Message

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EPA Publishes MON RTR, But Delays Responding to Comments on Its Controversial Risk Assessment for Ethylene Oxide

Wednesday, August 12, 2020

Three Steps for the Regulated Industry to Take Now

On August 12, the United States Environmental Protection Agency (EPA) published the final "residual risk and technology" (RTR) rule for the Miscellaneous Organic Chemical Manufacturing (MON) source category (Final Rule or MON RTR). (85 Fed. Reg. 49084). In doing so, EPA indefinitely delayed responding to industry comments and criticism of its controversial decision to rely on the IRIS model as the basis for its assessment of the risks posed by ethylene oxide (EO) emissions. Chemical manufacturers strongly criticized the IRIS EO assessment as scientifically indefensible, arguing that errors in the IRIS development process resulted in an IRIS value that overstated the risks of low-level EO exposure by orders of magnitude. EPA initially rejected an industry petition to reconsider the IRIS value based on these scientific deficiencies, stating that it would address the issues raised in the Final Rule; when the Final Rule was issued, however, the Agency again deferred its response, stating only that it would do so "in the near future."

The Final Rule is likely to please no one. Industry argues that the Agency's continued reliance on the IRIS value for EO, and its refusal to address the scientific concerns raised by industry and the Texas Commission on Environmental Quality (TCEQ), result in a rule that significantly overestimates the risks from low-level EO exposures. At the same time, EPA's decision that its calculated residual risk level of over 100 in 1 million was acceptable given the uncertainties in the data has angered environmental groups, who argued for even more stringent standards. Further, both state regulators and mass tort plaintiffs are using the IRIS value in lawsuits brought against EO manufacturers, medical equipment sterilizers, and EO users. We anticipate significant litigation and further Agency action before the question of the IRIS value is resolved.

The Final Rule is effective upon publication but gives existing sources up to three years to come into compliance with most of its requirements. In the meantime, manufacturers can take the following actions now to prepare for compliance with the rule and mitigate the risks of litigation.

1. Prepare for compliance. While the Final Rule generally provides three years to comply with its provisions, the compliance schedule provides shorter periods for some requirements, including one year for equipment leak reductions and two years for process vent and storage tank modifications. (84 Fed. Reg. 69182). Furthermore, given the likelihood of COVID-19-related delays in obtaining and installing additional equipment necessary for compliance, companies should begin their compliance efforts sooner rather than later.

2. Evaluate litigation risks. Companies should evaluate their EO emissions through, for example, facility audits. Companies should also understand the potential impact of such emissions on affected communities and develop best practices for managing such emissions.

3. Prepare for Litigation. Companies should review and understand the alternative risk methodologies for EO offered by the American Chemistry Council, TCEQ, and others, and evaluate their risk profile under these methodologies, as well as under the IRIS value.

Rule Background

The Clean Air Act (CAA) requires EPA to conduct a residual risk and technology review (RTR) within eight years of promulgation of the initial maximum achievable control technology or "MACT" standard. EPA includes within its RTR rulemaking two different analyses. First, it evaluates whether there have been any technological advancements since the promulgation of the MACT standard. CAA § 112(d)(6). Second, it evaluates whether unacceptable residual risks remain after implementation of MACT controls; if necessary, EPA then promulgates more rigorous standards to provide an ample margin of safety to protect the public. CAA 112(f)(2).

The MON, codified at 40 CFR Part 63 Subpart FFFF, regulates hazardous pollutant emissions from miscellaneous organic chemical manufacturing process units not otherwise regulated under the CAA that are located at major sources. Practically speaking, the rule largely applies to specialty chemical production facilities and regulates a range of emissions sources, including process vents, storage tanks, transfer racks, and heat exchange systems. The MON – the original MACT standard for this source category – was adopted in 2003. Despite the CAA's requirement for an RTR update eight years after initial promulgation, EPA never updated the MON. In 2017, a Court ordered EPA to complete the MON RTR (along with RTRs for other source categories). *See California Communities Against Toxics, et al. v. Scott Pruitt*, 241 F. Supp. 3d 199 (DDC 2017). The August 12 Final Rule is the result of that ruling.

The Final Rule includes, among other things, the following changes to the MON:

- provisions regulating emissions during startup, shutdown and malfunction (SSM);
- technology standards for heat exchange systems and equipment leaks;
- monitoring and operational requirements for flares that control emissions of olefins, polyolefins, and EO, including allowing facilities outside the source category to use MON flare requirements in lieu of their applicable flare requirements;
- provisions requiring electronic reporting and monitoring; and
- requirements for controlling EO emissions from storage tanks, process vents, and equipment leaks.

