State of Tennessee
Office of the Attorney General & Reporter

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SUBMITTED
ELECTRONICALLY VIA
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U.S. Environmental Protection Agency
EPA Docket Center
(28221T) 1200 Pennsylvania Ave. NW.
Washington, DC 20460

Re: Pesticide Registration Review; Proposed Interim Decision and Draft Risk Assessment Addendum for Ethylene Oxide; Notice of Availability, No. EPA-HQ-OPP-2013-0244

National Emissions Standards for Hazardous Air Pollutants; Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review, No. EPA-HQ-OAR-2019-0178

Dear Administrator Regan,

The States of Tennessee, Alabama, Arkansas, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, North Dakota, Ohio, Oklahoma, South Carolina, Utah, Virginia, and West Virginia appreciate the chance to comment on the pesticide registration review for Ethylene Oxide (EtO) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (the "FIFRA review"), *see* 88 Fed. Reg. 22,447, 22,447–49 (Apr. 13, 2023), and the related emissions standards promulgated under the Clean Air Act (CAA) (the "NESHAP standard"), *see* 88 Fed. Reg. 22,790–857 (Apr. 13, 2023). (Together, the "Proposed Regulations").[1]

The States generally agree with commercial sterilizers' objections to the Proposed Regulations. The States wish to underscore four other reasons why the EPA should forgo or defer regulating the use of EtO by commercial sterilizers. As you know, EtO is key to sterilizing medical devices—and there are no substitutes. Therefore, any regulation of EtO use and emissions threatens the medical device supply chain and

[1] Because the Proposed Regulations "complement each other," EPA, *Ethylene Oxide Proposed Interim Registration Review Decision Case Number 2275*, at 53 (Mar. 2023) (EPA-HQ-2013-0244-0045), and because many of the States' concerns overlap, the States provide a single comment letter for both agency actions.

thus the provision of healthcare in the States. Given the critical importance of the medical device supply chain—as the recent COVID-19 pandemic highlights—and the other issues with the Proposed Regulations, EPA should stay its hand.

Comment

I. The Proposed Regulations do not properly reflect their disruptive effect on the medical device supply chain.

A. The Proposed Regulations will likely disrupt the medical supply chain.

"EtO is primarily used as a sterilant for new, single-use, and reusable medical devices and equipment. EtO is used to sterilize 50% of all sterilized medical devices, annually, including an estimated 95% of all surgical kits." EPA, *Ethylene Oxide Proposed Interim Registration Review Decision Case Number 2275*, at 12 (Mar. 2023) (EPA-HQ-2013-0244-0045) [hereinafter PID]. In total, EtO is used to sterilize "20 billion devices, annually." *Id.* at 69.

In this role, EtO stands above other chemicals. There are "no viable alternatives to EtO for the sterilization of certain medical devices and equipment . . . ." *Id.* at 28. So "if commercial sterilization and healthcare facilities no longer had access to EtO to sterilize medical devices, the result would likely be a disruption to the medical device supply chain, which could in turn result in a nationwide public health crisis." *Id.* at 69.

The States, therefore, agree that banning EtO is improper. *See id.*at 70. Furthermore, the States agree that any regulation of EtO must be carefully drawn to minimize the negative effect the regulation would have on the medical device supply chain. *See id.*; *see also* 88 Fed. Reg. at 22,793 (NESHAP rule). The Proposed Regulations fail to do that.

First, the Proposed Regulations will increase the time it takes to sterilize products. For example, the restrictions set out in the FIFRA review[2] "may have high impacts to the customers of commercial sterilization facilities." PID, *supra*, at 51. One way this can arise is from increasing the amount of time it takes to sterilize medical

[2] While the FIFRA review analyzes whether EtO "continues to satisfy the statutory standard for registration," Pesticide Registration Review; Proposed Interim Decision and Draft Risk Assessment Addendum for Ethylene Oxide; Notice of Availability, 88 Fed. Reg. 22,447, 22,448 (Apr. 13, 2023), FIFRA prohibits using "any registered pesticide in a manner inconsistent with its labeling," 7 U.S.C. § 136j(a)(2)(G); *see also Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991–92 (1984) ("FIFRA regulate[s] the use, as well as the sale and labeling, of pesticides."). Where the States reference restrictions or regulations or standards in the FIFRA review, that is a shorthand for changes EPA proposes to make to EtO's labeling, which affect EtO's use.

devices—which is the result of requiring that commercial sterilization facilities use "less EtO . . . ." *Id.*; *see also id.* at 50 (noting the cycle calculation approach "could make it difficult for sterilization providers to maximize their output and could reduce overall device availability for patients"); *id.* at 58 (noting "potential impacts on the supply chain of sterilized medical devices related to the costs and potential downtime of sterilizing equipment"). Similarly, requiring employees to evacuate a facility if EtO concentrations exceed 10 ppb as an alternative to distributing expensive respirators, *see id.* at 59, will slow the sterilization process and disrupt the medical device supply chain.

