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EPA Accepting Public Comments on Amended Ethylene Oxide Regulations

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The U.S. Environmental Protection Agency (EPA), in its continued efforts to reduce emissions of ethylene oxide (EO), recently proposed amended National Emissions Standard for Hazardous Air Pollutants (NESHAPs) under the Clean Air Act (CAA) for Synthetic Organic Chemical Manufacturing Industry (SOCMI) as well as the Commercial Sterilizer Industry. Public comments on the two rules are currently due **June 26 and June 27, 2023**, respectively.[1] These regulations will significantly impact companies in the organic chemical and medical sterilization industries and are likely to result in significant additional compliance burdens and costs.

The Regulatory Landscape. Widely used in the chemical industry, EO became the focus of increased and intense scrutiny after the EPA released its 2016 Integrated Risk Information System (IRIS) Assessment, which increased the EO unit risk estimate (URE) to claim that EO is approximately 60 times more toxic than previous estimates. Since that time, the EPA and its state counterparts have endeavored to further investigate and limit EO emissions, while plaintiffs have begun filing private causes of action in courts around the country. On the regulatory side, the EPA's primary focus has been to update federal NESHAPs related to various industries with EO emissions. Those efforts were initially delayed by challenges to the EPA's URE for EO, but in December 2022, the EPA affirmed its decision to rely on the 2016 IRIS URE in future regulations and issued its final NESHAP for the Miscellaneous Organic Chemical Manufacturing industry (MON).[2] In that publication, the EPA explicitly rejected challenges to its use of the URE for purposes of evaluating risk under the CAA, as well as calls for the EPA to adopt the orders-of-magnitude-lower risk value for EO proposed by the Texas Commission on Environmental Quality. The MON included a number of requirements to reduce emissions, including efforts to address EO emissions from storage tanks, process vents, and equipment leaks, such as requiring venting emissions through a closed vent system to a control device or a flare meeting certain operating requirements. In its latest MON revision, the EPA extended and expanded on many of those requirements by including additional requirements for other industry sectors using EO.

Hazardous Organic NESHAP (HON) and Group I and II Polymers and Resins NESHAP Amendments. The EPA proposed amendments to the NESHAP for the SOCMI (Subparts F, G, H, and I), which is more commonly known as the hazardous organic NESHAP or HON. Those amendments concern heat exchange systems, process vents, storage vessels, transfer racks, wastewater, and equipment leaks at chemical facilities that use organic chemicals and do not fall under other CAA classifications. The requirements reflect technical assessments of operations and releases at these facilities and impose substantially more stringent monitoring and control requirements

[1] On April 6, 2023, the EPA announced its proposed rule to reduce emissions of EO from source in the SOCMI as well as Group I and II Polymers and Resins Industries. 88 Fed. Reg. 20580 (Apr. 25, 2023). On April 11, 2023, the EPA proposed amendments to the NESHAP for Commercial Sterilization Facilities. 88 Fed. Reg. 22790 (Apr. 13, 2023). On March 28, 2023, the EPA also published a Proposed Interim Decision and Draft Assessment Addendum, Docket No. EPA-HQ-OPP-2013-0244, to regulate EO under the Federal Insecticide, Fungicide, and Rodenticide Act in connection with EO's use as a pesticide to sterilize certain equipment, including some medical devices. 88 Fed. Reg. 22447 (Apr. 13, 2023).

[2] 87 Fed. Reg. 77985 (Dec. 21, 2022).

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for Hazardous Air Pollutant (HAP) emissions, including EO. For example, among the EPA's amendments to Subpart H (pertaining to equipment leaks) are revisions to the leak detection and repair (LDAR) provisions. These include proposals to lower leak definitions and to require more frequent monitoring of certain equipment and components.

The proposed amendments to Group I and II Polymers and Resins Industries (P&R I (Subpart U) and P&R II (Subpart W)) reflect a similar approach and generally incorporate the revisions to the HON.

Significantly, the EPA's proposed rule also seeks to implement fence line monitoring as a new technology for HON and P&R I facilities that use, produce, store, or emit any of six certain HAPs, including EO. That proposal requires facilities to establish canister monitoring networks for the measurement of EO (with the option to request other types of monitoring networks), and to conduct a root cause analysis and initiate corrective action upon exceeding an annual average concentration action level set at 0.2 μg/m^3. The EPA proposes a 24-hour sampling period every five days, with eight canisters evenly spaced on the perimeter of the facility.

Commercial Sterilizer NESHAP Amendments. The EPA's proposed amendments to the Commercial Sterilizer NESHAP represent a more direct effort to control EO emissions from what is viewed as one of the more significant sources.

Based on its technical review of the industry and risk assessment, the EPA proposes new standards for presently unregulated emissions, most notably from two new categories of sources—chamber exhaust vent (CEV) and room air.[3] For example, the regulations pertaining to CEV emissions, which concern residual EO remaining in the sterilization chamber with the sterilized product after most EO is vented, concern facilities where EO use is less than 1 ton-per-year (tpy), at least 1 tpy but less than 10 tpy, and at least 10 tpy.[4] These emissions were at one time regulated, though the EPA removed the original regulations in 2001 in response to explosion-related safety concerns.[5] As it concerns room air emissions, the EPA proposes two "groups" based on whether the emissions are pre- or post-aeration: Group 1 includes indoor EO storage, EO dispensing, vacuum pump operation, and pre-aeration handling of sterilized materials, while Group 2 includes post-aeration handling of sterilized material.[6]

The EPA also proposes tightening various sterilization chamber vent and aeration room vent emissions standards, delineated in the same manner as the CEV proposals by a facility's tpy EO use.[7] The Commercial Sterilizer NESHAP amendments also propose revisions to "startup, shutdown, and malfunction" requirements, primarily to remove exemptions in response to the D.C. Circuit vacating those provisions in *Sierra Club v. EPA,* 551 F.3d 1019 (D.C. Cir. 2008).[8] Lastly, the proposal suggests revisions to performance test procedures and methods; revisions to monitoring, recordkeeping, and reporting requirements (requiring Continuous Emission Monitoring Systems or alternatives); and making clarifications related to single-item sterilization processes.[9]

Conclusions. With the publication of these proposed NESHAP amendments, it is evident that the EPA will continue to anchor its future regulatory actions in the EO space to the conservative URE developed in 2016 and will expand the regulatory requirements related to all industries using EO. Although the EPA has not recently revised its timeline[10] for completing updates to EO-related NESHAPs, revisions to the NESHAPs for Polyether Polyols Production, Chemical Manufacturing Area Sources, and Hospital Sterilizers are still ahead and expected to follow suit with the above-described amendments. Any company in these industries should be familiar with these developments, how they will affect business operations, and whether it is in the company's interest to provide comments to the EPA by the public-comment deadlines.

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[3] 88 Fed. Reg. 22790, at 22793.
[4] *Id.* at 22793, 22814.
[5] *Id.* at 22814.
[6] *Id.* at 22818.
[7] *Id.*
[8] *Id.* at 22841.
[9] There is a separate NESHAP for Hospital Sterilizers (40 CFR part 63, subpart WWWWW). The EPA notes that it will address those sterilizers in the future. *See* 88 Fed. Reg. 22790, at 22797 n.8 (defining "hospitals").
[10] The EPA's original timeline published in 2021 for completing revisions to EO-related NESHAPs was as follows: Commercial Sterilizers (2022); Hospital Sterilizers (2023); Group 1 Polymers and Resins (Neoprene) (2024); Synthetic Organic Chemicals Manufacturing Industry (2024); Polyether Polyols Production (2024); Chemical Manufacturing Area Sources (2024).

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