HB3885

LRB10113376CPF63059b

101ST GENERAL ASSEMBLY

State of Illinois

2019 and 2020

HB3885

by Rep. Jim Durkin

SYNOPSIS AS INTRODUCED:

415 ILCS 5/9.16

Amends the Environmental Protection Act. Provides that nothing within provisions regarding the control of ethylene oxide sterilization sources shall limit the ability of a home rule unit of local government to adopt an ordinance that imposes additional operating restrictions upon or prohibits ethylene oxide sterilization operations of a facility that is located within the boundaries of the home rule unit of local government and is permitted to emit ethylene oxide. Effective immediately.

LRB101 13376 CPF 63059 b

A BILL FOR

AN ACT concerning safety.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 5. The Environmental Protection Act is amended by changing Section 9.16, as added by Public Act 101-22, as follows:

(415 ILCS 5/9.16)

Sec. 9.16. Control of ethylene oxide sterilization sources.

(a) As used in this Section:

"Ethylene oxide sterilization operations" means the process of using ethylene oxide at an ethylene oxide sterilization source to make one or more items free from microorganisms, pathogens, or both microorganisms and pathogens.

"Ethylene oxide sterilization source" means any stationary source with ethylene oxide usage that would subject it to the emissions standards in 40 CFR 63.362. "Ethylene oxide sterilization source" does not include beehive fumigators, research or laboratory facilities, hospitals, doctors' offices, clinics, or other stationary sources for which the primary purpose is to provide medical services to humans or animals.

"Exhaust point" means any point through which ethylene oxide-laden air exits an ethylene oxide sterilization source.

"Stationary source" has the meaning set forth in subsection 1 of Section 39.5.

(b) Beginning 180 days after the effective date of this amendatory Act of the 101st General Assembly, no person shall conduct ethylene oxide sterilization operations, unless the ethylene oxide sterilization source captures, and demonstrates that it captures, 100% of all ethylene oxide emissions and reduces ethylene oxide emissions to the atmosphere from each exhaust point at the ethylene oxide sterilization source by at least 99.9% or to 0.2 parts per million.

(1) Within 180 days after the effective date of this amendatory Act of the 101st General Assembly for any existing ethylene oxide sterilization source, or prior to any ethylene oxide sterilization operation for any source that first becomes subject to regulation after the effective date of this amendatory Act of the 101st General Assembly as an ethylene oxide sterilization source under this Section, the owner or operator of the ethylene oxide sterilization source shall conduct an initial emissions test in accordance with all of the requirements set forth in this paragraph (1) to verify that ethylene oxide emissions to the atmosphere from each exhaust point at the ethylene oxide sterilization source have been reduced by at least 99.9% or to 0.2 parts per million:

(A) At least 30 days prior to the scheduled emissions test date, the owner or operator of the ethylene oxide sterilization source shall submit a notification of the scheduled emissions test date and a copy of the proposed emissions test protocol to the Agency for review and written approval. Emissions test protocols submitted to the Agency shall address the manner in which testing will be conducted, including, but not limited to:

(i) the name of the independent third party company that will be performing sampling and analysis and the company's experience with similar emissions tests;

(ii) the methodologies to be used;

(iii) the conditions under which emissions tests will be performed, including a discussion of why these conditions will be representative of maximum emissions from each of the 3 cycles of operation (chamber evacuation, back vent, and aeration) and the means by which the operating parameters for the emission unit and any control equipment will be determined;

(iv) the specific determinations of emissions and operations that are intended to be made, including sampling and monitoring locations; and

(v) any changes to the test method or methods

proposed to accommodate the specific circumstances of testing, with justification.

(B) The owner or operator of the ethylene oxide sterilization source shall perform emissions testing in accordance with an Agency-approved test protocol and at representative conditions to verify that ethylene oxide emissions to the atmosphere from each exhaust point at the ethylene oxide sterilization source have been reduced by at least 99.9% or to 0.2 parts per million. The duration of the test must incorporate all 3 cycles of operation for determination of the emission reduction efficiency.

(C) Upon Agency approval of the test protocol, any source that first becomes subject to regulation after the effective date of this amendatory Act of the 101st General Assembly as an ethylene oxide sterilization source under this Section may undertake ethylene oxide sterilization operations in accordance with the Agency-approved test protocol for the sole purpose of demonstrating compliance with this subsection (b).