Diverting time and resources to refitting plants or providing equipment or training employees to comply with the Proposed Regulations will also disrupt the medical device supply chain. *See*, *e.g.*, *id.* at 58 (noting the possible "necessary downtime" to retrofit plants to comply with the proposed engineering controls); *id.* at 61 (noting the "costs of training and fit testing" for PPE); 88 Fed. Reg. at 22,853 (noting, for the NESHAP standards, that "facilities will need to cease operations for a certain period of time in order to implement" the necessary systems and the risk of disruption to the medical device supply chain). That disruption will be compounded if commercial sterilizers have trouble acquiring the equipment that is necessary to comply with the Proposed Regulations. *Cf. id.* at 59 (asking for comment "on the feasibility of real time monitoring to a 10 ppb level").

Second, the Proposed Regulations will increase costs, which will predictably result in at least some commercial sterilizer facilities shutting down or moving offshore. Plainly, if facilities shut down, then there will be a drop in the number of medical devices being sterilized.

Off-shoring is doubly concerning because it produces both short-term and long-term supply chain challenges. In the short term, the process of moving facilities will likely disrupt the medical device supply chain in much the same way that refitting plants will disrupt the supply chain. Longer-term, moving this part of the medical device supply chain off-shore increases the country's dependence on "foreign sources for components of its public health supplies," which "contribut[es] to the insecurity of public health supply chains . . . ." Dep't of Health & Human Servs., *Public Health Supply Chain and Industrial Base – One-Year Report in Response to Executive Order 14017*, at 7 (2022) (emphasis added).

In this respect, the Proposed Regulations are contrary to this administration's policies. As the COVID-19 pandemic showed, there is a pressing need for "adequate domestic stockpiles [of medical products] and capable domestic suppliers with surge capacity." *Id.* So the Department of Health and Human Services is working "to build domestic manufacturing capacity" to address "the lack of on- or near-shore

manufacturing" of health products. *Id.* at 7, 33. Increasing costs on medical device sterilizers, as the Proposed Regulations will, undermines that policy.[3]

One particularly troublesome way the Proposed Regulations will increase costs is by forcing the adoption of new, untested technologies and designs. The FIFRA review is particularly concerning on this front. The review imposes standards on sterilizers that require them to use designs or technologies that are not yet in common use—or are still theoretical—to reduce EtO use. For example, the FIFRA review mentions the cycle calculation approach or the cycle design optimization as ways to decrease EtO concentration limits in sterilizing facilities. *See* PID, *supra*, at 49–51. But as the review says, those designs are not in common use; their inclusion is "to direct the user community to a more efficient use of EtO." *Id.* at 51. But it is impossible to tell *ex ante* if new designs or technologies that are not yet common in the industry are more efficient. What may be more efficient in a lab or ideal setting may not be so in practice. To require industry to adopt them is therefore dislocating and disruptive, but does not ensure that, in the long run, there are net efficiency gains. So even if EPA rejects the alternatives the States discuss below, *see infra* Comment § I.B, EPA should forgo the EtO use rate reduction labeling change in the FIFRA review.

B. EPA should forgo regulating or extend the compliance period to avoid those disruptions.

Fortunately, there are alternatives to the Proposed Regulations that protect the medical device supply chain. The first and best option: not regulating. As comments from industry note, there is less risk from EtO than the analysis underpinning the Proposed Regulations suggests. There is thus less reason to regulate than the analyses in the Proposed Regulations suggest. That is especially so since industry may adopt many of the requirements on its own. For example, if certain cycle designs reduce EtO use "by a significant amount," PID, *supra*, at 41, then commercial sterilizers have an economic incentive to adopt the new designs. There is little reason to force a technological change on commercial sterilizers at this juncture; market pressures will do the work with less disruption than the Proposed Regulations.

