomedix Services	2072 Southport Road	Spartanburg	SC	29306	<ul style="list-style-type: none"> Ethylene oxide (CASRN: 75-21-8)
Steritec, Inc.	1705 Enterprise Street	Athens	TX	75751	<ul style="list-style-type: none"> Ethylene oxide (CASRN: 75-21-8)
Trinity Sterile, Inc.	201 Kiley Drive	Salisbury	MD	21801	<ul style="list-style-type: none"> Ethylene oxide (CASRN: 75-21-8)

Nothing in this determination should be read as limiting the scope of the “facility” subject to this determination to a single establishment listed in Table 1, should additional buildings, equipment, or sites on adjacent and/or contiguous land with a common operator or operator also fall within the scope of the facility. *See* EPCRA § 329(4), 42 U.S.C. § 11049(4); 40 CFR 372.3.

III. CONSEQUENCES OF THIS DECISION: REPORTING AND RECORDKEEPING UNDER EPCRA SECTION 313(a)

The EPA decision to apply the requirements of EPCRA to these facilities makes the owner and operator

of each facility specified in Table 1 subject to TRI reporting requirements under EPCRA Section 313. *See* EPCRA § 313, 42 U.S.C. § 110023; 40 CFR 372. If that facility subsequently manufactures, processes, or otherwise uses ethylene oxide (or ethylene glycol, where noted) above the activity thresholds, EPCRA Section 313(a) would require the facility's current owner or operator to report for that chemical pursuant to the statute and the EPA implementing regulations. Nothing in this determination alters the requirements of EPCRA Sections 313(a) and 313(g) or requires an owner or operator to report if the facility does not meet the chemical activity threshold requirements in EPCRA Section 313(f) or 40 CFR 372, subpart. B. This determination under EPCRA Section 313(b)(2) applies the TRI reporting requirements in EPCRA Section 313(a) to the facilities listed in Table 1, without regard to their industry sector (*i.e.*, North American Industry Classification System (NAICS) code) or the number of full-time employee-equivalents.

A. Consequences of Failing to Comply with EPCRA Section 313(a)

Failure to comply with any reporting requirements of EPCRA Section 313 is a violation of EPCRA and could subject you to civil and administrative penalties under EPCRA Section 325. EPCRA § 325, 42 U.S.C. § 11045; 40 C.F.R. pt. 19 (implementing civil penalties adjustments). Each day a facility fails to meet any of the requirements constitutes a separate violation of the specific requirement. Submission of false information to the EPA or knowing failure to file an EPCRA Section 313 report may also be subject to criminal penalties under 18 U.S.C. § 1001.

B. Paperwork Reduction Act Notice

The current collection of information under the EPA TRI regulations is approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. § 3501 et seq. *See* OMB Control No. 2070-0212. The EPA is currently revising its information collection request (ICR) for the TRI regulations to account for potential reporting by additional facilities under EPCRA Section 313(b)(2), specifically ethylene oxide-using facilities (some of which also include ethylene glycol, where noted). These revisions are currently pending approval with OMB. The normal clearance procedures under the PRA require agencies to provide a 60-day public comment opportunity before submitting an ICR to OMB for review and approval. The OMB review and approval process involves another mandated 30 days for additional public comment. The 60-day public comment period for collecting information under this discretionary authority began on November 15, 2021. *See* Proposed Revisions to an Existing Collection: Toxic Chemical Release Reporting, 86 Fed. Reg. 63025.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The annual public burden related to the Form R is estimated to be 35.7 hours per response for a facility filing a report on one chemical. The annual public burden related to the Form A is estimated to average 21.96 hours per response for a facility filing a report on one chemical. Under the PRA, burden is defined at 5 CFR 1320.3(b). Send comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the Regulatory Support Division Director, U.S. Environmental Protection Agency (2821T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed TRI form to this address.

While the EPA cannot enforce recordkeeping from entities subject to this determination pursuant to its

TRI regulations until OMB has approved the ICR, the EPA reminds covered entities that persons subject to the statutory reporting and recordkeeping requirements in EPCRA Sections 313(a) and 313(g) are nevertheless subject to enforcement under EPCRA Section 325(c)(1) should they fail to comply with those requirements. *See* 5 CFR 1320.6(e) (observing that penalties protections under 5 CFR 1320.6(a) do not “preclude the imposition of a penalty on a person for failing to comply with a collection of information that is imposed on the person by statute”). The EPA anticipates that OMB will approve the ICR in Spring 2022.

IV. FOR FURTHER INFORMATION CONTACT

For technical information contact: Stephanie Griffin, Data Collection Branch, Data Gathering and Analysis Division (7410M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001; telephone number: (202) 564-1463; email address: griffin.stephanie@epa.gov.

For general TRI support and contacts, see the TRI Program Contacts webpage:
<https://www.epa.gov/toxics-release-inventory-tri-program/forms/tri-program-contacts>.

V. SIGNATURE

Under the authority of EPCRA Section 313(b)(2) the United States Environmental Protection Agency hereby issues this Determination to take effect on the date of my signature

Dated: DEC 16 2021.

Michael S. Regan,



Administrator.

Enclosures:

Appendix A: Factors for Extending Reporting Requirements to the Identified Facilities

Appendix B: References