(D) The owner or operator of the ethylene oxide sterilization source shall submit to the Agency the results of any and all emissions testing conducted after the effective date of this amendatory Act of the 101st General Assembly, until the Agency accepts testing results under subparagraph (E) of paragraph

(1) of this subsection (b), for any existing source or prior to any ethylene oxide sterilization operation for any source that first becomes subject to regulation after the effective date of this amendatory Act of the 101st General Assembly as an ethylene oxide sterilization source under this Section. The results documentation shall include at a minimum:

(i) a summary of results;

(ii) a description of test method or methods, including description of sample points, sampling train, analysis equipment, and test schedule;

(iii) a detailed description of test conditions, including process information and control equipment information; and

(iv) data and calculations, including copies of all raw data sheets, opacity observation records and records of laboratory analyses, sample calculations, and equipment calibration.

(E) Within 30 days of receipt, the Agency shall accept, accept with conditions, or decline to accept a stack testing protocol and the testing results submitted to demonstrate compliance with paragraph (1) of this subsection (b). If the Agency accepts with conditions or declines to accept the results submitted, the owner or operator of the ethylene oxide sterilization source shall submit revised results of

the emissions testing or conduct emissions testing again. If the owner or operator revises the results, the revised results shall be submitted within 15 days after the owner or operator of the ethylene oxide sterilization source receives written notice of the Agency's conditional acceptance or rejection of the emissions testing results. If the owner or operator conducts emissions testing again, such new emissions testing shall conform to the requirements of this subsection (b).

(2) The owner or operator of the ethylene oxide sterilization source shall conduct emissions testing on all exhaust points at the ethylene oxide sterilization source at least once each calendar year to demonstrate compliance with the requirements of this Section and any applicable requirements concerning ethylene oxide that are set forth in either United States Environmental Protection Agency rules or Board rules. Annual emissions tests required under this paragraph (2) shall take place at least 6 months apart. An initial emissions test conducted under paragraph (1) of this subsection (b) satisfies the testing requirement of this paragraph (2) for the calendar year in which the initial emissions test is conducted.

(3) At least 30 days before conducting the annual emissions test required under paragraph (2) of this subsection (b), the owner or operator shall submit a

notification of the scheduled emissions test date and a copy of the proposed emissions test protocol to the Agency for review and written approval. Emissions test protocols submitted to the Agency under this paragraph (3) must address each item listed in subparagraph (A) of paragraph (1) of this subsection (b). Emissions testing shall be performed in accordance with an Agency-approved test protocol and at representative conditions. In addition, as soon as practicable, but no later than 30 days after the emissions test date, the owner or operator shall submit to the Agency the results of the emissions testing required under paragraph (2) of this subsection (b). Such results must include each item listed in subparagraph (D) of paragraph (1) of this subsection (b).

(4) If the owner or operator of an ethylene oxide sterilization source conducts any emissions testing in addition to tests required by this amendatory Act of the 101st General Assembly, the owner or operator shall submit to the Agency the results of such emissions testing within 30 days after the emissions test date.

(5) The Agency shall accept, accept with conditions, or decline to accept testing results submitted to demonstrate compliance with paragraph (2) of this subsection (b). If the Agency accepts with conditions or declines to accept the results submitted, the owner or operator of the ethylene oxide sterilization source shall submit revised

results of the emissions testing or conduct emissions testing again. If the owner or operator revises the results, the revised results shall be submitted within 15 days after the owner or operator of the ethylene oxide sterilization source receives written notice of the Agency's conditional acceptance or rejection of the emissions testing results. If the owner or operator conducts emissions testing again, such new emissions testing shall conform to the requirements of this subsection (b).

(c) If any emissions test conducted more than 180 days after the effective date of this amendatory Act of the 101st General Assembly fails to demonstrate that ethylene oxide emissions to the atmosphere from each exhaust point at the ethylene oxide sterilization source have been reduced by at least 99.9% or to 0.2 parts per million, the owner or operator of the ethylene oxide sterilization source shall immediately cease ethylene oxide sterilization operations and notify the Agency within 24 hours of becoming aware of the failed emissions test. Within 60 days after the date of the test, the owner or operator of the ethylene oxide sterilization source shall:

(1) complete an analysis to determine the root cause of the failed emissions test;

(2) take any actions necessary to address that root cause;

(3) submit a report to the Agency describing the findings of the root cause analysis, any work undertaken to address findings of the root cause analysis, and identifying any feasible best management practices to enhance capture and further reduce ethylene oxide levels within the ethylene oxide sterilization source, including a schedule for implementing such practices; and

(4) upon approval by the Agency of the report required by paragraph (3) of this subsection, restart ethylene oxide sterilization operations only to the extent necessary to conduct additional emissions test or tests. The ethylene oxide sterilization source shall conduct such emissions test or tests under the same requirements as the annual test described in paragraphs (2) and (3) of subsection (b). The ethylene oxide sterilization source may restart operations once an emissions test successfully demonstrates that ethylene oxide emissions to the atmosphere from each exhaust point at the ethylene oxide sterilization source have been reduced by at least 99.9% or to 0.2 parts per million, the source has submitted the results of all emissions testing conducted under this subsection to the Agency, and the Agency has approved the results demonstrating compliance.