Ethylene Oxide Risk and IRIS

EPA's risk assessments are typically based on the IRIS values for the chemicals involved. The IRIS values – part of the Integrated Risk Information System – are intended to reflect the best current scientific understanding of the risks associated with different pollutants, based on the available information. An IRIS value is often expressed as a unit risk estimate ("URE"), which is an attempt to estimate the number of excess cancer cases in a population that is continuously exposed to $1 \mu g/m^3$ of a pollutant.

In developing the MON RTR, EPA determined that much of the risk from miscellaneous chemical manufacturing operations are associated with EO emissions, based on the URE for EO that was updated in 2016 – an update that increased the URE value by orders of magnitude over the prior value (*i.e.*, calculated much higher cancer incidence at much lower exposures). That update, however, has been heavily criticized for a number of scientific deficiencies, including ignoring available data that did not support the lower figure and selecting a statistical

model that is inconsistent with available biological data, among others. These concerns were raised not just by industry, but also by TCEQ, which developed its own task force to assess the EO data and the revised IRIS value, and which concluded that the IRIS value significantly overstated the risks of EO exposure.

At proposal (84 Fed. Reg. 69182), EPA requested comment on the methodology for determining EO risk, including its use of the updated IRIS URE. The Agency received a significant number of comments, which focused on whether EPA should use the IRIS assessment in rulemakings generally and whether the 2016 update to the EO assessment was scientifically valid. Also before the Agency was the American Chemistry Council's (ACC's) Request for Correction submitted under the Information Quality Act, directly challenging the IRIS assessment itself, as well as similar comments EPA had received as part of the RTR for the Hydrochloric Acid Production NEHSAP (84 Fed. Reg. 15484). The Agency responded to ACC's Request for Correction by deferring, noting that the issues ACC raised would be addressed in the then-pending MON RTR. In the Final Rule, however, EPA again deferred its response to the many questions raised about the validity of the IRIS value, stating that "given the time available and in light of other resource constraints … [a response was] not practicable." [cite to the Federal Register]. EPA committed to addressing the issue "in the near future," but gave no additional details.

Faced with EPA's delay, states have begun to adopt their own standards, often in conflict with the IRIS value and with one another. For example, as part of TCEQ's analysis of the IRIS value, it prepared its own EO risk assessment, including its own less stringent value. By contrast, the Illinois legislature relied heavily on the IRIS assessment to promulgate two laws (SB 1852 and SB 1854) tightening restrictions on EO emissions in the state.

Risk Acceptability and Margin of Safety Determination

In the 1989 Benzene NESHAP (54 Fed. Reg. 38044), EPA established a two-step process for addressing risk that Congress incorporated in the 1990 CAA amendments as part of the residual risk analysis. First, EPA looks only at health information to determine an "acceptable risk" level. Second, EPA looks at cost and other data to set a standard that provides an "ample margin of safety" to protect public health. Under this framework, EPA typically views risks below 1 in 10 thousand (100 in a million) as acceptable. This figure is a benchmark, however, not a firm cutoff; in the Benzene NESHAP itself, the Agency concluded that risks of 600 in a million were acceptable.

In the MON RTR, EPA concluded that a similar departure was appropriate and accepted a 2 in 10 thousand risk at one facility subject to the standard. (85 Fed. Reg. 49088). EPA's decision to depart from the benchmark was founded in the significant uncertainty surrounding the IRIS value, noting that the IRIS assessment's methodology "potentially contribut[es] to the conservative (i.e., health-protective) nature of the final 2016 URE." (85 Fed. Reg. 49102). In effect, while EPA determined that the IRIS assessment could be used to evaluate residual risk, the Agency acknowledged that the 2016 update to the EO IRIS assessment overestimated risk and thus justified accepting a higher risk within the model. As noted above, this resolution pleased no one, and litigation is likely.

Meanwhile, EPA has issued an Advanced Notice of Proposed Rulemaking (ANPRM) to solicit information related to the Ethylene Oxide Commercial Sterilization NESHAP (84 Fed. Reg. 67889). This source category has already undergone an RTR, but EPA is evaluating the need for additional regulation. Further, we have seen both states like Illinois and toxic tort plaintiffs use the IRIS value in litigation against companies for their EO emissions. For example, residents in Willowbrook, Illinois, have brought dozens of suits against Sterigenics, alleging injury from EO emissions at its sterilization facility. The complaints typically reference the EO IRIS Assessment in establishing such claims. Citizens groups have filed similar suits against other sterilization facilities in other states, including Georgia.

Regardless of the trajectory of the MON and anticipated litigation, EPA's revised risk assessment may have longer-term impact rulemaking under the RTRs. And, it is clear that the Agency's focus on EO emissions will remain a priority under this Administration and the next.

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