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EPA Under Fire For Overdue Ethylene Oxide Regulations

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As we noted in our last report, on September 19, 2022, a Cook County (Illinois) jury awarded \$363 million to a plaintiff who alleged that she developed breast cancer as a result of ethylene oxide emissions from the Sterigenics Willowbrook plant. This was the first ethylene oxide personal injury case to go to trial.

The day after the Illinois verdict, multiple environmentalist groups (including Earthjustice, California Communities Against Toxics, Clean Power Lake County, Rio Grande International Study Center, Sierra Club and Union of Concerned Scientists) announced a notice of intent to sue the EPA for failing to tighten its air regulations with respect to commercial sterilizers and Ethylene Oxide (EtO) emissions from same. The EPA had previously self-imposed a deadline in August of this year to revise these regulations and issue a proposal with a final rule to be issued in October 2023.

Under the Clean Air Act Section 112, the EPA is obligated to conduct technology reviews of its air toxics standards every eight years. If the EPA ascertains that there are better control technologies or methods that are both available and cost-effective, it is supposed to then tighten and strengthen its regulations. The EPA is eight years overdue in issuing new emissions standards for sterilization facilities, as in 2006 it finalized a risk and technology review concerning EtO emissions from sterilization facilities, but ultimately determined that it would not enact new emissions standards. In 2016, the EPA did issue a new risk assessment concerning EtO in which it noted that it was 60 times more toxic than had previously thought to have been the case.

Analysis

Should the EPA delay or fail to enact more stringent regulations with respect to the emissions of EtO from commercial sterilization facilities, there are a number of public interest groups ready to force the issue. It would seem that the recent jury verdict in Illinois would provide ammunition to these groups in their effort to have the EPA issue tighter EtO regulations.

Presumably, commercial sterilization facilities will need to reevaluate and significantly reduce their EtO emissions, whether by EPA fiat or concern that failure to do so will lead to heftier and additional plaintiff verdicts in the tort system. Surely the EPA is not unaware of the recent Illinois verdict and is feeling the heat to pay increased attention to EtO emissions from commercial sterilization facilities. We expect that between the Illinois jury verdict and the threat of litigation from various environmental

groups, the EPA will be issuing new standards for EtO emissions in the near future.

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