IN THE CIRCUIT COURT OF THE EIGHTEENTH JUDICIAL CIRCUIT
DUPAGE COUNTY, ILLINOIS
CHANCERY DIVISION

PEOPLE OF THE STATE OF ILLINOIS *ex rel* LISA MADIGAN Attorney General of the State of Illinois, and *ex rel* ROBERT BERLIN, State's Attorney for DuPage County, Illinois Plaintiffs, v STERIGENICS U.S., LLC a Delaware limited liability company, Defendant.	)))))))))))	No. 2018 CH 001329 Hon. Paul Fullerton Room 2005

MOTION FOR LEAVE TO FILE THE AMICUS BRIEF OF JOHN F. CURRAN; JAMES B. DURKIN AND DEANNE M. MAZZOCHI REGARDING THE INTERPRETATION OF SB 1852/Public Act 101-0022, The Matt Haller Act, 415 ILCS 5/9.16

1. Presently pending before the Court are various motions to intervene on behalf of various municipalities; as well as a proposed Consent Order that has been submitted by the parties to the above-captioned action. The subject matter pertains to Sterigenics U.S. LLC, which will be, at least in part, governed by "The Matt Haller Act," Public Act 101-0022, 415 ILCS 5/9.16, which was signed into law in June of 2019.

2. Movants are John Curran, an Illinois State Senator for the 41st Senate district; Jim Durkin, the Minority Leader of the Illinois House of Representatives, representing the 82nd House District; and Deanne Mazzochi, an Illinois State Representative for the 47th District. All served as chief sponsors or co-sponsors for the Matt Haller Act, and were intimately involved in the Act's negotiation and passage.

3. The Sterigenics facility directly impacts residents in the Curran, Durkin and Mazzochi districts.

4. The Matt Haller Act is a new law. Its interpretation and the application of various provisions of the Act will be of considerable public interest and importance. The legislative history is complicated, and involves provisions sourced from multiple competing bills. Amici submit that the Court may need to consider the intent and purpose of the Act in the context of the proposed Consent Order (which will necessitate an opportunity for the public to be heard prior to entering, entering with modifications, or rejecting it).

5. Movants' proposed Amicus brief details and compiles for the Court's convenience aspects of the legislative history for the Act, and in particular the relevance and intent and goals of certain subsections in the Act that *amici* anticipate will be relevant to the issues raised in the pending lawsuit; consent order; and construction permits going forward.

6. In view of the foregoing, Movants respectfully request that this Court accept for consideration Movants' proposed Amicus Brief of John F. Curran; James B. Durkin and Deanne M. Mazzochi Regarding the Interpretation of SB 1852/Public Act 101-0022, The Matt Haller Act, 415 ILCS 5/9.16. A copy of the proposed brief, and accompanying Exhibits A-M, is attached as Exhibit 1 to this Motion.

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Dated: July 23, 2019

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EXHIBIT 1 to Motion for Leave to File Amicus Brief

IN THE CIRCUIT COURT OF THE EIGHTEENTH JUDICIAL CIRCUIT
DUPAGE COUNTY, ILLINOIS
CHANCERY DIVISION

PEOPLE OF THE STATE OF ILLINOIS *ex rel* KWAME RAOUL Attorney General of the State of Illinois, and *ex rel* ROBERT BERLIN, State's Attorney for DuPage County, Illinois *Plaintiffs,*	)	No. 2018 CH 001329 Hon. Paul Fullerton Room 2005
v	)	
STERIGENICS U.S., LLC a Delaware limited liability company, *Defendant.*	)	

AMICUS BRIEF OF JOHN F. CURRAN; JAMES B. DURKIN AND DEANNE M. MAZZOCHI REGARDING THE INTERPRETATION OF SB 1852/Public Act 101-0022, The Matt Haller Act, 415 ILCS 5/9.16

Dated: July 23, 2019

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TABLE OF EXHIBITS

Exhibit	Description
A	Proposed Consent Order submitted by the State of Illinois et al. and Sterigenics U.S. LLC
B	SB1854, reprinted from www.ilga.gov
C	SB1853, Amendment 3, reprinted from www.ilga.gov
D	HB1841 Amendment 1 (relevant excerpts), reprinted from www.ilga.gov
E	HB457, Amendment 4, reprinted from www.ilga.gov
F	SB1852 as-introduced; and as-enrolled, reprinted from www.ilga.gov
G	Report of Air Pollution Testing of an Ethylene Oxide Emission-control System Operated by Sterigenics, US, LLC in Willowbrook, Illinois on September 21, 2018, excerpts. A full copy of the 176 page report is at https://www2.illinois.gov/epa/topics/community-relations/sites/sterigenics/Documents/WBI%20rev1.pdf (last entered 7/19/2019).
H	Annotated excerpts of data from Exhibit G; green text and yellow highlighting added.
I	Collection of reports of Sterigenics non-compliance with legal standards.
J	Statement of Illinois Attorney General's Office reported by Capitol Fax, July 19, 2019.
K	Seal Order, Illinois EPA, dated 2/15/2019
L	Table summarizing USEPA ethylene oxide test results, found at https://www.epa.gov/sites/production/files/2019-03/documents/copy_of_031519_willowbrook_eto_master_data_table_for_web.pdf (last entered 7/19/2019)
M	March 29, 2019 Cancer Incidence Assessment near Sterigenics in Willowbrook, IL 1995-2015 (Abstract). http://www.dph.illinois.gov/sites/default/files/publications/sterigenicswillowbrookcancer-investigation-final.pdf (last entered 7/19/2019).

I. Introduction

On June 21, 2019, SB1852, "The Matt Haller Act," Public Act 101-0022, 415 ILCS 5/9.16, was signed into law. John Curran, the original chief sponsor, is an Illinois State Senator for the 41st Senate district. Jim Durkin is the Minority Leader of the Illinois House of Representatives, representing the 82nd House District. Deanne Mazzochi is an Illinois State Representative for the 47th District. Both were chief co-sponsors for SB 1852 in the House. The Sterigenics facility directly impacts residents in the Curran, Durkin and Mazzochi districts.

On July 18, 2019, this matter came before the Court, including for a proposed Consent Order. (Exhibit A). Counsel for Sterigenics proposed that the Consent Order moots this suit, despite pending intervention motions. The Court acknowledged the new ethylene oxide law. The Illinois Attorney General later made statements about its legislative scope and purpose. Curran, Durkin and Mazzochi submit this *amicus* brief to provide additional background about the law's language and intent that may prove helpful to the Court going forward.

II. Legislative history.

SB1852 was not the first or only ethylene oxide-related bill before the General Assembly:

- In February 2019, Curran introduced SB1854. As-introduced, it banned facilities that had fugitive ethylene oxide emissions "above zero." (Exhibit B, SB1854 at 2, line 10).

- On March 15, 2019, Curran introduced Amendment 3 to SB1853, limiting ethylene oxide use to only medical technology that the Agency determines lacks substitute sterilization technology; and within one-year of the law's effective date, revoked the CAAPP permits of any facility emitting ethylene oxide within one mile of a school, childcare center or residence. (Exhibit C, SB1853 Amend. 3).

- In March 2019, Durkin and Mazzochi cosponsored HB1841 House Amendment 1, with specific findings that "the emission of ethylene oxide may constitute a threat to public health and welfare, depress property values, and diminish quality of life"; called for Agency emergency rulemaking to "ensure that no ethylene oxide is discharged into the atmosphere or water without being given the degree of treatment and control necessary"; and "set the rules to maximize the health and safety of both workers" and "members of the public exposed as a result of ethylene oxide emissions." (Exhibit D, HB1841 Amend. 1 (relevant excerpts), p. 17, l. 6 – 18, l. 17).

- On April 11, 2019, for the Illinois EPA and Attorney General's office, State Representative Sam Yingling authorized filing Amendment 4 to HB 457. (Exhibit E).

During bill negotiations, Illinois EPA representatives indicated that any rules the Agency was inclined to adopt under HB1841 were those generally set forth in HB 457 at proposed paragraphs (b)-(i). (*Compare, e.g.,* Exhibit E, pp. 2-10; with 415 ILCS 5/9.16(b)(1), (c), (d), and (f)).

The legislators argued that the Agency needed better standards than those set forth under, *e.g.,* the Illinois EPA's dispersion modeling approach, including target atmospheric goals no greater than statistical background levels. ***Representatives from the offices of the Illinois EPA, Illinois Attorney General and the Governor refused to accept such language for the final bill.***

Concerned that the Administration's language was insufficiently aggressive, legislative negotiators nevertheless issued an ultimatum: include the subsection (g) "Seal Order" requirements, or they would withdraw their sponsorship and support for the bill. It reads:

> (g) A facility [1] permitted to emit ethylene oxide [2] 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 [3] 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 [4] (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. ... [5] A facility is not subject to the requirements of this subsection if the supporting findings of the seal order ... are found to be without merit by a court of competent jurisdiction.

(*Cf.* Exhibit F, SB1852 (introduced) with SB 1852 (enrolled) (bracketed numbers added)).

This "Seal Order" language was essential given reports alleging that Sterigenics released ethylene oxide into the air despite promises that its equipment adequately captured emissions. For example, the House's Energy and Environment committee (Mazzochi is a member) reviewed a test report from ECSi, Inc. (retained by Sterigenics) on "an ethylene oxide (EtO) emission-control device operated by Sterigenics US, LLC at their Willowbrook I ethylene oxide

sterilization facility," to "control emissions from fourteen sterilizer backvents, and three aeration rooms." (Exhibit G, ECSi report page 1).[1] The report proposed that ethylene oxide was "ND" (not detected) in *any* outlet chromatograms, to yield over 99.5% efficiency; but this was questioned at the House hearing when raw exit data displayed off-kilter baselines, potential ethylene oxide signal, and "unknown" compounds. (*See* Exhibit H, annotated Run 3BV inlet/outlet results). Sterigenics also had a reported history of non-compliance and unauthorized releases. (*See* Exhibit I). This all raised questions about Sterigenics' real-world compliance.

Separately, the legislators also added subsection (k), which provides that "[n]othing in this Section shall be interpreted to excuse the ethylene oxide sterilization source from complying with any applicable local requirements." 415 ILCS 5/9.16(k). Legislators knew that nuisance claims were raised in the above-captioned litigation; and that building modifications would require additional local code compliance. It was purposeful to ***not*** have the statute preempt or moot those common law claims; or local ordinance requirements. It ***was not*** the legislative intent to deny local municipalities Sterigenics nuisance claims; or to prevent municipalities from denying construction permits or enforcing building codes. A more detailed explanation of the legislators' intent and envisioned application about this negotiated language is set forth below.

III. The subsection (g) Seal Order language's legislative intent and goals.

The Illinois Attorney General's Office has asserted that:

> Sterigenics could have qualified for the [subsection g] exception if it proved to a court that the findings of the seal order were without merit. The consent order takes away Sterigenics' ability to even make this argument in court. As a result, Sterigenics no longer has the ability to qualify for the exception to the certification requirements.

[1] This testing "was to demonstrate compliance with the conditions established in Section 6 of the Construction Permit ... granted to Sterigenics by the ... IEPA." (*Id.*) It evaluated inlet and outlet concentrations for a series of samples. But the detection method changed for the inlet ethylene oxide emissions and the outlet system. (*Id.* at report page 7 (FID vs. PID methods)). The report assumed this was an adequate apples-to-apples comparison. (*Id.* at 8-9 (mass control efficiency measurements from inlet/outlet calculated using equation in Section 5.9).

(Exhibit J, Capitol Fax, July 19, 2019). That does not accurately characterize how subsection (g) was designed to work, which is why the proposed consent order perversely makes it easier for Sterigenics to reopen. As noted above, subsection (g) provides that:

> a facility "[1] permitted to emit ethylene oxide [2] that has been subject to a seal order ... **is prohibited** from using ethylene oxide for sterilization or fumigation purposes, **unless** [3] (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** [4] (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**.

This prohibition-presumption provision would not apply only "where the [5] "supporting findings of the seal order... **are found to be without merit by a court of competent jurisdiction**." When SB 1852's language was drafted; discussed in the House's Energy and Environment committee; and ultimately approved, it was known to all parties that on February 15, 2019, the Illinois EPA had issued a Seal Order against the Sterigenics facility in Willowbrook to shut it down. (*See, e.g.,* Exhibit K). Such a facility thus qualifies as a subsection (g) facility, because the Agency previously "[1] permitted [it] to emit ethylene oxide" and it had "[2] been subject to a seal order." This renders Sterigenics "prohibited from using ethylene oxide for sterilization or fumigation purposes." 415 ILCS 5/9.16(g).

A. Only a court can make a "without merit" finding.

The Illinois Attorney General's Office has reportedly asserted that its proposed consent order "takes away" Sterigenics' ability to argue the validity of the original Seal Order. (Exhibit J). That is misleading; the Consent Order proposes to "resolv[e] the legal challenges made by Sterigenics to the findings and assertions set forth in the Seal Order, ***without any admission by Sterigenics as to their veracity***, ... and ***which Sterigenics continues to dispute.***" (Exhibit K, Consent Order at I.C, ¶ 2 (emphasis added)). For Sterigenics to avoid this prohibition, it must

invoke the subsection (g) text following bracket 5 to demonstrate:

> [5] ... the supporting findings of the seal order under Section 34 are ***found to be without merit by a court*** of ***competent jurisdiction***.

The legislative intent behind the subsection (g) language as-enacted was to ensure that a party ever subjected to a Seal Order was excused from the ethylene oxide prohibition absent ***a court*** of competent jurisdiction having "found" that the allegations in the Seal Order were "without merit." The statute does not allow the Agency and litigants to "agree to disagree," or otherwise punt on the merits, as the Attorney General seeks to do in the Consent Order here.

Legislators were well aware that Sterigenics disputed the Seal Order's validity; and that Sterigenics challenged the Illinois EPA's grounds for issuing the Seal Order. However, even assuming that the Seal Order issued on shaky assertions, factual findings within it plainly were meritorious—ethylene oxide testing around the Sterigenics facility witnessed a remarkable drop in ethylene oxide emissions post-shutdown. (*See* Exhibit L (Village Hall readings that repeatedly spiked up to the 4-19 $\mu g/m^3$ range pre-shutdown never exceeded 0.4 $\mu g/m^3$ post-shutdown)). In March 2019, the Illinois Department of Public Health issued a report concluding that its cancer study results "when taken as a whole, indicated that some cancers were elevated in populations living near the Sterigenics facility in Willowbrook, Illinois." (Exhibit M, Report p. 4). ***It is surprising that the Illinois Attorney General implies with its statements that it does not believe it can defend the Seal Order's original findings: that Sterigenics was emitting ethylene oxide at above-ambient levels in a manner that harmed to the surrounding community.*** The Illinois Attorney General need not have all of its evidence in-hand the day the Seal Order issued. Legislators understood that a party issuing, or receiving, a Seal Order may need to later develop evidence as to a given Seal Order's merits. But legislators were not willing to let the Agency (or the Illinois Attorney General, for that matter) have unfettered discretion to revoke or nullify a

Seal Order once one issues to the exclusion of public interest considerations. Ethylene oxide involves heightened public health and safety concerns. Multiple parties may have personal or legal interests impacted by a Seal Order, including members of the public; businesses; and local municipalities. Given these competing interests, it is most appropriate to resolve the scientific merits of a Seal Order's underlying findings by generating evidence through appropriate discovery channels, and/or with the assistance of expert testimony. This is why the statutory language deliberately and intentionally placed the decision on whether the factual justifications for a Seal Order are meritorious within "a court of competent jurisdiction." This gives all sides court access; necessary due process protections; while adequately protecting the public interest.

Ensuring that independent findings are made on the merits of a Seal Order also serves multiple policy goals. First, it ensures that a state agency does not issue a Seal Order lightly; it should be prepared to defend its actions in court with facts, not fiction. Second, it ensures that a litigant subjected to such an Order secures due process rights, including the right to present evidence and witnesses on its behalf. Third, it ensures that anyone else impacted by potentially unsafe ethylene oxide emissions secures a public forum and opportunity to be heard on the merits. Courts can then do what they do best – serve as a neutral arbiter of the facts, and render a decision. Such decisions will, in turn, allow the legislature to ascertain whether more (or less) is needed to achieve its public policy goals of safe air for Illinois residents.

To reiterate: when legislators supported SB 1852, they knew that Sterigenics was the subject of a seal order; and that Sterigenics had challenged the seal order's merits. They were aware that the Seal Order insisted that emissions from Sterigenics "are continuing to contribute to ambient levels of ethylene oxide in the atmosphere" in a way that created "an imminent and substantial endangerment to public health or welfare." (Exhibit K at ¶ 18). They were aware

that, *e.g.*, test results indicated that Sterigenics as it stood was emitting ethylene oxide from the facility into the ambient air; and that those emissions significantly dropped after the seal order was put in place and Sterigenics stopped operations. The legislature heard testimony about the real-world cancer and health impacts attributed to ethylene oxide emitting from the Sterigenics facility, including from the Act's namesake, Matt Haller, who lived nearby; and the ongoing adverse impact that the facility has had on Willowbrook (including driving employees away from other businesses in the area) and surrounding municipalities. To date, no-one has issued findings that pre-shutdown conditions ***did not*** place the public health and welfare in jeopardy. The factual basis for, *e.g.*, the Seal Order's Paragraph 18 allegation have not been shown in this Court to lack merit. Unless and until such findings are made, under subsection (g) Sterigenics remains "prohibited from using ethylene oxide for sterilization or fumigation purposes."

B. The subsection (g) exceptions.

The Illinois Attorney General's statement separately asserts that Sterigenics "***could have*** qualified for the exception" in subsection (g) following brackets 3 and 4 above. (Exhibit J) (emphasis added). It offered no substantive analysis to support this (troubling) blanket assertion. This is perhaps not surprising, because it is utterly premature and unfounded.

Again: Sterigenics in the present day remains prohibited from using ethylene oxide under subsection (g) given the Seal Order, "unless" two additional requirements are satisfied:

> [3] (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**
>
> [4] (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**.

These items were added as part of the compromise negotiations given the terms found in Amendment 3 to SB1853. The only exception to the continued closure and prohibition is limited

to a specific set of circumstances, and ***Sterigenics and the Agency each*** must do their part to ensure that Sterigenics actually (not "could") satisfies both to be legally compliant. That means that first, Sterigenics must "provide a certification to the [Illinois EPA] 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." 415 ILCS 5/9.16(g). Sterigenics nowhere does so in the Consent Order; in its construction permit application; and the Agency has not required it in the proposed Consent Order either. Neither Sterigenics nor the Agency has discretion to waive this statutory requirement; and without a substantive record to consider, the Illinois Attorney General cannot presume Sterigenics can secure any valid certifications. Second, Sterigenics also cannot restart any ethylene oxide use until "(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.***" 415 ILCS 5/9.16(g) (emphasis added). Neither the Attorney General nor the Agency can presume that of the thousands of products Sterigenics might seek to sterilize, the Agency can or will validly confirm that the Sterigenics approach to sterilizing ***each*** product will use "technology that produces the greatest reduction in ethylene oxide emissions currently available." This subsection (g) standard is far more stringent than subsection (b), and requires a separate and independent Agency analysis that, to date, cannot or could be done, let alone published, or otherwise reviewed.

Moreover, the Agency may not assume that Sterigenics "might" be able to comply with these exceptions in the future, particularly where, as here, the Sterigenics construction permit proposed and accompanying modeling necessitates assuming an 87 foot stack height contra to local height restrictions; and other aspects of Sterigenics operations would require new construction permits that it may not obtain as a matter of right from the Village of Willowbrook.

IV. The proposed consent order.

As noted above, it appears to be the position of the presently-named parties in their proposed Consent Order that the merits of the underlying Sterigenics Seal Order need not be resolved; that Sterigenics can reopen in the future without having the health, safety and welfare issues that the Seal Order raised left unvetted by this Court; and that Sterigenics is not prohibited from using ethylene oxide going forward even though neither it nor the Agency have performed the additional certification steps found in subsection (g) (either in the proposed Consent Order or proposed construction permit) as discussed in Section III(B), above. *Amici* submit that this interpretation is inconsistent with the subsection (g) statutory framework and its intent.

The Illinois Attorney General has asserted its consent decree is a "Loophole Closure" that will "eliminate Sterigenics' eligibility for the exception to certification requirements." (Exhibit J). The proposed Consent Order creates, rather than closes, a loophole. The Agency's consent order makes a troubling commitment that, "[n]otwithstanding any other provision in this Consent Order" and "solely at the discretion of the State, the State may approve temporary, limited Operations at Willowbrook I [even if the construction permit is not approved] if the State obtains information identifying a critical need for sterilization of one or more medical devices necessary to protect public health," and states that this decision is "not subject to … review by the Court." (Exhibit A, Consent Order at Section III.B ¶ 7). The legislature did not adopt this new and nebulous "critical need" standard in subsection (g) – it set a standard where the ***only*** exception to Sterigenics' use of ethylene oxide is if Sterigenics suppliers certify ethylene oxide sterilization is the "***only*** available method" to sterilize that product, and the Agency makes independent findings that Sterigenics will sterilize that product using technology yielding "the greatest reduction in ethylene oxide emissions currently available." Nor does subsection (g) shield such decisions from judicial review, as the Consent Order proposes.

Nor can a construction permit to the Agency sidestep these provisions once Sterigenics was subject to a Seal Order, absent a court concluding the Seal Order findings were without merit. Since the proposed Consent Order expressly avoids asking the Court for this finding, no construction permit can or should issue unless and until Sterigenics provides the requisite certifications; ***and*** the Agency separately reviews and certifies for each product that Sterigenics' proposed method will yield the greatest reductions available on a per product basis. This has not been done, and the terms of the Consent Order will not ensure that this is done.[2]

V. Conclusion

The Illinois Legislature acted to address ethylene oxide with highly restrictive sterilization limits, with an eye towards balancing medical product sterilization needs against the devastating effects ethylene oxide has had on district residents, their daily activity, and property. The legislature chose to particularly scrutinize and constrain the permissible activities of entities found to have put public health and safety so at risk that it necessitated issuing a Seal Order—and ensures that this issue cannot be mooted by the Agency and company alone. Given the lengthy and complex legislative record that rests in multiple places and bills; the potential misapplication of the statutory language and requirements in the proposed Consent Order; and that this Court's interpretations will be keenly watched and followed, *Amici* respectfully requests that this Court consider the relevant aspects of the legislative history for The Matt Haller Act in the above-captioned matter set forth above. *Amici* are available to assist the Court on any matter set forth above or other issues relating to legislative intent at the Court's desire and convenience.

[2] It also is doubtful the construction permit complies since it does not capture and control post-sterilization product being loaded into shipping trucks, where off-gassing can continue to occur.

Respectfully submitted:

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July 23, 2019

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Amicus - EXHIBIT A

IN THE CIRCUIT COURT OF THE EIGHTEENTH JUDICIAL CIRCUIT
DUPAGE COUNTY, ILLINOIS
CHANCERY DIVISION

PEOPLE OF THE STATE OF ILLINOIS, *ex rel.* KWAME RAOUL, Attorney General of the State of Illinois, and *ex rel.* ROBERT BERLIN, State's Attorney for DuPage County, Illinois,	)	
Plaintiff,	)	
v.	)	No. 2018 CH 001329
STERIGENICS U.S., LLC, a Delaware limited liability company,	)	
Defendant.	)	

CONSENT ORDER

This matter coming before the Court pursuant to the agreement of the Parties (as defined below): (i) PEOPLE OF THE STATE OF ILLINOIS, *ex rel.* KWAME RAOUL, Attorney General of the State of Illinois, and *ex rel.* ROBERT BERLIN, State's Attorney for DuPage County, Illinois ("Plaintiff"), and the ILLINOIS ENVIRONMENTAL PROTECTION AGENCY ("Illinois EPA" and together with Plaintiff, the "State"), and (ii) Defendant, STERIGENICS U.S., LLC ("Sterigenics" or "Defendant"); the Court having jurisdiction over the State and Defendant (collectively, the "Parties") and the subject matter herein; the Parties being represented in open court or having waived appearance; the Court having reviewed the First Amended Complaint for Injunctive Relief and Civil Penalties filed on June 6, 2019 ("Complaint"); the Parties having agreed to the making of this Consent Order and submitting it to this Court for approval; and the Court otherwise being fully advised in the premises; the Court enters this Consent Order and orders the specified relief.

