799 9th Street NW
Suite 210
Washington, DC 20001

T (202) 354-2600
vizientinc.com

June 27, 2023

Submitted via the Federal eRulemaking Portal: http://www.regulations.gov

The Honorable Michael S. Regan
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460

Re: Pesticide Registration Review: Proposed Interim Decision and Draft Risk Assessment Addendum for Ethylene Oxide (EPA-HQ-OPP-2013-0244)

Dear Administrator Regan,

Vizient, Inc. appreciates the opportunity to comment on the Environmental Protection Agency (EPA) proposed interim decisions for ethylene oxide and the draft risk assessment addendum (hereinafter "EPA EtO Documents"). The EPA EtO Documents inform EPA's registration review of EtO pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act. As EPA notes, after the public comment period, EPA will issue an interim or final registration review decision for ethylene oxide. Vizient urges EPA to ensure that access to healthcare, including sterilized medical devices, is not negatively impacted by any registration review decision released. Further, we discourage new requirements for healthcare facilities that would be excessively burdensome and create additional challenges in providing care. However, Vizient does appreciate EPA's ongoing commitment to identifying opportunities to protect public health.

Background

Vizient, Inc. provides solutions and services that improve the delivery of high-value care by aligning cost, quality, and market performance for more than 60% of the nation's acute care providers, which includes 97% of the nation's academic medical centers, and more than 20% of ambulatory providers. Vizient provides expertise, analytics, and advisory services, as well as a contract portfolio that represents more than $130 billion in annual purchasing volume, to improve patient outcomes and lower costs. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

Recommendations

Vizient recognizes the critical importance of policies that protect public health, and we appreciate EPA's efforts to gain stakeholder input regarding the EPA EtO Documents. However, we are concerned that the healthcare industry may be inadvertently, negatively impacted by the Proposed Rule given the scope of medical devices which are sterilized by EtO and for which no other

sterilization methods are currently available.[1] Also, more than 20 billion devices sold in the U.S. every year are sterilized with EtO which is approximately half of all devices that require sterilization.[2] In addition, regarding EPA's recent regulatory activity related to EtO, FDA Commissioner Califf expressed concern, indicating "I'm very worried."[3] Vizient's comments to EPA urge the agency to ensure that any policy finalized related to EtO not disrupt the medical supply chain as this would negatively impact patients.

Proposed Termination of Uses
In the EPA EtO Documents, EPA proposes to terminate several uses of EtO (e.g., museum materials, library materials, musical instruments). Vizient thanks EPA for not including medical devices on this list.

Healthcare Facilities' Occupational Risk
In the EPA EtO Documents, EPA proposes changes that would impact healthcare facilities such as mitigation for occupational risk, including engineering controls for healthcare facilities. For example, EPA proposes to require engineering controls related to physical separation of EtO sterilization spaces, negative air pressure, ventilation of EtO through exterior ventilation stacks, and abatement devices. EPA also notes in in the EPA EtO Documents that additional rulemaking for healthcare facilities is forthcoming. Vizient appreciates the efforts of EPA to mitigate the potential impacts of EtO on employees, but we are concerned that the agency's approach to addressing healthcare facility requirements through piecemeal policies may create additional, unnecessary burdens for healthcare facilities as they would be challenged in developing and implementing compliance plans that account for future requirements.

Vizient encourages EPA to consider working with healthcare facilities to better understand the implications of the requirements provide in the EPA EtO Documents. Currently, hospitals are under significant financial strains, with approximately half of U.S. hospitals having negative margins in 2022 "as growth expenses outpaced revenue increases."[4] As such, additional costs to comply and delays in operations can have far reaching consequences on patient care. Vizient again notes our concerns regarding EPA's approach for healthcare facilities and urges the agency to work more collaboratively with providers before of advancing requirements given the critical role EtO plays in the medical supply chain and the challenges hospitals may have in meeting new requirements.

Commercial Sterilization Facilities and Device Manufacturers
EPA proposes various requirements, particularly for commercial sterilization facilities and device manufacturers, to reduce EtO use rates and address occupational concerns. While Vizient appreciates that EPA is seeking comment regarding policies to reduce EtO use rates for medical devices, we urge EPA to clarify that it will not finalize changes that could disrupt medical device supply chains, including delays or potential downstream cost increases. For example, Vizient is concerned that EPA acknowledges that "using less EtO may also result in the need for longer sterilization times" and "it would also require medical device manufacturers and other customers to recalculate and revalidate the sterilization methods, including the concentration of EtO used and

[1] https://www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization
[2] https://www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization
[3] https://www.politico.com/newsletters/prescription-pulse/2023/04/28/device-makers-await-cms-redo-00094345, FDA Commissioner Robert Califf stated at the Medial Device Manufacturers Association conference, "Make your voice heard... This issue is very much on the forefront for us. We are highly aware of it and we're engaged in the discussions. I'm very worried."
[4] https://www.kaufmanhall.com/sites/default/files/2023-01/KH_NHFR_2023-01.pdf

duration in the chamber, for each specific product sterilized by EtO."[5] In addition, EPA notes additional labor demands, including for FDA employees as a result of the proposed requirements. However, EPA does not appear to recognize the harm to patient care that could result should the impacts come to fruition given no additional information to quantify these impacts is noted. Further, the agency seeks feedback from stakeholders that could be challenging to respond to accurately as circumstances, such as FDA staffing capabilities, may change. Vizient urges EPA to work more closely with commercial sterilizers, device manufacturers, FDA and providers to better understand the potential implications to patients should the proposed requirements be finalized. While Vizient, like EPA, believes there is a critical need to protect the public health, we are concerned that the approach outlined by EPA may create public health issues as patient care could be significantly limited if sterilized medical devices are not available.

Conclusion

Vizient appreciates the opportunity to comment on the EPA EtO Documents. On behalf of Vizient, I would like to thank EPA for advancing rulemaking that aims to address public health challenges. We recommend EPA ensure that medical device supply chain disruptions will not occur due to new potential requirements for commercial sterilization facilities and healthcare facilities. Please feel free to contact me at (202) 354-2600 or Jenna Stern, AVP, Regulatory Affairs and Government Relations (Jenna.Stern@vizientinc.com), if you have any questions or if Vizient can provide any assistance as you consider these issues.

Respectfully submitted,

Shoshana Krilow Sr. Vice President of Public Policy and Government Relations
Vizient, Inc

[5] https://www.epa.gov/system/files/documents/2023-04/eto-pid.pdf