

**THE ATTORNEYS GENERAL OF NEW YORK, CONNECTICUT, ILLINOIS,  
MARYLAND, MASSACHUSETTS, MICHIGAN, NEW JERSEY, OREGON,  
RHODE ISLAND, VERMONT, AND WISCONSIN**

June 27, 2023

***Via Electronic Filing***

**EPA-HQ-OPP-2013-0244**

Michael Regan, Administrator  
U.S. Environmental Protection Agency  
Office of Pesticides Programs  
1200 Pennsylvania Ave. NW  
Washington, D.C. 20460

**Re: *Pesticide Registration Review; Proposed Interim Decision and Draft Risk Assessment Addendum for Ethylene Oxide; Notice of Availability, 88 Fed. Reg. 22,447 (Apr. 13, 2023)***

Dear Administrator Regan:

The Attorneys General of New York, Connecticut, Illinois, Maryland, Massachusetts, Michigan, New Jersey, Oregon, Rhode Island, Vermont, and Wisconsin submit these comments regarding the U.S. Environmental Protection Agency Office of Pesticide Programs' proposed interim registration review decision ("Proposed Interim Decision")<sup>1</sup> and draft risk assessment for ethylene oxide.<sup>2</sup>

EPA regulates ethylene oxide's use as a sterilant, which is considered an antimicrobial pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA").<sup>3</sup> Our states have a significant interest in ensuring that the registration review decision and risk assessment for ethylene oxide are prepared in

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<sup>1</sup> See EPA, Ethylene Oxide Proposed Interim Registration Review Decision, Case Number 2275 (Mar. 2023), <https://www.regulations.gov/document/EPA-HQ-OPP-2013-0244-0045>.

<sup>2</sup> Certain Attorneys General are also submitting comments regarding EPA's other recent proposals concerning ethylene oxide, *National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review*, 88 Fed. Reg. 22,790 (Apr. 13, 2023), and *New Source Performance Standards for the Synthetic Organic Chemical Manufacturing Industry and National Emission Standards for Hazardous Air Pollutants for the Synthetic Organic Chemical Manufacturing Industry and Group I & II Polymers and Resins Industry*, 88 Fed. Reg. 25,080 (Apr. 25, 2023).

<sup>3</sup> 7 U.S.C. § 136 *et seq.*

accordance with FIFRA and the EPA implementing regulations at 40 C.F.R. part 155, subpart C. Ethylene oxide is widely used to sterilize medical devices, as well as some plastics and packaged spices, and is a known carcinogen. As EPA found, ethylene oxide endangers people who live, work, or attend school near facilities that use ethylene oxide.

EPA published the interim registration review decision and draft risk assessment under FIFRA, which prohibits the sale, distribution, shipment, or receipt of any pesticide that is not registered with EPA. FIFRA requires EPA to, among other things, periodically review pesticide registrations every 15 years to ensure that risk assessments and decisions reflect the best available science, and that they appropriately address identified risks such that the pesticide does not cause unreasonable adverse effects on the environment.

As explained below, EPA's Proposed Interim Decision and draft risk assessment do not meet the requirements of FIFRA and EPA's own implementing regulations. EPA is required to fully assess the risk to workers at all facilities that use ethylene oxide as a pesticide, as well as the risk to communities near these facilities. In turn, EPA should cancel as many registrations as possible. To the extent that EPA does not cancel a registration, EPA must require mitigation measures to reduce the risk to acceptable levels. Accordingly, we urge EPA to revise the interim decision and risk assessment so that its registration of ethylene oxide fully complies with the agency's obligations under FIFRA to ensure that products can carry out their intended function without creating unreasonable risks to human health and the environment.

## **I. States' Interests in the Registration of Ethylene Oxide**

### **A. Ethylene Oxide is Widely Used and Poses Serious Public Health Harms**

Ethylene oxide is a flammable, colorless gas commonly used largely to sterilize medical devices and equipment, as well as some packaged spices.<sup>4</sup> Half of all medical equipment nationwide is sterilized with ethylene oxide.<sup>5</sup> Ethylene oxide is also used to make chemicals for manufacturing other products, including

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<sup>4</sup> EPA, *Our Current Understanding of Ethylene Oxide (EtO)*, <https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/our-current-understanding-ethylene-oxide-eto>; Union of Concerned Scientists, *Invisible Threat, Inequitable Impact* (Feb. 7, 2023), <https://www.ucsusa.org/resources/invisible-threat-inequitable-impact#read-online-content>.