I. INTRODUCTION

This stipulation of facts is made and agreed upon for purposes of settlement only and as a factual basis for the Court's entry of the Consent Order and issuance of any injunctive relief. It is the intent of the Parties to this Consent Order that it be a final judgment on the merits of this matter.

A. Stipulated Facts.

1. Since at least January 30, 2006, Sterigenics has been and is a Delaware limited liability company duly authorized to transact business in the State of Illinois.

2. Since at least January 30, 2006 to present, Sterigenics has operated an ethylene oxide gas ("EtO") commercial sterilization enterprise.

3. From at least January 30, 2006, Sterigenics conducted EtO sterilization at two facilities located in Willowbrook, Illinois, in DuPage County. The first facility is located at 7775 South Quincy Street in Willowbrook ("Willowbrook I"), and the second facility is located at 830 Midway Street in Willowbrook ("Willowbrook II," and together with Willowbrook I, the "Site").

4. On June 8, 2015, Illinois EPA issued Clean Air Act Program Permit (CAAPP) No. 95120085 to Sterigenics, which permit remains in effect as of the date of this Consent Order.

5. On October 30, 2018, Plaintiff filed the original complaint, which was amended on June 6, 2019. The Complaint alleges that Sterigenics, through its emissions of EtO, (a) caused, threatened or allowed air pollution in violation of Section 9(a) of the Illinois Environmental Protection Act ("Act"), 415 ILCS 5/9(a) (2016), and Section 201.141 of the Pollution Control Board ("Board") Air Pollution Regulations, 35 Ill. Adm. Code 201.141; and (b) created and maintained a common law public nuisance.

6. On February 15, 2019, John Kim, Acting Director of Illinois EPA, issued a Seal Order pursuant to 415 ILCS 5/34(b) that sealed "[a]ll storage containers of ethylene oxide" at the

Site (the "Seal Order").

7. On February 18, 2019, Sterigenics challenged the Seal Order by filing an action in the United States District Court for the Northern District of Illinois, styled as *Sterigenics U.S., LLC v. Kim et al.*, Case No. 19-cv-1219 (U.S. Dist. Ct., N.D. Ill.) ("Federal Litigation"), which the District Court dismissed on May 3, 2019. On May 6, 2019, Sterigenics filed an action in the Circuit Court for DuPage County, *Sterigenics U.S., LLC v. Kim et al.*, Case No. 2019CH000566 (Cir. Ct., DuPage County) (the "State Seal Order Litigation"). In both the Federal Litigation and the State Seal Order Litigation, Sterigenics named Acting Director Kim and Illinois EPA as defendants.

8. Public Act 101-0022 took effect on June 21, 2019, and such Public Act applies to Willowbrook I and II. Defendant has stated its intention to comply with Public Act 101-0022 and acknowledges its obligation to do so.

B. Allegations of Non-Compliance

Plaintiff contends that Defendant has violated the following provisions of the Act, Board regulations and the common law:

Count I: Air Pollution in violation of Section 9(a) of the Act, 415 ILCS 5/9(a) (2016), and Section 201.141 of the Pollution Control Board Air Pollution Regulations, 35 Ill. Adm. Code 201.141.

Count II: Common Law Public Nuisance.

C. Non-Admission of Violations

1. Defendant represents that it has entered into this Consent Order for the purpose of settling and compromising disputed claims without having to incur the expense of contested litigation. By entering into this Consent Order and complying with its terms, Defendant does not admit the allegations of violation within the Complaint referenced above, and Defendant's compliance with this Consent Order shall not be interpreted as including any such admission.

Defendant specifically denies the alleged violations in the Complaint and states that it is agreeing to this Consent Order to avoid the cost of litigation and further disruption of its operations. Except as expressly set forth in Paragraph II.1, this Consent Order shall not be used in any other proceeding.

2. The Parties agree that by entering into this Consent Order, they are resolving the legal challenges made by Sterigenics to the findings and assertions set forth in the Seal Order, without any admission by Sterigenics as to their veracity, reliability or admissibility in other legal proceedings, and which Sterigenics continues to dispute. The Parties further agree that the Seal Order does not represent a final determination of any fact or legal conclusion by a court of law or the Illinois Pollution Control Board under 415 ILCS 5/34(b) or (d) and is not an adjudication of wrongdoing. The Parties further agree that by entering this Consent Order, the Court makes no determination as to the merits of the supporting findings of the Seal Order.

D. Duty to Cooperate

The Parties shall cooperate with each other in the implementation of this Consent Order.

II. APPLICABILITY

1. This Consent Order shall apply to and be binding upon the Parties to the Consent Order. Defendant waives as a defense to any enforcement action taken pursuant to this Consent Order the failure of any of its officers, directors, managers, members, agents, employees or successors or assigns to take such action as shall be required to comply with the provisions of this Consent Order. Plaintiff may use this Consent Order against Defendant in any subsequent enforcement action or permit proceeding as provided by Sections 39 and 42 of the Act, 415 ILCS 5/39 and 42 (2018).

2. Defendant shall notify each contractor to be retained to perform work required in

this Consent Order of each of the requirements of this Consent Order relevant to the activities to be performed by that contractor, including all relevant work schedules and reporting deadlines, and shall provide a copy of this Consent Order to each contractor already retained no later than 30 calendar days after the date of entry of this Consent Order. In addition, Defendant shall provide copies of all schedules for implementation of the provisions of this Consent Order to the prime vendor(s) supplying the control technology systems and other equipment required by this Consent Order.

3. No change in ownership, corporate status or operator of the Site shall in any way alter the responsibilities of Defendant under this Consent Order. In the event that Defendant proposes to sell or transfer any real property or operations subject to this Consent Order, Defendant shall notify Plaintiff 30 calendar days prior to the conveyance of title, ownership or other interest, including a leasehold interest in the Site or a portion thereof. Defendant shall make as a condition of any such sale or transfer, that the purchaser or successor provide to Defendant Site access and all cooperation necessary for Defendant to perform to completion any compliance obligation(s) required by this Consent Order. Defendant shall provide a copy of this Consent Order to any such successor in interest and Defendant shall continue to be bound by and remain liable for performance of all obligations under this Consent Order. In appropriate circumstances, however, Defendant and such proposed purchaser or operator of the Site may jointly request, and Plaintiff, in its discretion, may consider modification of this Consent Order to obligate such proposed purchaser or operator to carry out future requirements of this Consent Order in place of, or in addition to, Defendant. This provision does not relieve Defendant from compliance with any regulatory requirement regarding notice and transfer of applicable permits.

III. JUDGMENT ORDER

This Court has jurisdiction of the subject matter herein and of the Parties to the Consent Order and, having considered the stipulated facts and being advised in the premises, finds the following relief appropriate:

IT IS HEREBY ORDERED, ADJUDGED AND DECREED:

A. Beneficial Project(s)

1. Within 60 days of entry of this Consent Order, Defendant shall propose to Plaintiff, for its review and approval, one or more projects ("Project(s)") designed to benefit the environment in the State of Illinois, preferably in the Village of Willowbrook or neighboring communities of DuPage County. The Project(s) may include physical improvements or activities, such as educational scholarships or programming. Defendant may either perform the Project(s) or fund the Project(s) in whole or in part. Defendant shall contribute $300,000.00 towards the Project(s). The Project(s) shall neither displace any other source of funding for the fund, program, or project, nor fund any activity that Defendant is required by law to conduct or for which, as of the date of entry of the Consent Order, the Defendant has committed funds. Within 30 days of entry of this Consent Order, Defendant shall deposit the $300,000.00 for the Project(s) with an escrow agent approved by the Plaintiff, with instructions approved by the Plaintiff that disbursements shall be made only for Projects approved by Plaintiff under this Section III.A and only upon the joint direction of Plaintiff and Defendant.

2. Defendant's proposal shall include an implementation schedule, which shall be subject to the review and approval of Plaintiff.

3. Upon approval of Plaintiff, Defendant shall implement the Project(s) in accordance with the approved schedule.

4. Defendant shall complete the Project(s) no later than one year from entry of the Consent Order, unless an extended schedule is otherwise agreed to in writing by Plaintiff.

5. Within 30 days after the completion of the Project(s), the Defendant shall submit a Project(s) completion report, including a summary of all expenditures, to the contact persons identified in Section III.I of this Consent Order for review and confirmation that the Project(s) was performed pursuant to this Consent Order.

6. Within 30 days of the determination that any approved Project cannot be completed or the summary of expenditures for the approved Projects do not total the amount in Section III.A.1, above, Defendant shall propose one or more additional Projects designed to benefit the environment in the State of Illinois, preferably in the Village of Willowbrook or neighboring communities of DuPage County following the procedures above in Section III.A.2-5.

B. Stipulated Penalties, Interest and Default

1. If Defendant fails to complete any activity or fails to comply with any response or reporting requirement by the date specified in this Consent Order, Defendant shall provide notice to Plaintiff of each failure to comply with this Consent Order and shall pay stipulated penalties in the amount of $400 per day per violation for up to the first 15 days of violation, $500 per day per violation for the next 15 days of violation, and $1,000 per day per violation thereafter until such time that compliance is achieved. Plaintiff may make a demand for stipulated penalties upon Defendant for its noncompliance with this Consent Order. However, failure by Plaintiff to make this demand shall not relieve Defendant of the obligation to pay stipulated penalties. All stipulated penalties shall be payable within 30 calendar days of the date Defendant knows or should have known of its noncompliance with any provision of this Consent Order.

2. If Defendant fails to make any payment required by this Consent Order on or before

the date upon which the payment is due, Defendant shall be in default and the remaining unpaid balance of the penalty, plus any accrued interest, shall be due and owing immediately. In the event of default, Plaintiff shall be entitled to reasonable costs of collection, including reasonable attorney's fees.

3. Pursuant to Section 42(g) of the Act, interest shall accrue on any penalty amount owed by Defendant not paid within the time prescribed herein. Interest on unpaid penalties shall begin to accrue from the date such are due and continue to accrue to the date full payment is received. Where partial payment is made on any penalty amount that is due, such partial payment shall be first applied to any interest on unpaid penalties then owing.

4. The stipulated penalties shall be enforceable by Plaintiff. Nothing herein shall preclude Plaintiff from seeking remedies or sanctions arising from the failure to comply with this Consent Order, other than additional civil penalties under the Act.

C. Stipulated Penalty and Interest Payment Procedures

1. All payments required by Section III.B of this Consent Order shall be made by certified check or money order payable to Illinois EPA for deposit into the Environmental Protection Trust Fund. Payments shall be sent by first class mail and delivered to:

Illinois Environmental Protection Agency
Fiscal Services
1021 North Grand Avenue East
P.O. Box 19276
Springfield, IL 62794-9276

2. The case name and case number shall appear on the face of the certified check or money order. A copy of the certified check or money order and any transmittal letter shall be sent to:

Daniel Rottenberg
Assistant Attorney General

Environmental Bureau
Illinois Attorney General's Office
69 W. Washington Street, Suite 1800
Chicago, Illinois 60602

D. Future Compliance

1. ***Prohibition on Operations at Willowbrook I.*** Subject to Paragraph III.D.7 (Emergency Temporary Operations) herein, Defendant shall not conduct any EtO sterilization operations (hereinafter "Operations") at Willowbrook I until Defendant has satisfied the requirements, and obtained the written approval, specified in Paragraph III.D.4(a) (Conditions Precedent to Restarting Operations at Willowbrook I). Upon Defendant's restart of Operations at Willowbrook I in accordance with the terms of this Consent Order, Defendant shall continue to comply with the terms of this Consent Order.

2. ***Construction Permit for Additional Capture and Control Measures at Willowbrook I.*** On June 24, 2019, Defendant submitted to Illinois EPA a construction permit application, requesting the issuance of a construction permit containing additional capture and control measures at Willowbrook I (the "Construction Permit"). Defendant addressed or included at least the following in its construction permit application for Willowbrook I:

a. Air dispersion modeling demonstrating that the planned modifications at Willowbrook I will be sufficient to ensure that the maximum long-term average modeled concentrations of EtO in micrograms per cubic meter ($\mu g/m^3$) attributable to any future Operations at Willowbrook I will be at or below a level satisfactory to the Illinois EPA. The air dispersion modeling shall not include background EtO;

b. A description of the installation of the additional capture and control measures at Willowbrook I, including (i) permanent total enclosure providing 100% capture in accordance with U.S. Environmental Protection Agency Method 204 of all areas

containing EtO (namely, processed product shipping areas, processed product storage areas, chamber areas and chamber work aisles) (aeration rooms, which are already under negative pressure, shall be included within the permanent total enclosure) ("PTE") and (ii) an overall control efficiency of 99.9% based on total mass of EtO measured at the inlet and the exhaust of the control system or 0.2 parts per million at the exhaust of the control system ("Required Control Efficiency");

c. A description of the air emission controls necessary to comply with the Required Control Efficiency;

d. A description of the routing of the existing Chemrox DEOXX packed tower chemical scrubber that currently exhausts through its own stack at Willowbrook I into the two-stage Advanced Air Technologies Safe Cell emission control system and dry bed reactor for additional treatment of the vacuum pump/chamber emissions;

e. A proposed annual EtO usage limit;

f. A proposed annual emissions limit;

g. A description regarding the elimination of the stack currently associated with the DEOXX scrubber;

h. A description with supporting technical information of the height to which the remaining stack will be raised to eliminate building-induced adverse effects of downwash; and

i. A description of continuous emissions monitoring to continuously measure EtO utilizing an enhanced FTIR following PS-15 or such other method approved by Illinois EPA.

3. ***Additional Plan Submissions to Illinois EPA.*** No later than 30 days after the date

of entry of this Consent Order:

a. Defendant shall have submitted to Illinois EPA, for review and approval as set forth in Paragraph III.D.8, a protocol ("Stack Test Protocol") for emissions testing of the control system at Willowbrook I to demonstrate compliance with the Required Control Efficiency ("Stack Testing"). The Stack Test Protocol shall include, at a minimum:

i. A requirement that Defendant submit a written notification of the expected date of the Stack Testing;

ii. A description of the specific procedures for the Stack Testing, which shall be representative of actual Operations and includes agreed-upon operating conditions and addresses the full cycle of the batch sterilization process commencing with the introduction of EtO from the sterilization chambers into the control system (first evacuation of chamber) and concluding when sterilized materials have been in the aeration room for at least one hour. Such procedures shall also include:

aa. The person(s) who will be performing sampling and analysis and their experience with similar stack tests;

bb. The specific conditions under which testing will be performed, including a discussion of why these conditions will be representative and the means by which the operating parameters for the emission unit(s) and any control equipment will be determined;

cc. The specific determinations of emissions and operations which are intended to be made, including sampling and monitoring locations;

dd. The test method(s) that will be used, including the specific U.S. Environmental Protection Agency-approved analytical and sampling technique if the specified test method can be used with different analytical and sampling techniques; and

ee. Any changes in standard methodology proposed to accommodate the specific circumstances of testing, with justification;

iii. A requirement that at least 5 business days prior to the actual date of the Stack Testing, Defendant shall submit to Illinois EPA a written notification of the actual date and expected time of the Stack Testing;

iv. A proposed schedule that provides Stack Testing will occur within 14 days after Defendant's restart of Operations at Willowbrook I; and

v. A requirement that as soon as practicable but no later than 30 days after the date of the Stack Testing, Defendant shall submit to Illinois EPA, for review and approval as set forth in Paragraph III.D.8, a report of the results of such testing (the "Stack Test Results Report"). The Stack Test Results Report shall include, at a minimum:

aa. A summary of results;

bb. A detailed description of the test method(s), including a description of sample points, sampling train, analysis equipment and test schedule;

cc. A detailed description of test conditions, including process information and control equipment information, *e.g.*, equipment condition and operating parameters during testing; and

dd. Data and calculations, including copies of all raw data sheets, and records of laboratory analyses, sample calculations and data on equipment calibration.

b. Defendant shall have submitted to Illinois EPA, for review and approval as set forth in Paragraph III.D.8, an ambient air monitoring plan ("Air Monitoring Plan") that includes, at a minimum:

i. a detailed description of the process for collecting and analyzing air samples for EtO at various locations near the Site and in the community every third day over a 30-day period while the Site is in operation;

ii. a schedule for implementation that includes a commencement date for ambient air monitoring not later than 14 days of the date of Illinois EPA's written approval of the Stack Test Results Report, provided, however, in the event that Willowbrook I is not in

operation, Defendant shall propose an alternative start date to Illinois EPA for its approval; and

iii. A requirement that as soon as practicable but no later than 30 days after the date of the collection of the air samples pursuant to the approved Air Monitoring Plan, Defendant shall submit to Illinois EPA, for review and approval as set forth in Paragraph III.D.8, a report of the results of such testing (the "Air Monitoring Results Report"). The Air Monitoring Results Report shall include, at a minimum:

aa. A summary of results;

bb. A description of the test method(s), including a description of sample locations; and

cc. Wind and weather information for the sampling period.

4. ***Conditions Precedent to Restarting Operations at Willowbrook I.***

a. Construction Completion Report.

i. Prior to Defendant's restart of Operations at Willowbrook I, Defendant shall have submitted to the State, for review and approval as set forth in Paragraph III.D.8, a report (the "Construction Completion Report") which includes, at a minimum:

aa. A detailed description of Defendant's compliance with the Construction Permit issued by Illinois EPA;

bb. The dates of Illinois EPA's written approval of the (i) Stack Test Protocol and (ii) Air Monitoring Plan; and

cc. A certification of Defendant's demonstration of 100% capture of all areas containing EtO in accordance with U.S. Environmental Protection Agency Method 204 ("PTE Demonstration").

ii. The State's approval of the Construction Completion Report shall be conditioned upon Defendant's compliance with the Illinois EPA-issued Construction Permit, Illinois EPA's approval, in writing, of the Stack Test Protocol and Air Monitoring Plan and Defendant's certification of the PTE Demonstration. If such conditions are met, the State shall provide written approval of the Construction Completion Report to Defendant.

5. ***Cessation of Operations Upon Test Failure.*** If the Stack Testing demonstrates that the Required Control Efficiency is not being met, without any further order of Court, Defendant shall immediately cease Operations at Willowbrook I until (a) measures are in place that ensure the Required Control Efficiency is met and (b) the State approves such measures in writing.

6. ***Best Management Practices ("BMPs").*** Following Defendant's restart of Operations at Willowbrook I, Defendant shall implement and maintain the following BMPs:

a. Reduce the Lower Explosive Limit ("LEL") trigger for opening sterilization chambers to remove product from 25% to 5% of the LEL;

b. Minimize the generation of EtO emissions within the facility, including:

i. when emptying sterilization chambers of product, remove and immediately transport pallets directly to an aeration room, and in no event shall pallets be staged in the aisle before transporting to an aeration room; and

ii. maximize, to the extent practicable, the duration that a product remains in an aeration room before removal, consistent with approvals by the U.S. Food and Drug Administration and customer shipping demands for each particular product;

c. Monitor and manage the dry bed reactor media;

d. Review and update the BMPs identified in Paragraphs 6(a)-(c) at Willowbrook I on an annual basis; and

e. Keep a record, in writing, at Willowbrook I of all of the BMPs identified in Paragraphs 6(a)-(c) for up to 3 years, which record shall be made available for review by Illinois EPA upon request.

7. ***Emergency Temporary Operations.*** Notwithstanding any other provision in this Consent Order, and solely at the discretion of the State, the State may approve temporary, limited Operations at Willowbrook I if the State obtains information identifying a critical need for sterilization of one or more medical devices necessary to protect public health. The State's approval of temporary limited Operations, if granted under this paragraph, will be in writing and will include specific parameters that will govern such Operations. Defendant's operations under this paragraph shall comply with the terms and conditions in the State's written approval. Defendant acknowledges and agrees that the decision to approve temporary, limited re-opening under this provision is not subject to Dispute Resolution under Section III.H or review by the Court.

8. ***Review Process for Defendant's Submittals Required Under This Consent Order.*** With respect to each of the plans and reports that Defendant submits to Illinois EPA or the State, as applicable, under this Consent Order, the following review process shall apply:

a Illinois EPA's review and approval of any of Defendant's submissions shall be in consultation with Plaintiff.

b. For submissions subject to review and approval by the State, the State shall provide a single, joint response accepting, accepting with conditions, or rejecting each such submission.

c. If any plan or report is accepted with conditions or rejected, within 10 business days after the date of the written notice of such acceptance with conditions or rejection, Defendant shall submit a revised plan or report to Illinois EPA or the State, as applicable, that addresses all of the identified conditions or deficiencies.

d. Upon issuance of a written approval of any plan or report, Defendant shall implement such plan or report in accordance with its approved terms and schedule.

e. Illinois EPA and the State, as applicable, shall make every effort to expedite review of Defendant's submittals with a goal of providing a written response within 30 days of receipt of each submittal. If Illinois EPA or the State, as applicable, is unable to provide a response within 30 days of receipt, Defendant shall be notified that additional time for review is required and shall provide the reason why additional time is necessary. Following such notification, Illinois EPA or the State, as applicable, shall have no more than 15 days to complete the review. Defendant may seek relief from the Court to the extent the process of reviewing and approving any submittal has become unreasonably delayed beyond the additional time requested for review. Notwithstanding anything herein to the

contrary, the provisions set forth in the Act regarding permit applications, including any required deadlines, govern Illinois EPA's review of the construction permit application described in Paragraph III.D.2. In addition to the foregoing, Illinois EPA or the State, as applicable, shall not unreasonably withhold its written approval of a submission made by Defendant under this Consent Order.

9. ***Prohibition on Operations at Willowbrook II.*** Defendant shall not conduct Operations at Willowbrook II unless and until: (a) it receives a final, effective construction permit from Illinois EPA; (b) the Parties amend this Consent Order by attaching that final, effective construction permit to this Consent Order; and (c) the Court enters such amendment. The Parties' intent is for any resumption of Operations at Willowbrook II to adhere to a similar process to that which is required for resumption of Operations of Willowbrook I and include an enforceable schedule, recognizing, however, that the modifications that will be made to Willowbrook II prior to any resumption of Operations are likely to differ in scope and in kind. The Parties agree that the construction permit application must include, at a minimum:

a. A schedule for Defendant's submission of a construction permit application for Willowbrook II, and a list of items that must be set forth in such application, including, without limitation, 100% capture and an overall control efficiency of 99.9% based on total mass of EtO measured at the inlet and the exhaust of the control system or 0.2 parts per million at the exhaust of the control system;

b. A schedule for Defendant's submission of a stack test protocol and ambient air monitoring plan for Willowbrook II, and a list of items that must be included in such protocol and plan;

c. The conditions precedent to Defendant's restart of Operations at

Willowbrook II, including the requirement that Defendant shall submit to the State for approval a Construction Completion Report and receive approval from the State prior to the resumption of Operations at Willowbrook II;

d. The cessation of Operations at Willowbrook II if the stack testing at Willowbrook II demonstrates that the Required Control Efficiency is not being met; and

e. A list of the best management practices at Willowbrook II.

10. ***Operating Permit Renewal.*** The terms and conditions of any Construction Permit(s) issued by Illinois EPA shall be included in the facility's operating permit renewal application for the Site.

11. Illinois EPA, its employees and representatives, shall have the right of entry into and upon Defendant's Site which is the subject of this Consent Order, at all reasonable times for the purposes of conducting inspections and evaluating compliance status. In conducting such inspections, Illinois EPA, its employees and representatives, may take photographs, collect samples and collect information, as they deem necessary. Defendant shall have the opportunity to assert that any such photographs or information collected from the Site be handled as trade secrets or confidential business information. Defendant shall be permitted to retain a copy of any documents collected from the Site. The Attorney General, his employees and representatives, and the DuPage County State's Attorney, his employees and representatives, may attend any inspection of the Site with Illinois EPA.

12. This Consent Order in no way affects the responsibilities of Defendant to comply with any other federal, state or local laws or regulations, including but not limited to the Act and the Board regulations.

13. Defendant shall (a) comply with the Illinois EPA-issued Construction Permit, and

(b) cease and desist from future violations of the Act and Board regulations that were the subject matter of the Complaint.

E. Complete Agreement

This Consent Order constitutes the final, complete, and exclusive agreement and understanding among the Parties with respect to the settlement embodied in this Consent Order and supersedes all prior agreements and understandings, whether oral or written, concerning the settlement embodied herein. Other than reports or other documents that are subsequently submitted and approved pursuant to this Consent Order, the Parties acknowledge that there are no representations, agreements or understandings relating to the settlement other than those expressly contained in this Consent Order.

