

Proposed Consent Order in *People v. Sterigenics*: Overview and Frequently Asked Questions (FAQ)

On July 17, 2019, the Illinois Attorney General and DuPage County State’s Attorney filed a motion seeking court approval of a proposed consent order (“Consent Order”) in their lawsuit against Sterigenics U.S, LLC (“Sterigenics”) related to emissions of ethylene oxide (“EtO”) from the company’s commercial sterilization facility in Willowbrook, Illinois. This document provides an overview of what the Consent Order is and responds to questions the public may have about it.

Overview

- The Consent Order is a court-enforced agreement that resolves the State of Illinois’ lawsuit against Sterigenics related to EtO emissions from the company’s Willowbrook facility, as well as Sterigenics’ lawsuit challenging and seeking to lift the February 15, 2019 order prohibiting the use of EtO at the Willowbrook facility.
- The Consent Order is consistent with and provides additional requirements beyond those in Illinois’ new ethylene oxide (“EtO”) law, 415 ILCS 5/9.16, also known as The Matt Haller Act (the “New EtO Law”), regulating EtO sterilization facilities like Sterigenics’ Willowbrook facility. The New EtO Law sets the strictest requirements in the nation for such facilities. The Consent Order builds on the new law and imposes additional requirements applicable specifically to Sterigenics’ Willowbrook facility which is comprised of two buildings: Willowbrook I, located at 7775 South Quincy Street, Willowbrook, Illinois, and Willowbrook II, located at 830 Midway Street, Willowbrook, Illinois.
- Under the Consent Order, Willowbrook I is prohibited from resuming sterilization operations using EtO unless and until Sterigenics installs new emissions capture and control systems that must be approved by IEPA. Sterigenics will also be required to demonstrate to IEPA, through testing, that these new systems work. If Sterigenics fails these tests, the Consent Order requires Willowbrook I to again cease sterilization operations using EtO.
- The Consent Order prohibits Willowbrook II from resuming sterilization operations using EtO, unless and until Sterigenics undertakes a separate process to meet the same stringent requirements applicable to Willowbrook I, which includes obtaining a construction permit from IEPA and amending the Consent Order to require compliance with the construction permit.
- Under the requirements imposed through the Consent Order and the New EtO Law:
 - Sterigenics will be reducing its EtO emissions from the Willowbrook facility to no more than 85 pounds per year—a drastic reduction from Sterigenics’ reported annual emissions from 2006 to 2018, which ranged from 2,840 pounds to 7,340 pounds per year; and
 - Sterigenics will not cause a lifetime cancer risk in the surrounding community that is above the 1 chance in 10,000 “upper bound” threshold that is relied upon by the United States Environmental Protection Agency (“USEPA”)— indeed, after the required improvements, the lifetime cancer risk from Sterigenics’ EtO emissions will be much closer to 1 chance in 1,000,000, USEPA’s most protective standard.

Litigation History

- On October 30, 2018, the State filed a lawsuit alleging that Sterigenics, through its emissions of ethylene oxide, (a) caused, threatened or allowed air pollution in violation of Section 9(a) of the Illinois Environmental Protection 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; and (b) created and maintained a common law public nuisance (the “State’s Case”).
- On February 15, 2019, John Kim, then Acting Director of the Illinois Environmental Protection Agency (“IEPA”), signed a seal order pursuant to 415 ILCS 5/34(b) that sealed “[a]ll storage containers of ethylene oxide” at Sterigenics’ Willowbrook facility in Willowbrook, Illinois (the “Seal Order”).
- On February 18, 2019, Sterigenics challenged the Seal Order by filing a lawsuit in the United States District Court for the Northern District of Illinois, *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 the basis of lack of federal jurisdiction. On May 6, 2019, Sterigenics filed another lawsuit in the Circuit Court for DuPage County, *Sterigenics U.S., LLC v. Kim et al.*, Case No. 2019CH000566 (Cir. Ct., DuPage County) (the “Seal Order Litigation”). In both the Federal Litigation and the Seal Order Litigation, Sterigenics named Director Kim and IEPA as defendants.
- On June 24, 2019, Sterigenics filed a construction permit application for Willowbrook I with the Illinois EPA.
- On July 17, 2019, the Attorney General’s Office, DuPage County State’s Attorney’s Office and Sterigenics filed a Joint Motion to Enter Consent Order with the DuPage County Circuit Court.