<sup>5</sup> Proposed Interim Decision at 12; EPA, *Our Current Understanding of Ethylene Oxide (EtO)*, <https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/our-current-understanding-ethylene-oxide-eto>; Union of Concerned Scientists, *Invisible Threat, Inequitable Impact: Ethylene Oxide, Frequently Asked Questions* at 1 (Feb. 7, 2023), <https://www.ucsusa.org/sites/default/files/2023-02/Invisible-Threat-Inequitable-Impact-fact-sheet.pdf>.

antifreeze, textiles, plastics, detergents, and adhesives.<sup>6</sup> EPA,<sup>7</sup> National Toxicology Program,<sup>8</sup> and World Health Organization International Agency for Research on Cancer<sup>9</sup> all classify ethylene oxide as a carcinogen, meaning that the chemical can cause cancer in humans.<sup>10</sup>

Ethylene oxide endangers workers at facilities that use ethylene oxide as well as communities near those facilities.<sup>11</sup> Long-term exposure to ethylene oxide through inhalation is associated with the development of cancers of white blood cells, such as non-Hodgkin's lymphoma, as well as breast cancer in women.<sup>12</sup> Children are particularly vulnerable to ethylene oxide, which can cause DNA mutations.<sup>13</sup> Short-term inhalation of ethylene oxide can also contribute to respiratory issues, headaches, nausea, vomiting, and fatigue.<sup>14</sup> Animals that live near facilities that release ethylene oxide to the outdoor air may also be exposed to, and affected by, ethylene oxide.<sup>15</sup>

## **B. Communities Near Facilities that Use Ethylene Oxide as a Sterilizer Face Serious Risk**

Among the most significant emitters of ethylene oxide are commercial sterilizers, which use ethylene oxide to sterilize medical devices and equipment, spices, and other products.<sup>16</sup> Although the United States has nearly 100

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<sup>6</sup> Union of Concerned Scientists, *Invisible Threat, Inequitable Impact* at 1 (Feb. 7, 2023), <https://www.ucsusa.org/resources/invisible-threat-inequitable-impact#read-online-content>.

<sup>7</sup> EPA, *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (Final Report)* (2016), [https://cfpub.epa.gov/ncea/iris\\_drafts/recordisplay.cfm?deid=329730](https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=329730).

<sup>8</sup> National Toxicology Program, Department of Health and Human Services, *Ethylene Oxide* (2021), <https://ntp.niehs.nih.gov/sites/default/files/ntp/roc/content/profiles/ethyleneoxide.pdf>.

<sup>9</sup> World Health Organization International Agency for Research on Cancer, *Chemical Agents and Related Occupations*, Volume 100 F: A Review of Human Carcinogens (2012), <https://monographs.iarc.who.int/wp-content/uploads/2018/06/mono100F.pdf>.

<sup>10</sup> Union of Concerned Scientists, *Invisible Threat, Inequitable Impact* (Feb. 7, 2023), <https://www.ucsusa.org/resources/invisible-threat-inequitable-impact#read-online-content>.

<sup>11</sup> Proposed Interim Decision at 17-18; Union of Concerned Scientists, *Invisible Threat, Inequitable Impact* (Feb. 7, 2023), <https://www.ucsusa.org/resources/invisible-threat-inequitable-impact#read-online-content>.

<sup>12</sup> EPA, *Our Current Understanding of Ethylene Oxide (EtO)*, <https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/our-current-understanding-ethylene-oxide-eto>; Union of Concerned Scientists, *Invisible Threat, Inequitable Impact* (Feb. 7, 2023), <https://www.ucsusa.org/resources/invisible-threat-inequitable-impact#read-online-content>.

<sup>13</sup> EPA, *Our Current Understanding of Ethylene Oxide (EtO)*, <https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/our-current-understanding-ethylene-oxide-eto>; Union of Concerned Scientists, *Invisible Threat, Inequitable Impact* (Feb. 7, 2023), <https://www.ucsusa.org/resources/invisible-threat-inequitable-impact#read-online-content>.

<sup>14</sup> *Id.*

<sup>15</sup> EPA, *Our Current Understanding of Ethylene Oxide (EtO)*, <https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/our-current-understanding-ethylene-oxide-eto>.

<sup>16</sup> Union of Concerned Scientists, *Invisible Threat, Inequitable Impact: Ethylene Oxide*, Frequently Asked Questions at 1 (Feb. 7, 2023), <https://www.ucsusa.org/sites/default/files/2023-02/Invisible-Threat-Inequitable-Impact-fact-sheet.pdf>.

commercial sterilizers, many people may not know that they live near a commercial sterilizer given that these facilities often look like warehouses.<sup>17</sup> Children who go to school or daycare near commercial sterilizers face serious potential harm.<sup>18</sup> In fact, risk levels for certain children may be over one in one million.<sup>19</sup>

In 2022, after assessing risks to communities near active commercial sterilizers, EPA found an elevated cancer risk in 23 communities, some of which EPA characterized as exceptionally high.<sup>20</sup> In particular, EPA found the maximum cancer risk level from ethylene oxide emissions to be greater than EPA's threshold of 100 additional cancer cases per one million people (or 1 in 10,000).<sup>21</sup>