F. *Force Majeure*

1. *Force majeure* is an event arising solely beyond the control of Defendant, which prevents the timely performance of any of the requirements of this Consent Order and shall include, but is not limited to, events such as floods, fires, tornadoes, other natural disasters, and labor disputes beyond the reasonable control of Defendant. An increase in costs associated with implementing any requirement of this Consent Order shall not, by itself, excuse Defendant for a failure to comply with such a requirement.

2. When a *force majeure* event occurs which causes or may cause a delay in the performance of any of the requirements of this Consent Order, Defendant shall orally notify Illinois EPA (James Morgan at 217.524.1376) within 48 hours of obtaining knowledge of the occurrence. Written notice shall be given to Plaintiff's representatives as listed in Section III.I of this Consent Order as soon as practicable, but no later than 10 calendar days after the claimed occurrence. This

section shall be of no effect as to the particular event involved if Defendant fails to comply with these notice requirements.

3. Within 10 calendar days of receipt of any written *force majeure* notice, Plaintiff shall respond in writing regarding Defendant's claim of a delay or impediment to performance. If Plaintiff agrees that the delay or impediment to performance has been or will be caused by circumstances beyond the control of Defendant and that Defendant could not have prevented the delay by the exercise of due diligence, the Parties shall stipulate to an extension of the required deadline(s) for all requirement(s) affected by the delay, by a period equivalent to the delay actually caused by such circumstances. Such stipulation may be filed as a modification to this Consent Order. Defendant shall not be liable for stipulated penalties for the period of any such stipulated extension.

4. If Plaintiff does not accept Defendant's claim of a *force majeure* event, the Defendant must file a petition with the Court within 20 calendar days of receipt of Plaintiff's determination in order to contest the imposition of stipulated penalties. Plaintiff shall have 20 calendar days to file its response to said petition. The burden of proof of establishing that a *force majeure* event prevented the timely performance shall be upon Defendant. If this Court determines that the delay or impediment to performance has been or will be caused by circumstances solely beyond the control of Defendant and that Defendant could not have prevented the delay by the exercise of due diligence, Defendant shall be excused as to that event (including any imposition of stipulated penalties), for all requirements affected by the delay, for a period of time equivalent to the delay or such other period as may be determined by this Court.

G. Enforcement and Modification of Consent Order

1. This Consent Order is a binding and enforceable order of this Court. This Court

shall retain jurisdiction of this matter and shall consider any motion by any Party for the purposes of interpreting and enforcing the terms and conditions of this Consent Order. The Parties agree that notice of any subsequent proceeding to enforce this Consent Order may be made by certified mail, and waive any requirement of service of process.

2. The Parties to the Consent Order may, by mutual written consent, extend any compliance dates or modify the terms of this Consent Order without leave of this Court (except relating to any restart of Operations at Willowbrook II in accordance with Paragraph III.D.9). A request for any modification shall be made in writing and submitted to the representatives designated in Section III.I of this Consent Order. Any such request shall be made by separate document, and shall not be submitted within any other report or submittal required by this Consent Order. Any such agreed modification shall be in writing and signed by authorized representatives of each party, for filing and incorporation by reference into this Consent Order.

H. Dispute Resolution

1. Except as provided herein, the Parties to the Consent Order may seek to informally resolve disputes arising under this Consent Order, including but not limited to Illinois EPA's or the State's decision regarding appropriate or necessary response activity, approval or denial of any report, plan or other submission, or Plaintiff's rejection of a request for modification or termination of the Consent Order. Plaintiff reserves the right to seek enforcement by the Court where Defendant has failed to satisfy any compliance deadline within this Consent Order. The following are also not subject to the dispute resolution procedures provided by this section: a claim of *force majeure*, a failure to make any required payment and any circumstances posing a substantial danger to the environment or to the public health or welfare of persons.

2. The dispute resolution procedure must be invoked by a Party through a written

notice describing the nature of the dispute and the party's position with regard to such dispute. The other Party shall acknowledge receipt of the notice and schedule a meeting to discuss the dispute informally not later than 14 calendar days from the receipt of such notice. These informal negotiations shall be concluded within 30 calendar days from the date of the first meeting between the Parties, unless the Parties agree, in writing, to shorten or extend this period. The invocation of dispute resolution, in and of itself, shall not excuse compliance with any requirement, obligation or deadline contained herein, and stipulated penalties may be assessed for failure or noncompliance during the period of dispute resolution; provided, however, while stipulated penalties may continue to accrue during any dispute resolution period, such stipulated penalties need not be paid until 30 days after the dispute is resolved. As part of the resolution of any dispute, the Parties to the Consent Order, by agreement or by order of this Court, may extend or modify the schedule for completion of work under this Consent Order to account for the delay in the work that occurred as a result of dispute resolution.

3. In the event that the Parties are unable to reach agreement during the informal negotiation period, Plaintiff shall provide Defendant with a written summary of its position regarding the dispute. The position advanced by Plaintiff shall be considered binding unless, within 20 calendar days of Defendant's receipt of the written summary of Plaintiff's position, Defendant files a petition with this Court seeking judicial resolution of the dispute. Plaintiff shall respond to the petition by filing the administrative record of the dispute and any argument responsive to the petition within 20 calendar days of service of Defendant's petition. The administrative record of the dispute shall include the written notice of the dispute, any responsive submittals, Plaintiff's written summary of its position, Defendant's petition before the Court and Plaintiff's response to

the petition. Plaintiff's position shall be affirmed unless, based upon the administrative record, it is against the manifest weight of the evidence.

I. Notice and Submittals

Except for payments, the submittal of any notice, reports or other documents required under this Consent Order, shall be delivered to the following designated representatives:

FOR PLAINTIFF
Daniel Rottenberg
Stephen Sylvester
Assistant Attorneys General, Environmental Bureau
Office of the Illinois Attorney General
69 W. Washington Street, 18th floor
Chicago, Illinois 60602
Phone: (312)814-3816/2087
Fax: (312)814-2347
drottenberg@atg.state.il.us
ssylvester@atg.state.il.us

Lisa A. Smith
Assistant State's Attorney
DuPage County State's Attorney
503 N. County Farm Road
Wheaton, IL 60137
Lisa.smith@dupageco.org

FOR ILLINOIS EPA
James Morgan
Deputy General Counsel, Division of Legal Counsel
Illinois Environmental Protection Agency
P.O. Box 19276
1021 North Grand Avenue East
Springfield, IL 62794-9276
James.morgan@Illinois.gov

Kevin Mattison
Compliance Section, Des Plaines (3rd Floor)
Illinois Environmental Protection Agency
9511 Harrison Street
Des Plaines, IL 60016
Kevin.Mattison@illinois.gov
(one hard copy of each submittal, and email copy)

Compliance Section #40
Bureau of Air
Illinois Environmental Protection Agency
1021 North Grand Avenue East
P.O. Box 19276
Springfield, IL 62794
kent.mohr@illinois.gov
(one hard copy of each submittal, and email copy)

FOR DEFENDANT
Sterigenics U.S., LLC
Attn: President, Vice President Environmental Health and Safety, and General Counsel
2015 Spring Road, Suite 650
Oak Brook, IL 60523

Byron F. Taylor
Sidley Austin LLP
1 S. Dearborn
Chicago, IL 60603

J. Release Provisions

1. ***Seal Order Release.*** Within 2 business days of the entry of this Consent Order, Illinois EPA shall remove the Seal Order. Upon removal of the Seal Order by Illinois EPA, (a) Defendant releases, waives and forever discharges the State, and any agent, officer, or employee thereof, from all actions, claims, causes of actions and demands for any costs, attorney's fees, damages or other relief that Defendant asserted in the Federal Litigation and the State Seal Order Litigation or could have asserted to challenge the Seal Order, including without limitation claims for damages based on the issuance of the Seal Order, as of the date the Court enters this Consent

Order, and (b) within 2 business days of Illinois EPA's removal of the Seal Order, the Parties shall file a joint stipulation of dismissal of the State Seal Order Litigation with prejudice.

2. ***Complaint Release.***

a. Upon written confirmation of the escrow agent's receipt of the escrow funds required under Section III.A. of this Consent Order, the State releases, waives and forever discharges Defendant from any monetary penalties or other monetary payments for alleged violations of the Act, Board regulations and common law that were the subject matter of the Complaint or that could have been asserted as of the date the Court enters this Consent Order based on the facts asserted in the Complaint.

b. Upon the earlier to occur of (i) Illinois EPA's written approval of the Construction Completion Report or (ii) any termination of this Consent Order pursuant to Section III.K. below, the State releases, waives and forever discharges Defendant from any and all further injunctive relief or any other liabilities, subject to Paragraph III.J.2.a above, for the alleged violations of the Act, Board regulations and common law that were the subject matter of the Complaint or that could have been asserted as of the date the Court enters this Consent Order based on the facts asserted in the Complaint.

c. Plaintiff reserves, and this Consent Order is without prejudice to, all rights of the State against Defendant with respect to all other matters, including but not limited to the following:

i. criminal liability;

ii. liability for future violations;

iii. liability for natural resources damage arising out of the alleged violations; and

iv. Defendant's failure to satisfy the requirements of this Consent Order.

Nothing in this Consent Order is intended as a waiver, discharge, release, or covenant not to sue for any claim or cause of action, administrative or judicial, civil or criminal, past or future, in law or in equity, which the State may have against any person, as defined by Section 3.315 of the Act, 415 ILCS 5/3.315, other than Defendant.

K. Termination

1. ***Continued Operations.***

a. Defendant may request that this Consent Order terminate no sooner than 5 years after Defendant has completed all actions required of Defendant in the Consent Order, provided that Defendant has been in compliance with the terms of the Consent Order for the 5 years preceding the request. Any such request must be made by notice to Plaintiff and include a statement that Defendant has completed all actions required by this Consent Order and has been in compliance with the terms of the Consent Order for the 5 years preceding the request and the following certification by a responsible corporate official of Defendant:

> I certify under penalty of law that this statement was prepared under my direction or supervision, and that the information submitted in or accompanying this statement of final compliance is to the best of my knowledge true, accurate and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and or imprisonment for knowing violations.

b. Plaintiff shall notify Defendant of its decision on the request within 45 calendar days of Plaintiff's receipt of the request. If Plaintiff agrees to terminate this Consent Order, Plaintiff and Defendant shall jointly file a notice with the Court that the

Consent Order is terminated. If Plaintiff does not agree to terminate this Consent Order, Plaintiff shall provide Defendant written notification stating the reasons why this Consent Order should not be terminated and Defendant may then invoke the Dispute Resolution provisions. The Consent Order shall remain in effect pending resolution of any dispute by the Parties or the Court concerning whether Defendant has completed its obligations under this Consent Order and is in compliance with the terms of the Consent Order.

2. ***Permanent Cessation of Operations.***

If Defendant permanently ceases Operations at either Willowbrook I and/or Willowbrook II, including surrendering its Illinois EPA-issued permits relating to such Operations, the Parties shall jointly file a request that the Consent Order be terminated, solely as to the facility ceasing Operations, pursuant to the provisions of Paragraph III.K.1., except that Defendant need not comply with the 5-year time requirement as to the affected facility ceasing Operations.

3. The provisions of Paragraph III.D.13 and Section III.J (Release Provisions) of this Consent Order shall survive and shall not be subject to and are not affected by the termination of any other provision of this Consent Order.

L. Execution and Entry of Consent Order

This Consent Order shall become effective only when executed by all Parties to the Consent Order and the Court. This Consent Order may be executed by the Parties in one or more counterparts, all of which taken together shall constitute one and the same instrument. The undersigned representatives for each Party certify that they are fully authorized by the Party whom they represent to enter into the terms and conditions of this Consent Order and to legally bind them to it.

[Remainder of Page Blank; Text Continues on Page 30]

WHEREFORE, the Parties, by their representatives, enter into this Consent Order and submit it to this Court that it may be approved and entered.

AGREED:

PEOPLE OF THE STATE OF ILLINOIS
ex rel. KWAME RAOUL, Attorney General
of the State of Illinois,

MATTHEW J. DUNN, Chief
Environmental Enforcement/Asbestos Litigation Division

By: Elizabeth Wallace
Elizabeth Wallace, Chief
Environmental Bureau
Assistant Attorney General

Date: 7/16/19

PEOPLE OF THE STATE OF ILLINOIS
ex. rel. ROBERT B. BERLIN, State's Attorney
for DuPage County, Illinois

BY:_____
Lisa Smith
Assistant State's Attorney

Date:_____

ILLINOIS ENVIRONMENTAL
PROTECTION AGENCY

JOHN J. KIM, Director
Illinois Environmental Protection Agency

BY: _____
DANA VETTERHOFFER
Acting Chief Legal Counsel

DATE: _____

WHEREFORE, the Parties, by their representatives, enter into this Consent Order and submit it to this Court that it may be approved and entered.

AGREED:

PEOPLE OF THE STATE OF ILLINOIS
ex rel. KWAME RAOUL, Attorney General
of the State of Illinois,

MATTHEW J. DUNN, Chief
Environmental Enforcement/Asbestos Litigation Division

By: _____
Elizabeth Wallace, Chief
Environmental Bureau
Assistant Attorney General

Date: _____

PEOPLE OF THE STATE OF ILLINOIS
ex. rel. ROBERT B. BERLIN, State's Attorney
for DuPage County, Illinois

BY: Lisa Smith
Lisa Smith
Assistant State's Attorney

Date: July 16, 2019

ILLINOIS ENVIRONMENTAL
PROTECTION AGENCY

JOHN J. KIM, Director
Illinois Environmental Protection Agency

BY: _____
DANA VETTERHOFFER
Acting Chief Legal Counsel

DATE: _____

WHEREFORE, the Parties, by their representatives, enter into this Consent Order and submit it to this Court that it may be approved and entered.

AGREED:

PEOPLE OF THE STATE OF ILLINOIS
ex rel. KWAME RAOUL, Attorney General
of the State of Illinois,

MATTHEW J. DUNN, Chief
Environmental Enforcement/Asbestos Litigation Division

By: _____
Elizabeth Wallace, Chief
Environmental Bureau
Assistant Attorney General

Date: _____

PEOPLE OF THE STATE OF ILLINOIS
ex. rel. ROBERT B. BERLIN, State's Attorney
for DuPage County, Illinois

BY: _____
Lisa Smith
Assistant State's Attorney

Date: _____

ILLINOIS ENVIRONMENTAL
PROTECTION AGENCY

JOHN J. KIM, Director
Illinois Environmental Protection Agency

BY: Dana Vetterhoffer
DANA VETTERHOFFER
Acting Chief Legal Counsel

DATE: 7-16-19

FOR DEFENDANT STERIGENICS U.S., LLC

BY: _____

Philip W. Macnabb
President of Sterigenics U.S., LLC

DATE: 16 July 2019

ENTERED: _____
JUDGE

DATED: _____

SB1854

Amicus-Exhibit B

LRB101 09540 CPF 54638 b

101ST GENERAL ASSEMBLY

State of Illinois

2019 and 2020

SB1854

Introduced 2/15/2019, by Sen. John F. Curran

SYNOPSIS AS INTRODUCED:

415 ILCS 5/9.16 new

Amends the Environmental Protection Act. Provides that beginning on the effective date of the amendatory Act no facility shall have fugitive emissions of ethylene oxide above zero. Provides that each facility shall be subject to regular and frequent inspections and testing to ensure that no fugitive emissions of ethylene oxide exist. Provides that inspections shall be unannounced and conducted by a third party chosen by the municipality in which the facility operates. Provides that each facility shall be subject to fence line ambient air testing, at random, once within every 90 to 120 days for a duration of 24-hour samples of no less than 6 consecutive days. Provides that the testing shall be conducted by a third party chosen by the municipality in which the facility operates. Defines "fugitive emissions". Effective immediately.

LRB101 09540 CPF 54638 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 adding Section 9.16 as follows:

(415 ILCS 5/9.16 new)

Sec. 9.16. Fugitive emissions of ethylene oxide ban.

(a) Beginning on the effective date of this amendatory Act of the 101st General Assembly, no facility shall have fugitive emissions of ethylene oxide above zero.

(b) Each facility shall be subject to regular and frequent inspections and testing to ensure that no fugitive emissions of ethylene oxide exist. Inspections shall be unannounced and conducted by a third party chosen by the municipality in which the facility operates.

(c) Each facility shall be subject to fence line ambient air testing, at random, once within every 90 to 120 days for a duration of 24-hour samples of no less than 6 consecutive days. Testing shall be conducted by a third party chosen by the municipality in which the facility operates.

(d) For purposes of this Section, "fugitive emissions" means those emissions which could not reasonably pass through a stack, chimney, vent, or other functionally-equivalent

opening.

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

Amicus - EXHIBIT C

Sen. John F. Curran

Filed: 3/15/2019

AMENDMENT TO SENATE BILL 1853

AMENDMENT NO. _____. Amend Senate Bill 1853 by replacing everything after the enacting clause with the following:

"Section 5. The Environmental Protection Act is amended by changing Section 39.5 and by adding Section 9.16 as follows:

(415 ILCS 5/9.16 new)

Sec. 9.16. Legislative findings; ethylene oxide emission standards; restrictions; notice for facilities.

(a) The General Assembly finds that the emission of ethylene oxide constitutes a threat to public health and welfare, depresses property values, and diminishes quality of life. It is the purpose of this Section to restore, maintain, and enhance the purity of the air of this State in order to protect health, welfare, and quality of life and to ensure that no air contaminants are discharged into the atmosphere without being given the necessary degree of treatment and control. The

General Assembly also finds that the protection of public health requires that proper sterilization of medical technology is allowed in Illinois, and it is the policy of the State to properly address these responsibilities.

(b) The Agency shall immediately reevaluate emissions standards and regulations for ethylene oxide and adopt new emissions standards and related regulations in accordance with the modern understanding of the properties of ethylene oxide. The Agency shall submit new regulations and emissions standards for ethylene oxide to the Board within 60 days of the effective date of this amendatory Act of the 101st General Assembly. The Agency shall immediately adopt new emission standards and regulations that shall achieve, at minimum, the following:

(1) Limit the use of ethylene oxide resulting in emissions high enough to require permitting under the Clean Air Act Permit Program established under Section 39.5 to the sterilization of medical technology or other medically necessary purposes. The use of ethylene oxide that requires permitting under the Clean Air Act Permit Program for any non-medical purpose shall not be allowed.

(2) Account for both short-term and long-term exposure to ethylene oxide.

(3) Maximize the health and safety of (i) workers who are exposed to ethylene oxide as a result of employment and (ii) members of the public exposed as a result of emissions.

(4) Protect the public health against both known and suspected health risks. If the Agency determines the risk associated with different exposure levels is uncertain, the emissions standards and regulations shall be designed to protect the public health against potential risks.

(5) Regulate and account for the emissions of ethylene oxide from all sources due to the actions of a permit holder, including, but not limited to, ventilation, unintentional emissions from facilities, and off-gassing of sterilized products.

(6) Set an annual limitation on the total pounds of ethylene oxide emitted by a facility.

(c) Any medical use of ethylene oxide that can be replaced by a substitute sterilization technology that does not use ethylene oxide shall be prohibited on or after January 1, 2022. If the Agency determines, based on the best scientific evidence and federal regulatory guidance, that there is no substitute sterilization technology available for sterilizing a particular medical product, then ethylene oxide may be used for that medical product. Cost shall not be considered in this determination. If the Agency determines there is a substitute sterilization technology for a particular medical product, then the Agency shall prohibit all use of ethylene oxide for that medical product.

(1) A determination of whether a substitute sterilization technology exists shall be based upon a

review of the products for which CAAPP permit applicants have applied to use ethylene oxide. The Agency may consider factors such as whether a potential substitute sterilization technology adequately sterilizes a medical product, whether that technology is able to do so without damaging the product, and whether federal law and regulations allow for a particular medical product to be sterilized without ethylene oxide.

(2) The Agency may issue regulations, emissions standards, or permit conditions that state which medical products or classes of medical products have substitute sterilization technologies.

(3) If the Agency determines a substitute sterilization technology exists for every use of ethylene oxide, the Agency shall prohibit all uses of ethylene oxide.

(4) For purposes of this subsection, "substitute sterilization technology" means a method of sterilization for a particular medical product that does not use ethylene oxide and is capable of sterilizing that medical product.

(d) The use of ethylene oxide for purposes other than sterilization of medical technology is impermissible and constitutes a violation of this Act if emitted at least 30 days following the effective date of this amendatory Act of the 101st General Assembly. The Agency shall immediately notify all Clean Air Act Permit Program permit holders permitted to use

ethylene oxide of this deadline.

(e) No Clean Air Act Permit Program permit shall be renewed if the Agency finds that the facility is emitting ethylene oxide at a level that violates any federal or State standards pertaining to ethylene oxide.

(f) Notwithstanding any other provision of this Section, the use of ethylene oxide that does not result in emissions high enough to require permitting under the Clean Air Act Permit Program it is not prohibited by this Section. Ethylene oxide may be used for purposes other than sterilization if it does not cause emissions of ethylene oxide to be released at levels that require a permit. The Agency may issue regulations regarding the use of ethylene oxide that does not cause emissions.

(g) Within 30 days of the approval by the Board of new regulations for ethylene oxide in accordance with subsection (b), the Agency shall reopen and modify all CAAPP permits which allow the use of ethylene oxide under paragraphs (a) and (f) of subsection 15 of Section 39.5 of this Act.

(h) Notwithstanding any other provision of this Act, a hospital licensed under the Hospital Licensing Act or operated under the University of Illinois Hospital Act shall be allowed at least 12 months and a maximum of 36 months from the effective date of this amendatory Act of the 101st General Assembly to discontinue any use of ethylene oxide for the sterilization of medical products.

(i) Within one year of the effective date of this amendatory Act of the 101st General Assembly, the Agency shall revoke the CAAPP permit of any facility emitting ethylene oxide within one mile of a school, child care center, or residence.

(415 ILCS 5/39.5) (from Ch. 111 1/2, par. 1039.5)

Sec. 39.5. Clean Air Act Permit Program.

1. Definitions. For purposes of this Section:

"Administrative permit amendment" means a permit revision subject to subsection 13 of this Section.

"Affected source for acid deposition" means a source that includes one or more affected units under Title IV of the Clean Air Act.

"Affected States" for purposes of formal distribution of a draft CAAPP permit to other States for comments prior to issuance, means all States:

(1) Whose air quality may be affected by the source covered by the draft permit and that are contiguous to Illinois; or

(2) That are within 50 miles of the source.

"Affected unit for acid deposition" shall have the meaning given to the term "affected unit" in the regulations promulgated under Title IV of the Clean Air Act.

"Applicable Clean Air Act requirement" means all of the following as they apply to emissions units in a source (including regulations that have been promulgated or approved

Amicus - EXHIBIT D

LRB101 05734 CPF 58782 a

Rep. Jim Durkin

Filed: 3/29/2019

AMENDMENT TO HOUSE BILL 1841

AMENDMENT NO. _____. Amend House Bill 1841 by replacing everything after the enacting clause with the following:

"Section 1. This Act may be referred to as the Matt Haller Act.

Section 5. The Illinois Administrative Procedure Act is amended by changing Section 5-45 as follows:

(5 ILCS 100/5-45) (from Ch. 127, par. 1005-45)

Sec. 5-45. Emergency rulemaking.

(a) "Emergency" means the existence of any situation that any agency finds reasonably constitutes a threat to the public interest, safety, or welfare.

(b) If any agency finds that an emergency exists that requires adoption of a rule upon fewer days than is required by Section 5-40 and states in writing its reasons for that

finding, the agency may adopt an emergency rule without prior notice or hearing upon filing a notice of emergency rulemaking with the Secretary of State under Section 5-70. The notice shall include the text of the emergency rule and shall be published in the Illinois Register. Consent orders or other court orders adopting settlements negotiated by an agency may be adopted under this Section. Subject to applicable constitutional or statutory provisions, an emergency rule becomes effective immediately upon filing under Section 5-65 or at a stated date less than 10 days thereafter. The agency's finding and a statement of the specific reasons for the finding shall be filed with the rule. The agency shall take reasonable and appropriate measures to make emergency rules known to the persons who may be affected by them.