Extending the period to implement the new regulations is another viable alternative. Indeed, EPA has already proposed extended compliance periods for at least parts of the Proposed Regulations. *See* PID, *supra*, at 48 (asking for comment on three and five-year compliance timelines for sterilizers to reduce EtO concentrations); 88 Fed. Reg. at 22,853–54; *see also* 42 U.S.C. § 7412(*i*)(3) (providing compliance timeframes for up to three years for existing sources). The States recommend expanding compliance times as much as possible. Doing so will give commercial sterilizers more

[3] The States find it telling and troubling that EPA is not listed as one of the agencies EPA "is working closely with" in preparing the FIFRA review. PID, *supra*, at 34–35.

time to comply and so limit disruptions to the supply chain that new regulations will cause.

II. The Proposed Regulations do not account for important reliance interests.

The Proposed Regulations also fail to consider the States' "legitimate reliance" on the *status quo*. *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1913 (2020) (quotations omitted). The regulations EPA is seeking to amend are well established. The NESHAP standard has been in force since 1994. *See* 88 Fed. Reg. at 22,796–97. And the last FIFRA reregistration decision for EtO was in 2008. PID, *supra*, at 4.

Such a long timeframe gives rise to reliance interests. That is certainly true for businesses who have invested in reliance on the current regulatory regimes. Those investments are also important to the States. *See* EPA, *Ethylene Oxide Commercial Sterilization Facilities* (last visited June 15, 2023), https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/ethylene-oxide-commercial-sterilization-facilities#tn (listing sterilization facilities by State). For example, DeRoyal Industries, a "world-renowned" sterilizing company, has a facility in Tennessee. Tenn. Dep't of Economic & Cmty. Dev., *Healthcare and Life Sciences*, Mastered in Tenn. (last visited June 15, 2023), https://tnecd.com/industries/healthcare-and-life-sciences/. Impairing its business success undermines the work Tennessee—and other States with commercial sterilizing facilities—has done to promote that industry for economic and public health reasons.

The States also have relied on federal rules and regulations that do not, at a minimum, unduly disrupt the medical device supply chain. States provide or pay for healthcare for their residents. *See*, *e.g.*, *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 581 (2012) (opinion of Roberts, C.J.) (noting that, in 2010, "Medicaid spending accounts for over 20 percent of the average State's total budget, with federal funds covering 50 to 83 percent of those costs"). Disrupting the medical device supply chain will increase healthcare costs or make them more volatile, which forces States to divert funds from other priorities or to incur costs to protect against the volatility. At the most extreme, the States may get into bidding wars with each other and the federal government over scarce medical supplies—as happened during the COVID-19 pandemic. *See* Clary Estes, *States Are Being Forced Into Bidding Wars to Get Medical Equipment to Combat Coronavirus*, Forbes (Mar. 28, 2020), https://www.forbes.com/sites/claryestes/2020/03/28/states-have-are-being-forced-into-bidding-wars-to-get-medical-equipment-to-combat-coronavirus/?sh=7b004e7a1cde.

This interest also involves the States' authority to protect "the public health . . . ." *Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1905). Disruptions to the medical device

supply chain—with the attendant risks to availability and the potential for increased costs—undermine public health and disrupt State plans to address public health crises. *See*, *e.g.*, Tenn. Dep't of Health, *State Department of Health Novel Virus/Pandemic Influenza Response Plan* (Mar. 2020); Mo. Dep't of Health & Senior Servs., *Missouri's Pandemic Influenza Response Plan* (Mar. 2020).

The Proposed Regulations do not discuss those interests or how to minimize negative impacts to them. *See Regents*, 140 S. Ct. at 1914 (discussing ways DHS could account for reliance interests). EPA should do so in the final rule—and such considerations should include forgoing the changes altogether or extending the compliance period for the Proposed Regulations.

III. There is no reason to engage in the environmental justice analysis in the Proposed Regulations.

EPA should also forgo the environmental justice analysis in the Proposed Regulations. *See* PID, *supra*, at 64–66; 88 Fed. Reg. at 22,832–839. The environmental justice analysis in practice looks at how the Proposed Regulations alter the effect EtO sterilization and emissions have on certain ethnic and racial groups, income groups, and education-level groups, and on the number of people who are linguistically isolated. *See* 88 Fed. Reg. at 22,834–839 tbls.24–29; PID, *supra*, at 65.

The analysis is not coherent. The Proposed Regulations say the environmental justice analysis is meant to "recogniz[e] that people of color and low-income populations often bear an unequal burden of environmental harms and risks." 88 Fed. Reg. at 22,832. Yet some of the proposed NESHAP standards will drastically increase the proportion of Hispanic and Latino individuals who face a significant cancer risk (≥100-in-1 million) from 18 percent to 51 percent. *Id.* at 22,834. That is, they *increase* the inequality of the burden on Hispanics and Latinos. EPA justifies this by pointing to the lower absolute "number of Hispanic or Latino people with risks greater than 100-in-1 million . . . ." *Id.* But if the goal is to maintain some sort of proportionality in terms of bearing the risks of EtO use, then it is unclear why absolute numbers matter.

