

June 27, 2023

OAR Docket # EPA-HQ-OAR-2019-0178
OPP Docket # EPA-HQ-OPP-2013-0244
Environmental Protection Agency Docket Center (EPA/DC)
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

Subject: Letter Urging Strengthening of Proposed Rule on Commercial Ethylene Oxide Sterilization Facilities and Proposed Interim Decision on Ethylene Oxide

The 114 undersigned business, community, environmental, faith, health, and labor organizations urge the EPA to include in its final commercial sterilizer rule: the regulation of offsite storage warehouses, fence-line monitoring, and a quicker compliance deadline. We further urge the agency to use its authority under FIFRA to better protect workers and communities from ethylene oxide.

Ethylene oxide is a potent carcinogen used to sterilize medical equipment, spices, and other dry foods. According to a February 2023 report from the Union of Concerned Scientists, nearly 14 million people live within five miles of a commercial sterilization facility where this process occurs.¹ Despite knowing that emissions from these facilities pose an elevated cancer risk to nearby communities, EPA has not reviewed its rules for sterilizers since 2006 and has not strengthened them since they were first put in place nearly 30 years ago. It is, therefore, particularly imperative for EPA to ensure that communities are quickly and comprehensively protected from this dangerous chemical.

Offsite warehouses must be regulated in the final rule

Once products are sterilized, they are often stored in warehouses before going to their final destination. These warehouses can have high emissions – essentially functioning as additional aeration chambers. For example, one warehouse in Georgia had estimated annual emissions of 5,600 pounds of ethylene oxide – enough to require its own air permit.²

These warehouses are often in the same communities as the sterilizer themselves – such as in Richmond, Virginia, where the warehouse is directly across the street.³ EPA identified communities like Richmond as being at an elevated risk of cancer from commercial sterilizers⁴ and stated that the rule will

¹ Union of Concerned Scientists. *Invisible Threat, Inequitable Impact. Communities Impacted by Cancer-Causing Ethylene Oxide Pollution*. Feb. 7, 2023. Available at: <https://www.ucsusa.org/resources/invisible-threat-inequitable-impact>

² Georgia Environmental Protection Division. *Georgia EPD Continues Oversight of Becton, Dickinson and Company; Issues Notice of Air Quality Rules Violation for Global Distribution Center*. December 18, 2019. Available at: <https://epd.georgia.gov/press-releases/2019-12-18/georgia-epd-continues-oversight-becton-dickinson-and-company-issues>

³ U.S. Environmental Protection Agency. *Response to 2021 Section 114 ICR from Sterilization Services of Virginia in Richmond, VA*. Available at: <https://www.regulations.gov/document/EPA-HQ-OAR-2019-0178-0246>

⁴ U.S. Environmental Protection Agency. *Community Engagement on Ethylene Oxide (EtO)*. Available at: <https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/forms/community-engagement-ethylene-oxide-eto>

reduce emissions from these facilities by 80%.⁵ However, by not including offsite aeration warehouses, the agency has neither quantified the additional emissions and associated risks from these sites nor is proposing to reduce those emissions and risks. And by including onsite warehouses and not offsite ones, the rule as proposed would incentivize facilities to move all sterilized products offsite, thereby exacerbating communities' cancer risk. This is worsened further by the fact that many companies failed to report the location of their warehouses to EPA – giving communities an incomplete picture of the locations and magnitude of the risk they face.

The final rule must include fenceline monitoring with health-protective action levels – both for the commercial sterilizers and offsite warehouses

As EPA noted in its recent proposed updates to the Synthetic Organic Chemical Manufacturing (SOCMI) emission standards (where ethylene oxide is also regulated), fenceline monitoring is an important way to “ground-truth emission estimates from a facility’s emissions estimates.” Communities near commercial sterilizers similarly deserve to know how much of a carcinogen they are being exposed to. Fenceline monitoring is critical to verifying that EPA’s proposed fugitive emission controls are working. And when monitors detect unsafe levels of ethylene oxide, EPA must require facilities to identify and fix the source of the increased emissions. Intra-facility monitoring systems, as the rule proposes to require, will not adequately protect communities from a chemical that is dangerous at extremely low levels. Fenceline monitoring saves lives.

The final rule must shorten the compliance deadline from the proposed 18 months

For decades, dozens of communities across the country have been exposed to largely uncontrolled ethylene oxide pollution from sterilization facilities. Industry has been on notice that updated emissions standards were coming; EPA was required to make those updates in 2014 but now is not slated to finalize the rule until March 2024. The agency has authority to require companies to install pollution control equipment within 90 days, yet the agency is proposing to give facilities 18 months – until September 2025. This compliance deadline must be shortened. Communities have already waited too long to be protected from this deadly chemical.