(c) An emergency rule may be effective for a period of not longer than 150 days, but the agency's authority to adopt an identical rule under Section 5-40 is not precluded. No emergency rule may be adopted more than once in any 24-month period, except that this limitation on the number of emergency rules that may be adopted in a 24-month period does not apply to (i) emergency rules that make additions to and deletions from the Drug Manual under Section 5-5.16 of the Illinois Public Aid Code or the generic drug formulary under Section 3.14 of the Illinois Food, Drug and Cosmetic Act, (ii) emergency rules adopted by the Pollution Control Board before July 1, 1997 to implement portions of the Livestock Management

implementation of the provisions of this amendatory Act of the 100th General Assembly, emergency rules implementing the Illinois Underground Natural Gas Storage Safety Act may be adopted in accordance with this subsection by the Department of Natural Resources. The adoption of emergency rules authorized by this subsection is deemed to be necessary for the public interest, safety, and welfare.

(ff) In order to provide for the expeditious and timely implementation of the provisions of this amendatory Act of the 101st General Assembly, emergency rules may be adopted by the Department of Labor in accordance with this subsection (ff) to implement the changes made by this amendatory Act of the 101st General Assembly to the Minimum Wage Law. The adoption of emergency rules authorized by this subsection (ff) is deemed to be necessary for the public interest, safety, and welfare.

(gg) In order to provide for the expeditious and timely implementation of the previsions of this amendatory Act of the 101st General Assembly, emergency rules may be adopted by the Pollution Control Board in accordance with this subsection (gg) to implement the provisions of this amendatory Act of the 101st General Assembly. The adoption of emergency rules authorized by this subsection is deemed to be necessary for the public interest, safety, and welfare.

(Source: P.A. 100-23, eff. 7-6-17; 100-554, eff. 11-16-17; 100-581, eff. 3-12-18; 100-587, Article 95, Section 95-5, eff. 6-4-18; 100-587, Article 110, Section 110-5, eff. 6-4-18;

100-864, eff. 8-14-18; 100-1172, eff. 1-4-19; 101-1, eff. 2-19-19.)

Section 10. The Environmental Protection Act is amended by changing Section 39.5 and by adding Section 9.16 as follows:

(415 ILCS 5/9.16 new)

Sec. 9.16. Emissions standards, rules, and notice for facilities emitting ethylene oxide.

(a) The General Assembly finds that the emission of ethylene oxide may constitute a threat to public health and welfare, depress property values, and diminish quality of life. The purpose of this Section is to maintain and enhance the quality of the air of this State in order to protect health, welfare, and quality of life and to ensure that no ethylene oxide is discharged into the atmosphere or water without being given the degree of treatment or control necessary.

(b) The Agency shall immediately reevaluate rules for ethylene oxide use as a sterilant or fumigant and adopt new rules in accordance with the most recently issued scientific understanding of ethylene oxide based on reports, findings, and statements on the health impacts of ethylene oxide produced by the USEPA, United States Food and Drug Administration, the United States Center for Disease Control, the Agency for Toxic Substances and Disease Registry, the National Institute for Occupational Safety and Health, and any other State or federal

agency that publishes materials on ethylene oxide. The Agency shall submit new rules for ethylene oxide use as a sterilant or fumigant to the Board within 90 days after the effective date of this amendatory Act of the 101st General Assembly.

(1) When determining rules for ethylene oxide use as a sterilant or fumigant, the Agency shall:

(A) measure, or have measured, what the current ambient levels of ethylene oxide are in the air throughout the state, this measurement shall take into account different land uses throughout the State;

(B) account for both short-term and long-term exposure to ethylene oxide;

(C) set the rules to maximize the health and safety of both workers who are exposed to ethylene oxide as a result of employment and members of the public exposed as a result of ethylene oxide emissions; and

(D) consider both the extent to which passive offgassing may occur at a facility permitted to emit ethylene oxide and the environmental controls that are necessary to control passive offgassing.

(2) 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:

(A) the nearest school or park is at least 10 miles from the permit applicant in counties with populations

greater than 50,000;

(B) 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

(C) 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:

(i) the State Representative for the representative district that the facility is located in;

(ii) the State Senator for the legislative district that the facility is located in;

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

(iv) the local municipal board members and executives.

(3) If any entity or any parent or subsidiary of an entity that owns or operates a facility permitted 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.

Any entity or any parent or subsidiary of an entity that owns or operates a facility permitted to emit ethylene oxide that has any property right in any intellectual 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.

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

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

(B) The date each patent was filed.

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

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

(c) The Agency shall not renew an air pollution operating permit if the Agency finds that the facility is emitting ethylene oxide at a level that violates any federal or State standards pertaining to ethylene oxide, or if the Agency otherwise finds the facility to be operating in violation of this Act. If the nonrenewal of the air pollution operating permit is upheld, any corrections shall be completed within 90 days of an entry of a final order. If the Agency determines that nonrenewal of the permit shall be reversed, the Agency shall renew the air pollution operating permit within 90 days.

(d) Within 30 days after the approval by the Board of new rules for ethylene oxide use as a sterilant or fumigant in accordance with paragraph (1) of subsection (b), the Agency shall reopen and modify all CAAPP permits that allow the use of ethylene oxide under paragraph c-5 of subsection 15 of Section 39.5. If the Agency reopens and modifies a CAAPP permit under this subsection, the facility shall be allowed no more than 6 months from the date of the modification to comply with the terms of the modified permit.

(e) Upon the Agency's receipt, or the provision to the Agency by the Department of Public Health or the Governor, of information in any form from any State or federal agency related to elevated emissions of ethylene oxide, an update of emissions standards for ethylene oxide, or increased instances of adverse public health effects related to emissions of ethylene oxide that are discovered by a State or federal

agency, the Agency shall within 7 days provide written notice of that information, either by mail or electronically, to every hospital, school district, and unit of local government within 5 miles of the emitting facility. The Agency and the Department of Public Health shall also post the notice on their respective websites and the Agency shall notify the Attorney General, the State Representative for the representative district that the facility is located in, the State Senator for the legislative district that the facility is located in, all members of the county board for the county in which the facility is located in, and the local municipal board members and executives, of the information.

The notice required under this subsection shall substantially comply with the standards set forth in the Crisis and Emergency Risk Communication manual published by the Centers for Disease Control and Prevention.

(f) The Agency, or its designee, shall test ambient levels of ethylene oxide within one mile of each facility permitted to emit ethylene oxide under paragraph c-5 of subsection 15 of Section 39.5 at least once per 12-month period. If a facility permitted to emit ethylene oxide is known or anticipated to cease ethylene oxide emissions, the Agency shall measure the ambient ethylene oxide levels within one mile of such a facility.

(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 the facility can provide a certification 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. The certification shall be made by a company representative with knowledge of the sterilization requirements of the product.

A facility shall not be subject to the requirements of this subsection if the Agency has certified that the facility's emission control system is using technology that produces the greatest reduction in ethylene oxide emissions currently available, or if the supporting findings of the seal order under Section 34 are found to be without merit by a court of competent jurisdiction.

(h) The Pollution Control Board may adopt emergency rules necessary to implement the provisions of this amendatory Act of the 101st General Assembly under subsection (qq) of Section 5-45 of the Illinois Administration Procedure Act.

(i) Nothing in this Section shall apply to a hospital licensed under the Hospital Licensing Act or operated under the University of Illinois Hospital Act.

(j) Nothing in this Section shall be construed to limit the ability of a facility to appeal a decision as provided in this Act.

(415 ILCS 5/39.5) (from Ch. 111 1/2, par. 1039.5)

Sec. 39.5. Clean Air Act Permit Program.

1. Definitions. For purposes of this Section:

"Administrative permit amendment" means a permit revision subject to subsection 13 of this Section.

"Affected source for acid deposition" means a source that includes one or more affected units under Title IV of the Clean Air Act.

"Affected States" for purposes of formal distribution of a draft CAAPP permit to other States for comments prior to issuance, means all States:

(1) Whose air quality may be affected by the source covered by the draft permit and that are contiguous to Illinois; or

(2) That are within 50 miles of the source.

"Affected unit for acid deposition" shall have the meaning given to the term "affected unit" in the regulations promulgated under Title IV of the Clean Air Act.

"Applicable Clean Air Act requirement" means all of the following as they apply to emissions units in a source (including regulations that have been promulgated or approved by USEPA pursuant to the Clean Air Act which directly impose requirements upon a source and other such federal requirements which have been adopted by the Board. These may include requirements and regulations which have future effective compliance dates. Requirements and regulations will be exempt

and the Clean Air Act. Any such proceeding shall be conducted pursuant to the Board's procedures for adjudicatory hearings and the Board shall render its decision within 120 days of the filing of the petition. The Agency shall take final action to revoke and reissue a CAAPP permit consistent with the Board's order.

c. Proceedings regarding a reopened CAAPP permit shall follow the same procedures as apply to initial permit issuance and shall affect only those parts of the permit for which cause to reopen exists.

c-5. A CAAPP permit issued prior to December 1, 2018 and allowing for the use of ethylene oxide may be reopened and revised, and shall not be subject to either process in paragraphs b or c. Within 15 days of the Agency's modification of a permit under this paragraph, the Agency shall submit the permit to the Board for review. The permit shall be effective until the Board votes to approve or reject the modifications.

d. Reopenings under paragraph (a) of this subsection shall not be initiated before a notice of such intent is provided to the CAAPP source by the Agency at least 30 days in advance of the date that the permit is to be reopened, except that the Agency may provide a shorter time period in the case of an emergency.

e. The Agency shall have the authority to adopt procedural rules, in accordance with the Illinois

Amicus - EXHIBIT E

LRB10103567AMC59682a

Rep. Sam Yingling

Filed: 4/11/2019

AMENDMENT TO HOUSE BILL 457

AMENDMENT NO. _____. Amend House Bill 457 by replacing everything after the enacting clause with the following:

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

(415 ILCS 5/9.16 new)

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.

"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 person or persons who will be performing sampling and analysis and their 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 such time as 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) The Agency shall accept, accept with conditions, or decline to accept 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, within 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. The Ambient Air Monitoring Plan shall include, at a minimum, 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) and a schedule for implementation.

(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 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.

(2) 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) 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.

(h) 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. Within 30 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.

(i) 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.

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

SB1852 Amicus - EXHIBIT F LRB101 09550 CPF 54648 b

101ST GENERAL ASSEMBLY

State of Illinois

2019 and 2020

SB1852

Introduced 2/15/2019, by Sen. John F. Curran

SYNOPSIS AS INTRODUCED:

415 ILCS 5/9.16 new

Amends the Environmental Protection Act. Provides that in the event of an ethylene oxide leak a facility shall issue a notice to all affected property owners and local government within 2,500 feet of the leak site. Effective immediately.

LRB101 09550 CPF 54648 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 adding Section 9.16 as follows:

(415 ILCS 5/9.16 new)

Sec. 9.16. Notice for facilities emitting ethylene oxide.

(a) Any facility that self-reports an ethylene oxide leak or is found to be in violation concerning an ethylene oxide leak shall issue a notice to all affected property owners and units of local government within 2,500 feet of the leak site. The notice system shall be funded by the facility. The notice shall, at a minimum, contain the following information:

(1) the name and address of the site or facility where the leak occurred or is suspected to have occurred;

(2) the identification and approximate amount of the contaminant leaked or suspected to have been leaked;

(3) information as to whether the contaminant was leaked or suspected to have been leaked into the air, land, or water;

(4) a brief description of the potential adverse health effects posed by the contaminant;

(5) the name, business address, and phone number of

persons at the Agency from whom additional information about the leak or suspected leak can be obtained; and

(6) the name, business address, and phone number of persons at the Department of Public Health from whom additional information about the health effects of the leak or suspected leak can be obtained.

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

AN ACT concerning safety.

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

Section 1. Short Title. This Act may be referred to as the Matt Haller Act.

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

(415 ILCS 5/9.16 new)

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.

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

Amicus - EXHIBIT G

REPORT OF AIR POLLUTION SOURCE TESTING OF AN ETHYLENE OXIDE EMISSION-CONTROL SYSTEM OPERATED BY STERIGENICS, US, LLC IN WILLOWBROOK, ILLINOIS ON SEPTEMBER 21, 2018

WILLOWBROOK I FACILITY

Submitted to:

ILLINOIS ENVIRONMENTAL PROTECTION AGENCY
1021 North Grand Avenue East
Springfield, Illinois 62794

Submitted by:

STERIGENICS US, LLC.
2015 Spring Road
Oak Brook, Illinois 60523

I.D. Number 043110AAC

Prepared by:

ECSI, INC.
PO Box 1498
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Revision 1

OCTOBER 30, 2018

ECSi

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TEST DATE

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1.0 INTRODUCTION

Revision 1 was completed at the request of USEPA and IEPA. Revisions made to the report include:

- Report address changed on page i for General Manager Paul Krett to reflect Willowbrook I facility address.
- Conversion made from wet ppm to dry ppm formula added to Section 5.9.
- Section 8.0 Test Results show efficiency changed from ≥99.6179 to ≥99.6132%.
- Tables 1 and 2: Added columns to show dry ppm conversion values for inlet and outlet concentrations
- Tables 1 and 2: Included moisture/temperature calculation averages for each run.
- Tables 1 and 2: Mass Flow values were previously calculated in lbs./second and labeled lbs./minute. Edit made to show values in lbs./minute.

On Friday, September 21, 2018, ECSi, Inc. performed air pollution source testing of an ethylene oxide (EtO) emission-control device operated by Sterigenics US, LLC at their Willowbrook I ethylene oxide sterilization facility located at 7775 Quincy Street. The control device tested was a two-stage Advanced Air Technologies (AAT) Safe Cell emission-control system, comprised of a packed-tower chemical scrubber and a dry-bed reactor, used to control emissions from fourteen sterilizer backvents, and three aeration rooms.

The purpose of the testing program was to demonstrate compliance with the conditions established in Section 6 of the Construction Permit (Application No: 18060020) granted to Sterigenics by the Illinois Environmental Protection Agency (IEPA) to control emissions from the sterilization chamber backvents. See Appendix L.

Test Protocols were submitted and approved by IEPA prior to testing. Copies of protocols and approval are included with Appendix L.

Representatives from Sterigenics were present during the testing as well as personnel listed below:

- Kevin Mattison, IEPA
- Ned Shappley, US EPA, OAQPS
- Margaret Sieffert, US EPA, Region 5
- Paul Farber, PE (Consultant for Village of Willowbrook)
- Lawrence Link, Tri-State Fire Department

4.0 TESTING

EtO source testing was conducted in accordance with the procedures outlined in US EPA Reference Methods 2, 3, 4 and 18. EtO emissions monitoring was conducted simultaneously at the inlet and outlet of the AAT System during the 15-minute duration of the backvent process. Three 15-minute test runs were performed.

4.1 TEST SCENARIO

Once a sterilization chamber cycle ends, a sample from inside the chamber is taken and measured to ensure the EtO concentrations are below 25% of the lower explosive limit (LEL) for safety reasons. Current controls interlocks will not allow the doors to be open if the concentration of EtO at the end of a cycle exceeds 25% LEL. Once this criterion has been met, the process requires the chamber door to be partially opened for 15 minutes which vents the EtO in the chamber to reduce levels in the chamber and exposure to employees. The 15-minute duration ensures the highest concentration of EtO is removed from the chamber prior to unloading the product. During this venting, EtO exhausts through the backvent and to the AAT scrubber. In accordance with the facility's procedures, workers are not allowed to enter or unload the chamber until the 15-minute time period has passed. Once the 15-minutes has passed, the product is unloaded to the aeration room.

To meet Condition 6 of the Construction Permit which requires conditions for testing to be conducted as representative of maximum emissions, each test run was completed on the backvents using freshly sterilized product from one chamber for a 15-minute duration, for a total of three test runs at each facility. The emission testing of the sterilization chambers occurred while running FDA validated cycles with higher ending EtO concentrations for testing. Each test interval tested the first 15 minutes the backvent is opened and exhausted to the AAT scrubber.

4.2 PROCESS PARAMETERS MONITORED

Based on the overall AAT scrubber liquor storage volume, relatively short duration of the test, and knowledge of the operation of the AAT system, the properties of the AAT scrubber liquor were not expected to change significantly during the test. Because of this, the AAT Scrubber tank level, pH, and

5.0 TEST METHOD REFERENCE

5.1 INTRODUCTION

EtO source testing was performed in accordance with US EPA Reference Methods 1, 2, 3, 4 and 18. EtO emissions monitoring was conducted simultaneously at the inlet and outlet of the AAT System during each 15-minute duration of the backvent process. A total of three test runs was performed.

During backvent testing, EtO emissions at the inlet and the outlet of the AAT Safe Cell System were determined using direct source sample injection into the gas chromatograph (GC). The GC used to analyze EtO concentrations was a SRI Model 8610 (also described in Section 5.3).

US EPA Method 1: Sample and Velocity Traverses for Stationary Sources (40 CFR 60 Appendix A)

Sample ports and flow traverse locations were located at the inlet and outlet of the AAT control device. Numbers of flow traverse locations were selected to exceed those recommended by Tables 1.1 and 1.2, and were spaced throughout the duct in accordance with Method 1. The average angle of cyclonic flow at each traverse point was less than the maximum average angle specified in Method 1. For further information on sample port locations, sample and velocity traverses, and cyclonic flow measurements please see Appendix B.

US EPA Method 2: Determination of Stack Gas Velocity and Volumetric Flow Rate (Type S Pitot Tube) (40 CFR 60 Appendix A).

The average gas velocity in a stack is determined from the gas density and from measurement of the average velocity head with a Type S (Stausscheibe or reverse type) Pitot tube. This method was used in its entirety as per the procedures outlined in Method 2.

ESCI performed a cyclonic flow check and velocity traverse using an S-type Pitot tube in each duct prior to the first test run. These results were used to calculate EtO mass flow rates. ESCI also used a standard Pitot tube constructed in accordance with Method 2C to measure velocity at a single point in the duct during the test runs to verify that gas flow rate remained steady during tests.

US EPA Method 3: Gas Analysis for the Determination of Dry Molecular Weight (40 CFR 60 Appendix A)

The Construction permit at 6(b) specifies testing using Method 3A or 3B (for calculating the dry molecular weight of the duct gases based on measurement of the duct gas oxygen and carbon dioxide concentrations). In accordance with Method 2, Section 8.6 and the approved Test Protocol, a dry molecular weight of 29.0 was assumed instead of by calculation. This is in accordance with Method 2 and is allowed by Method 3 because the process does not involve combustion and emits essentially ambient air.

US EPA Method 4: Determination of Moisture Content in Stack Gases (40 CFR 60 Appendix A)

The moisture concentrations in the duct gases were calculated assuming saturated conditions based on the measured gas temperature, duct static pressure and barometric pressure, in accordance with Method 4(16.4). For calculations pertaining to this method, see Appendix D.

- Barometric pressure was determined using local meteorological data from the time and date of the actual testing. See Appendix F.

- Duct static pressure was determined using an inclined oil manometer.

- Duct gas temperature was determined using from a type K thermocouple and thermometer.

US EPA Method 18: Measurement of Gaseous Organic Compound Emissions by Gas Chromatography

The major organic component of the gas mixture, EtO is separated by gas chromatography (GC). Measurement of EtO concentrations across the inlet/outlet ducts are expected to be uniform due to extensive air mixing throughout the emission control system. During backvent operations, constituents of the streams entering and exiting the AAT System were analyzed at a single point by an SRI, Model 8610, portable GC, equipped with the following: dual, heated sample loops and injectors; dual columns; and dual detectors. A flame ionization detector (FID) was used to quantify inlet EtO emissions, and photoionization detector (PID) was used to quantify low-level EtO emissions at the emission control system outlet. The PID was equipped with a 11.7eV lamp. For chromatographic data associated with the use of this method, see Appendix E. The sample transport system is described in Section 5.4 of this report.

Samples were continuously extracted and analyzed at approximately one- to two-minute intervals, for a total of 12 to 13 samples, during each 15-minute test run.

5.2 VOLUMETRIC FLOW MEASUREMENT

Exhaust gas flow at the inlet and outlet of the AAT scrubber was determined by Method 2, using an S-type pitot tube and an inclined-oil manometer. Sampling ports were located in accordance with Method 1. The test ports were located far enough from any flow disturbances and velocity was measured at multiple points within the duct cross-section to permit accurate flow measurement. Equal-area traverse points for pre-test velocity traverses were selected in accordance with Method 1. Confirmation of the absence of cyclonic flow occurred prior to the commencement of the three test runs. Please see Appendices B and F for additional Method 1 related information.

Because of the short duration of the backvent operation, traversing the entire stack during each minute of test run was infeasible. With approval of IEPA and US EPA, an average differential pressure point was determined before the test, and that parameter was used to confirm flow during each minute while concentration samples were collected. Please see Appendix F for tables of this information collected in the field.

Temperature measurements were obtained from a type K thermocouple (FLIR EA10) and thermometer attached to the sampling probe. Exhaust gas composition was assumed to be air saturated with water vapor.

5.3 CONTROL EFFICIENCY AND MASS EMISSIONS MEASUREMENT

During backvent operations, constituents of the streams entering and exiting the AAT System were analyzed by an SRI, Model 8610, portable gas chromatograph (GC), equipped with the following: dual, heated sample loops and injectors; dual columns; and dual detectors. A flame ionization detector (FID) was used to quantify inlet EtO emissions, and photoionization detector (PID) was used to quantify low-level EtO emissions at the emission control system outlet. The PID was equipped with an 11.7eV lamp. The mass of EtO in the inlet and outlet streams were determined using equation shown below in Section 5.9. EtO mass control efficiency during the backvent process was calculated by comparing the mass of EtO

vented to the system inlet to the mass of EtO vented from the system outlet. See equation shown in Section 5.9.

5.4 SAMPLE TRANSPORT

The Willowbrook I facility utilizes a dual stage AAT system equipped with a 15,500 cfm rated blower system that serves to quickly draw process emissions from the sources through the control system. The AAT Scrubber system efficiency operates at a very high level in large part due to the use of sulfuric acid in the scrubber liquor, which lowers the pH of the solution and acts as a catalyst - increasing the speed of the hydrolysis of ethylene oxide to ethylene glycol.

The gas sample was continuously pumped to the GC at approximately 1000 cubic centimeters per minute (cc/min) from the sample probe through two 100-foot lengths of heated and insulated 3/8" Teflon® sample line (.030 wall), each with an interior volume of approximately 1535 cubic centimeters. The source gas was pumped to the GC with a response time of approximately 1.5 seconds. See Appendix H for sample line volume and residence time calculations.

The lines were heated to ≥ 110 °C. Temperature of the heated lines was monitored before, during and after each trial run via observing the temperature on the heated lines temperature controller. See Appendix A for this data. The sample probe was constructed of stainless steel tubing and was not heated.

At the inlet of the Safe Cell System, the sampling ports were located in the duct immediately upstream of the packed tower scrubber. At the outlet of the AAT System, sampling ports were located in the exhaust stack downstream of the dry bed reactors. See Appendix B for sampling port location information.

5.5 GC INJECTION

Source-gas samples were then injected into the GC which was equipped with two heated sampling loops, each containing a volume of approximately 2 cubic centimeters (cc) and maintained at 100 degrees Celsius (°C). Injections occurred at approximately one to two-minute intervals during backvent testing. Helium was the carrier gas for both the FID and the PID.

5.6 GC CONDITIONS

The packed columns for the GC were both operated at 90 °C. The columns were stainless steel, 6 feet long, 0.125 inch outer diameter, packed with 1 percent SP-1000 on 60/80 mesh Carbopack B.

During the analysis, the FID was operated at 250 °C. The support gases for the FID were hydrogen (99.995% pure) and air (99.9999% pure). Any unused sample gas was vented from the GC system back to the inlet of the control device being tested.

5.7 CALIBRATION STANDARDS

The FID was calibrated for mid-range part-per-million-by-volume (ppmv) level analysis using gas proportions similar to the following:

1) 1000 ppmv EtO, balance nitrogen ***
2) 100 ppmv EtO, balance nitrogen
3) 50 ppmv EtO, balance nitrogen (audit gas)
4) 10 ppmv EtO, balance nitrogen
5) 1 ppmv EtO, balance nitrogen

***Note: Calibrations for this standard were performed following the test to confirm appropriate range of instrument.

The PID was calibrated for low-range ppmv level analyses using gas proportions similar to the following:

1) 100 ppmv EtO, balance nitrogen
2) 50 ppmv EtO, balance nitrogen (audit gas)
3) 10 ppmv EtO, balance nitrogen
4) 1 ppmv EtO, balance nitrogen

See Appendix J for calibration gas certifications. Please see Appendix I for triplicate calibration data performed before and after each set of test runs and calibration curves.

As a part of the test's quality assurance, limit of detection and recovery studies were performed. Refer to that section later in the document and Appendices K and I, respectively for further information.

