January 16, 2025

MEMORANDUM FOR THE ADMINISTRATOR OF THE ENVIRONMENTAL PROTECTION AGENCY AND THE SECRETARY OF HEALTH AND HUMAN SERVICES

SUBJECT: Orderly Implementation of the Air Toxics Standards for Ethylene Oxide Commercial Sterilizers

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Policy. The strengthened and updated Clean Air Act standards for ethylene oxide (EtO) emitted into the air from commercial sterilizing facilities issued by the Environmental Protection Agency (EPA) on April 5, 2024, *National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review*, *Final Rule*, 89 Fed. Reg. 24,090 (Apr. 5, 2024) ("EtO Rule"), achieved a new milestone in my Administration's efforts to protect public health for all Americans and to advance the objective of my Administration's Cancer Moonshot initiative to prevent cancer before it starts. EtO has been associated with elevated cancer risks in communities around the United States and can be particularly harmful to children. The loss of loved ones from environmentally related cancer is a tragedy that the Nation can and must work together to end, once and for all.

The EtO Rule was issued after careful consideration of public comments and public hearings. In this rule, EPA set standards under section 112 of the Clean Air Act, as amended (the "Act") (42 U.S.C. 7401 et seq.), to control emissions from commercial sterilizers through the use of demonstrated and achievable pollution control technologies and practices. These standards will significantly reduce emissions of the toxic air pollutant EtO.

The EtO Rule applies to facilities that sterilize medical products, including medical devices and pharmaceuticals. Sterilization is critical to maintaining a safe supply of medical devices for patients and hospitals and providing health

care to millions of Americans to help them stay healthy and fight diseases, including cancer. Consequently, EPA worked closely with the Department of Health and Human Services, including the Food and Drug Administration, to develop a final rule that protects communities exposed to pollution from sterilization facilities while also mitigating and managing the potential risk of any medical device supply disruptions.

EPA concluded that sterilization facilities will be able to install the appropriate technology to meet the standards of the EtO Rule before the compliance deadlines mandated by the Act. The EtO Rule also recognized that the President's authority under section 112(i)(4) of the Clean Air Act, 42 U.S.C. 7412(i)(4), to exempt individual facilities from compliance for a set period of time may provide an important mechanism to address the possibility that a facility may be unable to install all appropriate technology before the compliance deadline. 89 Fed. Reg. at 24,103. It is of vital national importance to ensure the reduction of EtO emissions to the level that EPA determined is required to protect public health pursuant to the Clean Air Act, while also avoiding the national security and public health effects that could result from a significant disruption to the medical device supply chain.

It is the policy of my Administration to safeguard the reliability of our Nation's supply of safe medical products. To advance orderly implementation of the EtO Rule, I am therefore establishing a process, provided below, for considering requests for Presidential exemptions, the duration of which shall be as short as possible and no longer than two years. This process will ensure consideration of such requests in the exceptional circumstances in which a commercial sterilizer can demonstrate that, notwithstanding due diligence and best efforts, it will be unable to meet a covered standard or limitation required by the EtO Rule before the compliance deadline due to the unavailability of control technology for the facility, leading to likely shutdown of the facility, and the best available information demonstrates that the shutdown of the facility will likely lead to a serious disruption to the supply of medical products, such as medical devices and pharmaceuticals, necessary for America's national security and public health.

To achieve the EtO Rule's critical health protections as soon as practicable, while safeguarding the supply of safe medical products from disruption that would compromise the health and welfare of the American people, I direct you to take the following actions:

Sec. 2. Implementation of a Process for Considering Presidential Exemptions. The Administrator of the EPA (Administrator) shall receive requests for a Presidential exemption from a standard or limitation in the EtO Rule under section 112(i)(4) of the Act (42 U.S.C. 7412(i)(4)), review them, and advise the President regarding whether to grant them through the following process:

(a) Any commercial sterilizer seeking such an exemption shall submit a request to the Administrator no earlier than 12 months and no later than 4 months before the compliance deadline for which an exemption is sought. The request shall include:

(i) specific information of sufficient detail to enable verification of the reason or reasons that the technology to implement the applicable standard or limitation is unavailable for installation and that, notwithstanding its due diligence and best efforts, the facility cannot be brought into compliance before the compliance deadline for the covered standard or limitation (e.g., contracts, documentation of communication with vendors or suppliers);

(ii) a plan for procuring, installing, and operating the technology as soon as feasible in order to achieve compliance with the EtO Rule, and an assurance as described in subsection (h)(ii) of this section;

(iii) a list of all available practicable measures (i.e., technological and operational) that have already been taken or that are planned to advance compliance and additional measures, if any, that will be implemented to reduce the emissions of EtO and resulting risks during the exemption period;

(iv) a list of any alternative steps available, in progress, or already taken to try to avoid the need for additional time for compliance;

(v) the type or types of products sterilized at the facility, the volume of products sterilized at the facility, and the facility's annual sterilization capacity; and

(vi) the name, title, and signature of the responsible official who is certifying the accuracy of the request.