Communities of color are disproportionately exposed to ethylene oxide emissions, posing significant environmental justice concerns, as documented in a recent Union of Concerned Scientists study.<sup>22</sup> According to the study, in the United States and Puerto Rico, 14.2 million people live within five miles of a commercial sterilizer that uses ethylene oxide or an ethylene oxide manufacturing facility.<sup>23</sup> Of these 14.2 million people, nearly 8.5 million (60%) identify as people of color; 4.8 million identify as people with low incomes (34%), and 1.2 million identify as people with limited English language proficiency (8%).<sup>24</sup> The Union of Concerned Scientists' analysis also identified ethylene oxide "sterilizer hotspots," where communities, and often communities of color, are potentially exposed to ethylene oxide from more than one facility.<sup>25</sup> The Union of Concerned Scientists found that 28 percent of commercial sterilizers are in sterilizer hotspots.<sup>26</sup>

The Union of Concerned Scientists' findings are consistent with a 2021 EPA Inspector General's report.<sup>27</sup> In that report, the EPA Inspector General found that

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<sup>17</sup> Union of Concerned Scientists, *Invisible Threat, Inequitable Impact: Ethylene Oxide*, Frequently Asked Questions at 1 (Feb. 7, 2023), <https://www.ucsusa.org/sites/default/files/2023-02/Invisible-Threat-Inequitable-Impact-fact-sheet.pdf>.

<sup>18</sup> EPA, *EPA Fact Sheet: EPA Issues Proposed Actions to Reduce Ethylene Oxide Exposures under the Nation's Pesticide Control Law* ("EPA Fact Sheet") at 3 (Apr. 2023), <https://www.epa.gov/system/files/documents/2023-04/fact-sheet-proposed-actions-eto.pdf>.

<sup>19</sup> EPA Fact Sheet.

<sup>20</sup> Union of Concerned Scientists, *Invisible Threat, Inequitable Impact* (Feb. 7, 2023), <https://www.ucsusa.org/resources/invisible-threat-inequitable-impact#read-online-content>; Proposed Interim Decision at 53.

<sup>21</sup> Union of Concerned Scientists, *Invisible Threat, Inequitable Impact* (Feb. 7, 2023), <https://www.ucsusa.org/resources/invisible-threat-inequitable-impact#read-online-content>.

<sup>22</sup> *Id.* The Union of Concerned Scientists analysis includes 96 commercial sterilizers, as well as eight manufacturing facilities.

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

<sup>27</sup> EPA, *Office of the Inspector General, EPA Should Conduct New Residual Risk and Technology Reviews for Chloroprene and Ethylene Oxide-Emitting Source Categories to Protect Human Health*, Report No. 21-P-0129 (May 6, 2021), [https://www.epa.gov/sites/default/files/2021-05/documents/epa\\_oig\\_20210506-21-p-0129.pdf](https://www.epa.gov/sites/default/files/2021-05/documents/epa_oig_20210506-21-p-0129.pdf).

“minorities or [people] part of low-income households” comprise more than half of the people living in census block groups of 14 (of 22) ethylene oxide-emitting facilities contributing to elevated cancer risks.<sup>28</sup> EPA also noted that workers at commercial sterilizers could also be disproportionately drawn from the Hispanic or Latino communities since many sterilizer facilities are located in Puerto Rico.<sup>29</sup>

Ethylene oxide is also emitted from healthcare facilities that use ethylene oxide to sterilize medical equipment, including hospitals, veterinarian offices, and dental offices.<sup>30</sup> In addition, off-site warehouses that store sterilized devices also emit ethylene oxide via the off-gassing of the sterilized items.<sup>31</sup>

### **C. Workers at Facilities that Use Ethylene Oxide as a Sterilizer Face Serious Risk**

Ethylene oxide also poses risks to workers at facilities that use ethylene oxide as a sterilizer, including commercial sterilization facilities, healthcare facilities, and facilities treating beekeeping equipment in North Carolina.<sup>32</sup> EPA’s latest risk assessment for ethylene oxide shows that risks to workers who sterilize products are more significant than they had previously thought.<sup>33</sup>

Specifically, EPA found the following risks for workers who handle ethylene oxide, without new, proposed practices or engineering controls.<sup>34</sup> As to workers in commercial sterilization facilities who apply ethylene oxide to medical devices, 1 in 17 workers to 1 in 10 workers would develop cancer if exposed to ethylene oxide over the course of their entire career.<sup>35</sup> As to workers in healthcare facilities who apply ethylene oxide, 1 in 25 workers to 1 in 12 workers would develop cancer if exposed to ethylene oxide over the course of their entire career.<sup>36</sup> As to workers in commercial sterilization facilities who apply ethylene oxide to spices, 1 in 36

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<sup>28</sup> EPA, *Office of the Inspector General, EPA Should Conduct New Residual Risk and Technology Reviews for Chloroprene and Ethylene Oxide-Emitting Source Categories to Protect Human Health*, Report No. 21-P-0129 (May 6, 2021), [https://www.epa.gov/sites/default/files/2021-05/documents/epaoig\\_20210506-21-p-0129.pdf](https://www.epa.gov/sites/default/files/2021-05/documents/epaoig_20210506-21-p-0129.pdf); Union of Concerned Scientists, *Invisible Threat, Inequitable Impact* (Feb. 7, 2023), <https://www.ucsusa.org/resources/invisible-threat-inequitable-impact#read-online-content>.