5.8 SAMPLING DURATION

Testing was performed in 15-minute increments in conjunction with normal production operations, for each of the three test runs while chamber backvents were operating.

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5.9 SAMPLE CALCULATIONS

Method 1

Equivalent diameter was calculated as follows:

$$D_e = \frac{2(L)(W)}{L+W}$$

Actual diameters of round ducts and equivalent diameters of square and rectangular ducts were used to evaluate whether sufficient distance existed between the sample ports and upstream and downstream flow disturbances. These figures were used in conjunction with Method 1's Table 1.1 and 1.2 to ensure that the minimum number of traverse points required for testing was exceeded.

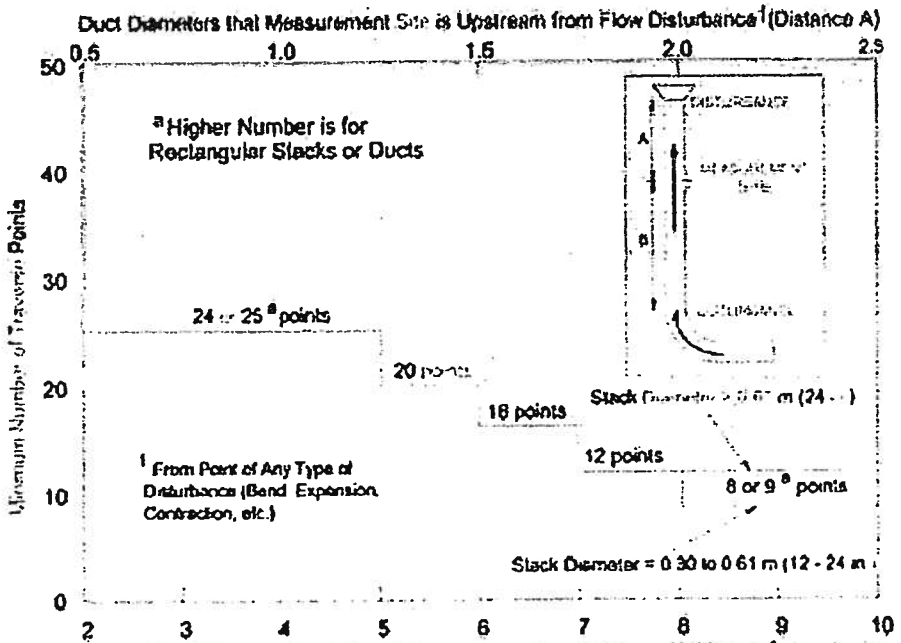

Figure 1-1. Minimum number of traverse points for particulate traverses

* * * * *

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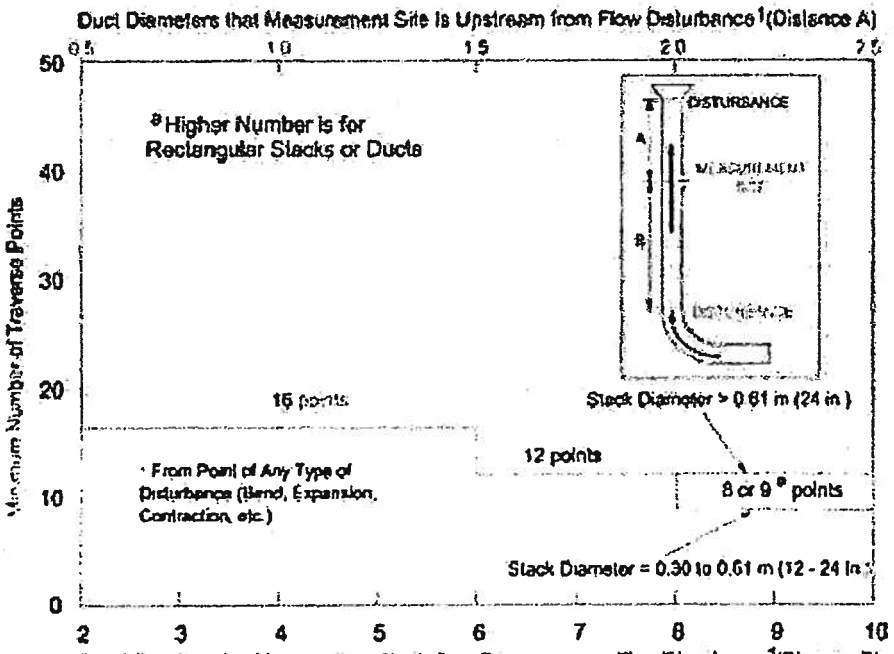

Figure 1-2. Minimum number of traverse points for velocity (nonparticulate) traverses

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Method 2

Stack gas velocity and volumetric flow rate were calculated using equation 2-7 and 2-8 as outlined in Method 2.

Q = Average Stack Gas Dry Volumetric Flow Rate (dscf/min)

$$= 60\,(1 - B_{ws})\,V_s\,A \left| \frac{T_{std}\,P_s}{T_{s(abavg)}\,P_{std}} \right|$$

V_s = Average Stack Gas Velocity

$$V_s = K_p\,C_p \left[\frac{\sum_{i=1}^{n} \sqrt{\Delta p_i}}{n} \right] \sqrt{\frac{T_{s(abavg)}}{P_s\,M_s}}$$

Where:

K_p = Velocity equation constant

$$= 85.49 \frac{ft}{\sec} \left[\frac{(lb/lb-mole)(in.\,Hg)}{(^{\circ}R)(in.\,H_2O)} \right]^{1/2}$$

C_p = Pitot Tube Coefficient = 0.84 (S-type pitot tube coefficient for geometric calibration)

Δp_i = Individual velocity head reading at traverse point "i" (in. Hg)

n = number of traverse points

$T_{s(abavg)}$ = Average absolute stack temperature (°R)

P_s = Absolute stack pressure ($P_{bar} + P_g$)

P_{bar} = Barometric pressure at measurement site (in. Hg)

P_g = Stack static pressure (in. Hg)

M_s = Molecular weight of stack gas, wet basis

$$M_s = M_d\,(1 - B_{ws}) + 18.0 B_{ws}$$

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Method 4

Moisture content was determined using the calculation for saturation in accordance with Method 4.

$$B_{ws(svp)}(\%) = 100\left(\frac{10^{\left(8.691-\left(\frac{3144}{T_{s\,(abs)}+390.86}\right)\right)}}{\left(P_b+\frac{P_{static}}{13.6}\right)}\right)$$

Where:

$B_{ws(svp)}(\%)$ = Saturated moisture concentration (% by volume)

$T_{s(abavg)}$ = Average absolute stack temperature (°F)

P_b = Barometric pressure at measurement site (in. Hg)

P_{static} = Stack static pressure (in. H_20)

Mass Emission Calculation

Mass emissions of EtO during backvent were calculated using the following equation:

$$W = (Q)(MolWt)(C/10^6)/(MolVol)$$

Where:

W	=	EtO mass flow rate, pounds per minute
Q	=	Corrected duct gas volumetric flow rate, dry standard cubic feet per minute at 68 degrees F and 29.92 in. Hg (see calculation under Method 2)
MolWt	=	44.05 pounds EtO per pound mole
C	=	EtO concentration, parts per million by volume
10^6	=	Conversion factor, ppmv per "cubic foot per cubic foot"
MolVol	=	385.32 cubic feet per pound mole at 68 degrees F and 29.92 in. Hg

Control Efficiency Calculation

Mass control efficiency of EtO during backvent was calculated using the following equation:

$$\text{Efficiency} = (W_i - W_o / W_i)(100)$$

Where:

W_i = Mass flow rate to the control device inlet, pounds per minute, calculated as described above where:

C_i = EtO concentration at the control device inlet, ppm

Q_i = Duct gas volumetric flow rate at the control device inlet, dry standard cubic feet per minute

W_o = Mass flow rate from the control device outlet, pounds per minute calculated as described above where:

C_o = EtO concentration at the control device outlet

Q_o = Duct gas volumetric flow rate at the control device outlet, dry standard cubic feet per minute

Correction to Dry Basis

Dry basis concentration = (wet basis concentration) / (1-w)

where:

w = fraction of emitted exhaust gas, by volume, which is water vapor.

Results of the control-efficiency testing are presented in Section 8.0 and in Table 1 and 2.

6.0 TEST SCENARIO

Backvent testing was performed during normal process load conditions, with freshly sterilized product in the sterilization chambers. Three test runs were conducted in series to verify the performance of the emission-control system.

Sterigenics scheduled three chambers to end the sterilization cycle to allow for the three test runs to run consecutively. The general testing sequence was as follows:

Timing	Task	Method
Prior to test	Sample locations established	Method 1
Prior to test	Sample traverse locations established	Method 1
One time prior to each set of runs	3-point calibration performed in triplicate.	Method 18
One time prior to each set of runs	Confirm absence of cyclonic flow	Method 1
One time prior to each set of runs	Collect AAT system scrubber liquor pH, tank level, and glycol % information. Note levels present from aeration.	N/A
One time prior to each set of runs	Flow traverse of inlet and outlet conducted to establish flow rate and measurement centroid	Method 2
Prior to each test run	Note temperature reading of heated lines	N/A
Over test duration	Chamber door opened approximately 12 inches, actuator switch activates backvent	N/A
Beginning of each run	First sample initiated	Method 18
Over test duration	Samples at inlet and outlet taken approximately every 1-minute for a total of 15-minutes	Method 18
Over test duration	Flow monitoring sampled approximately every 1-minute.	Method 2
Mid-Test	Note temperature reading of heated lines	Method 18
After each test run	Collect cycle number and ending backvent EtO concentration in chamber head space are noted	N/A
After each test run	Note temperature reading of heated lines	Method 18
After each test run	Conduct recovery study	Method 18
After conclusion of each set of test runs	Perform post calibration checks	Method 18
After conclusion of each set of test runs	Collect AAT system scrubber liquor pH, tank level, and glycol %.	N/A
One time following each set of runs	Obtain meteorological data for sampling time	N/A
At least once during two test days for WB I and WB II	Perform Limit of Detection Study	Method 18

TABLE 1
ETHYLENE OXIDE CONTROL EFFICIENCY SUMMARY – BACKVENT
FOR STERIGENICS - WILLOWBROOK, ILLINOIS (PLANT 1)
ON SEPTEMBER 21, 2018

Test Run	Inlet Average Concentration (ppm)	Inlet Average Mass Flow rate (lb/min)	Outlet Average Concentration (ppm)[1]	Outlet Average Mass Flow rate (lb/min) ≤	Control Efficiency ≥
1	70.86	0.07984	ND	0.00012	99.6192%
2	30.21	0.03401	ND	0.00012	99.6410%
3	25.40	0.02853	ND	0.00012	99.5795%

Control Efficiency ≥ 99.6132%

Efficiency = (MassFlowin - MassFlowout / MassFlowin)(100)
Mass Flow (lb/min) = (VolFlow)(MolWt)(C /10^{6})/(MolVol)

MW EtO = 44.05
MolVol = 385.32
C = Dry Concentration

[1] ND = Non Detect. Detection limit of the GC was determined to be 0.10 ppm.

	INLET		OUTLET	
	Average Temperature (°F)	Moisture Content (%)	Average Temperature (°F)	Moisture Content (%)
Run 1	103.8	7.4862	103.8	7.4767
Run 2	104.1	7.5373	104.1	7.5277
Run3	104.9	7.7264	104.9	7.7166

TABLE 2 - ETHYLENE OXIDE CONTROL EFFICIENCY – BACKVENT
FOR STERIGENICS - WILLOWBROOK, ILLINOIS (PLANT 1)
ON SEPTEMBER 21, 2018

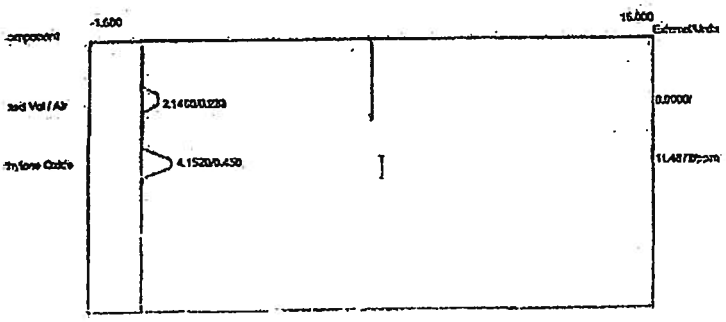
		INLET ETO				OUTLET ETO				
Run #	Time	Wet Concentration (PPM)[1]	Dry Concentration (PPM)[1]	Dry Volumetric Flow	Mass Flow[3] (lb/min)	Wet Concentration (PPM)[1,2]	Dry Concentration (PPM)[1,2]	Dry Volumetric Flow	Mass Flow[3] (lb/min) ≤	Control Efficiency[4] ≥
1	914	11.5	12.43058	9856.0	0.01401	ND	ND	9667.3	0.0001194	99.1472%
1	915	542	585.65843	9856.0	0.66011	ND	ND	9667.3	0.0001194	99.9819%
1	916	38.9	42.04777	9856.0	0.04738	ND	ND	9667.3	0.0001194	99.7479%
1	917	34.5	37.29173	9856.0	0.04202	ND	ND	9667.3	0.0001194	99.7157%
1	918	27.6	29.83338	9856.0	0.03361	ND	ND	9667.3	0.0001194	99.6447%
1	919	26.8	28.96865	9856.0	0.03264	ND	ND	9667.3	0.0001194	99.6340%
1	920	27	29.18483	9856.0	0.03288	ND	ND	9667.3	0.0001194	99.6368%
1	921	23.1	24.96924	9856.0	0.02813	ND	ND	9667.3	0.0001194	99.5754%
1	923	26.4	28.53628	9856.0	0.03215	ND	ND	9667.3	0.0001194	99.6285%
1	924	24	25.94207	9856.0	0.02923	ND	ND	9667.3	0.0001194	99.5914%
1	925	23.7	25.61779	9856.0	0.02886	ND	ND	9667.3	0.0001194	99.5862%
1	926	23.5	25.40161	9856.0	0.02862	ND	ND	9667.3	0.0001194	99.5827%
1	927	23.2	25.07733	9856.0	0.02828	ND	ND	9667.3	0.0001194	99.5773%
2	931	24	25.95640	9849.5	0.02923	ND	ND	9661.0	0.0001194	99.5914%
2	932	22.5	24.33413	9849.5	0.02740	ND	ND	9661.0	0.0001194	99.5641%
2	933	42.3	45.74816	9849.5	0.05151	ND	ND	9661.0	0.0001194	99.7681%
2	934	31.3	33.85148	9849.5	0.03812	ND	ND	9661.0	0.0001194	99.6867%
2	935	28.8	31.14768	9849.5	0.03507	ND	ND	9661.0	0.0001194	99.6595%
2	936	28.7	31.03953	9849.5	0.03495	ND	ND	9661.0	0.0001194	99.6583%
2	937	28.5	30.82323	9849.5	0.03471	ND	ND	9661.0	0.0001194	99.6559%
2	939	26.7	28.87650	9849.5	0.03252	ND	ND	9661.0	0.0001194	99.6327%
2	940	26.8	28.98465	9849.5	0.03264	ND	ND	9661.0	0.0001194	99.6340%
2	941	26.4	28.55204	9849.5	0.03215	ND	ND	9661.0	0.0001194	99.6285%
2	942	26.9	29.09280	9849.5	0.03276	ND	ND	9661.0	0.0001194	99.6354%
2	943	25	27.03792	9849.5	0.03044	ND	ND	9661.0	0.0001194	99.6077%
2	944	25.2	27.25422	9849.5	0.03069	ND	ND	9661.0	0.0001194	99.6108%
3	953	23.1	25.03424	9825.7	0.02812	ND	ND	9637.6	0.0001194	99.5754%
3	954	22.8	24.70912	9825.7	0.02776	ND	ND	9637.6	0.0001194	99.5698%
3	955	27.8	30.12779	9825.7	0.03384	ND	ND	9637.6	0.0001194	99.6472%
3	956	26	28.17707	9825.7	0.03165	ND	ND	9637.6	0.0001194	99.6228%
3	957	23.8	25.79286	9825.7	0.02897	ND	ND	9637.6	0.0001194	99.5879%
3	958	23	24.92587	9825.7	0.02800	ND	ND	9637.6	0.0001194	99.5736%
3	1000	22.3	24.16726	9825.7	0.02715	ND	ND	9637.6	0.0001194	99.5602%
3	1001	22.8	24.70912	9825.7	0.02776	ND	ND	9637.6	0.0001194	99.5698%
3	1002	22.8	24.70912	9825.7	0.02776	ND	ND	9637.6	0.0001194	99.5698%
3	1003	23.4	25.35936	9825.7	0.02849	ND	ND	9637.6	0.0001194	99.5809%
3	1004	21.7	23.51702	9825.7	0.02642	ND	ND	9637.6	0.0001194	99.5480%
3	1005	21.7	23.51702	9825.7	0.02642	ND	ND	9637.6	0.0001194	99.5480%

Notes
[1] PPM = parts per million by volume
[2] ND = Non Detect. Detection limit of the GC was determined to be 0.10 ppm.
[3] See Table 1 for Mass Flow Calculation
[4] See Table 1 for Control efficiency calculation

fficiency = (MassFlowin - MassFlowout / MassFlowin)(100)
· (lb/min) = (VolFlow)(MolWt)(C /10^6)/(MolVol)

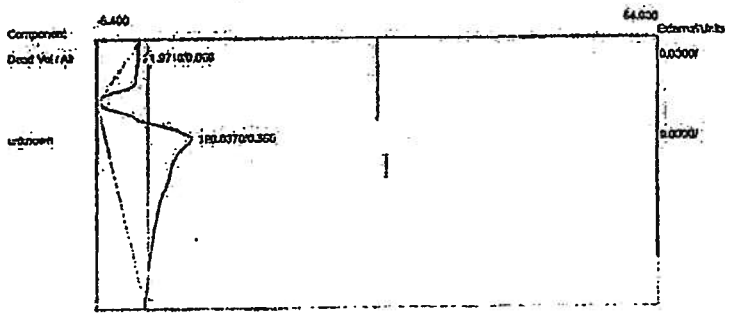
MW EtO = 44.05
MolVol = 385.32

Lab name: ECSI
Client: Sterigenics - Willowbrook 1
Client ID: Run#1BV
Analysis date: 09/21/2018 09:14:01
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Ster1WB2018-1B01.CHR (c:\peak359)
Sample: AAT Inlet
Operator: D. Kremer



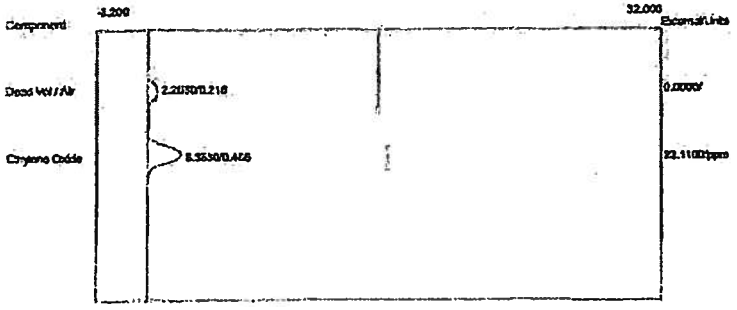
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1460	0.0000	
Ethylene Oxide	0.450	4.1520	11.4872	ppm
		6.2980	11.4872	

Lab name: ECSI
Client: Sterigenics - Willowbrook 1
Client ID: Run#1BV
Analysis date: 09/21/2018 09:14:01
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Ster1WB2018-1B01.CHR (c:\peak359)
Sample: AAT Outlet
Operator: D. Kremer



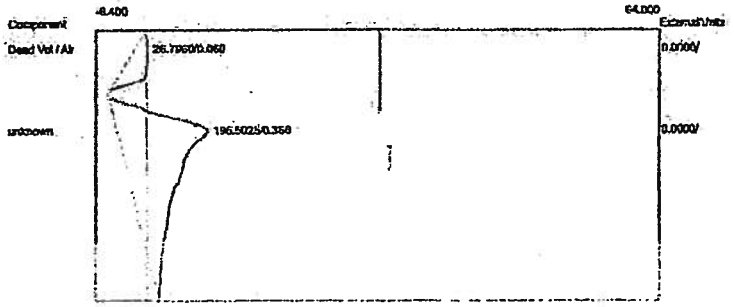
Component	Retention	Area	External	Units
Dead Vol / Air	0.066	21.9710	0.0000	
		21.9710	0.0000	

Lab name: ECSI
Client: Sterigenics - Willowbrook 1
Client ID: Run#3BV
Analysis date: 09/21/2018 09:53:04
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Ster1WB2018-3B01.CHR (c:\peak359)
Sample: AAT Inlet
Operator: D. Kremer



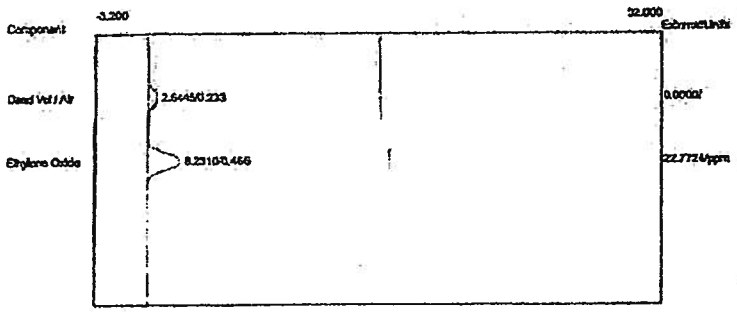
Component	Retention	Area	External	Units
Dead Vol / Air	0.216	2.2680	0.0000	
Ethylene Oxide	0.466	8.3530	23.1100	ppm
		10.6210	23.1100	

Lab name: ECSI
Client: Sterigenics - Willowbrook 1
Client ID: Run#3BV
Analysis date: 09/21/2018 09:53:04
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Ster1WB2018-3B01.CHR (c:\peak359)
Sample: AAT Outlet
Operator: D. Kremer



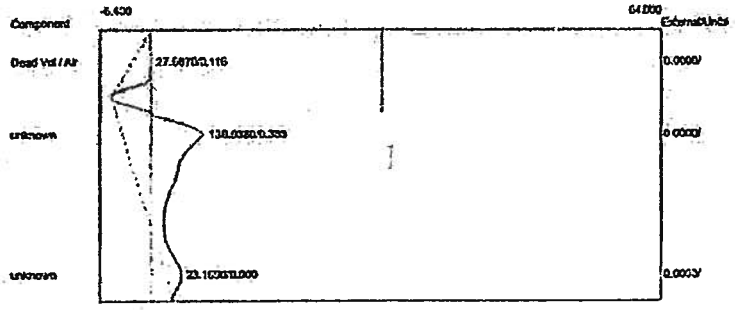
Component	Retention	Area	External	Units
Dead Vol / Air	0.066	26.7960	0.0000	
		26.7960	0.0000	

Lab name: ECSi
Client: Sterigenics - Willowbrook 1
Client ID: Run#3BV
Analysis date: 09/21/2018 09:54:14
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Ster1WB2018-3B02.CHR (c:\peak359)
Sample: AAT Inlet
Operator: D. Kremer



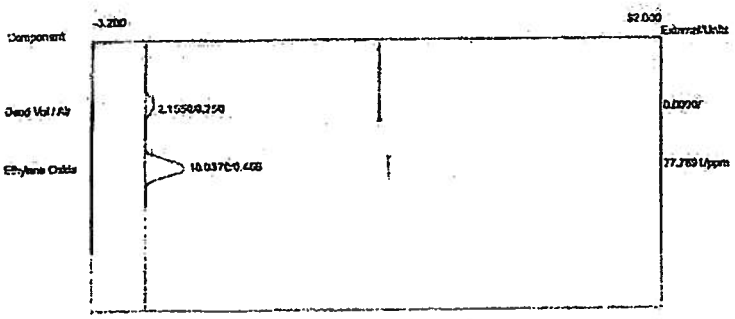
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.5445	0.0000	
Ethylene Oxide	0.466	8.2310	22.7724	ppm
		10.7755	22.7724	

Lab name: ECSi
Client: Sterigenics - Willowbrook 1
Client ID: Run#3BV
Analysis date: 09/21/2018 09:54:14
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Ster1WB2018-3B02.CHR (c:\peak359)
Sample: AAT Outlet
Operator: D. Kremer



