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Client Alert

JANUARY 28, 2022

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EPA's Reconsideration of Ethylene Oxide Under the Clean Air Act - A Sign of Future Chemicals Policy to Come?

On January 25, 2022, the U.S. Environmental Protection Agency ("EPA") reaffirmed its interpretation of ethylene oxide ("EtO") requirements which may signal EPA's increased scrutiny of chemical emissions generally and the Agency's increasingly protective approach to risk assessment. In a proposed rule to reconsider its August 2020 National Emission Standards for Hazardous Air Pollutants ("NESHAP"): Miscellaneous Organic Chemical Manufacturing ("MON") Residual Risk and Technology Review ("2020 MON final rule"), EPA addressed two issues raised by petitioners seeking review of the 2020 MON final rule. For both, the central issue was the Agency's approach to assessing human health risks in developing new regulations for EtO, the most frequently used substance to sterilize critical medical products in the United States.

In challenging the MON final rule, petitioners requested that EPA reconsider two aspects of the rule. First, petitioners challenged EPA's use of the 2016 Integrated Risk Information System ("IRIS") value for EtO in assessing cancer risk for EtO emissions. The IRIS has been used to identify potential health concerns at a high level, but petitioners argued that flaws in its methodology made it inappropriate as the basis for setting the risk standards that would affect critical medical device sterilization facilities across the United States. Second, petitioners urged EPA to adopt the Texas Commission on Environmental Quality's ("TCEQ") risk value for EtO as an alternative to the EPA's IRIS value. Based on its detailed review of a broader universe of epidemiological and toxicological studies on EtO and use of a more standard statistical model, TCEQ developed an alternative human health risk threshold that was considerably higher than EPA's in the proposed rule. However, EPA did not propose any changes to its risk assessment approach to the 2020 MON final rule in response to these requests but indicated that it would engage in a 45-day public comment period.

In its notice on the MON final rule, EPA announced that it would continue its reliance on the IRIS value to redefine EtO's risks. The Agency dismissed substantive complaints against the IRIS methodology and maintained all concerns were addressed and resolved in the 2020 MON final rule's docket and preamble. According to EPA, because petitioners presented "no new arguments" for changing the 2020 MON final rule's approach, it declined to restate its prior rationale behind adopting the IRIS value. EPA also asserted the difference in statistical models and analytical parameters between IRIS and TCEQ's methodology were closely evaluated and addressed by the Agency and the Science Advisory Board during rulemaking for the 2020 MON final rule. Because the petitions for reconsideration failed to identify new studies or information calling into question the reasoning of the 2016 IRIS EtO assessment, EPA reaffirmed its decision not to use TCEQ's risk estimate.

EPA's responses on its EtO assessment may not only impact future rulemakings for EtO manufacturers but may also foreshadow EPA's approach to risk-assessment more broadly. By declining to reconsider the science specifically considered in TCEQ's cancer assessment method and using an IRIS value as the basis for its EtO risk value, EPA may be adopting a more risk-averse approach to setting NESHAPs. Considering the potentially broad impact of this reconsideration, regulated companies should consider submitting comments to the Agency.

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