ETHYLENE OXIDE (ETO)

ISSUE SUMMARY:

EtO is primarily used as a sterilant for medical devices and equipment, used on approximately 50% of all sterilized medical devices, including an estimated 95% of all surgical kits. It is highly valuable because it is a penetrative gas that has a high throughput capacity, is effective at a wide range of temperatures, and is compatible with a broad range of materials. Presently, there are no viable alternatives to EtO for the sterilization of certain medical devices and equipment. The absence of EtO for use on medical devices and equipment would cause widespread disruption to the availability of sterile medical devices. In the U.S., EtO is also used during the processing and reconditioning of dried herbs and spices to reduce foodborne pathogens of concern such as *Salmonella* and *Escherichia coli*. EtO is a known carcinogen. The registered pesticidal uses of EtO pose inhalation risks to workers inside commercial sterilization facilities and healthcare facilities, and to those treating beekeeping equipment (limited to North Carolina), as well as to communities near facilities were EtO is used as a pesticide.

UPCOMING MILESTONES:

EPA is currently drafting the EtO ID, which is anticipated to be released by the end of 2024.

BACKGROUND:

EtO has received considerable media attention due to the public's concern over cancer risks from EtO exposure. EPA has been in discussions with the White House, Congress, and state regulators regarding the concerns related to EtO exposure. To increase interagency coordination on the regulation of EtO, EPA's Office of Pesticide Programs (OPP) has led the EtO Interagency Task Force since February 2020 with participating members including EPA's Office of Air and Radiation (OAR), the Food and Drug Administration (FDA), the Occupational Safety and Health Administration (OSHA), and the Center for Disease Control and Prevention Agency for Toxic Substances and Disease Registry (CDC-ATSDR). Concurrent with OAR's EtO Commercial Sterilizers Proposed Rulemaking, under the Clean Air Act, as part of the Registration Review program under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), in April 2023, OPP published the EtO Proposed Interim Decision (PID) and Draft Risk Assessment (DRA) Addendum for public comment. Based on EPA's 2016 Integrated Risk Information System (IRIS), cancer risks to workers via inhalation are as high as 1 in 10. In the PID, EPA proposed several mitigation measures to address EtO exposure to workers and nearby communities including termination of certain uses, concentration rate reductions, engineering controls, and respiratory protection for workers. The public comment period for the PID and DRA ended in June 2023, and EPA received over 30,000 comments from industry, NGOs, the public, and other federal agencies. OPP has been coordinating closely with OAR, FDA, and OSHA to address the public comments and refine a mitigation strategy for the upcoming EtO Interim Decision (ID).

KEY EXTERNAL STAKEHOLDERS:

☒ Congress ☒ Industry ☒States ☒ Tribes ☒ Media ☒ Other Federal Agency
☒ NGO ☒ Local Governments ☒ Public

MOVING FORWARD:

EPA expects to release the EtO ID in FY25. The ID will include measures to reduce exposures to workers and nearby communities.

LEAD OFFICE/REGION: OCSPP OTHER KEY OFFICES/REGIONS: (OAR, ORD, OGC, OECA)