What is a “consent order”?

A consent order is an agreement worked out between two or more parties to a dispute. It generally has the same effect as a court order and can be enforced by the court if anyone does not comply with what the order requires.

What does this Consent Order do?

The Consent Order replaces the February 15, 2019 Seal Order and keeps Sterigenics from conducting sterilization operations with EtO at its Willowbrook facility until Sterigenics completes significant improvements to limit its EtO emissions. The judge can hold Sterigenics in contempt and impose monetary penalties for violations of the Consent Order. The Consent Order prohibits Sterigenics from using EtO at Willowbrook I unless and until Sterigenics: (i) obtains a permit from IEPA to, among other things, install stringent new capture and control systems in the building that minimize EtO emissions; and (ii) receives multiple written approvals from IEPA regarding required testing of the new control systems. This process could take up to six months, during which time Willowbrook I is prohibited from operating. While Sterigenics may, at some later date, seek to resume sterilization operations using EtO at Willowbrook II under similarly stringent requirements, Willowbrook II will continue to be prohibited from operating for the immediately foreseeable future. Additional details regarding the requirements applicable to Willowbrook I and II are provided below.

As to Willowbrook I, the Consent Order:

- prohibits Sterigenics from resuming sterilization operations using EtO at Willowbrook I until Sterigenics meets the requirements in the Consent Order and obtains written authorization from the State to resume sterilization operations using EtO;
- acknowledges Sterigenics' submission of a construction permit application to IEPA for additional capture and control measures that was required to include:
 - air dispersion modeling demonstrating that EtO emissions attributable to any future sterilization operations using EtO will be at or below a level satisfactory to IEPA;
 - construction of a "permanent total enclosure" system that provides 100% capture of emissions;
 - demonstration of a control efficiency of 99.9% or 0.2 ppm;
 - installation of an additional scrubber;
 - a proposed annual EtO usage limit [The June 24, 2019 construction permit application seeks an annual EtO usage limit at Willowbrook I of 300,000 pounds, as compared to the 542.1 tons (1,284,000 lbs) limit in Sterigenics' current operating permit.];
 - a proposed annual emissions limit [The June 24, 2019 construction permit application seeks an annual EtO emissions limit at Willowbrook I of no more than 85 pounds per year, as opposed to the 36,400 pound-per-year limit in Sterigenics' current operating permit. In 2018, Sterigenics reported emitting 2,840 pounds.];
 - a proposal for a stack height increase; and
 - a continuous emissions monitoring system;
- requires enhanced emissions testing by Sterigenics to demonstrate compliance with the 99.9% or 0.2 ppm control efficiency during all phases of operation;
- requires Sterigenics to conduct ambient air sampling pursuant to an ambient air monitoring plan;
- requires Sterigenics to cease sterilization operations using EtO if emissions testing demonstrates non-compliance with the 99.9% or 0.2 ppm control efficiency and allows such operations to resume only if the cause of the noncompliance is identified, and approved corrective measures are implemented;
- prior to any resumption of sterilization operations using EtO, Sterigenics must obtain written approval from IEPA that Sterigenics has completed construction of the emissions capture and control systems;
- requires Sterigenics' implementation of best management practices set forth in the Consent Order;
- replaces the Seal Order with a court-enforceable Consent Order that prohibits resumption of sterilization operations using EtO at Willowbrook I until specific conditions in the Consent Order are met;

- requires Sterigenics' compliance with all other federal, state and local laws or regulations, which includes the New EtO Law;
- resolves the State's enforcement action against Sterigenics; and
- requires that Sterigenics dismiss its lawsuit challenging the issuance of the Seal Order.

