



Rep. Sam Yingling

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LRB101 03567 AMC 59682 a

1 AMENDMENT TO HOUSE BILL 457

2 AMENDMENT NO. \_\_\_\_\_. Amend House Bill 457 by replacing  
3 everything after the enacting clause with the following:

4 "Section 5. The Environmental Protection Act is amended by  
5 adding Section 9.16 as follows:

6 (415 ILCS 5/9.16 new)

7 Sec. 9.16. Control of ethylene oxide sterilization  
8 sources.

9 (a) As used in this Section:

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

15 "Ethylene oxide sterilization source" means any stationary  
16 source with ethylene oxide usage that would subject it to the

1 emissions standards in 40 CFR 63.362.

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

4 "Stationary source" has the meaning set forth in subsection  
5 1 of Section 39.5.

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

14 (1) Within 180 days after the effective date of this  
15 amendatory Act of the 101st General Assembly for any  
16 existing ethylene oxide sterilization source or prior to  
17 any ethylene oxide sterilization operation for any source  
18 that first becomes subject to regulation after the  
19 effective date of this amendatory Act of the 101st General  
20 Assembly as an ethylene oxide sterilization source under  
21 this Section, the owner or operator of the ethylene oxide  
22 sterilization source shall conduct an initial emissions  
23 test in accordance with all of the requirements set forth  
24 in this paragraph (1) to verify that ethylene oxide  
25 emissions to the atmosphere from each exhaust point at the  
26 ethylene oxide sterilization source have been reduced by at

1           least 99.9% or to 0.2 parts per million:

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

11           (i) the person or persons who will be  
12           performing sampling and analysis and their  
13           experience with similar emissions tests;

14           (ii) the methodologies to be used;

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

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

26           (v) any changes to the test method or methods

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

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

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

21           (D) The owner or operator of the ethylene oxide  
22           sterilization source shall submit to the Agency the  
23           results of any and all emissions testing conducted  
24           after the effective date of this amendatory Act of the  
25           101st General Assembly, until such time as the Agency  
26           accepts testing results under subparagraph (E) of

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

8                   (i) a summary of results;

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

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

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

19           (E) The Agency shall accept, accept with  
20           conditions, or decline to accept testing results  
21           submitted to demonstrate compliance with paragraph (1)  
22           of this subsection (b). If the Agency accepts with  
23           conditions or declines to accept the results  
24           submitted, the owner or operator of the ethylene oxide  
25           sterilization source shall submit revised results of  
26           the emissions testing or conduct emissions testing

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

10           (2) The owner or operator of the ethylene oxide  
11           sterilization source shall conduct emissions testing on  
12           all exhaust points at the ethylene oxide sterilization  
13           source at least once each calendar year to demonstrate  
14           compliance with the requirements of this Section and any  
15           applicable requirements concerning ethylene oxide that are  
16           set forth in either United States Environmental Protection  
17           Agency rules or Board rules. Annual emissions tests  
18           required under this paragraph (2) shall take place at least  
19           6 months apart. An initial emissions test conducted under  
20           paragraph (1) of this subsection (b) satisfies the testing  
21           requirement of this paragraph (2) for the calendar year in  
22           which the initial emissions test is conducted.

23           (3) At least 30 days before conducting the annual  
24           emissions test required under paragraph (2) of this  
25           subsection (b), the owner or operator shall submit a  
26           notification of the scheduled emissions test date and a

1 copy of the proposed emissions test protocol to the Agency  
2 for review and written approval. Emissions test protocols  
3 submitted to the Agency under this paragraph (3) must  
4 address each item listed in subparagraph (A) of paragraph  
5 (1) of this subsection (b). Emissions testing shall be  
6 performed in accordance with an Agency-approved test  
7 protocol and at representative conditions. In addition,  
8 within 30 days after the emissions test date, the owner or  
9 operator shall submit to the Agency the results of the  
10 emissions testing required under paragraph (2) of this  
11 subsection (b). Such results must include each item listed  
12 in subparagraph (D) of paragraph (1) of this subsection  
13 (b).

14 (4) If the owner or operator of an ethylene oxide  
15 sterilization source conducts any emissions testing in  
16 addition to tests required by this amendatory Act of the  
17 101st General Assembly, the owner or operator shall submit  
18 to the Agency the results of such emissions testing within  
19 30 days after the emissions test date.

