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April 17, 2023

The Honorable Michael S. Regan
Administrator
Environmental Protection Agency
Mail Code 1101A
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Submitted via the Federal eRulemaking Portal at https://www.regulations.gov

SUBJECT: 60-DAY COMMENT PERIOD EXTENSION FOR PROPOSED RULEMAKING, "NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS: ETHYLENE OXIDE EMISSIONS STANDARDS FOR STERILIZATION FACILITIES RESIDUAL RISK AND TECHNOLOGY REVIEW" (DOCKET ID NO. EPA-HQ-OAR-2019-0178)

Dear Administrator Regan:

AdvaMed, the Advanced Medical Technology Association, submits this letter to request an extension of the comment period for the EPA's proposed rulemaking, "National Emission Standards for Hazardous Air Pollutants [(NESHAP)]: Ethylene Oxide [(EtO)] Emissions Standards for Sterilization Facilities Residual Risk and Technology Review" (EtO Commercial Sterilizer NESHAP).

AdvaMed is the world's largest medical technology association, with 450 member companies dedicated to advancing clinician and patient access to safe, effective medical technologies. AdvaMed members serve patients nationwide and globally, allowing people to live longer, healthier, and more productive lives. We are carefully monitoring the U.S. Environmental Protection Agency's (EPA) proposed decision-making involving the ethylene oxide (EtO) sterilization of medical technology for the potential impact on our members' ability to ensure continued patient access to the adequate supply of sterile medical technology while protecting employees and community members.

Currently, the proposal, published in the *Federal Register* on April 13, 2023, provides 60 days for public comment, until June 12, 2023. For the reasons provided below, including that the EtO Commercial Sterilizer NESHAP contains hundreds of documents that span thousands of pages, AdvaMed requests that the EPA extend

the comment period by an additional 60 days for the EtO Commercial Sterilizer NESHAP.

As EPA stated in the *Federal Register*, "Commercial sterilization facilities play a vital role in maintaining an adequate supply of medical devices," and about 50 percent of all medical devices are sterilized with EtO.[1] Our members place the highest priority on safety to employees, communities, and the millions of patients we serve.

The EtO Commercial Sterilizer NESHAP proposes significant new regulations and major changes to dozens of existing standards, to say nothing of the hundreds of supporting documents spanning more than 80,000 pages. The current 60-day comment period is insufficient to review these materials or meaningfully comment on the agency's proposals.

Compounding this difficulty, the EtO Commercial Sterilizer NESHAP is not the only sweeping EtO rulemaking proposal EPA published on April 13. On the same day, and with the same 60-day comment period, EPA also published in the *Federal Register* the "Pesticide Registration Review; Proposed Interim Decision and Draft Risk Assessment Addendum for Ethylene Oxide; Notice of Availability" (EtO PID and Draft RA)[2] that also directly impacts the EtO commercial sterilizer industry. In addition to assessing both of these major regulatory proposals at the same time, affected businesses will also have to consider how the two sets of regulations interact and the combined effect both schemes will have on the medical technology supply chain and timely patient care. AdvaMed is concurrently requesting a 60-day extension of the comment period for EPA's EtO PID and Draft RA.

Due to the number of changes that EPA is proposing, it is key that we and other members of the public have time to properly analyze all the potential impacts of and inputs to the proposal to ensure that we can continue to provide sterilized medical technology to patients while protecting the environment. As the EPA is aware, decisions by other regulators led to shutdowns of key medical device sterilization infrastructure in the midst of the COVID-19 pandemic.

Finally, unlike with other regulations that provide weeks between when a version is posted on the EPA's website until it is published in the *Federal Register* and starting the official comment period, the public was provided with only two days between when a version appeared on the EPA's website and formal publication.

AdvaMed and its members are committed to providing critical medical technology for patients in an environmentally responsible manner. In order to effectively work with the EPA to meet these goals, however, we will need additional time to analyze and

[1] 88 Fed. Reg. at 22793/1.
[2] 88 Fed. Reg. 22477 (Apr. 13, 2023); EPA Dkt. EPA-HQ-OPP-2013-0244-0044.

comment on the EtO Commercial Sterilizer NESHAP, especially given that these new rules may remain in place for years, as with the EPA's prior EtO regulations.

Thank you for considering our request to extend the comment period for EPA's proposed EtO Commercial Sterilizer NESHAP regulation and the EtO PID Draft RA. If you have any questions, please contact Khatereh Calleja, VP, Technology & Regulatory Affairs at kcalleja@advamed.org.

Sincerely,

Scott Whitaker

CC: Joseph Goffman