As to Willowbrook II, the Consent Order:

- prohibits Sterigenics' resumption of sterilization operations using EtO at Willowbrook II unless and until Sterigenics undertakes a separate process to meet the same stringent requirements applicable to Willowbrook I, which includes obtaining a construction permit from IEPA and amending the Consent Order to require compliance with the construction permit.

How long will the Consent Order remain in effect?

The Consent Order may terminate only if Sterigenics demonstrates that it has been in compliance with the terms of the Consent Order for at least five years or if Sterigenics permanently ceases operations at the Willowbrook facility.

Why is the Seal Order replaced with the Consent Order?

- The Consent Order is a stronger legal tool than the Seal Order. The Seal Order has been challenged both in federal and state court by Sterigenics. If litigation had continued, Sterigenics could have potentially gotten the Seal Order lifted and resumed operations before completing needed improvements for controlling EtO emissions. By contrast, once the Consent Order is in place, Sterigenics will have no legal ability to challenge its requirements or to resume operations prior to meeting those requirements.
- The Consent Order ensures that Sterigenics' Willowbrook facility is prohibited from resuming sterilization operations using EtO until it can reopen consistent with the requirements in the Consent Order and the New EtO Law. The State's Attorney and the Attorney General's Office can seek to enforce the Consent Order in DuPage County Circuit Court immediately upon a violation, rather than re-starting the enforcement process with a new administrative proceeding or court action.
- Implementation of the Consent Order's requirements will meet the standard articulated in the Seal Order for when Sterigenics could resume use of EtO. Paragraph 19 of the Seal Order stated:

The Illinois Environmental Protection Agency should seal such portions of [Sterigenics'] buildings as are necessary to prevent the commencement of any new sterilization cycles using EtO until measures are in place to prevent emissions of EtO that contribute to ambient levels of EtO which present a public health hazard to residents and off-site workers in the Willowbrook community.

Once the requirements of the Consent Order are implemented, “measures” will be “in place” that prevent Sterigenics from causing a “public health hazard” through EtO emissions from its Willowbrook facility. As noted above, the risk from Sterigenics’ EtO emissions will fall significantly below the 1 in 10,000 risk threshold used by USEPA.

When will Sterigenics reopen?

- Sterigenics will only be able to resume sterilization operations with EtO if it is able to comply with the Consent Order and the New EtO Law. At this point, it is difficult to say exactly when or if that will occur. The process for installing the improvements required by the Consent Order could take up to six months, during which time the Willowbrook facility is prohibited from conducting sterilization operations with EtO.

What does the Consent Order provide as compared to the New EtO Law ?

Many of the provisions in the Consent Order mirror requirements in the New EtO Law. Sterigenics will be required to comply with both sets of requirements. The provisions of the Consent Order go beyond the provisions of the New EtO Law and are also specific to Sterigenics. Both the Consent Order and the New EtO Law:

- provide the strictest requirements on EtO emissions at EtO sterilization sources in the nation, though the Consent Order only applies to Sterigenics’ Willowbrook facility;
- 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;
- require a limit on EtO usage;
- require Sterigenics, as an EtO sterilization source, to (a) conduct EtO emissions testing pursuant to an IEPA-approved protocol and (b) submit documentation of the results of such tests to IEPA;
- require cessation of commercial sterilization operations if emission stack testing demonstrates non-compliance with the 99.9% or 0.2 ppm control efficiency;
- 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;
- require continuous emissions monitoring of EtO emissions pursuant to an IEPA-approved plan;
- require ambient air monitoring pursuant to an IEPA-approved plan; and
- require dispersion modeling that demonstrates to IEPA’s satisfaction that EtO emissions will be adequately controlled.

The Consent Order also includes requirements that go beyond the New EtO Law, such as:

- prohibiting Sterigenics' Willowbrook facility from resuming commercial sterilization operations until after Sterigenics constructs new emissions control systems and receives written approval from IEPA;
- requiring 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;
- subjecting Sterigenics to penalties and contempt of court for non-compliance with the terms of the Consent Order; and
- prohibiting resumption of commercial sterilization operations at Willowbrook II for the immediately foreseeable future.