<sup>29</sup> Proposed Interim Decision at 65.

<sup>30</sup> See Proposed Interim Decision at 12.

<sup>31</sup> Darya Minovi, *EPA’s Strengthened Ethylene Oxide Regulations Will Help Protect Fenceline Communities and Workers, Rules Should Go Further* (Apr. 11, 2023), <https://www.ucsusa.org/about/news/epas-strengthened-ethylene-oxide-regulations-will-help-protect-fenceline-communities>.

<sup>32</sup> Proposed Interim Decision at 3.

<sup>33</sup> EPA Fact Sheet at 1.

<sup>34</sup> *Id.* at 3.

<sup>35</sup> EPA estimates the duration of a career as 8 hours per day, for 240 days a year, for 35 years. Proposed Interim Decision at 21.

<sup>36</sup> EPA Fact Sheet; Proposed Interim Decision at 22.

workers to 1 in 16 workers would develop cancer if exposed to ethylene oxide over the course of their entire career.<sup>37</sup>

EPA also found that continuous, long-term exposure to ethylene oxide could also lead to elevated cancer risk for workers who do not directly handle ethylene oxide but work in other areas of the facilities.<sup>38</sup>

EPA further found that people working in warehousing and storage, such as those who would be employed in these facilities, moving materials into and out of chambers for fumigation, could be disproportionately drawn from communities of color.<sup>39</sup> Specifically, warehousing and storage workers are approximately 22% Black or African American and 36% Hispanic or Latino.<sup>40</sup>

#### **D. Ethylene Oxide is Used as a Pesticide within the States**

There are numerous facilities that use ethylene oxide as a pesticide to sterilize equipment within our coalition of states.

In New York, there are two commercial sterilization facilities that use ethylene oxide. First, Sterigenics US LLC began operating at 84 Park Road in Kingsbury, NY in 1994.<sup>41</sup> The facility uses ethylene oxide to sterilize medical devices.<sup>42</sup> In 2021, Sterigenics reportedly used 157.5 tons of ethylene oxide.<sup>43</sup> The facility operates 11 sterilization chambers.<sup>44</sup> To control emissions, the facility is equipped with a catalytic oxidizer, which was installed in 1993, and a wet scrubber, which was installed in 1995.<sup>45</sup> Approximately 30 workers are employed at this facility. EPA reported that the majority of the risk from the Kingsbury location is being caused by fugitive (leakage) emissions, as opposed to controlled (stack) emissions.<sup>46</sup>

The nearby community consists of numerous residences, with an estimated 1,375 people living within one mile.<sup>47</sup> Most of the houses on Dean Road are within

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<sup>37</sup> EPA Fact Sheet; Proposed Interim Decision at 22.

<sup>38</sup> EPA Fact Sheet.

<sup>39</sup> Proposed Interim Decision at 65.

<sup>40</sup> *Id.*

<sup>41</sup> EPA Kingsbury NY EtO Community Meeting Presentation (Feb. 16, 2023), <https://www.epa.gov/system/files/documents/2023-02/Kingsbury%20NY%20EtO%20Community%20Meeting%20Presentation.pdf>.

<sup>42</sup> *Id.*

<sup>43</sup> *Id.*

<sup>44</sup> EPA, Queensbury, NY (Sterigenics US LLC-Kingsbury), <https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/forms/queensbury-ny-sterigenics-us-llc-kingsbury>.

<sup>45</sup> EPA Kingsbury NY EtO Community Meeting Presentation (Feb. 16, 2023), <https://www.epa.gov/system/files/documents/2023-02/Kingsbury%20NY%20EtO%20Community%20Meeting%20Presentation.pdf>.

<sup>46</sup> *Id.*

<sup>47</sup> EPA EJSCREEN Census 2010 Summary Report.



a half mile of the facility. Dean Road is also east of Sterigenics and since the wind comes predominantly from the north, parts of Dean Road are in the path of wind. Additionally, a daycare center is only .57 miles from Sterigenics and also in the path of wind.

Based on an examination using EPA EJSCREEN, the New York Disadvantaged Communities' map, and the Agency for Toxic Substances and Disease Registry's Environmental Justice Index,<sup>48</sup> the community within one mile of the Sterigenics facility has several health and socioeconomic vulnerabilities, including high air toxics cancer risk (99<sup>th</sup> percentile, state), high percentage of children under age 5 (93<sup>rd</sup> percentile, state), high percent of low-income households (65<sup>th</sup> percentile, state), high levels of respiratory-related emergency department visits (asthma and chronic obstructive pulmonary disease (COPD) (77<sup>th</sup> percentile, state and 72<sup>nd</sup> percentile, state)), and lower levels of formal education.

