Facts about ethylene oxide and safe medical sterilization

Ethylene oxide (EO) is essential to public health

- More than 50% – or 20 billion – healthcare products are sterilized with EO every year in the U.S., including the vast majority of medical supplies required for surgery.
- EO sterilization is used in 40 industrialized countries.

There is no alternative to EO sterilization

- Some surgical packs have up to 200 items made of a mix of cotton, gauze, plastic, metal, rubber, paper and more.
  - Gamma and e-beam radiation can make plastics brittle, or cause certain materials to disintegrate.
  - Steam is high temperature and melts plastics or damages heat sensitive products.
  - Hydrogen peroxide and gas plasma cannot penetrate into complex devices to fully sterilize them.

Restricting or banning EO would lead to an immediate public health crisis

- Medline supplies surgical packs to 75% of Illinois’ urban and rural hospitals. Other suppliers’ manufacturing capacity cannot make up the gap.
- Limiting access to sterilized medical packs needed for life-saving surgeries (typically just two to four days of supply on hand) would force them to shut down operating rooms.
- Critical care facilities with high volumes of surgeries would be impacted immediately, canceling trauma surgeries for emergencies like car accidents and gunshot wounds, as well as organ transplants, open-heart surgeries, tumor removal, knee replacements, tonsillectomies, C-sections and many more.

Science supports EO safety

- Ethylene oxide is the only globally accepted, FDA-approved clinically and scientifically-valid sterilization method for many types of medical supplies.

- Thirteen studies of ethylene oxide workers conducted over 40 years in five countries show no pattern of increase for any type of cancer.

- EO is naturally emitted by plant decay, animal waste, human respiration and compost, and is also in auto exhaust and heated cooking oil.

- Normal human breath carries EO at a level hundreds of times over the levels suggested as “risky”.

Medline safely controls EO emissions

- EO is removed in a de-gas/aeration room via several vacuum and nitrogen washes.
- Any remaining EO gas is routed through a wet scrubber, captured and converted to ethylene glycol.
- The ethylene glycol mix is captured and recycled for industrial use (i.e. making polyester fibers).
- The air in the heated de-gas room is routed through both a scrubber system and an abator.
- These systems operate above a minimum of 99% efficiency – the EPA requirement for reducing EO in emissions.

The faulty 2016 EPA IRIS Assessment

- The EPA IRIS report is a staff-level working document that uses questionable data and a flawed statistical model to predict cancer risk from exposure to EO.

- The IRIS report has come under heavy criticism from the scientific community. Scientists have submitted an IQA (Independent Quality Assurance) request to re-examine the flawed report, and Medline is seeking a National Academy of Sciences review.

- The National Air Toxics Assessment map that was produced from this report does not reflect actual reported cancer rates.

- The EPA itself has said it must do more study before any conclusions can be drawn.