The New EtO Law also contains other requirements that are separate from the Consent Order. Sterigenics must comply with the New EtO Law regardless of whether the provisions of the new law also appear in the Consent Order. The New EtO Law also:

- prohibits any facility that has been the subject of a seal order from using EtO for sterilization or fumigation purposes unless: (i) a supplier of a product to be sterilized certifies that EtO sterilization is the only available method to completely sterilize the product; and (ii) IEPA certifies that the facility's emissions control system uses technology that produces the greatest reduction in EtO emissions currently available; OR, if a court finds that the supporting findings of the seal order are without merit;
- requires a company using EtO to notify IEPA if such company acquires any intellectual property right in a technology that does not involve EtO;
- sets forth location and notice requirements on any new EtO sterilization facilities not in existence prior to January 1, 2020;
- requires each EtO sterilization source to apply for and obtain (i) a construction permit from IEPA for any modifications made to the source to comply with the requirements of the new law and (ii) an operating permit to incorporate such modifications made to the source;
- requires each EtO sterilization source to notify IEPA within 5 days after discovering any deviation from any of the requirements of the New EtO Law, the Illinois Environmental Protection Act, the USEPA's rules or the Illinois Pollution Control Board's rules relating to EtO;
- requires IEPA to conduct at least one unannounced inspection annually;
- requires an EtO sterilization source to perform quarterly ambient air monitoring indefinitely; and

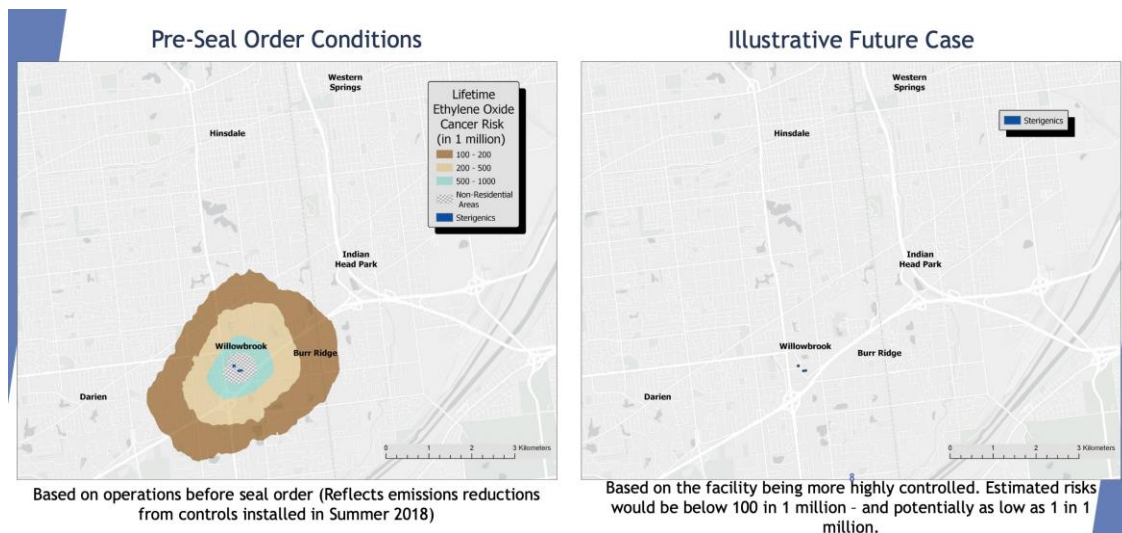
- requires IEPA to conduct air testing to determine the ambient levels of EtO throughout the State.

What if an ambient air monitor detects ethylene oxide?

- Following the issuance of the Seal Order, USEPA's monitoring program still detected EtO in the Willowbrook area which USEPA has described as an "urban background" that is not attributable to Sterigenics. USEPA has not attributed this EtO to any particular source or sources but is continuing its evaluation.
- If an ambient air monitor detects a level of ethylene oxide above what could reasonably be considered "urban background," IEPA will investigate whether Sterigenics is the source and take appropriate action.

How does the Consent Order reduce cancer risk?

