SB2264

LRB10113323CPF62165b

101ST GENERAL ASSEMBLY

State of Illinois

2019 and 2020

SB2264

Introduced 10/28/2019, by Sen. John F. Curran

SYNOPSIS AS INTRODUCED:

415 ILCS 5/9.18 new

Amends the Environmental Protection Act. Provides that by January 1, 2021 ethylene oxide shall only be used to sterilize medical products, and only if the Environmental Protection Agency determines that there is no substitute sterilization technology available for sterilizing a particular medical product. Prohibits the Agency from accepting permit applications for the use of ethylene oxide unless the application is for the use of ethylene oxide for the sterilization of medical products. Requires the Agency to prohibit all uses of ethylene oxide that require a CAAPP permit by January 1, 2022. Effective immediately.

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A BILL FOR

AN ACT concerning safety.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 5. The Environmental Protection Act is amended by adding Section 9.18 as follows:

(415 ILCS 5/9.18 new)

Sec. 9.18. Emissions standards, regulations, and notice for facilities emitting ethylene oxide.

(a) The General Assembly finds that the emission of ethylene oxide constitutes a threat to public health and welfare, depresses property values, and diminishes quality of life. It is the purpose of this Section to restore, maintain, and enhance the purity of the air of this State in order to protect health, welfare, and quality of life and to assure that no air contaminants are discharged into the atmosphere without being given the degree of treatment or control necessary.

(b) Except as otherwise provided in this subsection, on and after January 1, 2021 the use of ethylene oxide requiring a CAAPP permit shall be limited to the sterilization of medical products. If the Agency determines, based on the best scientific evidence, that there is no substitute sterilization technology available for sterilizing a particular medical product, then ethylene oxide may be used for that medical

product. This subsection shall apply to any group of products packaged together and sterilized as a single product if sterilization or fumigation is the only available method to completely sterilize or fumigate more than half of the individual products contained in the package. Cost shall not be considered in this determination. If the Agency determines there is a substitute technology for a particular medical product or half or more of the individual products in a package, then the Agency shall prohibit all use of ethylene oxide for that medical product or package of medical products.

(1) "Substitute sterilization technology" means a method of sterilization for a particular medical product that does not use ethylene oxide and is capable of sterilizing that medical product.

(2) In determining whether a substitute sterilization technology exists, the Agency shall make the determination based upon a review of the products for which CAAPP permit applicants have applied to use ethylene oxide. The Agency may consider factors such as whether a potential substitute sterilization technology adequately eliminates, removes, kills, or deactivates all forms of life and other biological agents from a medical product and whether a potential substitute sterilization technology is able to adequately sterilize a medical product without damaging the product. The Agency may rely on federal Food and Drug Administration guidance in making its determination under

this subsection.

(3) The Agency may issue regulations, emissions standards, or permit conditions that state which medical products or classes of medical products have substitute sterilization technologies.

(4) If the Agency determines a substitute sterilization technology exists for every use of ethylene oxide, the Agency shall prohibit all uses of ethylene oxide.

On and after the effective date of this amendatory Act of the 101st General Assembly, the Agency shall not accept permit applications for the use of ethylene oxide unless the application is for the use of ethylene oxide for the sterilization of medical products as provided under this subsection.

The Agency shall prohibit all uses of ethylene oxide that require a CAAPP permit by January 1, 2022.

(c) On and after January 1, 2021, the use of ethylene oxide requiring a CAAPP permit in a manner that results in the emission of ethylene oxide for purposes other than sterilization of medical products is a violation of this Act. The Agency shall immediately notify all CAAPP permit holders permitted to use ethylene oxide of this deadline. The Agency shall have the authority to adopt rules, in accordance with the Illinois Administrative Procedure Act, as the Agency deems necessary, to implement this subsection.

Section 99. Effective date. This Act takes effect upon becoming law.