



# COMPLY FIRST, CHALLENGE LATER: THE STERIGENICS AFFAIR AND FACILITY SHUTDOWN ORDERS

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The on-going saga of the Sterigenics facility in Smyrna continues to be the dominant environmental news story in Georgia. The facility, which uses ethylene oxide to sterilize a variety of medical instruments and devices, became the target of intense community, political, and regulatory pressure following a news article published by WebMD and Georgia Health News (GHN) on July 19<sup>th</sup> of this year.<sup>1</sup> According to the article, the United States Environmental Protection Agency's (USEPA's) most recent National Air Toxics Assessment indicated that the estimated risk of cancer due to ambient concentrations of ethylene oxide in the vicinity of this facility was higher than in previous assessments. Protests of the facility soon emerged, with several local residents and politicians demanding that the facility be shut down. In response to this pressure, the facility and the Georgia Environmental Protection Division (GEPD) entered into a consent order in which the facility agreed, among other things, to install new equipment and other facility improvements, and to implement new operational practices in order to minimize ethylene oxide emissions.<sup>2</sup> The facility has ceased operations while it installs the new equipment and makes the required facility improvements pursuant to the terms of the consent order. In addition, the local fire marshal's office has ordered the facility to remain closed pending the completion of a review of the facility's compliance with applicable fire safety standards.<sup>3</sup> Finally, several new legal challenges against the facility are being pursued.

The WebMD/GHN Article included a report on another Sterigenics sterilization facility in the Chicago suburb of Willowbrook, Illinois. According to this part of the story, similar concerns about ambient air concentrations of ethylene oxide in the area around the facility in Willowbrook

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<sup>1</sup> Brenda Goodman and Andy Miller, *Residents Unaware of Cancer-Causing Toxin in Air*, jointly reported by WebMD and Georgia Health News, July 19, 2019 - <https://www.webmd.com/cancer/news/20190719/residents-unaware-of-cancer-causing-toxin-in-air>, <http://www.georgiahealthnews.com/2019/07/neighborhoods-unaware-airborne-toxin/> (referred to herein as the WebMD/GHN Article)

<sup>2</sup> *In re: Sterigenics U.S. LLC*, Order No. EPD-AQC-6980 (Ga. Env'tl Protection Div. Aug. 7, 2019)(referred to herein as the "Consent Order").

<sup>3</sup> Official Press Release from Cobb County website, Sept. 26, 2019 -

<https://www.cobbcounty.org/communications/news/latest-sterigenics-plant-situation#n>

In the latest twist to this part of the story, the Cobb County fire marshal's office has ordered the facility to refrain from any construction activity prior to completion of the review of compliance with applicable fire safety standards. Meris Lutz, *Cobb: Sterigenics Barred From Construction, Sterilization*, Atlanta Journal-Constitution website, Oct. 1, 2019 - <https://www.ajc.com/news/local-govt--politics/cobb-sterigenics-barred-from-construction-sterilization/rhxWbsQEnmnK3y8t5maU3M/>



arose almost a year earlier. As with the Sterigenics facility in Smyrna, opposition to the Sterigenics facility in Willowbrook emerged shortly after information about ambient air concentrations and assessments of associated cancer risks was publicized.<sup>4</sup>

An intriguing – and perhaps overlooked – aspect of this part of WebMD/GHN Article was the regulatory response in Illinois. It was immediate and severe. Among other actions, the Illinois Environmental Protection Agency (IEPA) issued what is known as a seal order pursuant to its authority under Section 34(b) of the Illinois Environmental Protection Act (the “Act”). The order required that “[a]ll storage containers of ethylene oxide” be immediately “sealed.”<sup>5</sup> This had the practical effect of shutting the facility down.

Section 34(b) of the Act provides IEPA with the authority to “[s]eal any equipment, vehicle, vessel, aircraft, or other facility...” where the Agency finds that “[a]n imminent and substantial endangerment to the public health or welfare of the environment exists.”<sup>6</sup> Under Section 34(c) of the Act, the breaking of any such seal, or the operation of “[a]ny sealed equipment, vehicle, vessel, aircraft, or other facility...” is a Class A misdemeanor.<sup>7</sup> Importantly, a facility subject to a seal order under Section 34(b) **must comply first, and then seek legal recourse afterwards** (emphasis added).<sup>8</sup> Under Section 34(d) of the Act, the owner or operator of a “sealed” facility may either seek an administrative hearing or immediate injunctive relief in court.<sup>9</sup>

The exercise of broad authority by a state environmental agency to order the immediate shutdown of a facility prior to the exercise of any right of appeal does not happen often. As a result, the threat of the exercise of such authority is perhaps underappreciated. Environmental professionals are generally familiar with authority possessed by the USEPA – as well as state and local authorities – under RCRA, CERCLA, and other specific regulatory programs to order responses to environmental threats prior to any administrative or judicial review. However, this authority is usually exercised to require remediation and other response activities in connection with current or historical waste management and disposal operations.