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

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

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

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

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

26               (3) submit a report to the Agency describing the



1 findings of the root cause analysis, any work undertaken to  
2 address findings of the root cause analysis, and  
3 identifying any feasible best management practices to  
4 enhance capture and further reduce ethylene oxide levels  
5 within the ethylene oxide sterilization source, including  
6 a schedule for implementing such practices; and

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

23 (d) Beginning 180 days after the effective date of this  
24 amendatory Act of the 101st General Assembly for any existing  
25 source or prior to any ethylene oxide sterilization operation  
26 for any source that first becomes subject to regulation after

1 the effective date of this amendatory Act of the 101st General  
2 Assembly as an ethylene oxide sterilization source under this  
3 Section, no person shall conduct ethylene oxide sterilization  
4 operations unless the owner or operator of the ethylene oxide  
5 sterilization source submits for review and approval by the  
6 Agency a plan describing how the owner or operator will  
7 continuously collect emissions information at the ethylene  
8 oxide sterilization source. This plan must also specify  
9 locations at the ethylene oxide sterilization source from which  
10 emissions will be collected and identify equipment used for  
11 collection and analysis, including the individual system  
12 components.

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

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

23 (e) Beginning 180 days after the effective date of this  
24 amendatory Act of the 101st General Assembly for any existing  
25 source or prior to any ethylene oxide sterilization operation  
26 for any source that first becomes subject to regulation after

1 the effective date of this amendatory Act of the 101st General  
2 Assembly as an ethylene oxide sterilization source under this  
3 Section, no person shall conduct ethylene oxide sterilization  
4 operations unless the owner or operator of the ethylene oxide  
5 sterilization source submits for review and approval by the  
6 Agency an Ambient Air Monitoring Plan. The Ambient Air  
7 Monitoring Plan shall include, at a minimum, detailed plans to  
8 collect and analyze air samples for ethylene oxide on at least  
9 a quarterly basis near the property boundaries of the ethylene  
10 oxide sterilization source and at community locations with the  
11 highest modeled impact pursuant to the modeling conducted under  
12 subsection (f) and a schedule for implementation.

13 (1) The owner or operator of the ethylene oxide  
14 sterilization source must provide a notice of acceptance of  
15 any conditions added by the Agency to the Ambient Air  
16 Monitoring Plan, or correct any deficiencies identified by  
17 the Agency in the Ambient Air Monitoring Plan, within 3  
18 business days after receiving the Agency's conditional  
19 acceptance or denial of the plan.

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

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

1 for any source that first becomes subject to regulation after  
2 the effective date of this amendatory Act of the 101st General  
3 Assembly as an ethylene oxide sterilization source under this  
4 Section, no person shall conduct ethylene oxide sterilization  
5 operations unless the owner or operator of the ethylene oxide  
6 sterilization source has performed dispersion modeling and the  
7 Agency approves such modeling.

8 (1) Dispersion modeling must:

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

14 (B) use emissions and stack parameter data from the  
15 emissions test conducted in accordance with paragraph  
16 (1) of subsection (b), and use 5 years of hourly  
17 meteorological data that is representative of the  
18 source's location; and

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

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

5           (g) The owner or operator of an ethylene oxide  
6           sterilization source must apply for and obtain a construction  
7           permit from the Agency for any modifications made to the source  
8           to comply with the requirements of this amendatory Act of the  
9           101st General Assembly, including, but not limited to,  
10           installation of a permanent total enclosure, modification of  
11           airflow to create negative pressure within the source, and  
12           addition of one or more control devices. Additionally, the  
13           owner or operator of the ethylene oxide sterilization source  
14           must apply for and obtain from the Agency a modification of the  
15           source's operating permit to incorporate such modifications  
16           made to the source. Both the construction permit and operating  
17           permit must include a limit on ethylene oxide usage at the  
18           source.

19           (h) The owner or operator of an ethylene oxide  
20           sterilization source must notify the Agency within 5 days after  
21           discovering any deviation from any of the requirements in this  
22           Section or deviations from any applicable requirements  
23           concerning ethylene oxide that are set forth in this Act,  
24           United States Environmental Protection Agency rules, or Board  
25           rules. Within 30 days after the Agency receives such  
26           notification, the Agency must post a notice on its website and

1 notify the members of the General Assembly from the Legislative  
2 and Representative Districts in which the source in question is  
3 located, the county board members of the county in which the  
4 source in question is located, the corporate authorities of the  
5 municipality in which the source in question is located, and  
6 the Illinois Department of Public Health.

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

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