- The Consent Order ensures a dramatic reduction of EtO emissions from Sterigenics' Willowbrook facility to an amount that is less than 1% of the emissions allowed under Sterigenics' current operating permit.
- Dispersion modeling shows that, following the required controls in the Consent Order, the lifetime cancer risk to the community from Sterigenics' EtO emissions will be reduced to well below USEPA's "upper bound" cancer risk estimate of 1 chance in 10,000 people over a lifetime. In fact, the risk to the community from Sterigenics' emissions will be much closer to USEPA's most protective standard of 1 chance in 1,000,000 people over a lifetime.
- Dispersion modeling shows that the improvements required by the Consent Order and the law will be sufficient to ensure that Sterigenics will not cause or contribute to a cancer risk that would show up on the National Air Toxics Assessment (NATA) map.
- In its updated risk assessment, USEPA modeled risk using Sterigenics' EtO emissions prior to the Seal Order, but after Sterigenics controlled its "back vent" emissions. Using that emissions number, USEPA identified an elevated risk. However, USEPA also included an "illustrative example" in its updated risk assessment that reflected the kind of controls required by the Consent Order. In that "illustrative example," the modeled pre-Seal Order risk is eliminated.



Available at <https://www.epa.gov/sites/production/files/2019-05/documents/risk-assessment-results-sterigenics-willowbrook.pdf>

How will the State monitor Sterigenics' compliance with the Consent Order?

- The Consent Order requires compliance with the construction permit which will specify the measures to be implemented and how sterilization operations using EtO will be monitored and verified to assure compliance.
- The New EtO Law requires the collection of continuous emissions information that will provide real-time data on Sterigenics' EtO emissions. If, upon reviewing that information, IEPA determines that Sterigenics is not complying with the Consent Order, the State can go to court to seek an order requiring that Sterigenics comply and seeking penalties for non-compliance.
- The New EtO Law requires that IEPA conduct at least one unannounced inspection of all ethylene oxide sterilization sources per year.
- The Consent Order requires that Sterigenics conduct emissions testing and prepare dispersion modeling, which is subject to IEPA's review and approval.

Will the required emissions test be representative of maximum emissions?

- Yes. The Consent Order expressly states that Sterigenics must submit a written test plan that ensures that the emissions test is representative of (a) the entirety of the batch process and (b) maximum EtO emissions from each of the cycles of commercial sterilization operations. If the testing demonstrates that the required control efficiency is not being met, Sterigenics must immediately cease sterilization operations using EtO until (i) measures are in place that ensure the efficiency is met and (ii) the State approves such measures in writing.

What is the reason for the increase in Willowbrook I's stack height, and what are the effects of any such increase?

- The presence of buildings near a stack can affect plume rise and initial dispersion of pollutants within the atmosphere. The purpose of the stack height increase is to address the possibility of this occurring at Willowbrook I. Specifically, an extended stack would minimize building-induced downwash of the plume, which may occur when the stack interacts with the building creating a current or eddy and pulling the plume to the ground, resulting in excessive nearby ambient concentrations. A stack height increase has no effect on the quantity of emissions. Rather, it limits downwash and thereby substantially reduces all ethylene oxide ambient impacts regardless of location.

Does the Consent Order resolve any lawsuits other than *People v. Sterigenics* and *Sterigenics v. IEPA*?

- No. The Consent Order only resolves those two lawsuits and not any other lawsuits that have been or may be brought by other persons against Sterigenics.

Does the Consent Order require Sterigenics to pay a civil penalty?

- In this case, the State believes all monies obtained from Sterigenics in the settlement should go to benefit the environment, in particular in the area in and around Willowbrook. Therefore, the Consent Order requires Sterigenics to put \$300,000 into an escrow account within 30 days of entry of the Consent Order, and within 60 days of entry, to propose one or more projects to the State for approval that are 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. The Projects must be completed within one year of entry of the Consent Order, unless otherwise agreed to by the State.
- The Consent Decree imposes the following penalties in the event Sterigenics fails to comply with any of its terms: 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. In addition, if Sterigenics does not comply with the terms of the Consent Order, the Court may hold Sterigenics in contempt.