EPA must use its authority under FIFRA to better protect workers and communities from ethylene oxide

EPA has also revisited ethylene oxide’s registration under the Federal Insecticide, Fungicide and Rodenticide Act (“FIFRA”), which covers not only commercial sterilization facilities but also hospitals and healthcare facilities where the chemical is used to sterilize equipment on site. Under FIFRA, EPA cannot maintain any ethylene oxide registration that presents unreasonable risks to public health or the environment. Given EPA’s findings of extreme cancer risks to workers in those facilities (as high as 1-in-10),⁶ as well as the known harms to surrounding communities, EPA must cancel all non-essential

⁵ U.S. Environmental Protection Agency. *Actions to Protect Workers and Communities from Ethylene Oxide (EtO) Risk*. Available at: <https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/actions-protect-workers-and-communities-ethylene-oxide-eto>

⁶ U.S. Environmental Protection Agency. *Ethylene Oxide (EtO). Addendum to “Draft Human Health and Ecological Risk Assessment in Support of Registration Review” - Inhalation Exposure Risk Assessment in Support of*

ethylene oxide registrations and impose additional limits on any uses that remain. To start, EPA must prohibit the use of ethylene oxide to sterilize spices, as the European Union has already done for decades. EPA must also use its FIFRA authority to address ethylene oxide sources that are not currently covered by the proposed Clean Air Act rule – such as offsite warehouses and healthcare facilities – and strengthen its occupational controls to reduce worker exposures to the greatest extent practicable before the consideration of personal protective equipment.

Signed,

Accelerate Neighborhood Climate Action
ACFAN, Athens County's Future Action Network
AFGE Local 704
Air Alliance Houston
Alaska Community Action on Toxics
Alianza Nacional de Campesinas, Inc.
Alliance of Nurses for Healthy Environments
Appalachian Voices
Beaver County Marcellus Awareness Community (BCMAC)/EyesOnShell
Beyond Plastics
Black Millennials 4 Flint
Black Women for Wellness
Breast Cancer Prevention Partners
Breathe Project
Bullard Center for Environmental and Climate Justice at Texas Southern University
California Communities Against Toxics
California Safe Schools
Call to Action Colorado
CatholicNetwork US
Center for Biological Diversity
Center for Environmental Health
Center For Food Safety
Citizens 4 Clean Air IL
Clean Air Coalition of North Whittier and Avocado Heights
Clean Air Council
Clean Power Lake County
Clean+Healthy
CleanAirNow_EJ
Coalition for a Safe Environment (CFASE)
Colorado Businesses for a Livable Climate
Coming Clean
Comite Dialogo Ambiental, Inc.
Comite Pro Uno
Community Dreams

Registration Review. Available at: <https://www.epa.gov/system/files/documents/2023-04/eto-draft-human-health-ra-add.pdf>

Community for Sustainable Energy
Connecticut Coalition for Environmental Justice
Defend Our Health
Downwinders at Risk Education Fund
Dr. Yolanda Whyte Pediatrics
Earth Ethics
Earthjustice
Endangered Species Coalition
Environment America
Environmental Defense Fund
Environmental Justice Health Alliance for Chemical Policy Reform (EJHA)
Environmental Law & Policy Center
Environmental Protection Network
Farmworker Association of Florida
Fire Drill Fridays
FracTracker Alliance
FreshWater Accountability Project
Greater New Orleans Housing Alliance
GreenLatinos
Healthy Environment Alliance of Utah (HEAL Utah)
Healthy Gulf
Honor the Earth
I-70 Citizens Advisory Group
Indivisible Ambassadors
Labor Council for Latin American Advancement (LCLAA)
Larimer Alliance for Health, Safety and Environment
League of Conservation Voters
Littleton Business Alliance
Liveable Arlington
Mallory Heights Community Development Corporation
Mayfair Park Neighborhood Association Board
Mental Health & Inclusion Ministries
Micah Six Eight Mission
Moms Clean Air Force
Moms for a Nontoxic New York
Montbello Neighborhood Improvement Association
Northeastern Environmental Justice Research Collaborative
Northwest Center for Alternatives to Pesticides
Nuclear Information and Resource Service
Occidental Arts and Ecology Center
Ohio River Guardians
Ohio Valley Allies
Physicians for Social Responsibility Pennsylvania
Physicians for Social Responsibility- Los Angeles
Pipeline Safety Coalition
PODER
Port Arthur Community Action Network (PACAN)
Presente.org

Protect Our Aquifer
Protect PT
Public Citizen
RapidShift Network
Respiratory Health Association
Rio Grande International Study Center (RGISC)
RISEstjames
Rural Coalition
Safer States
Save EPA
Sierra Club
Small Business Alliance
Southwest Organization for Sustainability
Spirit of the Sun, Inc.
Stop Sterigenics
Story of Stuff Project
System Change Not Climate Change
Tackling the A-Z Impact of Plastic & Petrochemicals
The Climate Reality Project
The Descendants Project
The Green House Connection Center
The Mind's Eye
Toxic Free NC
U.S. PIRG
Union of Concerned Scientists
Unite North Metro Denver
Until Justice Data Partners
Wall of Women
Waterkeeper Alliance
Western Slope Businesses for a Livable Climate
Womxn from the Mountain
Working for Racial Equity