Regardless, the environmental justice analysis is irrelevant. It does not appear that registration decisions under FIFRA, *see* 7 U.S.C. §§ 136(bb), 136(c)(5); 40 C.F.R. § 155.40(a), or emissions standards under the CAA, *see NRDC v. EPA*, 529 F.3d 1077, 1079–80 (D.C. Cir. 2008) (summarizing the statutory regime), turn on how the regulations alter the risks a particular population subgroup faces from a pesticide or

air emission.[4] So a decision that relies on the environmental justice concerns reflected in the Proposed Regulations would be arbitrary and capricious for relying "on factors which Congress has not intended [you] to consider." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). More than that, a decision to regulate that turns on whether the regulation benefits particular racial or ethnic subgroups would be constitutionally suspect. *See Adarand Constructors, Inc. v. Pena*, 515 U.S. 200, 235 (1995) (requiring federal racial classifications to pass strict scrutiny). EPA appears to have spent numerous pages on an analysis that has no bearing on the question before it.

For that reason, EPA should abandon the environmental justice analyses analysis in this rulemaking and forgo it in all future proposed rules. The purpose "of the APA's notice and comment requirements are '(1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review.'" *Prometheus Radio Project v. FCC*, 652 F.3d 431, 449 (3d Cir. 2011) (quoting *Int'l Union, United Min Workers of Am. v. Mine Safety & Health Admin.*, 407 F.3d 1250, 1259 (D.C. Cir. 2005)). Including irrelevant material in proposed rules undermines those purposes. Commentators may feel the need to address irrelevant material in case the agency relies on it or because an agency says it is important. But commentators, like everyone else, do not have infinite resources. So time spent addressing material that is irrelevant legally, but still being improperly considered by an agency, subtracts from time spent addressing relevant matters. That detracts from the public's ability "to communicate [relevant] concerns in a comprehensive and systematic fashion . . . ." *Hoctor v. U.S. Dep't of Agric.*, 82 F.3d 165, 171 (7th Cir. 1996). For a similar reason, it detracts from the ability of commentators to provide evidence supporting their criticism of a proposed rule. And by undermining commentators' ability to make their case before the agency, the agency undermines the fundamental fairness of the process.

IV. EPA should reconsider the Proposed Regulations to ensure they comply with the proper scope of federal authority under the Commerce Clause.

EPA should also tailor the Proposed Regulations to comply with the proper scope of federal power under the Interstate Commerce Clause. U.S. Const. art. I, § 8, cl. 3; *see United States v. Ho*, 311 F.3d 589, 601–02 (5th Cir. 2002) (analyzing whether a particular application of the CAA violated Congress's commerce power); *Chevron*

[4] Arguably, considering the effect of EtO exposure on groups within close proximity to sterilization facilities, *see* PID, *supra*, at 65; 88 Fed. Reg. at 22,832, is more reasonable under FIFRA and the CAA. Assuming that is so, it still does not justify analyzing other demographic factors.

Chem. Co. v. Costle, 641 F.2d 104, 106 (3d Cir. 1981) (linking FIFRA to federal regulation of "the sale in interstate commerce of agricultural fungicides and pesticides").

Older case law, to be sure, suggests that "the power conferred by the Commerce Clause [is] broad enough to permit congressional regulation of activities causing air or water pollution, or other environmental hazards that may have effects in more than one State." *Hodel v. Va. Surface Mining & Reclamation Ass'n, Inc.*, 452 U.S. 264, 282 (1981). But the Supreme Court clarified in later decisions "that the power to regulate commerce, though broad indeed, has limits." *United States v Lopez*, 514 U.S. 549, 557 (1995) (quotations omitted). Those decisions "do not exempt environmental regulations from Commerce Clause scrutiny," or the limits the Constitution places on Congress's use of that power. *Ho*, 311 F.3d at 604 n.16 (discussing *Lopez* and *United States v. Morrison*, 529 U.S. 598 (2000)). And indeed, the Supreme Court has applied those limits in the environmental context. *See Solid Waste Agency of N. Cook Cty. v. U.S. Army Corps of Eng'rs*, 531 U.S. 159, 173 (2001) (looking to those precedents in analyzing regulatory jurisdiction under the Clean Water Act); *see also Sackett v. EPA*, 143 S. Ct. 1322, 1358 (2023) (Thomas, J., concurring) (noting the tension between federal environmental laws, the proper interpretation of the Commerce Clause, and "more recent precedents reining in the commerce power").