(b) In reviewing an exemption request, and the information provided pursuant to this section, the Administrator, in consultation with the Secretary of Health and Human Services (Secretary), shall consider:

(i) whether the technology to implement a covered standard or limitation will be unavailable in time for installation and operation of the technology at a specific facility before the compliance deadline for such standard or limitation, due, for example, to shortages of labor, parts, control technology supply, supply-chain disruption, or other factors out of the facility's control;

(ii) the amount of time needed for installation and operation to occur in order to achieve compliance with the EtO Rule;

(iii) the risk of a serious disruption to the supply of medical products (including pharmaceuticals and medical devices) should the facility be required to temporarily pause sterilization activities or reduce capacity until installation and operation can occur (including any potential alternatives to assure a sufficient supply of sterilization and sterilized medical products);

(iv) the potential effect of any such disruption on public health and welfare, and any other information that may be relevant to an evaluation of whether granting an exemption is in the national security interests of the United States; and

(vi) any other information that the Administrator, in consultation with the Secretary, deems relevant.

(c) No later than 30 days after receiving a request pursuant to subsection (a) of this section, the Administrator shall confirm receipt of the request, notify the requester of any additional information needed to evaluate the request, set a deadline of no later than 15 days for the requester to provide the requested information, and provide public notification that the request was submitted (including the name of, the location of, and any other information regarding the facility requesting the exemption that the Administrator, in consultation with the Secretary, deems relevant and appropriate to publish).

(d) As soon as practicable and no later than 30 days after receiving all necessary information to evaluate a request pursuant to this section, the Administrator, in consultation with the Secretary, shall provide the Chairman of the Council on Environmental Quality (CEQ) with the request and accompanying information from the requester, any additional information that the Administrator deems relevant, and a recommendation regarding whether an exemption is warranted, including the basis for the recommendation, and if recommending that the President grant an exemption: the recommended duration, and any other accompanying terms or conditions (such as a schedule for status reports regarding planned steps and progress to achieve compliance with the EtO Rule).

(e) As soon as practicable and generally within 45 days after receiving a recommendation from the Administrator pursuant to subsection (d) of this section, the Chairman of CEQ, in consultation with the Assistant to the President for National Security Affairs, the Assistant to the President for Economic Policy, the Assistant to the President for Domestic Policy, the Director of the Office of Pandemic Preparedness and Response Policy, and the Director of the Office of Science and Technology Policy, shall advise the President concerning the request for an exemption.

(f) As expeditiously as practicable after the grant or denial of any exemption by the President under this process, and no later than 10 days after such a grant or denial, the Administrator shall notify the applicant.

(g) Within 60 days of the grant of any exemption by the President under this process, the Administrator shall make publicly available online the name of, location of, and any other appropriate and relevant information regarding the facility receiving the exemption and the duration of any exemption, and shall submit to Congress the report required by section 112(i)(4) of the Act (42 U.S.C. 7412(i)(4)) on behalf of the President.

(h) The Administrator shall, as appropriate:

(i) provide technical assistance to any facility that receives an exemption to promote compliance with the EtO Rule;

(ii) seek information and assurance from any facility that requests an exemption that the facility will use its best efforts and will take reasonable and

appropriate steps to demonstrate diligent action to install and operate necessary technology as expeditiously as practicable (including to fulfill any accompanying terms or conditions) to achieve compliance with the EtO Rule; and

(iii) inform the Chairman of CEQ when installation of such technology is complete.

Sec. 3. Federal Coordination. The Secretary, in consultation with the Administrator, shall consider taking additional steps, as appropriate, to further advance the goal of protecting the public from cancer and other harms from EtO exposure, including spurring innovation to reduce exposure to EtO and other carcinogenic air pollutants and to expand access to safe, effective, and reliable alternative methods for sterilization of medical equipment and pharmaceuticals that do not depend on EtO, and continuing to strengthen the resilience of our Nation's medical supply chain. Within 2 years of the date of this memorandum, the Secretary shall provide a report to the Chairman of CEQ regarding progress toward this directive and any steps taken or planned.

Sec. 4. General Provisions. (a) Nothing in this memorandum shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This memorandum shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) The Administrator is authorized and directed to publish this memorandum in the *Federal Register*.

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