

Department of Legislative Services
Maryland General Assembly
2023 Session

FISCAL AND POLICY NOTE
First Reader

Senate Bill 916 (Senator Beidle)
Education, Energy, and the Environment

Environment - Ethylene Oxide - Prohibition

This bill prohibits a person from using, manufacturing, selling, offering for sale, or distributing ethylene oxide (EtO) in the State. A person who violates that prohibition is subject to a civil penalty of up to \$1,000 for a first violation and up to \$5,000 for a second or subsequent violation. The Maryland Department of the Environment (MDE) must adopt regulations to implement the bill. **The bill takes effect July 1, 2023.**

Fiscal Summary

State Effect: Special fund revenues for MDE and the Maryland Department of Agriculture (MDA) decrease minimally beginning in FY 2024. MDE can implement the bill with existing budgeted resources. The extent to which any State agencies use EtO and are affected by the bill's prohibition is unknown, as discussed below. The bill's penalty provisions are not anticipated to materially affect State revenues.

Local Effect: The extent to which any local governments use EtO and are affected by the bill's prohibition is unknown, as discussed below. The bill otherwise has no effect on local government finances or operations.

Small Business Effect: Potential meaningful.

Analysis

Current Law:

Related Air Pollution Laws

EtO is regulated at the federal and State level. At the federal level, EtO is considered a hazardous air pollutant and is regulated under the federal Clean Air Act's (CAA) National Emission Standards for Hazardous Air Pollutants (NESHAP). NESHAPs are stationary source standards for hazardous air pollutants (those pollutants that are known or suspected to cause cancer or other serious health effects, such as reproductive effects or birth defects, or adverse environmental effects). Sources subject to NESHAPs are required to perform an initial performance test to demonstrate compliance. To demonstrate continuous compliance, sources are generally required to monitor control device operating parameters that are established during the initial performance test. Sources may also be required to install and operate continuous emission monitors to demonstrate compliance.

At the State level, pursuant to current regulations, EtO is designated as a Class I Toxic Air Pollutant and is considered a probable human carcinogen. Further, regulations specify that EtO is a toxic air pollutant that requires emission estimates or ambient impact analysis for existing sources of the pollutant. Due to these classifications and federal requirements, commercial sterilization facilities in the State that use EtO must obtain an air quality State permit to operate. Sources that require such a permit must pay an annual fee that consists of a base fee of \$500 or \$1,000, plus an emissions-based fee for each ton of emissions of a regulated pollutant (excluding carbon monoxide). In addition, regulated facilities must submit annual emissions certification reports by April 1 each year.

EtO is also classified as a toxic waste unless otherwise designated or exempted.

The Maryland Pesticide Registration and Labeling Law

The State Chemist, within MDA, is responsible for administering the Maryland Pesticide Registration and Labeling Law subject to the supervision of the Secretary of Agriculture. The law requires pesticides to be registered before being distributed in the State and establishes requirements for the packaging and labeling of pesticides. A pesticide must comply with federal pesticide laws and regulations before it can be registered by the Secretary. MDA regulations establish that a person may only use or recommend pesticides that are registered with the department.

The Maryland Pesticide Registration and Labeling Law prohibits the distribution, sale, or transportation in the State of unregistered, adulterated, or misbranded pesticides and authorizes the Secretary to adopt rules and regulations providing for the collection and

examination of samples of pesticides. An annual fee of \$110 must be paid to the Secretary for each product registered, which is deposited in the State Chemist Fund. The fund is used to administer the Maryland Pesticide Registration and Labeling Law and other laws.

State/Local Fiscal Effect:

State Revenues

According to MDA, there are 11 pesticides that are registered in the State that list EtO as an active ingredient. MDA is not aware of any alternative products that can be used as a substitute in those pesticides. Thus, banning the use of EtO in the State results in a decrease in special fund revenues for the State Chemist Fund of an estimated \$1,210 annually from foregone product registration fees.

According to MDE, there are four commercial spice sterilization facilities in the State that use EtO and pay yearly emissions-based fees. Depending on the alternative sterilization chemical or process that affected facilities switch to due to the bill's prohibition, special fund revenues for the Maryland Clean Air Fund may decrease, likely minimally, beginning in fiscal 2024.

Maryland Department of the Environment Operational Impact

MDE advises that it may need to process permits for affected facilities to use a substitute chemical or process to replace EtO. MDE advises that it can absorb any additional duties related to permit review and promulgate the regulations with existing budgeted resources.

Effect of the Prohibition on Other State Agencies and Local Governments

The extent to which any State agencies or local governments use EtO is unknown. Broadly, any State agency or local government that uses EtO is affected to the extent that an alternative sterilization process is not readily available or does not work as well as EtO. Additionally, since EtO waste products are considered toxic waste, there may also be costs to dispose of unused EtO.

Small Business Effect: According to the U.S. Environmental Protection Agency (EPA), EtO is a colorless gas that is used at commercial sterilizers to sterilize devices that cannot be sterilized using steam or radiation, such as some medical and dental equipment. According to the U.S. Food and Drug Administration, approximately 50% of sterile medical devices are treated with EtO. EtO is also used to sterilize some food products, such as spices, certain dried herbs, dried vegetables, sesame seeds and walnuts. Likewise, MDA advises that, in addition to being used as an active ingredient in some pesticides, EtO is

used in several areas of industry, such as spice manufacturing, health care, contract sterilization facilities, cosmetics, and clothing, among others.

The bill negatively affects any businesses that manufacture, sell, or use EtO – or products containing EtO – in the State. The extent to which affected entities are small businesses is unknown. According to MDE, the bill’s prohibition likely affects four commercial spice sterilization facilities in the State that use EtO. In addition, MDA advises that there is one commercial sterilization facility in the State that serves the health care industry and uses EtO. Any small businesses that use EtO are negatively affected to the extent that an alternative sterilization process is not readily available or does not work as well as EtO. Additionally, since EtO waste products are considered toxic waste, affected small businesses may incur costs to dispose of unused EtO.

Additional Comments: EPA is currently reviewing CAA regulations to further reduce EtO emissions from industrial facilities, with particular attention to rules to control toxic air emissions from commercial sterilizers and facilities that manufacture chemicals.

Additional Information

Prior Introductions: Similar legislation has not been introduced within the last three years.

Designated Cross File: None.

Information Source(s): Judiciary (Administrative Office of the Courts); Maryland Department of Agriculture; Maryland Department of the Environment; U.S. Environmental Protection Agency; Department of Legislative Services

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