

EPA Feeling The Heat For Dragging Its Feet on Ethylene Oxide Standards

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As we've noted in [prior reports](#), environmental groups have long been frustrated with the EPA and its failure to modify its air pollution regulations with respect to medical sterilization plants that utilize and emit Ethylene Oxide (EtO). The EPA last updated its EtO emissions requirements in 2006. In an attempt to translate its dissatisfaction with the EPA's perceived foot dragging into concrete action, last week the environmental group Earthjustice filed suit against the EPA on behalf of the Union of Concerned Scientists, California Communities Against Toxics, Clean Power Lake County, Rio Grande Study Center, and the Sierra Club. For its part, the EPA had no comment on the suit. The case is [California Communities Against Toxics et al. v. Michael S. Regan](#), case number 1:22-cv-03724, and was filed in the U.S. District Court for the District of Columbia.

Although the EPA did issue a rule in 2020 to reduce EtO emission and in 2021 initiated reporting requirement for EtO emissions, Earthjustice alleges that a comprehensive review is needed by the EPA of its rules concerning sterilization plants, and wants the courts to mandate that EPA either do this or else revise the standards (or decide that no revision is necessary). This suit aims to prod the EPA into doing what environmental groups allege hasn't been done in terms of updating EtO emissions regulations.

The past few months have seen the first two EtO cases go to verdict, both in Illinois and both involving the Willowbrook plant (we have reported on same). The plaintiffs in both cases alleged that EtO emitted by the Willowbrook plant caused their cancers. The first trial resulted in a \$363 million dollar verdict, while the second trial resulted in a defense verdict. In the next year, we anticipate a number of other cases involving the Willowbrook plant to go trial, and we may see trials in some other states as well (Georgia, Delaware, and Pennsylvania are in the running). Surely, the EPA is not unaware of the Illinois trials, and is presumably feeling some heat to update its EtO regulations.

Implications of the Earthjustice Suit

Medical sterilization plants utilizing and emitting EtO must pay close attention to whether the EPA takes action and revises and broadens its EtO emission regulations. Should the EPA beef up its EtO emission standards, we expect even more cases to be filed as plaintiff firms will surely cite the EPA regulations and argue that defendants are in violation of same, and that their clients developed cancer as a result. While EtO litigation is currently confined to a handful of states (primarily Illinois,

Georgia, Delaware, and Pennsylvania), in the wake of the recent \$363 million dollar verdict in Illinois it is certainly within the realm of possibility that EtO cases will be filed in other states in which large medical sterilization plants are sited.

Potential defendants include owners and operators of sterilization plants as well, but as we've seen with other mass tort litigation (asbestos, talc, opioids etc) eventually even peripheral players are dragged into the litigation vortex. So, customers of sterilization plants, suppliers to sterilization plants, and so on may find themselves enmeshed in litigation down the road unless they take precautions now. Our constant refrain has been that no litigation is the best litigation. The chances of avoiding litigation in the first place are certainly enhanced by vigilance with respect to making sure that any EtO emissions are minimal and within current regulations, and this includes making sure that as regulations are tightened so is compliance with same. It also includes contractual language by suppliers to plants demanding indemnification should they be brought into litigation on the basis of the plant's EtO emissions.

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