In addition, the nearby community bears additional environmental burdens, including its proximity to several EPA Risk Management Program facilities. In addition, according to EPA Envirofacts, the area has over 11 Resource Conservation and Recovery Act (RCRA) facilities, one additional air pollution facility, and three additional state/tribal "facilities of interest," including an asphalt plant, a photographic equipment and supply facility, a machine shop, a construction contractor, a hazardous waste transporter, and a fabric finishing mill. The area is also adjacent to the Floyd Bennett Memorial Airport in Warren County.

Second, Long Island Sterilization, owned by Busse Hospital Disposables, has operated at 175 Wireless Blvd. in Hauppauge, NY since 2001.<sup>49</sup> The facility sterilizes medical devices. The nearby community contains many residences, with 4,645 people living within 1 mile of the facility.<sup>50</sup> There is also one school within a mile of the facility, with two additional schools nearby.

Based on an examination using EPA EJSCREEN, the New York Disadvantaged Communities' map, and the Agency for Toxic Substances and Disease Registry's Environmental Justice Index,<sup>51</sup> the community within one mile of the Long Island Sterilization facility has several health and socioeconomic vulnerabilities, including high air toxics cancer risk (85<sup>th</sup> percentile, state), high levels of respiratory-related emergency department visits (asthma and chronic obstructive pulmonary disease (COPD) (67<sup>th</sup> percentile, state and 75<sup>th</sup> percentile, state), and high rates of diabetes and mental health challenges.

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<sup>48</sup> Agency for Toxic Substances and Disease Registry, *Environmental Justice Index* (2023).

<sup>49</sup> Long Island Sterilization, <https://www.listerilization.com/>.

<sup>50</sup> EPA EJSCREEN 2016-2020 American Community Survey Report, <https://ejscreen.epa.gov/mapper/index.html?wherestr=175+Wireless+Blvd%2C+Hauppauge%2C+NY>.

<sup>51</sup> Agency for Toxic Substances and Disease Registry, *Environmental Justice Index* (2023).

In addition, the nearby community bears additional environmental burdens, including a high percentage of households living within a one-mile radius of an EPA Risk Management Program facility, high traffic proximity, a Superfund site leading to high levels of hazardous waste site within the area, and two Toxic Release Inventory facilities within one mile of the site. Additionally, one tract near the facility is identified as “disadvantaged” by the Justice40 Initiative criteria based on workforce development.

According to the New York State Department of Environmental Conservation, there are also 15 healthcare facilities that use ethylene oxide as a sterilizer. Furthermore, there may also be additional warehouses that store products that have been sterilized with ethylene oxide.

In Massachusetts, STERIS Applied Sterilization Technologies, 435 Whitney Street, Northborough, operates a medical device manufacturing facility, including ethylene oxide sterilization services. This facility is near multiple environmental justice areas.

## **II. Registration of Ethylene Oxide under FIFRA**

### **A. Overview of Pesticide Registration under FIFRA**

FIFRA prohibits the sale, distribution, shipment, or receipt of any pesticide that is not registered with EPA.<sup>52</sup> A registration functions as a license setting forth the conditions under which the pesticide may be sold, distributed, and used.<sup>53</sup> EPA may not issue a registration for a pesticide that causes “unreasonable adverse effects on the environment.”<sup>54</sup> “[U]nreasonable adverse effects on the environment include ‘any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.’”<sup>55</sup> “This is commonly referred to as the FIFRA safety standard.”<sup>56</sup>

“In 2007, Congress added a new process called ‘registration review’ to the FIFRA scheme governing pesticides, instructing EPA to ‘periodically review’ pesticide registrations every fifteen years.”<sup>57</sup> EPA has promulgated regulations governing the process for registration review.<sup>58</sup>

The regulations require EPA to assess any new information regarding risks to human health and the environment that emerged since EPA last issued a

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<sup>52</sup> 7 U.S.C. §§ 136 *et seq.*

<sup>53</sup> 7 U.S.C. §§ 136(a).

<sup>54</sup> 7 U.S.C. § 136a(c)(5)(C); *see also* 40 C.F.R. § 152.112(e); *NRDC v. EPA*, 38 F.4th 34, 40 (9th Cir. 2022).

<sup>55</sup> *NRDC*, 38 F.4th at 40 (quoting 7 U.S.C. § 136(bb)).

<sup>56</sup> *Id.*

<sup>57</sup> *Id.* (quoting 7 U.S.C. § 136a(g)(1)(A)).

