

Oral Testimony for EPA Public Hearing on Proposed Amendments to the Miscellaneous Organic Chemical (MON) Manufacturing: National Emission Standards for Hazardous Air Pollutants (NESHAP)

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Good Morning, my name is Owen Jappen and I manage industry relations for the Society of Chemical Manufacturers & Affiliates, SOCMA. As an organization SOCMA appreciates the opportunity to testify today, and as a chemical engineer, I am especially grateful to have time to share these comments with you this morning.

SOCMA is the only U.S.-based trade association solely dedicated to the specialty and fine chemical industry – a \$300 billion industry that is fueling the U.S. economy. Our members play an indispensable role in the global chemical supply chain, supplying to companies in markets ranging from aerospace, and electronics, to pharmaceuticals and agriculture, and ensures processes are in place for the protection of human health, safety and environment.

My goal today is to help the agency more fully appreciate two particular problems with the MON and the adverse impacts that they would cause for the specialty chemical value chain:

1. The failure to use sound science for setting risk levels, and the resulting confusion of communities across the US about the actual risks they face; and
2. The limitations of monitoring as a compliance measure, given ambient levels of EO and process operations.

First – SOCMA is concerned that the proposed stringent limitations on the use of Ethylene Oxide, or EO, would have a negative effect on U.S. specialty chemical manufacturing. The amendments call for a reduction by more than 99.9% by weight of EO air emissions, or to a concentration to less than 1ppm per vent for processes and storage tanks, or to less than 5 lb/year for all process vents. The resulting diminished availability of fundamental, building block chemistry used in the domestic manufacture of many critical products – from consumer and household products and military, to the health care industry – could result in shortages.

Concern over this molecule stems from EPA's Integrated Risk Information System (IRIS) program, which set a risk value 19,000 times lower than the normal, naturally created levels of EO in the human body¹. SOCMA fundamentally supports approaches to regulating chemicals based on sound science and risk. This past Fall, the Illinois House Committee on Energy & Environment held a hearing in which numerous individuals and groups in the scientific community cited the risk assessment as being “significantly flawed”, going as far as to say that the risks are so over-inflated that they should be rendered meaningless, as it would otherwise assert normal human metabolism is sufficient to cause cancer. In addition, Texas A&M

¹ Kirman CR, Hays SM. 2017. *Derivation of endogenous equivalent values to support risk assessment and risk management decisions for an endogenous carcinogen: Ethylene oxide*. Regul Toxicol Pharmacol, 91: 165-72.

University², the National Academy of Sciences³, US Government Accountability Office⁴, two EPA Science Advisory Boards^{5,6} and the Texas Commission on Environmental Quality⁷ have also released reports that challenge the IRIS assessment. Any regulatory standard based on this flawed evaluation of EO would provide only illusory protections to human health and not provide added protection to communities intended to benefit from this regulatory change.

EO is an intermediate chemistry present in virtually every aspect of the modern environment around us – from paints and coatings, polyesters, cosmetics, vehicular antifreeze, and numerous agricultural applications. As such, current measurement technologies will capture this molecule even in areas where manufacturing or industrial and commercial use of EO does not exist. EPA’s own report on EO ambient concentrations at NATA stations from Oct 2018 through March 2019 reports 165 ppt average measurements⁸ across the country, orders of magnitude above the 0.1 ppt limits established by the IRIS assessments, and upon which this risk and technology review relies.

Second – currently, the MON NESHAP allows for design evaluation in lieu of performance testing to validate compliance – enabling manufacturers to demonstrate through calculations and engineering documentation that they have implemented process controls to prevent fugitive, and non-compliant, emissions. This approach avoids needing to measure existing EO levels surrounding their facilities, which may reflect completely different sources. SOCMA urges the agency to continue this allowance, as it is critical to manufacturers operating batch reactions. Batch operations cannot be reasonably run under the proposed feedback loops based on continuous monitoring due to the inherent dynamic nature of their processes over time. Many in this demographic are also classified as “conditional major sources” – a separate delineation from Title V, allowing them a legal maximum for HAP emissions in exchange for relief from MACT standards. The proposed amendments could shift small facilities under the MACT standards, placing a significant financial burden on small facilities; we recommend that the exemption from these standards continue for conditional major area sources.

² Bogen, K.T.; Sheehan, P.J.; Valdez-Flores, C.; Li, A.A. Reevaluation of Historical Exposures to Ethylene Oxide Among U.S. Sterilization Workers in the National Institute of Occupational Safety and Health (NIOSH) Study Cohort. *Int. J. Environ. Res. Public Health* 2019, 16, 1738.

³ National Research Council. 2011. *Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/13142>.

⁴ United States Government Accountability Office. 2019. *Chemical Assessments: Status of EPA's Efforts to Produce Assessments and Implement the Toxic Substances Control Act*. Washington, DC: US GAO.

⁵ National Research Council. 2014. *Review of EPA's Integrated Risk Information System (IRIS) Process*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/18764>.

⁶ National Academies of Sciences, Engineering, and Medicine. 2018. *Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25086>.

⁷ Texas Commission on Environmental Quality. 2019. *Ethylene Oxide Carcinogen Dose-Response Assessment*. Austin, TX: TCEQ.

⁸ Environmental Protection Agency. 2019. *Ethylene Oxide Ambient Concentrations at National Air Toxics Trends Stations and Urban Air Toxics Monitoring Program Stations October 1, 2018 – March 31, 2019*. Washington, DC: EPA. https://www.epa.gov/sites/production/files/2019-11/documents/data_summary_stations.pdf.

Local communities deserve timely and science-based information to understand the level of risk, if any, they are exposed to. As outlined above the existing regulation ensures current EO emissions are safe at current levels, as validated through current means of enforcement.

We appreciate that the agency has engaged stakeholders on these amendments and allowed for what we hope is a constructive and sustained dialogue. We will submit a more thorough analysis as requested to FR Doc. 2019-27154, detailing these points and providing additional background, and urge the Agency to consider this input before amending the current MON NESHAP, to assure manufacturing competitiveness, and maintain trust between communities and local industry in protecting human health and the environment.

Thank you for your time today.

Respectfully Submitted,

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