

EPA Continues to Implement Stricter Ethylene Oxide Air Toxics Rules

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As we have noted in prior posts, the Biden administration and the EPA have been emphasizing environmental justice, including a stronger focus on the negative health effects of Ethylene Oxide (EtO), an industrial solvent widely used as a sterilizing agent for medical equipment that cannot otherwise be sterilized by heat/steam. EtO may also be used as a component for producing other chemicals, including glycol and polyglycol ethers, emulsifiers, detergents, and solvents. Allegations that exposure to EtO may increase the risk of certain cancers will increasingly subject certain companies and industries to governmental regulation and/or private tort actions. In particular, the chemical and healthcare industries must take notice of the increased attention paid to EtO emissions.

Recent EPA Action

Last week, in response to a suit brought against it by various environmental justice organizations including California Communities Against Toxics and the Union of Concerned Scientists, the EPA stated that it would implement a rule by March 1, 2024, designed to reduce EtO emissions from medical device sterilizers. The new rule will mandate that the 86 commercial sterilizers in the United States implement new emission control measures.

The suit alleged that the EPA had failed to review sterilization facility air emission standards at least every eight years as it was required to do under the Clean Air Act, and, in fact, had not updated its EtO emission regulations for 16 years. Under the consent decree, the EPA will, within 15 business days of the final rule being signed by the appropriate agency official, forward the document for publication in the Federal Register.

We also note that in April, the EPA issued a proposed interim decision under the Federal Insecticide, Fungicide and Rodenticide Act designed to protect workers who are exposed to EtO. The EPA will prohibit certain uses of EtO where alternatives exist, and will endeavor to reduce the amount of EtO that may be used for medical device sterilization while meeting sterility standards.

Analysis

Under the Biden Administration, the EPA is exercising its clout to increase its regulation of EtO emissions. The EPA considers EtO a human carcinogen (though we note this is not an opinion

universally shared). Prudence dictates that companies monitor their EtO emissions, and, to the extent possible, reduce them in order to avoid current and future expanded EPA regulation and/or private tort litigation. Invariably, plaintiff lawyers cite government (here EPA) findings and regulations to support their private actions. So, to the extent that your business utilizes EtO or contracts with operations that utilize EtO, be mindful of increasing governmental regulation, which may also result in ensuing private litigation from the plaintiff bar.

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