<sup>58</sup> *Id.*; 40 C.F.R. §§ 155.23-155.58.



registration decision for a pesticide to verify that the pesticide continues to satisfy the FIFRA safety standard.<sup>59</sup> “By periodically re-evaluating pesticides as science, public policy, and pesticide-use practices change, the Agency ensures that the public can continue to use products in the marketplace that do not present unreasonable adverse effects.”<sup>60</sup>

The process concludes with a registration review decision, which sets forth EPA’s determination as to “whether a pesticide meets, or does not meet,” the FIFRA safety standard.<sup>61</sup> The regulations also permit EPA to issue an “interim registration review decision” prior to the registration review decision.<sup>62</sup> “[T]he interim registration review decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for . . . completing the registration review.”<sup>63</sup>

If EPA finds that a pesticide does not satisfy the FIFRA safety standard, EPA may initiate cancellation proceedings to rescind a pesticide’s registration,<sup>64</sup> or may require mitigation measures to reduce risk to acceptable levels.<sup>65</sup>

## **B. EPA’s Registration Review of Ethylene Oxide**

In 1966, ethylene oxide was first registered as a pesticide in the U.S.<sup>66</sup> In 2008, EPA issued a re-registration eligibility decision.<sup>67</sup> EPA has maintained registrations for ethylene oxide as a pesticide under FIFRA. Ethylene oxide is registered for sterilization of medical devices and equipment (including veterinary equipment), laboratory items, pharmaceuticals, and aseptic packaging.<sup>68</sup> Ethylene oxide is also registered to reduce the microbial load on dried herbs and spices, processed vegetables that have been dried or dehydrated, archival and museum materials, musical instruments, and cosmetics.<sup>69</sup> Additionally, ethylene oxide is registered for use under a special local needs registration in North Carolina for use on beekeeping equipment contaminated with American foulbrood bacterial disease

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<sup>59</sup> See, e.g., 40 C.F.R. §§ 155.40, 155.53(a); *NRDC*, 38 F.4th at 40.

<sup>60</sup> Proposed Interim Decision at 4.

<sup>61</sup> 40 C.F.R. § 155.57; *NRDC*, 38 F.4th at 40.

<sup>62</sup> 40 C.F.R. § 155.56; *NRDC*, 38 F.4th at 40.

<sup>63</sup> 40 C.F.R. § 155.56; *NRDC*, 38 F.4th at 40.

<sup>64</sup> 7 U.S.C. §§ 136a(g)(1)(A)(v), 136d(b); 40 C.F.R. § 155.40(a)(2).

<sup>65</sup> See 40 C.F.R. § 155.58.

<sup>66</sup> Proposed Interim Decision at 4.

<sup>67</sup> *Id.*

<sup>68</sup> *Id.* at 11.

<sup>69</sup> *Id.*

or other pests.<sup>70</sup> Approximately 14 million pounds of ethylene oxide are used as a pesticide annually.<sup>71</sup>

In September 2013, EPA formally initiated registration review for ethylene oxide.<sup>72</sup> Registration review of ethylene oxide was to be completed by October 1, 2022.<sup>73</sup>

In November 2020, EPA released a draft human health and ecological risk assessment for ethylene oxide.<sup>74</sup> In April 2023, EPA released its response to public comments on the 2020 human health and ecological risk assessment.<sup>75</sup>

In April 2023, EPA released a draft risk assessment addendum that provides additional information on cancer risks from ethylene oxide.<sup>76</sup> The addendum did not revise the human health dietary risk assessment or the ecological risk assessment.<sup>77</sup>

Also, in April 2023, EPA released the Proposed Interim Decision for ethylene oxide.<sup>78</sup> EPA found that mitigation of inhalation risk is necessary to meet the FIFRA standard for continued ethylene oxide registration.<sup>79</sup> According to EPA, the Proposed Interim Decision proposes measures to mitigate ethylene oxide's risk to human health as quickly as possible.<sup>80</sup>

EPA's risk reduction measures include the termination of certain uses where alternatives exist, including with respect to museum materials, library materials, archival materials, cosmetics, musical instruments, and beekeeping equipment (in North Carolina).<sup>81</sup> EPA also proposes to lower the amount of ethylene oxide used per sterilization cycle for medical devices at sterilization facilities while continuing to meet U.S. Food and Drug Administration requirements for sterility assurance.<sup>82</sup> EPA is also proposing to require certain engineering controls and personal protective equipment in facilities that use ethylene oxide to sterilize medical

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<sup>70</sup> *Id.*

<sup>71</sup> *Id.* at 11-12.

<sup>72</sup> Proposed Interim Decision at 6.

<sup>73</sup> 7 U.S.C. § 136a(g)(1)(A)(iii)(I).

<sup>74</sup> EPA, *Regulation of Ethylene Oxide (EtO) Under the Federal Insecticide, Fungicide, and Rodenticide Act*, <https://www.epa.gov/ingredients-used-pesticide-products/regulation-ethylene-oxide-eto-under-federal-insecticide>.

<sup>75</sup> *Id.*

<sup>76</sup> *Id.*

<sup>77</sup> *Id.*

<sup>78</sup> *Id.*

<sup>79</sup> Proposed Interim Decision at 44.

<sup>80</sup> EPA, *Regulation of Ethylene Oxide (EtO) Under the Federal Insecticide, Fungicide, and Rodenticide Act*, <https://www.epa.gov/ingredients-used-pesticide-products/regulation-ethylene-oxide-eto-under-federal-insecticide>.