When urgent concerns about an industrial facility’s air emissions, water discharges, or potential process hazards arise, it is often the state environmental agency that finds itself on the front line, and it will be under considerable pressure to make use of the most effective tools in its emergency response toolbox. For a state environmental agency with broad authority to order facility shutdowns, such authority is likely to be its most effective emergency response tool. Understandably, the prospect of being the target of the exercise of this authority can be sobering.

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<sup>4</sup> See WebMD/GHN Article.

<sup>5</sup> *In the Matter of: Sterigenics U.S., LLC*, Seal Order (Ill. Env’tl Protection Agency Feb. 15, 2019)(referred to herein as the “Seal Order”).

<sup>6</sup> Illinois Env’tl Protection Act, § 34(b).

<sup>7</sup> The Act, § 34(c).

<sup>8</sup> See *Sterigenics U.S., LLC v. Kim* (E.D. Ill. May 3, 2019).

<sup>9</sup> The Act § 34(d). *Sterigenics* sought and failed to obtain relief from the seal order in federal district court in Illinois. See *Sterigenics v. Kim*.



In the extreme, it can represent an existential threat to a manufacturing organization's continued viability.

So, where might the threat of being the target of such a draconian sanction exist? Certainly, industrial manufacturing and processing facilities in Illinois must be cognizant of such a threat. Closer to home, GEPC does not appear to have a clear and close analog to IEPA's seal order authority. However, Georgia's neighbor to the east – South Carolina – does possess similar authority. Pursuant to the South Carolina Department of Health and Environmental Control's (SCDHEC's) emergency order authority in Section 48-1-290 of the South Carolina Pollution Control Act, whenever SCDHEC

[f]inds that an emergency exists requiring immediate action to protect the public health or property, the Department, with concurrent notice to the Governor, may **without notice or hearing** issue an order reciting the existence of such an emergency and requiring that such action be taken as the Department deems necessary to meet the emergency. **Such order shall be effective immediately...**

(emphasis added). The target facility is to be afforded a hearing within forty-eight hours.<sup>10</sup> In more recent years, SCDHEC has typically exercised such authority to address emergency conditions involving small dams or waste disposal facilities. However, SCDHEC has exercised such authority to order industrial manufacturing and processing facilities to immediately cease all or certain parts of their respective operations, including on at least three occasions in the late 1990s and early 2000s.

If a facility has reason to believe that it may be the target of such an order, what can the facility do to prepare for such a possibility, and respond once the order has been issued? The receipt of such an order may give one the impression that the sky is falling. However, while nothing in life is a guarantee, there are certain actions that can be taken which would at least give the facility a fighting chance to eventually return to normal operations. The following is an illustrative, but by no means exhaustive list of some of actions to consider when faced with such a daunting prospect:

### ***Prior to the Issuance of the Order***

- If a set of facts and circumstances exist that make the prospect of being the target of such an order possible, the chances are good that the facility is already facing legal threats from multiple directions. If it has not already done so, the facility should assemble a legal team to identify and address these threats.
- The legal team should be prepared to respond rapidly to the issuance of an emergency order requiring an immediate shutdown. As part of such planning, there should be a recognition of

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<sup>10</sup> S.C. Code § 48-1-290.



the possibility of such an order being issued late in the afternoon after the close of business, or even late on a Friday after business has closed for the working week. There are several reasons why this is both a possibility and a concern. These are as follows:

- It is natural to expect such an order to be issued at the end of a day's worth of deliberations. The state environmental agency knows that the issuance of such an order will face a lot of scrutiny from the press, the public, political officials, and of course, the target facility. The agency will want to make sure that it has its ducks in a row. However, given the urgent nature of the action being contemplated, it is unlikely that the agency will take time to sleep on the matter once everything is lined up and in place.
- Once such an order is issued, the agency's version of circumstances and events can evolve into entrenched facts on the ground as each hour passes prior to the filing of a challenge. These entrenched facts can be difficult to overcome when the challenge is finally heard.
- With each hour that passes before a challenge is ultimately heard, the financial and operational pressure on the target facility will intensify. Pursuant to the terms of the order itself, the target facility will (or at least should) be ceasing or curtailing operations. The longer such a shutdown or curtailment lasts, the more pressure the target facility will feel to settle with the agency on the agency's terms. (Of course, this assumes that there is room for a settlement in the first place. Given the nature of these kinds of orders, this is not always the case.)
- It is possible that the relationship with the state environmental agency will have already deteriorated by the time the prospect of being the target of an emergency order emerges. Nonetheless, the facility should continue to cooperate to the extent possible. Even if such cooperation does not stave off the ultimate issuance of an emergency order, it may allow the facility to address some of the concerns that have arisen. This in turn may result in the issuance of an emergency order that is narrower in scope than what had been originally contemplated.
- The facility should consider implementing contingency plans such as the build-up of inventory or the shifting of production to other locations in order to minimize disruption to business in the event an emergency order requiring an immediate shutdown is issued.