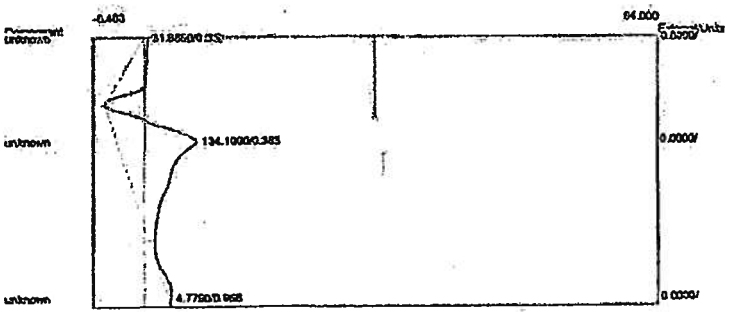
Component	Retention	Area	External	Units
Dead Vol / Air	0.116	27.6870	0.0000	
		27.6870	0.0000	

Lab name: ECSI
Client: Sterigenics - Willowbrook 1
Client ID: Run#3BV
Analysis date: 09/21/2018 09:55:22
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Ster1WB2018-3B03.CHR (c:\peak359)
Sample: AAT Inlet
Operator: D. Kremer



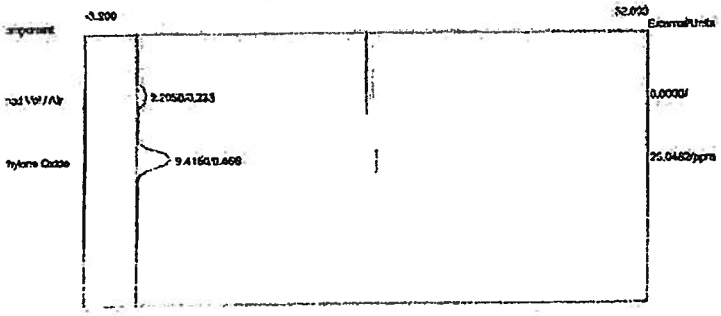
Component	Retention	Area	External	Units
Dead Vol / Air	0.250	2.1550	0.0000	
Ethylene Oxide	0.466	10.0370	27.7691	ppm
		12.1920	27.7691	

Lab name: ECSI
Client: Sterigenics - Willowbrook 1
Client ID: Run#3BV
Analysis date: 09/21/2018 09:55:22
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Ster1WB2018-3B03.CHR (c:\peak359)
Sample: AAT Outlet
Operator: D. Kremer



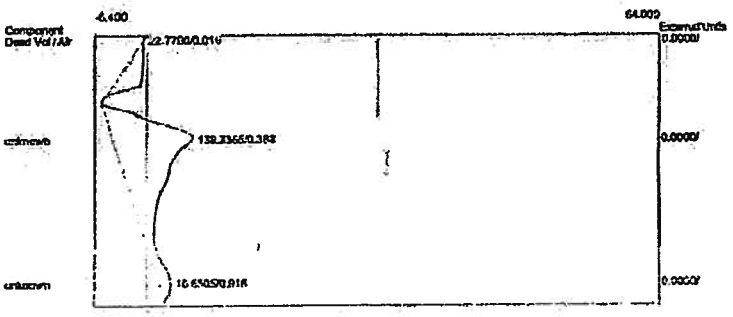
Component	Retention	Area	External	Units
		0.0000	0.0000	

Lab name: ECSI
Client: Sterigenics - Willowbrook 1
Client ID: Run#3BV
Analysis date: 09/21/2018 09:56:32
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Ster1WB2018-3B04.CHR (c:\peak359)
Sample: AAT Inlet
Operator: D. Kremer



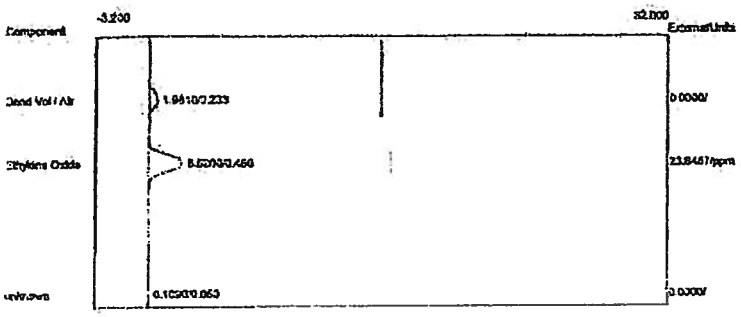
Component	Retention	Area	External	Units
)ead Vol / Air	0.233	2.2050	0.0000	
:thylene Oxide	0.466	9.4150	26.0482	ppm
		11.6200	26.0482	

Lab name: ECSI
Client: Sterigenics - Willowbrook 1
Client ID: Run#3BV
Analysis date: 09/21/2018 09:56:32
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Ster1WB2018-3B04.CHR (c:\peak359)
Sample: AAT Outlet
Operator: D. Kremer



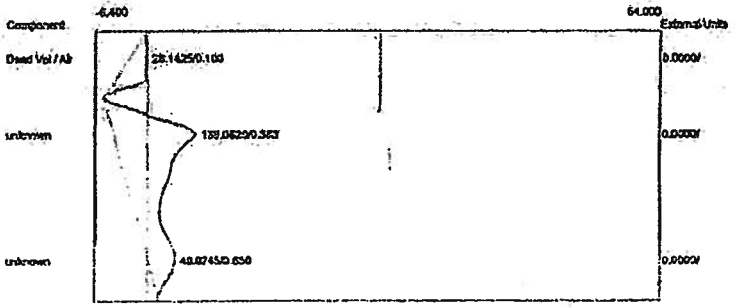
Component	Retention	Area	External	Units
Dead Vol / Air	0.016	22.7790	0.0000	
		22.7790	0.0000	

Lab name: ECSI
Client: Sterigenics - Willowbrook 1
Client ID: Run#3BV
Analysis date: 09/21/2018 09:57:46
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Ster1WB2018-3B05.CHR (c:\peak359)
Sample: AAT Inlet
Operator: D. Kremer



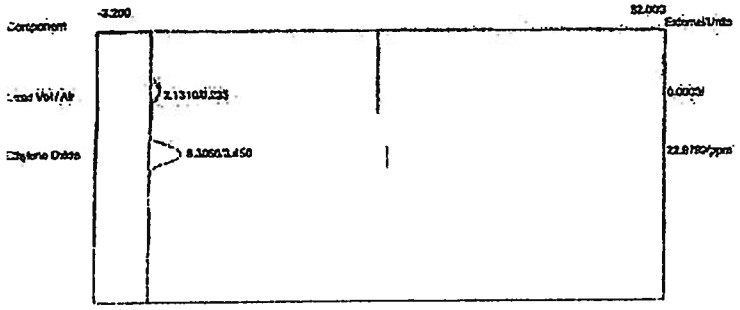
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	1.9810	0.0000	
Ethylene Oxide	0.466	8.6200	23.8487	ppm
		10.6010	23.8487	

Lab name: ECSI
Client: Sterigenics - Willowbrook 1
Client ID: Run#3BV
Analysis date: 09/21/2018 09:57:46
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Ster1WB2018-3B05.CHR (c:\peak359)
Sample: AAT Outlet
Operator: D. Kremer



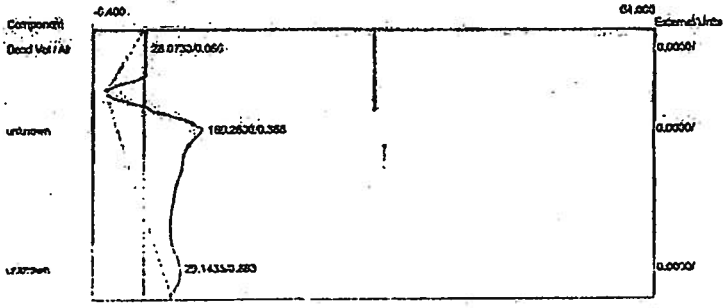
Component	Retention	Area	External	Units
Dead Vol / Air	0.100	28.1425	0.0000	
		28.1425	0.0000	

Lab name: ECSI
Client: Sterigenics - Willowbrook 1
Client ID: Run#3BV
Analysis date: 09/21/2018 09:58:56
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Ster1WB2018-3B06.CHR (c:\peak359)
Sample: AAT Inlet
Operator: D. Kremer



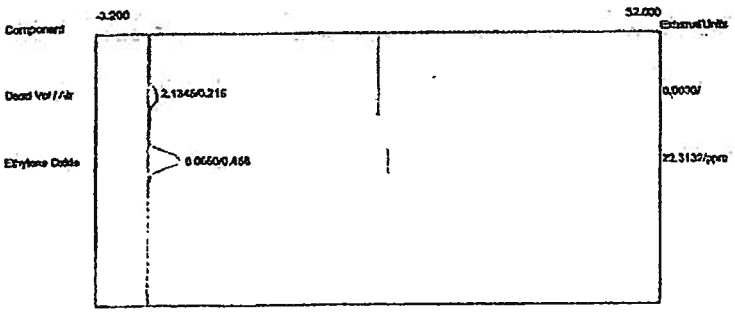
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1310	0.0000	
Ethylene Oxide	0.450	8.3060	22.9799	ppm
		10.4370	22.9799	

Lab name: ECSI
Client: Sterigenics - Willowbrook 1
Client ID: Run#3BV
Analysis date: 09/21/2018 09:58:56
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Ster1WB2018-3B06.CHR (c:\peak359)
Sample: AAT Outlet
Operator: D. Kremer



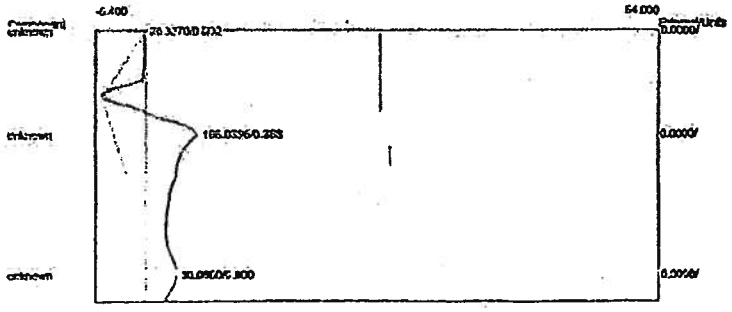
Component	Retention	Area	External	Units
Dead Vol / Air	0.066	28.0730	0.0000	
		28.0730	0.0000	

Lab name: ECSI
Client: Sterigenics - Willowbrook 1
Client ID: Run#3BV
Analysis date: 09/21/2018 10:00:07
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Ster1WB2018-3B07.CHR (c:\peak359)
Sample: AAT Inlet
Operator: D. Kremer



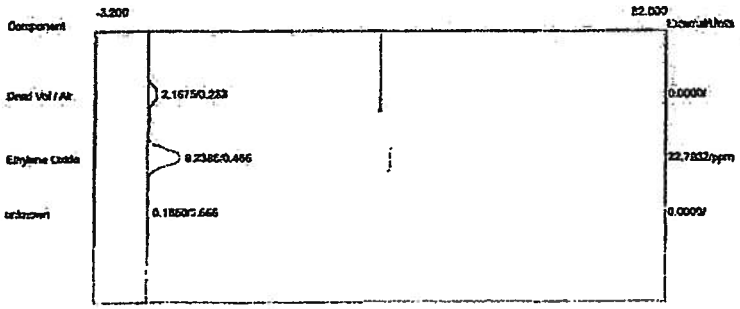
Component	Retention	Area	External	Units
Dead Vol / Air	0.216	2.1345	0.0000	
Ethylene Oxide	0.466	8.0650	22.3132	ppm
		10.1995	22.3132	

Lab name: ECSI
Client: Sterigenics - Willowbrook 1
Client ID: Run#3BV
Analysis date: 09/21/2018 10:00:07
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Ster1WB2018-3B07.CHR (c:\peak359)
Sample: AAT Outlet
Operator: D. Kremer



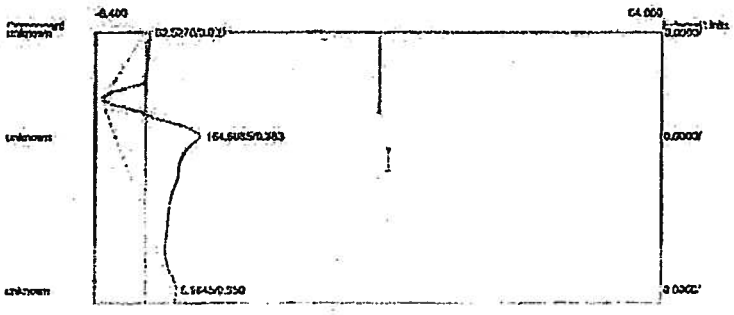
Component	Retention	Area	External	Units
		0.0000	0.0000	

Lab name: ECSI
Client: Sterigenics - Willowbrook 1
Client ID: Run#3BV
Analysis date: 09/21/2018 10:01:14
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Ster1WB2018-3B08.CHR (c:\peak359)
Sample: AAT Inlet
Operator: D. Kramer



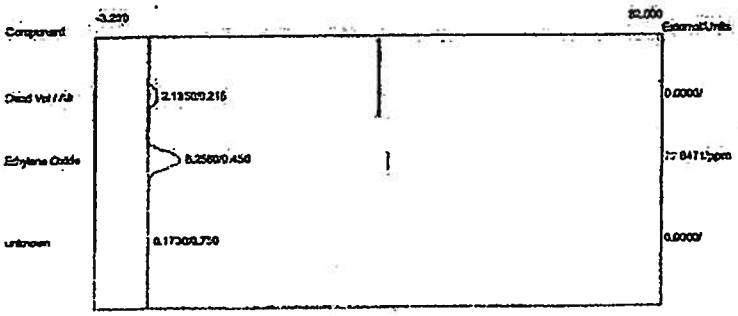
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1675	0.0000	
Ethylene Oxide	0.466	8.2385	22.7932	ppm
		10.4060	22.7932	

Lab name: ECSI
Client: Sterigenics - Willowbrook 1
Client ID: Run#3BV
Analysis date: 09/21/2018 10:01:14
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Ster1WB2018-3B08.CHR (c:\peak359)
Sample: AAT Outlet
Operator: D. Kramer



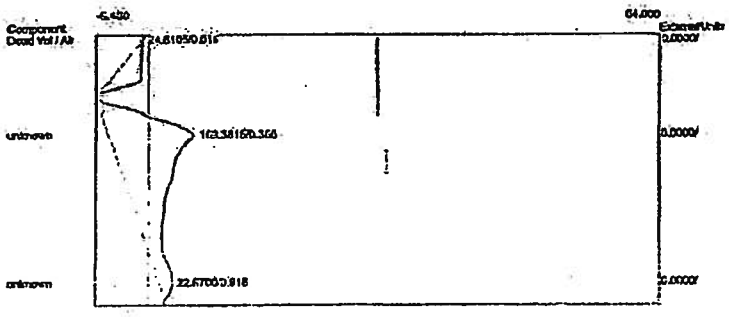
Component	Retention	Area	External	Units
		0.0000	0.0000	

Lab name: ECSI
Client: Sterigenics - Willowbrook 1
Client ID: Run#3BV
Analysis date: 09/21/2018 10:02:23
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Ster1WB2018-3B09.CHR (c:\peak359)
Sample: AAT Inlet
Operator: D. Kremer



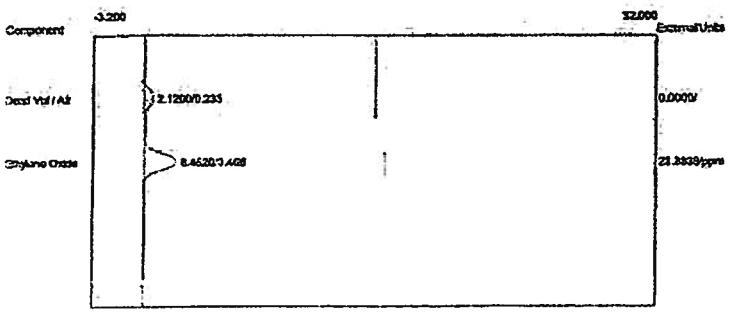
Component	Retention	Area	External	Units
Dead Vol / Air	0.216	2.1350	0.0000	
Ethylene Oxide	0.450	8.2580	22.8471	ppm
		10.3930	22.8471	

Lab name: ECSI
Client: Sterigenics - Willowbrook 1
Client ID: Run#3BV
Analysis date: 09/21/2018 10:02:23
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Ster1WB2018-3B09.CHR (c:\peak359)
Sample: AAT Outlet
Operator: D. Kremer



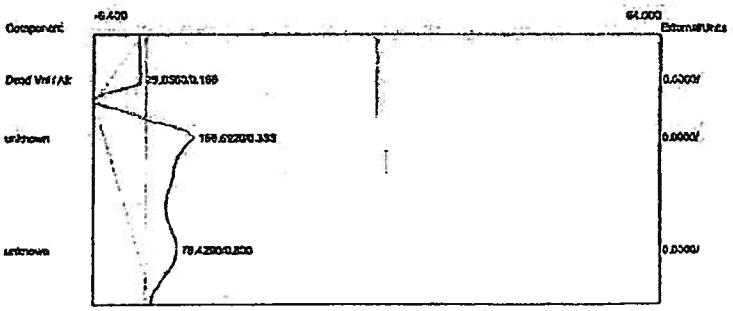
Component	Retention	Area	External	Units
Dead Vol / Air	0.016	24.8105	0.0000	
		24.8105	0.0000	

Lab name: ECSI
Client: Sterigenics - Willowbrook 1
Client ID: Run#3BV
Analysis date: 09/21/2018 10:03:40
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Ster1WB2018-3B10.CHR (c:\peak359)
Sample: AAT Inlet
Operator: D. Kremer



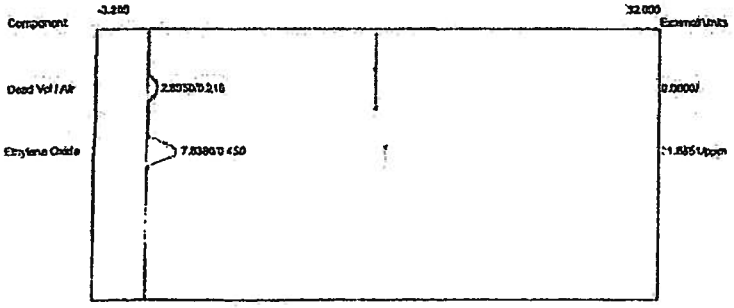
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1200	0.0000	
Ethylene Oxide	0.466	8.4520	23.3839	ppm
		10.5720	23.3839	

Lab name: ECSI
Client: Sterigenics - Willowbrook 1
Client ID: Run#3BV
Analysis date: 09/21/2018 10:03:40
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Ster1WB2018-3B10.CHR (c:\peak359)
Sample: AAT Outlet
Operator: D. Kremer



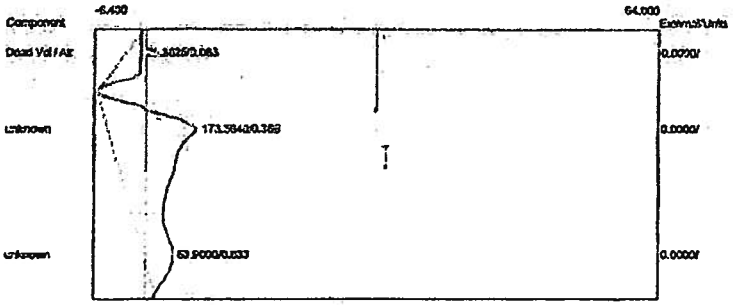
Component	Retention	Area	External	Units
Dead Vol / Air	0.166	28.6560	0.0000	
		28.6560	0.0000	

Lab name: ECSI
Client: Sterigenics - Willowbrook 1
Client ID: Run#3BV
Analysis date: 09/21/2018 10:04:53
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Ster1WB2018-3B11.CHR (c:\peak359)
Sample: AAT Inlet
Operator: D. Kremer



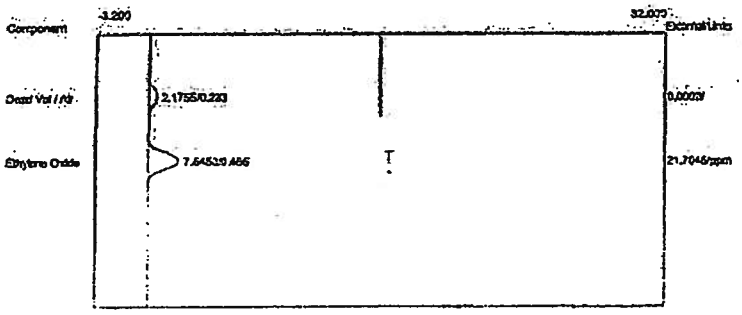
Component	Retention	Area	External	Units
Dead Vol / Air	0.216	2.8950	0.0000	
Ethylene Oxide	0.450	7.8380	21.6851	ppm
		10.7330	21.6851	

Lab name: ECSI
Client: Sterigenics - Willowbrook 1
Client ID: Run#3BV
Analysis date: 09/21/2018 10:04:53
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Ster1WB2018-3B11.CHR (c:\peak359)
Sample: AAT Outlet
Operator: D. Kremer



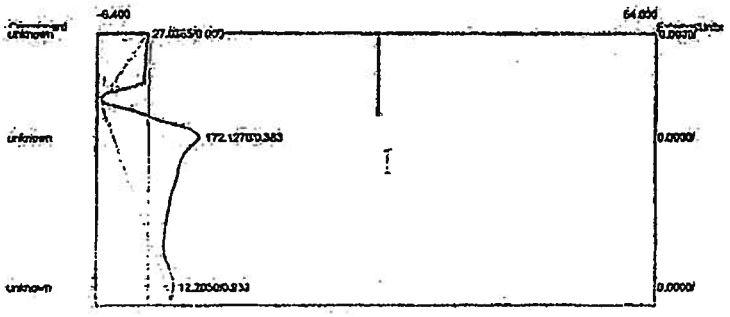
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	25.3625	0.0000	
		25.3625	0.0000	

Lab name: ECSI
Client: Sterigenics - Willowbrook 1
Client ID: Run#3BV
Analysis date: 09/21/2018 10:06:02
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Ster1WB2018-3B12.CHR (c:\peak359)
Sample: AAT Inlet
Operator: D. Kremer



Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1755	0.0000	
Ethylene Oxide	0.466	7.8450	21.7045	ppm
		10.0205	21.7045	

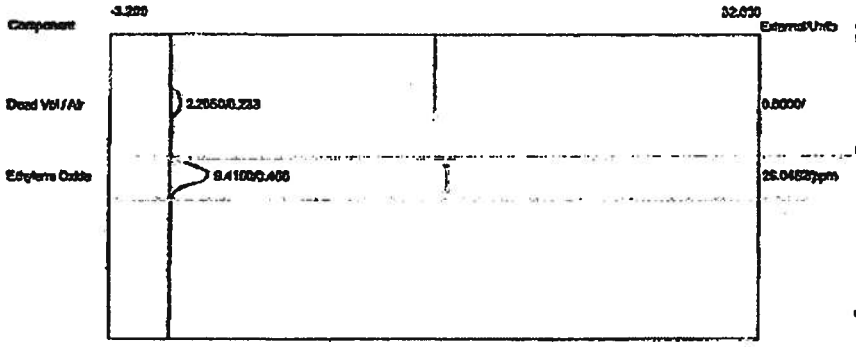
Lab name: ECSI
Client: Sterigenics - Willowbrook 1
Client ID: Run#3BV
Analysis date: 09/21/2018 10:06:02
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Ster1WB2018-3B12.CHR (c:\peak359)
Sample: AAT Outlet
Operator: D. Kremer



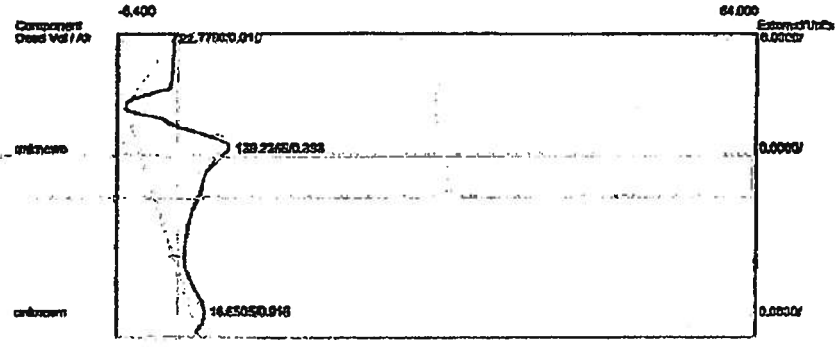
Component	Retention	Area	External	Units
		0.0000	0.0000	

