

EPA's National Rule for Commercial Sterilizers

William L. Wehrum

Assistant Administrator, EPA Office of Air and Radiation

EPA Response to 2014 NATA: Two-pronged strategy for addressing ethylene oxide emissions

- Prong 1: Review Clean Air Act regulations for facilities that emit ethylene oxide (EtO) to ensure that they protect the public from significant risk.
 - Two reviews in progress:
 - Air toxics standards for commercial sterilizers
 - Air toxics standards for miscellaneous organic chemical manufacturing (the “MON”)
- Prong 2: For areas with highest risk, gather additional information on emissions of ethylene oxide.
 - To support regulatory review
 - To seek near-term emission reduction opportunities.

Commercial Sterilizer Rule

- Rule history
 - **November 1994** –Rule limits EtO emissions from commercial sterilizers
 - **November 2001** – Rule amended due to safety concerns
 - **April 2006** –EPA completes review, retains 1994 rule (as amended)
- August 2018
 - NATA identifies census tracts with potentially elevated risk from EtO exposure
- • EPA begins technology review of current rule under Clean Air Act
 - More than 100 major and area sources will be affected
 - Reviewing advancements in control technology
 - Considering other information, such as risks and costs
- Anticipate proposal in summer 2019

EPA Regulatory Process

- **Step 1:** EPA proposes a regulation
 - Includes specific periods for public input
 - Written comments
 - Public hearing
 - Proposed regulation is published in the Federal Register
- **Step 2:** EPA collects and considers comments from the public to develop a final rule
 - Written comments and comments at a hearing have the same weight
- **Step 3:** Final regulation is published in the Federal Register, then is added to the Code of Federal Regulations

Preparing to make comments on a proposed rule

- Held a public webinar April 24 on “Techniques and Skills for Providing Effective Input in the EPA Rulemaking Process”
 - Slides and recording are available on the Web to help you prepare
 - Slides: <https://www.epa.gov/il/webinar-information-sterigenics-willowbrook-facility>
 - Recording: https://www.youtube.com/watch?v=jvWjA_3oUmw&feature=youtu.be