<sup>81</sup> *Id.*

<sup>82</sup> *Id.*

equipment and/or fumigate spices and new data requirements for commercial sterilization facilities.<sup>83</sup> EPA is also proposing to require certain engineering controls in healthcare facilities.<sup>84</sup>

### **III. EPA's Proposed Interim Decision and Risk Assessment for Ethylene Oxide Do Not Satisfy FIFRA**

#### **A. EPA Understates the Risk of Ethylene Oxide**

As discussed above, as part of the re-registration process, EPA must assess any new information regarding risks to human health and the environment that have emerged since EPA last issued a registration decision for a pesticide to verify that the pesticide continues to satisfy the FIFRA safety standard.<sup>85</sup> EPA may not issue a registration for a pesticide that causes “unreasonable adverse effects on the environment.”<sup>86</sup> “[U]nreasonable adverse effects on the environment’ include ‘any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.’”<sup>87</sup> Although EPA found that ethylene oxide endangers workers that are exposed to ethylene oxide on the job, as well as people who live, work, or go to school or daycare near sterilization facilities that emit ethylene oxide, in violation of FIFRA, EPA fails to fully assess the risk of ethylene oxide when used as a pesticide, as described below.<sup>88</sup>

#### **1. EPA Must Fully Assess the Risk to Workers at All Facilities that Use Ethylene Oxide as a Pesticide as well as the Risk to the Communities Near these Facilities**

For workers that handle ethylene oxide at commercial sterilization facilities and healthcare facilities, EPA estimated the cancer risk to be a staggering 1 in 25 workers to 1 in 10 workers.<sup>89</sup> However, in reality, the cancer risk to workers may actually be even higher. As EPA acknowledged, workers who handle ethylene oxide may also live in nearby communities.<sup>90</sup> EPA must aggregate these exposures in calculating the actual cancer risk for workers under FIFRA.

EPA states that it also anticipates cancer risks of concern for occupational, residential, and non-residential bystanders at commercial sterilization and healthcare facilities.<sup>91</sup> However, EPA failed to determine the exact concentrations

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<sup>83</sup> *Id.*

<sup>84</sup> *Id.*

<sup>85</sup> *See, e.g.*, 40 C.F.R. §§ 155.40, 155.53(a); *NRDC*, 38 F.4th at 40.

<sup>86</sup> 7 U.S.C. § 136a(c)(5)(C); *see also* 40 C.F.R. § 152.112(e); *NRDC*, 38 F.4th at 40.

<sup>87</sup> *NRDC*, 38 F.4th at 40 (quoting 7 U.S.C. § 136(bb)).

<sup>88</sup> EPA Fact Sheet at 1.

<sup>89</sup> Proposed Interim Decision at 68.

<sup>90</sup> *Id.* at 65.

<sup>91</sup> *Id.* at 68.

and quantitatively assess the risks to these populations.<sup>92</sup> Under FIFRA, EPA must also assess the cancer risks for these populations. EPA must further assess the cancer risk for workers and occupational, residential, and non-residential bystanders at warehouses that store sterilized products.

EPA's failure to fully assess the risk to workers at all facilities that use ethylene oxide and the risk to the communities near these facilities understates the risk of ethylene oxide as a pesticide.

## **2. EPA Must Consider the Impacts of Venting on Nearby Communities**

EPA proposes to require that commercial sterilization facilities that use ethylene oxide have adequate ventilation in spaces where ethylene oxide-sterilized product is stored.<sup>93</sup> EPA also proposes that all exhaust from all-in-one ethylene oxide healthcare facility sterilization devices be directed through exterior ventilation stacks.<sup>94</sup> According to EPA, this would ensure that there is minimal ethylene oxide exposure for workers and bystanders within healthcare facilities.<sup>95</sup> While venting may prove beneficial for workers, EPA must also consider the environmental and health impacts of venting on nearby communities.

## **3. EPA Must Conduct an Environmental Justice Analysis**

EPA failed to conduct an environmental justice analysis, but is requesting information on any other groups or segments of the population who, as a result of their proximity and exposure to pesticides, unique exposure pathway (e.g., as a result of cultural practices), location relative to physical infrastructure, exposure to multiple stressors and cumulative impacts, lower capacity to participate in decision making, or other factors, may have unusually high exposure to ethylene oxide compared to the general population or who may otherwise be disproportionately affected by the use of ethylene oxide as a pesticide.<sup>96</sup> EPA must conduct an environmental justice analysis.<sup>97</sup> Without this information, EPA's risk assessment

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<sup>92</sup> *Id.* at 18, 55.

<sup>93</sup> *Id.* at 56.

<sup>94</sup> *Id.* at 54.

<sup>95</sup> *Id.* at 54-55.

<sup>96</sup> *Id.* at 75-76.