### ***After Issuance of the Order***

- Once such an order has been issued, the top priority should be to ensure compliance with the order. The consequences for failure to comply with such an order can be quite severe.
- Scrutinize the order carefully. What appears at first glance to be a broad order to shut down a facility may be more limited in scope. This is especially important in jurisdictions where the nature and scope of such emergency order authority places an obligation on the state



environmental agency to narrowly tailor any such order only to the extent necessary to address the emergency. For example, SCDHEC’s emergency order authority is limited to requiring “[s]uch action as ... necessary to meet the emergency.”<sup>11</sup> The existence of this or similar language may cause a state environmental agency to issue an emergency order that is narrower in scope than a broad requirement to shut down all operations.

- The agency issuing the order may not have a full and complete understanding of the steps necessary for a safe and orderly shutdown or curtailment of operations at the target facility. Thus, the target facility will probably need to communicate and coordinate with the agency to ensure that it can undertake such a safe and orderly shutdown or curtailment without risking additional legal consequences.
- Even after such an order has been issued and while a hearing is still pending, cooperate with the agency to the extent possible to address its concerns and possibly persuade the agency to narrow the scope of its order. To take SCDHEC’s emergency order authority as an example again, even after SCDHEC issues an emergency order, it is required to “[r]evoke all emergency orders as soon as conditions or operations conditions change to the extent that an emergency no longer exists.”<sup>12</sup>

### ***During Litigating of the Order***

- If such an order is litigated, the way in which such litigation proceeds will depend on the individual facts and circumstances in existence at the time the order was issued. Having said that, there are two considerations that should always be kept in mind. These are as follows:
  - The adjudicator hearing a challenge is being told by the agency responsible for environmental protection in the state that there is an environmental emergency. The adjudicator will likely go into such a hearing trusting that the agency is sincere in its belief that such an emergency exists. As a result, the target facility will need to demonstrate that it has taken all reasonable measures to mitigate the state environmental agency’s concerns, regardless of whether the target facility agrees that an emergency condition exists.
  - At the same time, the adjudicator will expect the agency to demonstrate that it has acted, and continues to act, with urgency and due haste in its response. Indications on the record of delays in performing tests, obtaining results, reviewing expert reports and ultimately issuing the order can undercut the agency’s position that an actual emergency exists.

Even state environmental agencies lacking specific emergency order authority can apply considerable pressure to facilities that may be the sources of environmental emergencies. Other

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<sup>11</sup> S.C. Code § 48-1-290.

<sup>12</sup> This obligation exists even where no hearing is held. S.C. Code § 48-1-290.



state and local authorities can apply pressure as well. It is important to remember that Sterigenics entered into the Consent Order with GEPD despite statements in the order itself that Sterigenics' Smyrna facility appeared to be in compliance with its permits.<sup>13</sup> Also, as was previously noted, the county fire marshal's office has ordered the facility remain shutdown until a complete review of the facility's compliance with applicable fire protection standards can be completed.

Facing the prospect of a seal order, emergency order, or any equivalent can certainly be a daunting prospect. It can represent in the truest sense of the oft-repeated phrase, a "bet the facility" (if not "bet the company") prospect. To appreciate the nature of this threat, one can look to the latest news to come out of Illinois where in response to its legal wrangling with state authorities, Sterigenics has decided to permanently shut down its Willowbrook facility.<sup>14</sup> Sometimes, such a result cannot be avoided. Nonetheless, with a commitment to addressing the urgent and emergency concerns that exist; proper planning; and clear and rational thinking, a facility facing such a daunting prospect can navigate its way back to something approaching normalcy.

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<sup>13</sup> Consent Order, p. 2.

<sup>14</sup> *Sterigenics' Willowbrook Facility Will Permanently Close, Company Announces*, WLS-TV Website - <https://abc7chicago.com/health/sterigenics-will-permanently-close-willowbrook-facility-company-announces/5579321/>