Amicus - EXHIBIT H

Report, Run #3BV
Ethylene oxide calibration standard on left; stack test result on right; Yellow highlighted box around ethylene oxide signal region



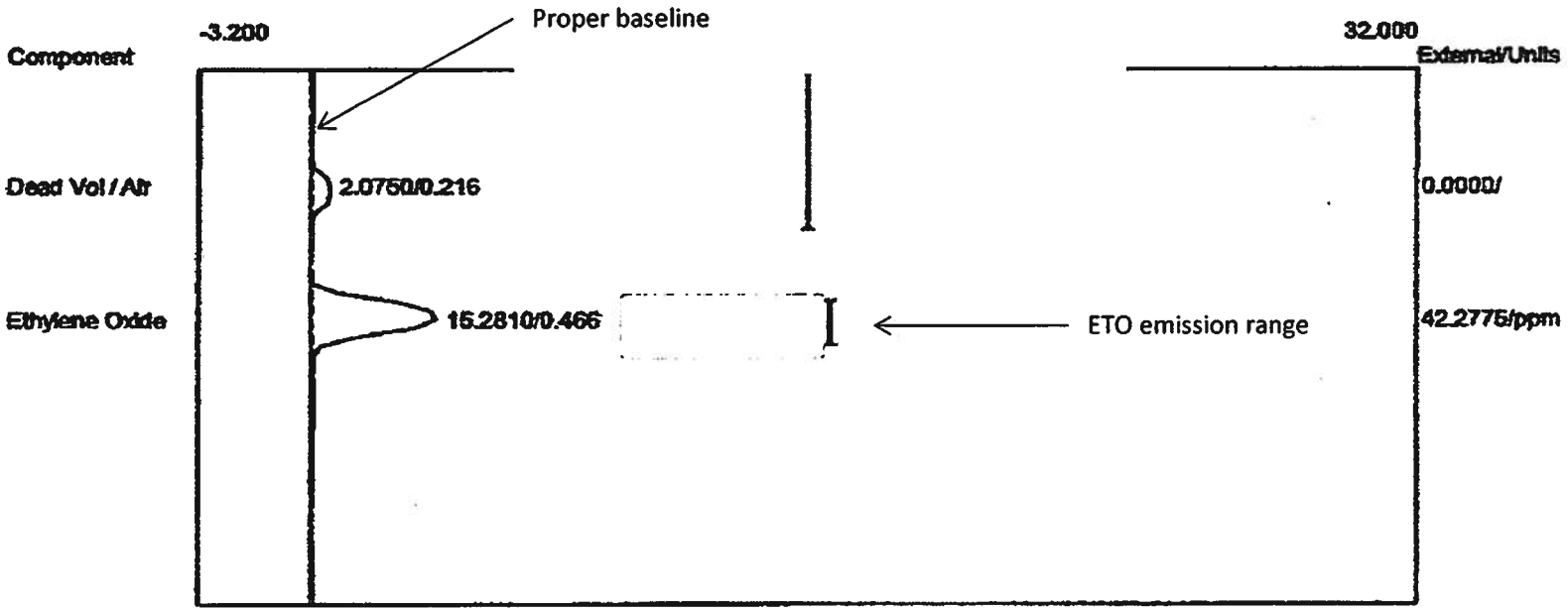
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.2050	0.0000	
Ethylene Oxide	0.466	9.4150	26.0482	ppm
		11.6200	26.0482	



Component	Retention	Area	External	Units
Dead Vol / Air	0.016	22.7790	0.0000	
		22.7790	0.0000	

Inlet data, highlight/green text added

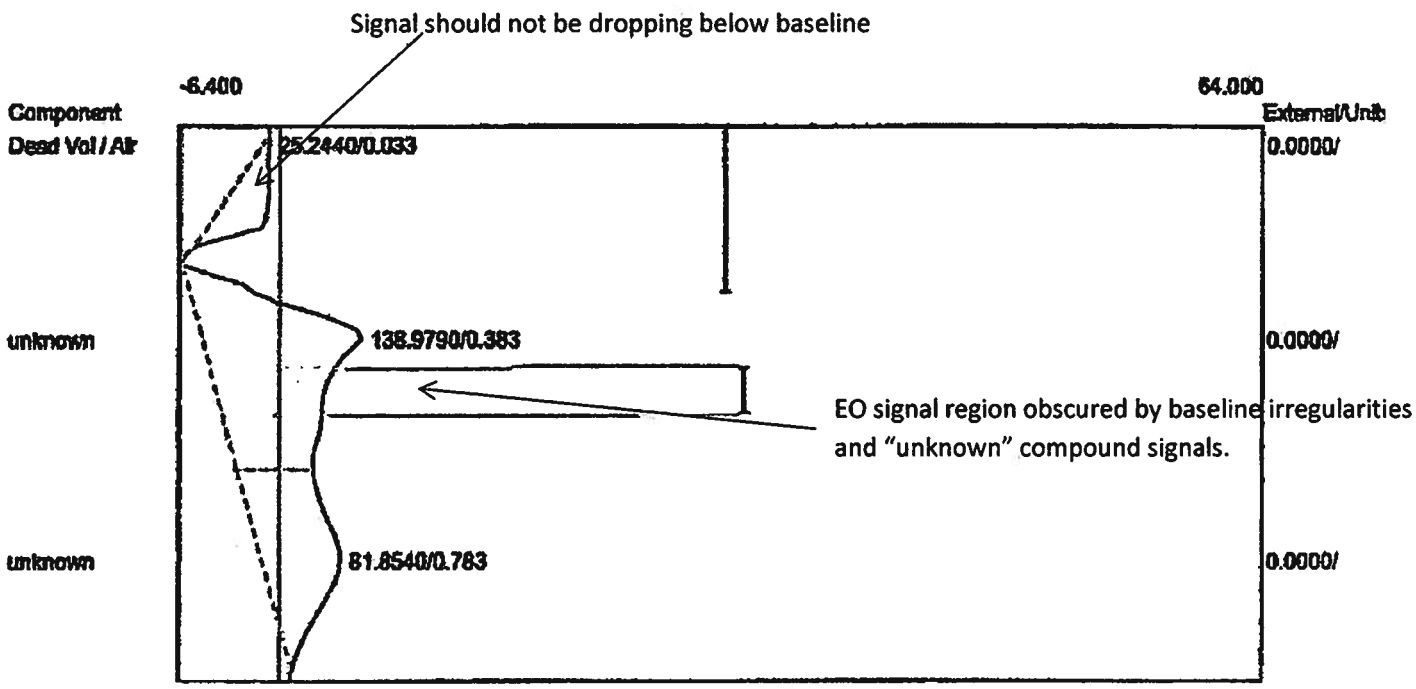
Sample: AAT Inlet
Operator: D. Kremer



Component	Retention	Area	External	Units
Dead Vol / Air	0.216	2.0750	0.0000	
Ethylene Oxide	0.466	15.2810	42.2775	ppm
		17.3560	42.2775	

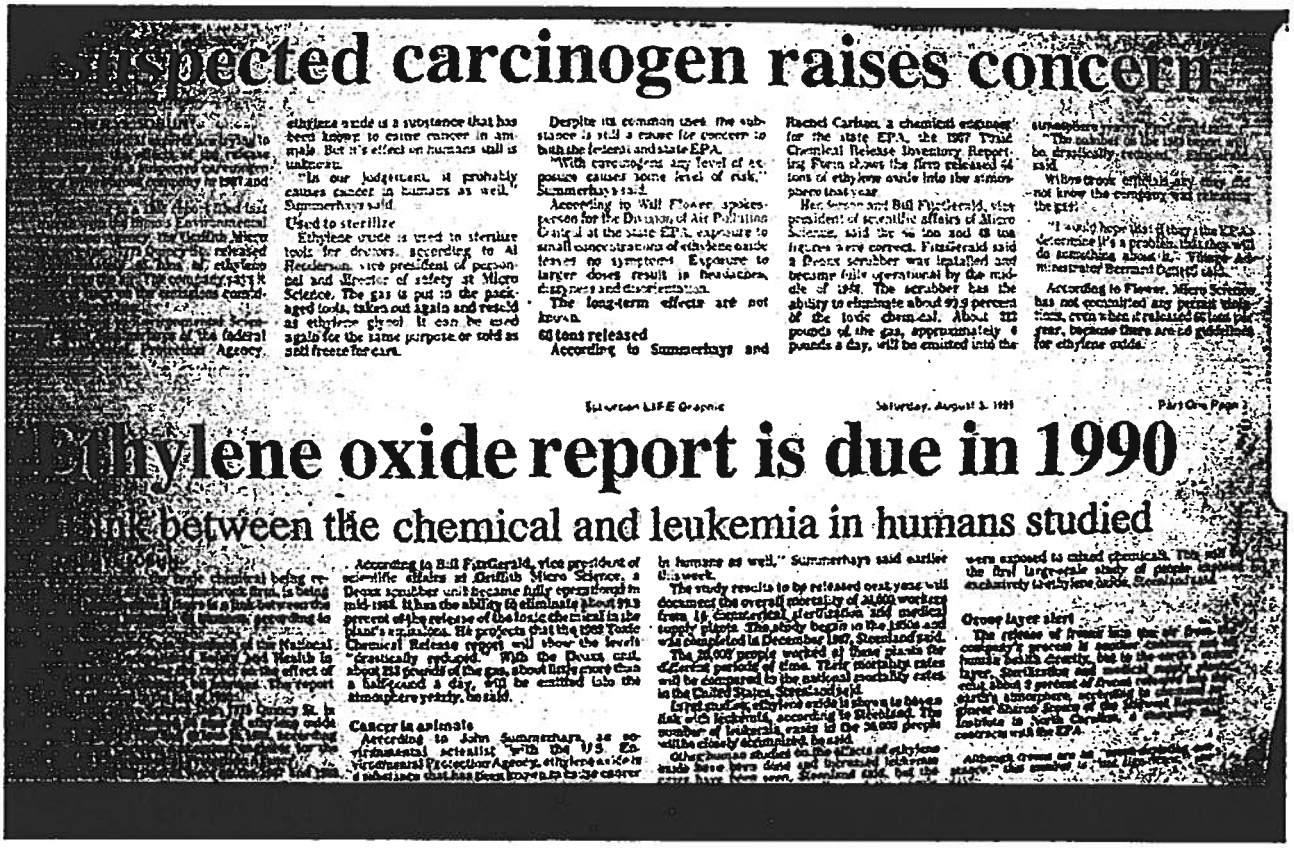
Sample: AAT Outlet
Operator: D. Kremer

Outlet data, highlight/green text added



Component	Retention	Area	External	Units
Dead Vol / Air	0.033	25.2440	0.0000	
		25.2440	0.0000	

My Suburban Life, August 5, 1989, p. 3, discussing corporate successor Griffith Micro Sciences, Inc.



...spected carcinogen raises concern

ethylene oxide is a substance that has been known to cause cancer in animals. But it's effect on humans still is unknown.

"In our judgement, it probably causes cancer in humans as well," Summerhays said.

Used to sterilize

Ethylene oxide is used to sterilize tools for doctors, according to Al Henderson, vice president of personnel and director of safety at Micro Science. The gas is put in the packaged tools, taken out again and resold as ethylene glycol it can be used again for the same purpose or sold as anti freeze for cars.

Despite its common uses the substance is still a cause for concern to both the federal and state EPA.

"With carcinogens any level of exposure causes some level of risk," Summerhays said.

According to Will Flower, spokesperson for the Division of Air Pollution Control at the state EPA, exposure to small concentrations of ethylene oxide fewer no symptoms. Exposure to larger doses result in headaches, dizziness and disorientation.

The long-term effects are not known.

68 tons released

According to Summerhays and Rachel Carlson, a chemical engineer for the state EPA, the 1987 Toxic Chemical Release Inventory Reporting Form shows the firm released 68 tons of ethylene oxide into the atmosphere that year.

Her boss and Bill Fitzgerald, vice president of scientific affairs of Micro Science, said the 68 ton and 68 ton figures were correct. Fitzgerald said a fumes scrubber was installed and became fully operational by the middle of 1988. The scrubber has the ability to eliminate about 99.9 percent of the toxic chemical. About 222 pounds of the gas, approximately 6 pounds a day, will be emitted into the atmosphere [illegible]

"The number of the 100 largest will be drastically reduced," Rachel Carlson said.

Wilbur Brooks officials say they did not know the company was releasing the gas.

"I would hope that if they (the EPA) determine it's a problem that they will do something about it," Village Administrator Bernard Dentel said.

According to Flower, Micro Science has not exceeded any permit limitations, even when it released 68 tons per year, because there are no guidelines for ethylene oxide.

Suburban LIFE Graphic — Saturday, August 5, 1989 — Part One Page 3

Ethylene oxide report is due in 1990

...link between the chemical and leukemia in humans studied

According to Bill FitzGerald, vice president of scientific affairs at Griffith Micro Science, a fumes scrubber unit became fully operational in mid-1988. It has the ability to eliminate about 99.9 percent of the release of the toxic chemical in the plant's emissions. He projects that the 1988 Toxic Chemical Release report will show the levels "drastically reduced." With the fumes unit, about 222 pounds of the gas, about little more than a half pound a day, will be emitted into the atmosphere yearly, he said.

Cancer in animals

According to John Summerhays, an environmental scientist with the U.S. Environmental Protection Agency, ethylene oxide is a substance that has been known to cause cancer in humans as well," Summerhays said earlier this week.

The study results to be released next year will document the overall mortality of 24,000 workers from 14 commercial sterilization and medical supply plants. The study began in the 1950s and was completed in December 1987, Steenland said.

The 24,000 people worked at these plants for different periods of time. Their mortality rates will be compared to the national mortality rates in the United States, Steenland said.

In past studies, ethylene oxide is shown to have a link with leukemia, according to Steenland. The link with leukemia, according to Steenland. The number of leukemia cases in the 24,000 people will be closely scrutinized, he said.

Other human studied on the effects of ethylene oxide have been done and increased leukemia cases have been seen, Steenland said, but the workers were exposed to mixed chemicals. This will be the first large-scale study of people exposed exclusively to ethylene oxide, Steenland said.

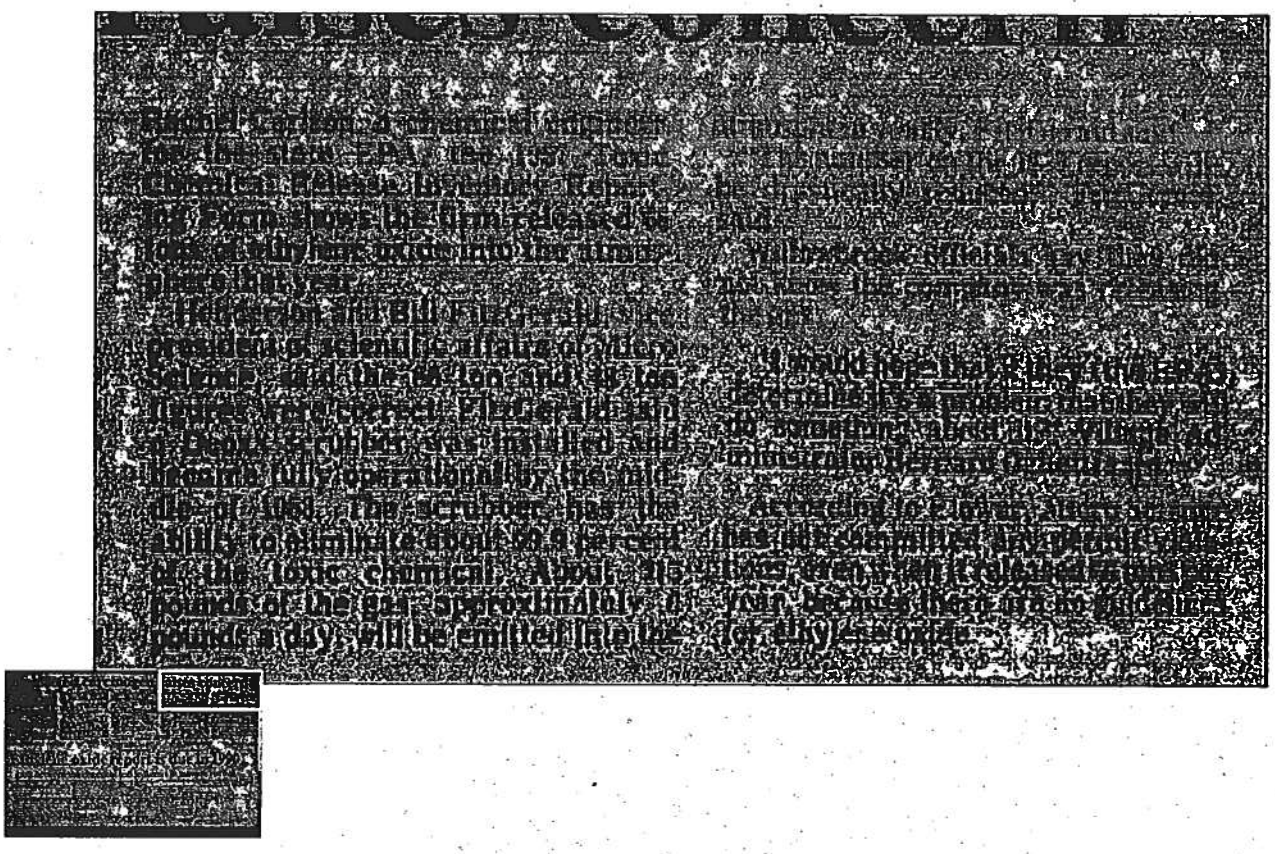
Ozone layer alert

The release of fumes into the air from the company's process is another [illegible] harmful to human health directly, but to the earth's ozone layer. Sterilization and medical supply [illegible] called a percent of fumes released into the earth's atmosphere, according to [illegible] Glover Sharon Sperry of the Solvent Recovery Institute in North Carolina, a manufacturers [illegible] with the EPA.

Although fumes are an [illegible] people," she [illegible]

Amicus - EXHIBIT I

Enlargement; Griffin Microsciences represents in 1989 that its scrubber "***has the ability to eliminate about 99.9 percent of the toxic chemical***" and that "[a]bout 213 pounds of the gas … will be emitted into the atmosphere yearly." (emphasis added)



The Doings, November 27, 1996, discussing ethylene oxide emissions by corporate successor Griffith Micro Sciences, Inc.

Foul wind blows here, watchdog group says

By Susan Frick Carlman
Doings Staff Writer

Despite recent improvements in harmful industrial emissions, DuPage County ranked in the top 20 percent of all U.S. counties in the release of airborne carcinogens in 1996, according to a report released recently by the Environmental Defense Fund through its government-data analysis web site.

Although the vast majority of the emissions came from a foam products plant in West Chicago, upwind of The Doings' circulation area, two local businesses appear on the list of the top 15 releasers of cancer-causing agents into the air. The data is based on chemical releases and transfers reported by manufacturers to the Toxics Release Inventory. Major sources of pollution or toxic chemicals not covered by the inventory are not taken into account in the EDF report.

No-Sag Foam Products topped the list, with a reported 510,384 pounds of dichloromethane released throughout the year. The next business on the ranking, Metals Technology Corp. of Addison, let loose 80,853 pounds of carcinogens during 1996, the most recent period for which figures are available.

Griffith Micro Science Inc., an Oak Brook-based business that specializes in sterilizing medical equipment, was ranked third, with a total of 22,420 pounds of emissions reported during the period, most of which was ethylene oxide, according to the report. The tally put the manufacturer in the top 20 percent of all Illinois facilities in terms of total production-related waste. The company's service center, the site where the release was monitored, is located in the Willowbrook Executive Plaza, between Madison Street and Route 83 just north of Interstate 55.

Company vice president Frank Lange, in a statement faxed to The Doings Nov. 18, said Griffith meets all requirements of the Environmental Protection Agency, the Occupational Safety & Health Administration and the Food and Drug Administration, all of which regulate the company's operations.

"Our facilities have extensive emission control systems, which minimize the release of ethylene oxide. In addition, we are currently installing supplemental equipment at our Willowbrook facility to further control emissions," Lange wrote.

The sixth-place position is occupied by a Burr Ridge business, Meaden Screw Products Co. The EDF reported that Meaden's air release of carcinogenic substances, principally trichloroethylene, came to 6,159 pounds in 1996. The facility ranked 130th in airborne carcinogens out of 269 facilities reporting to the TRI.

Company president Tom Meaden cautioned that the figures reported in the inventory represent only a portion of the emissions, so his company's actual ranking probably is different from that shown in the report. Meaden said last week that the plant has improved its emissions total notably in the past couple of years, principally by installing water wash systems.

"We've reduced it tremendously," he said.

The report, which can be reviewed online at www.scorecard.org, shows that in general the amount of material released from smokestacks is roughly equal to the amount coming through "fugitive" air releases. The total from both sources has decreased significantly since 1988, when almost 2.5 million pounds of air pollutants was released in the county. The figure for 1996 came to about 884,500 pounds.

However, the EDF report suggests that No-Sag did not contribute to the improvement, in fact increasing its own releases by 441 percent.

"That's a problem, from our perspective. You like to see these names on these bad-actor lists going down rather than up," EDF senior scientist Bill Pease told The Doings this week.

Representatives for No-Sag, contacted for comment, did not return The Doings' phone calls.

The EDF web page offers users an opportunity to contact the management of the companies named in its lists, and the companies also have a way to respond to the report online if they wish.

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EPA e-mail: fugitive emissions

"Morris, Stephen"
<SMorris@sterigenics.com>
01/26/2006 10:00 AM

To David Markwordt/RTP/USEPA/US@EPA
cc "Hoffman, Kathy" <KHoffman@sterigenics.com>
bcc
Subject Sterigenics Willowbrook Fugitive Emissions

Mr. Markwordt,

Per our conversation, this is to confirm that the fugitive emissions that were listed
in our 2003 Emission Report was exclusively from our chamber backvents. The data
was from our 2002 ethylene oxide usage for our Willowbrook facility. The backvents were not connected to a control device in 2002; therefore, we treated them
as fugitive. Subsequently, the backvents were connected to a control device and
the emissions to the atmosphere were significantly reduced.

I hope that this clarifies the levels of ethylene oxide emissions from our Willowbrook facility.

Regards,

Stephen Morris
Director EH&S
Phone 630-928-1724
Fax 630-928-1701
E Mail: SMorris@Sterigenics.com

Failure to control

IEMA **Illinois Emergency Management Agency**

Return to the main IEMA website

Hazardous Materials Incident Report

*NOTE: The following fields have been deleted or removed from some of the reports contained in this database: Callback Phone, Number Injured, Number Killed, On Scene Contact Phone, Responsible Party Contact Person, Responsible Party Callback Phone.

