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Client Alert

JUNE 5, 2020

EPA's Revised Rule for Ethylene Oxide ("EtO") Manufacturers

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In a just-released air toxics rule for miscellaneous organic chemical manufacturing ("MON") sources, the U.S. Environmental Protection Agency ("EPA") retains its controversial risk value for ethylene oxide ("EtO"). In doing so, EPA elected to not adopt the Texas Commission on Environmental Quality's ("TCEQ") less stringent risk value for EtO. The rule still imposes additional air pollution controls designed to reduce annual EtO emissions from these sources, but instead of achieving a 10 ton per year ("tpy") reduction (based on the proposed controls), the final rule achieves a 0.76 tpy reduction.

On December 17, 2019, EPA proposed revisions to the MON national emission standards for hazardous air pollutants ("NESHAP") based on its residual risk and technology review ("RTR") and requested comments on the proposed revisions. EPA proposed to address risk by revising the MON rule to require control of EtO from process vents, storage tanks, and equipment leaks.

Regarding process vents, EPA proposed to either reduce emissions of EtO by (1) venting emissions through a closed-vent system to a control device that reduces ethylene oxide by greater than or equal to 99.9 percent by weight, to a concentration less than 1 part per million by volume (ppmv) for each process vent, or to less than five pounds per year (lb/yr) for all combined process vents; or (2) venting emissions through a closed-vent system to a flare meeting the proposed flare operating requirements.

EPA also requested comment on the use for regulatory purposes of an alternative unit risk estimate ("URE") for EtO. The URE is an upper-bound estimate of an individual's incremental risk of contracting cancer over a lifetime of exposure to a concentration of 1 microgram of the pollutant per cubic meter of air. EPA's proposed URE for EtO was based on its 2016 IRIS value, equating to 0.02 micrograms per cubic meter. In a controversial move, EPA sought comment on whether to use its IRIS value even though EPA historically uses UREs from IRIS.

In the final rule, EPA adopted the rule for process vents and weakened those control options through changes to relevant definitions based on comments received on the proposed rule. EPA revised the proposed definition of "in ethylene oxide service" for process vents by removing "undiluted" from the mass-based criteria and removing the phrase "anywhere in the process." In the final rule, a process vent in ethylene oxide service means each batch and continuous process vent in a process that, when uncontrolled, contains a concentration of greater than or equal to 1 ppmv undiluted ethylene oxide, and when combined, the sum of all these process vents would emit uncontrolled, ethylene oxide emissions greater than or equal to 5 lb/yr [2.27 kilograms per year (kg/yr)]. EPA also revised the definitions of "batch process vent" and "continuous process vent" in the Final Rule to clarify: (1) the existing 50 ppmv hazardous air pollutant ("HAP") and 200 lb/yr uncontrolled HAP emission cut-offs do not apply to batch process vents in ethylene oxide service; and (2) the existing 0.005 weight percent total organic HAP cut-off in 40 CFR 63.107(d) does not apply to continuous process vents in ethylene oxide service.

EPA also elected to retain its IRIS-based URE but relaxed the standard that it applies for individual cancer risk. As proposed, EPA allows the cancer risk from EtO facilities to exceed 100-in-1 million, which has been the agency's upper bound for what is an acceptable risk. EPA notes that it has previously issued rules allowing risks higher than this threshold, and these have been upheld by courts. Based on revised allowable emission estimates, the maximum lifetime individual cancer risk could be as high as 800-in-1 million, with EtO from storage tanks, process vents, and equipment leaks driving the risk. The TCEQ submitted to EPA a draft cancer dose-response assessment for EtO for consideration as an alternative to the EPA URE for EtO. In its Final Rule, EPA acknowledges the TCEQ's assessment but states "the assessment had not yet undergone peer review, and the TCEQ dose-response value had not yet been finalized by the close of the public comment period for this rulemaking, . . . Therefore, the TCEQ dose-response value could not be considered for this rulemaking." EPA added that it remains open to new and updated scientific information, as well as new dose response values such as the TCEQ value, as they become available. Perhaps EPA is signaling that it may rely on an alternative approach in a forth coming rulemaking for Commercial Sterilizers, which EPA has announced will be proposed mid-2020.

The compliance dates for the new rule vary by requirement. Judicial review of EPA's final action is available by filing a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit by sixty days after the date of publication in the *Federal Register*. For a variety of reasons, the final rule is likely to be challenged, which may complicate compliance obligations and deadlines for the regulated industry if the rule is not stayed pending judicial review.