So for the Proposed Regulations to be valid exercises of the federal power over interstate commerce under current precedent, they must (1) "regulate the use of the channels of interstate commerce," (2) "regulate and protect the instrumentalities of interstate commerce, or persons or things in interstate commerce," or (3) "substantially affect interstate commerce." *Morrison*, 529 U.S. at 609 (quotations omitted). It is far from clear they do. For example, there is no showing that EtO emissions affect "air routes," and so affects a channel of interstate commerce. *Ho*, 311 F.3d at 597. Similarly, there is no reason to believe that air or air pollution constitutes a "thing[] in interstate commerce." *Lopez*, 514 U.S. at 558 (quotations omitted). Nor is it obvious how the intrastate use of EtO as a pesticide implicates the channels, instrumentalities, persons, or things in interstate commerce.

That leaves the question of whether the use of EtO in commercial sterilizing facilities (for the rules in the FIFRA review) and the emission of EtO (for the NESHAP standards) substantially affect interstate commerce. As the agency charged with implementing the CAA and FIFRA, EPA should do that analysis in the first instance. As an executive branch entity exercising the President's Take-Care power, *see*, *e.g.*, *Seila Law LLC v. CFPB*, 140 S. Ct. 2183, 2197 (2020), EPA "may decline to follow" a statutory mandate against which it has "a constitutional objection," *In re Aiken County*, 725 F.3d 255, 259 (D.C. Cir. 2013) (opinion of Kavanaugh, J.). Engaging in the Interstate Commerce Clause analysis is therefore a necessary first step for EPA

to exercise its discretion appropriately. And to the extent the analysis shows that EPA cannot constitutionally regulate some EtO use or emissions, the review may necessitate revisiting the analyses in the Proposed Regulations to determine the proper scope of any regulations.

And even if the analysis shows there are substantial effects interstate commerce, EPA should still decline to regulate. The original meaning of the Commerce Clause does not give Congress the power to regulate "activities that 'substantially affect' interstate commerce." *Lopez*, 514 U.S. at 587 (Thomas, J., concurring). That includes pairing the Commerce Clause with the Necessary and Proper Clause. If, by the combination of the two, Congress could regulate intrastate activities with a substantial effect on interstate commerce, "much if not all of Art. I, § 8 (including portions of the Commerce Clause itself) would be surplusage." *Id.* at 588–89. Such a construction also threatens to turn "the Tenth Amendment on its head" by giving "to the United States all powers not expressly *prohibited* by the Constitution." *Id.* at 589; *see also Printz v. United States*, 521 U.S. 898, 923–24 (1997) ("When a Law for carrying into Execution the Commerce Clause violates the principle of state sovereignty . . . it is not a Law proper for carrying into Execution the Commerce Clause.") (alterations and quotations omitted); *In re MCP No. 165*, 20 F.4th 264, 283 (6th Cir. 2021) (Sutton, C.J., dissenting from denial of initial hearing en banc) (The Commerce Clause is "not a clause that grants the national government all of the police powers customarily associated with state governments in order to fix any new societal challenge."). Refraining from regulating under the "substantial effects" theory thus adheres to the original—and proper—understanding of the Commerce Clause and vindicates the "'double security'" that the "proper balance between the States and the Federal Government" provides to the rights of Americans. *Gregory v. Ashcroft*, 501 U.S. 452, 459 (1991).

Conclusion

For those reasons, EPA should not promulgate or—at the very least, extend the compliance period for—the Proposed Regulations.

Sincerely,

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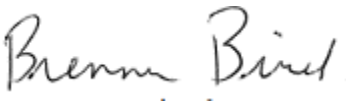

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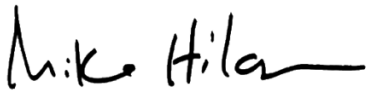

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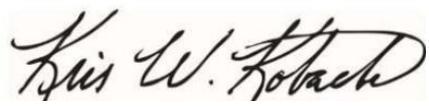

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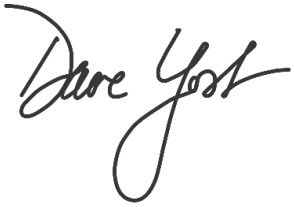

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