(d) Beginning 180 days after the effective date of this amendatory Act of the 101st General Assembly for any existing source or prior to any ethylene oxide sterilization operation

for any source that first becomes subject to regulation after the effective date of this amendatory Act of the 101st General Assembly as an ethylene oxide sterilization source under this Section, no person shall conduct ethylene oxide sterilization operations unless the owner or operator of the ethylene oxide sterilization source submits for review and approval by the Agency a plan describing how the owner or operator will continuously collect emissions information at the ethylene oxide sterilization source. This plan must also specify locations at the ethylene oxide sterilization source from which emissions will be collected and identify equipment used for collection and analysis, including the individual system components.

(1) The owner or operator of the ethylene oxide sterilization source must provide a notice of acceptance of any conditions added by the Agency to the plan, or correct any deficiencies identified by the Agency in the plan, within 3 business days after receiving the Agency's conditional acceptance or denial of the plan.

(2) Upon the Agency's approval of the plan, the owner or operator of the ethylene oxide sterilization source shall implement the plan in accordance with its approved terms.

(e) Beginning 180 days after the effective date of this amendatory Act of the 101st General Assembly for any existing source or prior to any ethylene oxide sterilization operation

for any source that first becomes subject to regulation after the effective date of this amendatory Act of the 101st General Assembly as an ethylene oxide sterilization source under this Section, no person shall conduct ethylene oxide sterilization operations unless the owner or operator of the ethylene oxide sterilization source submits for review and approval by the Agency an Ambient Air Monitoring Plan.

(1) The Ambient Air Monitoring Plan shall include, at a minimum, the following:

(A) Detailed plans to collect and analyze air samples for ethylene oxide on at least a quarterly basis near the property boundaries of the ethylene oxide sterilization source and at community locations with the highest modeled impact pursuant to the modeling conducted under subsection (f). Each quarterly sampling under this subsection shall be conducted over a multiple-day sampling period.

(B) A schedule for implementation.

(C) The name of the independent third party company that will be performing sampling and analysis and the company's experience with similar testing.

(2) The owner or operator of the ethylene oxide sterilization source must provide a notice of acceptance of any conditions added by the Agency to the Ambient Air Monitoring Plan, or correct any deficiencies identified by the Agency in the Ambient Air Monitoring Plan, within 3

business days after receiving the Agency's conditional acceptance or denial of the plan.

(3) Upon the Agency's approval of the plan, the owner or operator of the ethylene oxide sterilization source shall implement the Ambient Air Monitoring Plan in accordance with its approved terms.

(f) Beginning 180 days after the effective date of this amendatory Act of the 101st General Assembly for any existing source or prior to any ethylene oxide sterilization operation for any source that first becomes subject to regulation after the effective date of this amendatory Act of the 101st General Assembly as an ethylene oxide sterilization source under this Section, no person shall conduct ethylene oxide sterilization operations unless the owner or operator of the ethylene oxide sterilization source has performed dispersion modeling and the Agency approves such modeling.

(1) Dispersion modeling must:

(A) be conducted using accepted United States Environmental Protection Agency methodologies, including 40 CFR Part 51, Appendix W, except that no background ambient levels of ethylene oxide shall be used;

(B) use emissions and stack parameter data from the emissions test conducted in accordance with paragraph (1) of subsection (b), and use 5 years of hourly meteorological data that is representative of the

source's location; and

(C) use a receptor grid that extends to at least one kilometer around the source and ensure the modeling domain includes the area of maximum impact, with receptor spacing no greater than every 50 meters starting from the building walls of the source extending out to a distance of at least one-half kilometer, then every 100 meters extending out to a distance of at least one kilometer.

(2) The owner or operator of the ethylene oxide sterilization source shall submit revised results of all modeling if the Agency accepts with conditions or declines to accept the results submitted.

(g) A facility permitted to emit ethylene oxide that has been subject to a seal order under Section 34 is prohibited from using ethylene oxide for sterilization or fumigation purposes, unless (i) the facility can provide a certification to the Agency by the supplier of a product to be sterilized or fumigated that ethylene oxide sterilization or fumigation is the only available method to completely sterilize or fumigate the product and (ii) the Agency has certified that the facility's emission control system uses technology that produces the greatest reduction in ethylene oxide emissions currently available. The certification shall be made by a company representative with knowledge of the sterilization requirements of the product. The certification requirements of

this Section shall apply to any group of products packaged together and sterilized as a single product if sterilization or fumigation is the only available method to completely sterilize or fumigate more than half of the individual products contained in the package.