Incident Number:	H-2013-1147
Incident Report Date:	10/21/2013 1:50:12 PM
Street Address of Incident Location:	7775 S. Quincy St
Incident Location City:	Willowbrook
Incident Location County:	DuPage
Entered By:	Kutner, Paul (IEMA)
Data Input Status:	Closed
Leaking Underground Storage Tank (LUST)?:	No
Caller:	Kevin Wagner
Caller Represents:	Semignics
Hazmat Incident Type: HAZMAT:	Gas or vapor cloud
	Incident Location
Date/Time Occurred:	2013-10-20 16:49
Street:	7775 S Quincy St
City:	Willowbrook
State:	
County:	DuPage
Mahpost:	
Section:	
Township:	
Range:	
Area Involved:	Air
Latitude:	
Longitude:	
Media or medium into which the release occurred:	Air
	Weather Information
Temp:	Less 60s
Wind:	Unknown by caller
	Materials Involved
Name:	Ethylene Oxide
Type:	Gas
CHRIS CODE:	Unknown
CAS#:	75-21-8
UN/NA #:	Unknown

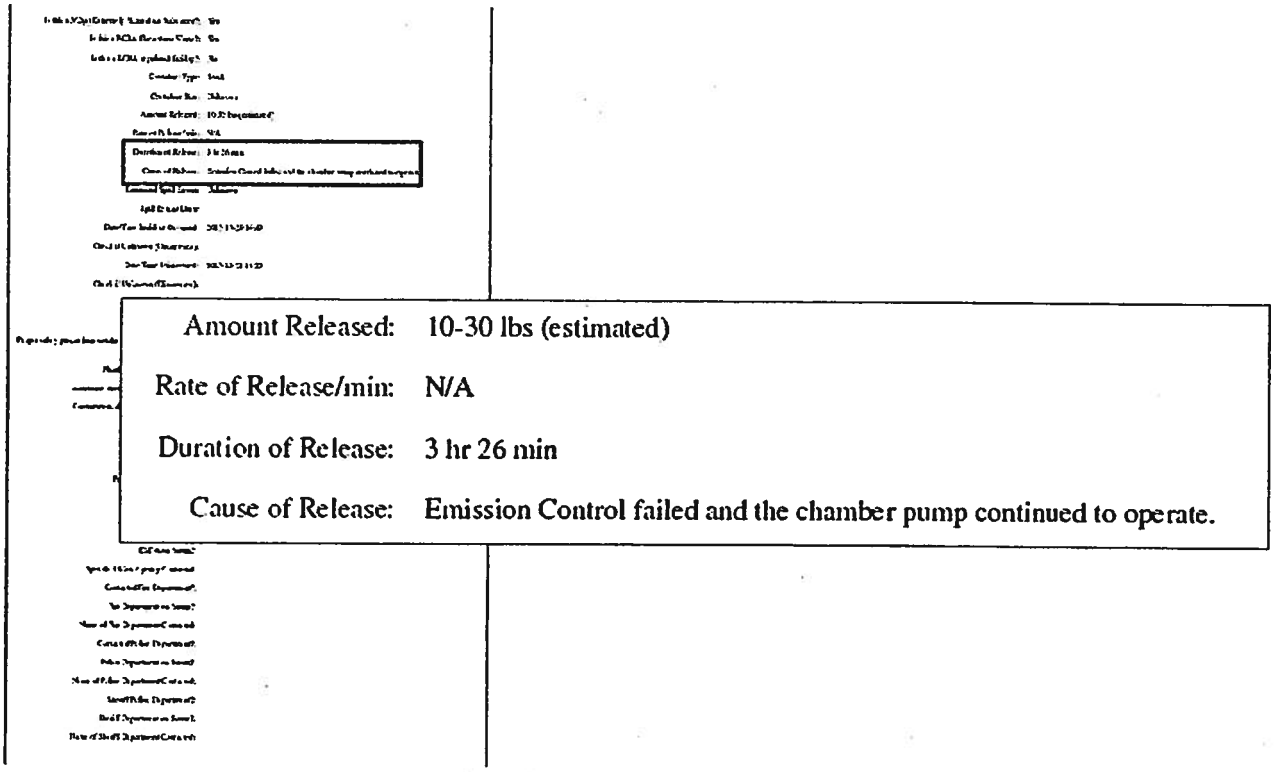
Incident Number:	H-2013-1147
Incident Report Date:	10/21/2013 1:50:12 PM

Name:	Ethylene Oxide
Type:	Gas

Non-compliance report

Incident Number:	H-2013-1147
Incident Report Date:	10/21/2013 1:50:12 PM

Name:	Ethylene Oxide
Type:	Gas



Amount Released:	10-30 lbs (estimated)
Rate of Release/min:	N/A
Duration of Release:	3 hr 26 min
Cause of Release:	Emission Control failed and the chamber pump continued to operate.

IN THE CIRCUIT COURT OF THE EIGHTEENTH JUDICIAL CIRCUIT
DUPAGE COUNTY, ILLINOIS
CHANCERY DIVISION

PEOPLE OF THE STATE OF ILLINOIS, *ex rel.* LISA MADIGAN, Attorney General of the State of Illinois,

Plaintiff,

v.

STERIGENICS U.S. LLC, a Delaware limited liability company,

Defendant.

2015CH000651

Status Date: 07/31/15

Assigned To: 2007

No.

FILED
Apr 03 2015 - 11:57 AM
CLERK OF THE 18TH JUDICIAL CIRCUIT DU PAGE COUNTY ILLINOIS

COMPLAINT FOR INJUNCTION AND CIVIL PENALTIES

Plaintiff, PEOPLE OF THE STATE OF ILLINOIS, *ex rel.* LISA MADIGAN, Attorney General of the State of Illinois, complains of the Defendant, STERIGENICS U.S. LLC, as follows:

Formal Enforcement –

State/EPA	Activity Type	Enforcement ID	Enforce-ment Code		Settlement Entered Date
State	Judicial	IL000A000017043000213	CIV	October 7, 2013 – release of ethylene glycol October 21 – release of 12lbs of ethylene oxide	09-18-05
EPA	Administrative	ICIS-05-2003-A072	113A	Violations for failure to monitor, fail to keep records, reporting, testing/samples	12-24-02
State	Administrative	IL000A000017043000213	SCAAAO		01-18-00
State	Administrative	IL000A000017043000213	SCAAAO		01-18-00
DOL	OSHA	308153717	Serious	Multiple violations	2-22-2006

Informal Enforcement—

State/EPA	Activity Type	Enforce-ment ID	Enforcement Code	Description	Date End
State	Administrative	IL000A000017043000213	NOV		11-12-13
State	Administrative	IL000A000017043000213	NOV	-ethylene oxide release	12-7-99
State	Administrative	IL000A000017043000213	NOV		6-26-92

Other —

State/EPA	Inspection Type	Source ID		Description	Date
State	Title V Annual Compliance Certificate	IL000043110AAC		Facility Report Deviations	5-1-18
State	Title V Annual Compliance Certificate	IL000043110AAC	In Violation	Facility Report Deviations	5-27-14

Amicus - EXHIBIT J

https://capitolfax.com/

Capitol Fax.com - Your Illin... ×

Web Slice Gallery ▾ Suggested Sites ▾

Sterigenics law vs. Sterigenics agreed order

Friday, Jul 19, 2019

* We've been talking a lot about Sterigenics, so I asked yesterday for a chart comparing the ethylene oxide regulations in the bill sponsored by House Republican Leader Durkin and signed into law by Gov. Pritzker with the additional regulations included in the consent order that was agreed to by Attorney General Kwame Raoul, DuPage County State's Attorney Robert Berlin, the IEPA and Sterigenics. Here's what the AG's office compiled. Click the pic if you need a better image...

Comparison of Legislation and Consent Order
Limiting EtO Emissions & Protecting Illinois Residents

STRICTEST IN NATION REGULATIONS IN LEGISLATION & CONSENT ORDER	ADDITIONAL STEPS TAKEN IN CONSENT ORDER
• **Emissions:** Provide the strictest requirements on EtO emissions at EtO sterilization sources in the nation • **Capture:** Require (a) 100% capture of all EtO emissions and a demonstration of such capture of emissions, and (b) that emissions to the atmosphere from each exhaust point at the source meet the control efficiency of at least 99.9% or 0.2 parts per million • **Limit:** Require a limit on EtO usage • **Testing:** Require EtO sterilization sources to (a) conduct EtO emissions testing pursuant to an IEPA-approved protocol and (b) submit documentation of the results of such tests to IEPA • **Monitoring:** Require continuous emissions monitoring of EtO emissions pursuant to an IEPA-approved plan, require ambient air monitoring pursuant to an IEPA-approved plan • **Corrective Action:** In the event of a test failure and cessation of commercial sterilization operations, require corrective actions and IEPA approval prior to resumption of commercial sterilization operations	On top of the strictest in the nation regulations passed by the legislature, the Consent Order goes above and beyond to further hold Sterigenics accountable: • **Monitoring:** Require ambient air monitoring near the Willowbrook facility and in the community every third day over one 30-day period while the facility is in operation • **Corrective Action:** Subject Sterigenics to penalties and contempt of court for non-compliance with the terms of the Consent Order • **Timing:** Prohibit Sterigenics' Willowbrook facility from resuming commercial sterilization operations until after Sterigenics constructs new emissions control systems and receives written approval from IEPA • **Loophole Closure:** Eliminate Sterigenics' eligibility for the exception to certification requirements

I followed up to ask about that loophole closure, which AG Raoul mentioned yesterday...

> The new law contains certification requirements that currently apply to Sterigenics, but the law contains an exception. Sterigenics could have qualified for the exception if it proved to a court that the findings of the seal order were without merit. The consent order takes away Sterigenics' ability to even make this argument in court. As a result, Sterigenics no longer has the ability to qualify for the exception to the certification requirements.

- Posted by **Rich Miller** Comments Off

Can't this state even do anything right?

Amicus - EXHIBIT K

ENVIRONMENTAL PROTECTION AGENCY
OF THE STATE OF ILLINOIS

IN THE MATTER OF:	)	
	)	
Commercial Sterilization Operations	)	
at 7775 South Quincy Street and	)	
830 Midway Street, Willowbrook,	)	
DuPage County, Illinois	)	**SO: 2019-**
	)	
RESPONDENT:	)	
Sterigenics U.S., LLC	)	

SEAL ORDER

This matter comes before the Acting Director of the Illinois Environmental Protection Agency, John J. Kim, pursuant to Section 34(b) of the Illinois Environmental Protection Act, 415 ILCS 5/34(b) (2018), for a Seal Order in this matter.

THE ILLINOIS ENVIRONMENTAL PROTECTION AGENCY HEREBY FINDS THAT:

1. There exist two buildings located in close proximity in the Village of Willowbrook, DuPage County, Illinois - one at 7775 South Quincy Street and the other at 830 Midway Street. Both buildings house commercial sterilization operations and associated storage and transshipment activities.
2. The owner of both buildings, and the operator of the commercial sterilization operations, is Respondent, Sterigenics U.S., LLC.
3. Respondent uses ethylene oxide in its sterilization operations, and ethylene oxide is released from Respondent's buildings to the atmosphere.
4. In 1990, the United States Environmental Protection Agency listed ethylene oxide as a hazardous air pollutant under Section 112(b)(1) of the Clean Air Act, 42 U.S.C. 7412(b)(1).
5. From 1985 to 2016, the United States Environmental Protection Agency categorized ethylene oxide as "probably carcinogenic to humans."
6. In December 2016, the United States Environmental Protection Agency's Integrated Risk Information System ("IRIS") program released an "Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide" ("2016 IRIS Evaluation"), which recharacterized ethylene oxide as "carcinogenic to humans" while increasing the lifetime inhalation cancer unit risk estimate for ethylene oxide about 30 times.
7. In the 2016 IRIS Evaluation, the United States Environmental Protection Agency recognized that an increased incidence and mortality of breast and lymphohematopoietic system cancers have been observed in workers at sterilization operations using ethylene oxide, and there is sufficient evidence to establish a causal relationship between ethylene oxide exposure and breast cancer in women.
8. The 2016 IRIS Evaluation noted that as a mutagenic carcinogen, ethylene oxide causes cancer by damaging DNA in cells which is then duplicated when the cells divide. Exposure to ethylene oxide increases the cancer risk because DNA damage may take place with each and every exposure that is passed on to more cells, increasing the number of mutated cells, which eventually leads to cancer in some people.

9. Respondent's operations are conducted in a densely populated, residential, industrial, commercial and governmental area with more than 19,000 people living within 1 mile of Respondent's two buildings and many more working there. Within 1 mile of Respondent's buildings, there are homes, schools, parks, government buildings and businesses.
10. The United States Environmental Protection Agency identified 7 census tracts near Respondent's operations as having cancer risk scores greater than 1 in 10,000, i.e., an additional 1 incidence of cancer per 10,000 people.
11. The United States Environmental Protection Agency collected ambient air samples at 26 discrete locations near Respondent's operations and utilized that data to model short-term and long-term ambient concentrations of ethylene oxide in the area. The United States Environmental Protection Agency provided the ambient sampling data and the results of its modeling to the United States Department of Human Services' Agency for Toxic Substances and Disease Registry ("ATSDR") and requested that the ATSDR determine: "if modeled and measured ethylene oxide concentrations represent long term conditions, would they pose a public health problem for people living and working in Willowbrook?"
12. On August 21, 2018, the ATSDR issued a Public Health Consultation Letter to the USEPA in answer to the request set forth in paragraph 11. In that Consultation Letter, the ATSDR concluded, in part, that:

    It is ATSDR's conclusion that the data U.S. EPA provided suggests that residents and workers are exposed to elevated airborne EtO [ethylene oxide] concentrations from facility emissions. It is difficult to assess long-term public health implications from facility emissions because there has been no historical air monitoring in the community. ATSDR assumed that these data represent long term exposures for area residents and workers. Specifically, ATSDR concludes the following:

    1) If measured and modeled data represent typical EtO ambient concentrations in ambient air, *an elevated cancer risk exists* (emphasis in original) for residents and off-site workers in the Willowbrook community surrounding the Sterigenics facility. These elevated cancer risks *present a public health hazard to these populations* (emphasis in original).
13. The ATSDR used the highest [then-available] residential area and commercial area sampling results (2.1 micrograms per meter^3 and 9.1 micrograms per meter^3, respectively) to reach its conclusion.
14. Ambient air sampling was conducted by the United States Environmental Protection Agency and the Village of Willowbrook in November and December of 2018 and January and February of 2019. The ambient data collected in November and December of 2018 consistently found outdoor ambient levels of ethylene oxide in commercial and residential areas as high or higher than the levels used by ATSDR.
15. Regulations promulgated by the United States Environmental Protection Agency under the Clean Air Act's National Emission Standards for Hazardous Air Pollutants ("NESHAP") for emission of ethylene oxide from commercial sterilization operations, 40 C.F.R. Part 63, Subpart O, well before the recognition of ethylene oxide as a human carcinogen, only required control of emissions (99% reduction of inlet emissions into the control device) from the sterilization chamber evacuation systems and the aeration rooms and did not require control of emissions from sterilization chamber back vents or from other operations at the facility (i.e., movement of sterilized material from the sterilization chamber to the aeration room and from the aeration room into storage or out on trucks for customer deliveries). So far, the emission levels from those other operations have only been crudely estimated.

16. The testing required by the federal NESHAP regulations from the sterilization process only determines the efficiency of the control equipment.
17. In the Spring of 2018, Respondent applied for and obtained a permit authorizing the connection of its back vent emissions to its existing control devices. After completing the connection, Respondent performed testing of the emissions under observation by the Illinois Environmental Protection Agency and the United States Environmental Protection Agency and demonstrated 99% control was achieved.
18. Respondent's emissions are continuing to contribute to ambient levels of ethylene oxide in the atmosphere. This impact creates an imminent and substantial endangerment to public health or welfare.
19. The Illinois Environmental Protection Agency should seal such portions of Respondent's buildings as are necessary to prevent the commencement of any new sterilization cycles using ethylene oxide until measures are in place to prevent emissions of ethylene oxide that contribute to ambient levels of ethylene oxide which present a public health hazard to residents and off-site workers in the Willowbrook community.

THEREFORE, PURSUANT TO THE AUTHORITY VESTED IN THE DIRECTOR OF THE ILLINOIS ENVIRONMENTAL PROTECTION AGENCY BY SECTION 34(b) OF THE ILLINOIS ENVIRONMENTAL PROTECTION ACT, I HEREBY ORDER THAT THE FOLLOWING PORTIONS OF RESPONDENT'S BUILDINGS ARE SEALED FORTHWITH:

All storage containers of ethylene oxide.

Persons authorized, in writing, by the Director of the Illinois Environmental Protection Agency may access the sealed portion of these properties to conduct activities within the scope of their specified authorization.

SAID PROPERTY SHALL REMAIN SEALED UNTIL SUCH TIME AS THIS SEAL ORDER HAS BEEN RESCINDED BY THE ILLINOIS ENVIRONMENTAL PROTECTION AGENCY.

It is a Class A misdemeanor to break any seal or operate any sealed facility until the seal is removed according to law.

Signed:

John J. Kim, Acting Director
Environmental Protection Agency of the State of Illinois
Date: 2-15-19

Amicus - EXHIBIT L

Willowbrook, IL Ethylene Oxide Concentrations in Outdoor Air [ug/m^3] - 24 Hour Samples

Sample Start Date	Willowbrook Village Hall	Willowbrook Village Hall 2	EPA Willowbrook Warehouse	EPA Willowbrook Warehouse 2	Gower Middle School	West Neighborhood	Water Tower	Willow Pond Park	Hinsdale South High School	Gower Elementary School
11/13/2018	Invalid	-	2.37	-	-	-	-	-	-	-
11/16/2018	0.824	-	1.81	1.81	-	-	-	-	-	-
11/19/2018	6.11	6.31	6.62	-	0.155	0.125	0.246	0.105	0.253	0.164
11/23/2018	0.284	-	0.180	Invalid	0.197	0.205	0.893	0.286	Invalid	0.202
11/25/2018	4.10	-	Invalid	Invalid	0.360	0.261	Invalid	0.345	0.665	0.411
11/28/2018	1.83	-	0.248	1.14	0.656	ND	0.699	0.455	0.376	0.474
12/1/2018	1.68	1.90	0.456	-	0.140	0.804	ND	0.211	0.629	0.464
12/6/2018	5.39	-	11.7	10.5	0.605	0.254	0.389	ND	0.486	ND
12/7/2018	0.737	0.822	2.26	-	0.112	ND	0.273	0.403	ND	0.164
12/10/2018	0.300	-	0.269	0.403	ND	0.213	0.248	ND	0.213	0.138
12/13/2018	2.04	2.13	0.436	-	0.255	1.06	0.211	0.365	0.244	0.401
12/16/2018	0.871	-	2.11	2.19	0.593	0.604	0.535	0.334	0.511	0.732
12/19/2018	0.521	0.338	0.345	-	0.360	0.197	1.67	0.546	0.267	0.311
12/22/2018	0.981	-	3.09	2.57	0.522	0.235	0.441	0.116	0.376	0.360
12/26/2018	10.8	10.5	Invalid	-	ND	1.17	0.151	0.166	0.566	0.497
12/28/2018	0.672	-	1.42	1.19	0.175	ND	Invalid	ND	0.264	0.133
1/2/2019	0.251	-	0.237	0.396	ND	ND	ND	0.217	ND	0.210
1/3/2019	0.372	0.257	ND	-	ND	ND	ND	ND	0.428	0.633
1/6/2019	7.59	6.62	ND	-	ND	1.56	ND	ND	0.249	0.249
1/9/2019	3.81	-	Invalid	0.685	0.354	0.115	ND	0.219	0.295	Invalid
1/12/2019	1.57	1.65	ND	-	ND	0.727	0.307	ND	0.264	0.237
1/15/2019	0.672	-	14.2	14.3	0.918	0.119	ND	0.107	0.239	ND
1/17/2019	0.517	0.591	13.1	-	1.66	0.151	0.316	0.144	0.134	ND
1/22/2019	1.51	-	4.10	4.05	0.349	1.07	10.8	2.21	0.349	0.598
1/24/2019	0.262	0.158	0.280	-	0.077	0.060	0.082	0.114	ND	0.095
1/27/2019	19.3	-	1.11	1.26	0.155	1.65	1.75	0.813	3.29	0.293
2/1/2019	0.954	0.882	0.133	-	0.101	0.129	9.49	3.71	0.322	0.157
2/2/2019	0.383	-	0.228	0.251	0.371	0.160	7.48	1.40	0.131	0.215
2/5/2019	17.3	15.6	26.4	-	3.29	5.35	0.208	0.174	0.237	1.38
2/8/2019	0.725	-	5.04	4.30	0.439	0.275	0.233	0.213	0.347	0.202
2/11/2019	3.98	4.72	ND	-	0.114	1.321	ND	0.089	0.309	0.398
2/14/2019	0.178	-	0.745	0.609	0.286	ND	0.495	0.244	0.258	ND
2/19/2019	0.239	0.197	0.150	-	0.202	0.298	0.222	ND	0.162	ND
2/20/2019	0.260	-	0.159	0.197	ND	ND	ND	0.111	ND	0.148
2/21/2019	0.144	-	ND	ND	-	-	-	-	-	-
2/22/2019	0.123	0.217	0.121	-	-	-	-	-	-	-
2/23/2019	0.128	-	0.132	ND	0.164	0.165	0.179	0.171	0.282	Invalid
2/26/2019	0.166	ND	0.119	-	ND	0.114	0.084	ND	0.188	ND
3/1/2019	ND	-	0.103	0.144	ND	ND	0.142	0.148	0.125	0.145
3/4/2019	0.161	0.068	ND	-	ND	0.113	ND	0.108	0.122	0.124
3/7/2019	0.099	-	0.096	0.085	0.093	0.112	0.165	0.122	ND	ND
3/10/2019	Invalid	0.204	0.075	-	0.171	0.201	0.081	0.244	0.102	0.097
3/13/2019	0.204	-	0.122	0.240	0.246	0.195	0.219	0.147	0.139	0.394
3/16/2019	0.461	0.058	0.171	-	0.267	0.109	ND	0.322	0.102	0.056
3/19/2019	0.136	0.091	0.056	-	0.082	0.037	0.079	0.206	0.082	0.215
3/22/2019	0.060	-	0.117	0.206	0.068	0.197	0.075	0.177	0.224	0.181
3/25/2019	0.078	0.183	0.134	-	0.084	0.102	0.093	0.130	0.133	0.106
3/28/2019	0.114	-	0.181	0.224	0.233	0.120	0.092	0.151	0.175	0.174
3/31/2019	0.057	0.112	ND	-	0.099	0.242	0.087	0.136	0.072	0.138

Note: For quality assurance, EPA's monitoring plan calls for collocated samples to be collected for each sampling day at the Willowbrook Village Hall or the EPA Willowbrook Warehouse – the expected locations of maximum concentrations. Those data are reported in the table as Willowbrook Village Hall 2 and EPA Willowbrook Warehouse 2.

ND – non detect. Ethylene Oxide was either not present in the sample or was at a level below the level the method could detect.

Invalid – the sample did not meet EPA's field, shipping, laboratory or other quality assurance criteria.

Trans -2- butene detected although concentration is too low to quantify.

Unscheduled samples at maximum concentration sites only.

Amicus - Exhibit M

Cancer Incidence Assessment near Sterigenics in Willowbrook, IL, 1995-2015

A publication of the

Illinois Department of Public Health

Division of Epidemiological Studies

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Cancer Incidence Assessment near Sterigenics in Willowbrook, IL, 1995-2015

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Abstract

Background: The Division of Epidemiologic Studies, Illinois Department of Public Health (IDPH), conducted an assessment to determine if there is elevated cancer incidence in the population surrounding the Sterigenics facility in Willowbrook, Illinois. The facility, operating since 1984, has been emitting ethylene oxide (EtO), a currently known carcinogen.

Methods and Data: Cancer cases were obtained from the Illinois State Cancer Registry (ISCR) for diagnosis years 1995-2015. Two study areas were created based on census tracts and an air sampling/exposure model. Study area 1 included nine census tracts around the Sterigenics facility, and study area 2 included study area 1 and eight additional census tracts. Cases were geocoded into the study areas based on addresses using a combination of GIS software and manual scrutiny. Two groups of cancers were examined. The first group included lymphohematopoietic cancers (non-Hodgkin's lymphoma, Hodgkin's lymphoma, myeloma, and lymphocytic leukemia) and female breast cancer, a group of cancers that have been documented to be associated with EtO exposure. The second group included other common cancer sites. Trends in the lymphohematopoietic and breast cancers were examined, and pediatric cancers were studied separately. Standardized incidence ratios (SIR's) and their 95% confidence intervals (CI) were calculated with comparable county and state populations as references.

Results: Significantly elevated Hodgkin's lymphoma cases in females were observed in study area 1 as compared to county (SIR 1.86, CI 1.12-2.91) and state averages (SIR

1.89, CI 1.14-2.95). Female breast cancer was elevated in both study areas when compared to the state average (Study Area 1: SIR 1.10, CI 1.02-1.18; Study Area 2: SIR 1.07, CI 1.02-1.13). The elevation, however, became non-significant when compared to the county average. Trends in SIR's showed a monotonic increase with time in female non-Hodgkin's lymphoma, with the SIR becoming statistically significant in the most recent time period, 2009-2015 (Study Area 1: SIR 1.61, CI 1.19-2.21; Study Area 2: SIR 1.33, CI 1.07-1.63). Pediatric lymphoma was observed to be elevated over the entire study period in females of both study areas. Other adult cancer sites observed to be elevated include prostate cancer, and female pancreatic, ovarian, and bladder cancers. Also, female leukemia was found to be significantly lower than expected, and lung cancer seemed to be lower in both males and females.

Conclusions: The study's results, when taken as a whole, indicated that some cancers were elevated in populations living near the Sterigenics facility in Willowbrook, Illinois. Many apparent differences and inconsistences, however, existed between genders, across study areas, and among cancer sites. Further studies, preferably with larger populations and multiple facilities, are strongly recommended to confirm this assessment's findings.