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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 ACTION TITLED, "PESTICIDE REGISTRATION REVIEW; PROPOSED INTERIM DECISION AND DRAFT RISK ASSESSMENT ADDENDUM FOR ETHYLENE OXIDE; NOTICE OF AVAILABILITY" (DOCKET ID NO. EPA-HQ-OPP-2013-00244)

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 interim registration review decision (PID) and draft risk assessment addendum for ethylene oxide (EtO) (Draft RA).

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.

EPA published a notice of availability in the *Federal Register* on April 13, 2023, that currently provides 60 days for public comment – until June 12, 2023.[1] For the

[1] 88 Fed. Reg. 22447 (Apr. 13, 2023).

reasons provided below – including that the PID and Draft RA combined are over a hundred pages of technical discussion and include multiple technical support documents within the docket – AdvaMed requests that the EPA extend the comment period by an additional 60 days for the PID and Draft RA.

As EPA stated in its PID, "**EtO is used to sterilize 50 percent of all sterilized medical devices, or 20 billion devices, annually.** EPA has investigated alternatives to EtO for sterilizing medical devices, including engaging in discussions with FDA about pursuing alternatives to EtO. EPA understands that, while there are alternative sterilization methods for some medical devices, **there are currently no available alternatives**—pesticidal or non-pesticidal—for some devices due to challenges such as material compatibility, scalability, and capacity.[2] (emphasis added). Our goal is to ensure medical devices are sterilized to prevent infections while protecting our communities and the millions of patients we serve.

The EtO PID proposes significant new regulations and major changes to dozens of existing standards, along with the draft RA. 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 PID is not the only sweeping 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 "National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review" (EtO Commercial Sterilizer NESHAP)[3] 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. AdvaMed is concurrently requesting a 60-day extension of the comment period for the EtO Commercial Sterilizer NESHAP.

Due to the significant changes that the 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. For example, we must analyze the potential impacts of modifying critical aspects of the sterilization process and designing fundamentally new systems for existing commercial sterilizers to understand the real-world impacts the regulations could have on the supply of sterilized medical technology and timely patient care.

[2] PID page 69.
[3] 88 Fed. Reg. 22790 (Apr. 13, 2023).

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 comment on the EtO PID, especially given that these new provisions will remain in place for years, as with prior PIDs.

Thank you for considering our request to extend the comment period for the EPA's proposed interim registration review decision and draft risk assessment addendum for ethylene oxide, along with the EtO Commercial Sterilizer NESHAP. If you have any questions, please contact Khatereh Calleja, VP, Technology & Regulatory Affairs at kcalleja@advamed.org.

Sincerely,

Scott Whitaker

CC: The Honorable Michal Ilana Freedhoff