A facility is not subject to the requirements of this subsection if the supporting findings of the seal order under Section 34 are found to be without merit by a court of competent jurisdiction.

(h) If an entity, or any parent or subsidiary of an entity, that owns or operates a facility permitted by the Agency to emit ethylene oxide acquires by purchase, license, or any other method of acquisition any intellectual property right in a sterilization technology that does not involve the use of ethylene oxide, or by purchase, merger, or any other method of acquisition of any entity that holds an intellectual property right in a sterilization technology that does not involve the use of ethylene oxide, that entity, parent, or subsidiary shall notify the Agency of the acquisition within 30 days of acquiring it. If that entity, parent, or subsidiary has not used the sterilization technology within 3 years of its acquisition, the entity shall notify the Agency within 30 days of the 3-year period elapsing.

An entity, or any parent or subsidiary of an entity, that owns or operates a facility permitted by the Agency to emit ethylene oxide that has any intellectual property right in any

sterilization technology that does not involve the use of ethylene oxide shall notify the Agency of any offers that it makes to license or otherwise allow the technology to be used by third parties within 30 days of making the offer.

An entity, or any parent or subsidiary of an entity, that owns or operates a facility permitted by the Agency to emit ethylene oxide shall provide the Agency with a list of all U.S. patent registrations for sterilization technology that the entity, parent, or subsidiary has any property right in. The list shall include the following:

(1) The patent number assigned by the United States Patent and Trademark Office for each patent.

(2) The date each patent was filed.

(3) The names and addresses of all owners or assignees of each patent.

(4) The names and addresses of all inventors of each patent.

(i) If a CAAPP permit applicant applies to use ethylene oxide as a sterilant or fumigant at a facility not in existence prior to January 1, 2020, the Agency shall issue a CAAPP permit for emission of ethylene oxide only if:

(1) the nearest school or park is at least 10 miles from the permit applicant in counties with populations greater than 50,000;

(2) the nearest school or park is at least 15 miles from the permit applicant in counties with populations less

than or equal to 50,000; and

(3) within 7 days after the application for a CAAPP permit, the permit applicant has published its permit request on its website, published notice in a local newspaper of general circulation, and provided notice to:

(A) the State Representative for the representative district in which the facility is located;

(B) the State Senator for the legislative district in which the facility is located;

(C) the members of the county board for the county in which the facility is located; and

(D) the local municipal board members and executives.

(j) The owner or operator of an ethylene oxide sterilization source must apply for and obtain a construction permit from the Agency for any modifications made to the source to comply with the requirements of this amendatory Act of the 101st General Assembly, including, but not limited to, installation of a permanent total enclosure, modification of airflow to create negative pressure within the source, and addition of one or more control devices. Additionally, the owner or operator of the ethylene oxide sterilization source must apply for and obtain from the Agency a modification of the source's operating permit to incorporate such modifications made to the source. Both the construction permit and operating

permit must include a limit on ethylene oxide usage at the source.

(k) Nothing in this Section shall be interpreted to excuse the ethylene oxide sterilization source from complying with any applicable local requirements.

(l) The owner or operator of an ethylene oxide sterilization source must notify the Agency within 5 days after discovering any deviation from any of the requirements in this Section or deviations from any applicable requirements concerning ethylene oxide that are set forth in this Act, United States Environmental Protection Agency rules, or Board rules. As soon as practicable, but no later than 5 business days, after the Agency receives such notification, the Agency must post a notice on its website and notify the members of the General Assembly from the Legislative and Representative Districts in which the source in question is located, the county board members of the county in which the source in question is located, the corporate authorities of the municipality in which the source in question is located, and the Illinois Department of Public Health.

(m) The Agency must conduct at least one unannounced inspection of all ethylene oxide sterilization sources subject to this Section per year. Nothing in this Section shall limit the Agency's authority under other provisions of this Act to conduct inspections of ethylene oxide sterilization sources.

(n) The Agency shall conduct air testing to determine the

ambient levels of ethylene oxide throughout the State. The Agency shall, within 180 days after the effective date of this amendatory Act of the 101st General Assembly, submit rules for ambient air testing of ethylene oxide to the Board.

(o) Nothing in this Section shall limit the ability of a home rule unit of local government to adopt an ordinance that imposes additional operating restrictions upon or prohibits ethylene oxide sterilization operations of a facility that is located within the boundaries of the home rule unit of local government and is permitted to emit ethylene oxide.

(Source: P.A. 101-22, eff. 6-21-19.)

Section 99. Effective date. This Act takes effect upon becoming law.