<sup>97</sup> *See, e.g.*, Exec. Order 14,096, 88 Fed. Reg. 25,251 (Apr. 26, 2023) (directing federal agencies to “make environmental justice part of its mission”); Exec. Order 14,008, 86 Fed. Reg. 7619 (Jan. 27, 2021) (directing federal agencies to “secure environmental justice and spur economic opportunity for disadvantaged communities that have been historically marginalized and overburdened by pollution and underinvestment” and “to address the disproportionately high and adverse human health, environmental, climate-related and other cumulative impacts on disadvantaged communities”); Exec. Order 13,985, 86 Fed. Reg. 7009 (Jan. 25, 2021) (directing all federal agencies to “work to redress inequities in their policies and programs that serve as barriers to equal opportunity”); Exec. Order 13,990, 86 Fed. Reg. 7037 (Jan. 25, 2021) (directing all executive departments and agencies to address any actions that conflict with goals of reducing greenhouse gas emissions and prioritizing

likely underestimate the cancer risk for communities near facilities that use ethylene oxide as a sterilizer.<sup>98</sup>

#### **4. EPA Did Not Take Into Account the Economic, Social, and Environmental Costs and Benefits**

To determine whether there is “unreasonable adverse effects on the environment” under FIFRA, EPA must “tak[e] into account the economic, social, and environmental costs and benefits.”<sup>99</sup> Although EPA considered some of the benefits of using ethylene oxide as a sterilizer on medical devices and spices, EPA failed to complete the required analysis by considering the economic, social, and environmental costs.<sup>100</sup> Especially given the severity of the cancer risk of ethylene oxide, EPA must take into account the costs as it is required to do under FIFRA.

#### **B. EPA’s Proposed Interim Decision Does Not Adequately Mitigate the Risks of Ethylene Oxide**

Although EPA understated the risks of ethylene oxide as a pesticide, EPA nonetheless properly found that ethylene oxide does not satisfy the FIFRA safety standard. As discussed above, if EPA finds that a pesticide does not satisfy the FIFRA safety standard, EPA may initiate cancellation proceedings to rescind a pesticide’s registration,<sup>101</sup> or may require mitigation measures to reduce risk to acceptable levels.<sup>102</sup> Given that ethylene oxide causes unreasonable adverse effects on the environment, EPA should cancel as many registrations as possible. To the extent that EPA does not cancel a registration, EPA must require mitigation measures to reduce risk to acceptable levels. We urge EPA to cancel additional registrations and propose additional mitigation measures for registrations that are not canceled.

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environmental justice, among other national objectives); Exec. Order 13,563, 76 Fed. Reg. 3821 (Jan. 21, 2011) (directing agencies to select regulatory approaches that maximize net benefits including “distributive impacts[] and equity”; “Where appropriate and permitted by law, each agency may consider (and discuss qualitatively) values that are difficult or impossible to quantify, including equity . . . and distributive impacts.”); Exec. Order 12,898, 59 Fed. Reg. 7629 (Feb. 16, 1994) (directing each federal agency to “make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations,” including “consider[ing] (and discuss[ing] qualitatively) values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts” and “multiple and cumulative exposures”); and Exec. Order 12,866, 51 Fed. Reg. 51,735 (Oct. 4, 1993) (ordering agencies to consider “distributive impacts[] and equity” in designing regulations).

<sup>98</sup> See Union of Concerned Scientists, *Invisible Threat, Inequitable Impact* (Feb. 7, 2023), <https://www.ucsusa.org/resources/invisible-threat-inequitable-impact#read-online-content>.

<sup>99</sup> Proposed Interim Decision at 68.

<sup>100</sup> Proposed Interim Decision at 27-28.

<sup>101</sup> 7 U.S.C. §§ 136a(g)(1)(A)(v), 136d(b); 40 C.F.R. § 155.40(a)(2).

<sup>102</sup> See 40 C.F.R. § 155.58.

## **1. EPA Should Exercise Due Discretion and Cancel as Many Registrations of Ethylene Oxide as Possible**

EPA properly proposes to terminate a number of uses of ethylene oxide, including in museum materials, library materials, archival materials, cosmetics, musical instruments, and beekeeping equipment.<sup>103</sup> As EPA found, because there are viable ethylene oxide alternatives available for these uses, continued registration of ethylene oxide provides minimal benefits.<sup>104</sup> Furthermore, EPA correctly found that there is no to low adverse impact expected as a result of the termination of these uses.<sup>105</sup>

For the same reasons, EPA should also terminate the use of ethylene oxide on certain medical devices. Indeed, EPA acknowledges that there are alternative sterilization methods for some devices.<sup>106</sup> These alternatives include gamma irradiation, X-ray sterilization, electron beam sterilization, and steam, as well as alternative sterilization methods in development including vaporized hydrogen peroxide, nitrogen dioxide, chlorine dioxide, and vaporized peracetic acid.<sup>107</sup> EPA should not defer identifying alternatives as part of a long-term risk reduction strategy.<sup>108</sup>

EPA should further terminate the use of ethylene oxide on spices. As EPA recognizes there are alternatives to ethylene oxide for the sanitization of dried herbs and spices from pathogens and filth, including irradiation, heat, steam, and propylene oxide.<sup>109</sup> Indeed, the European Union, in addition to other countries, do not allow food products to be sterilized with ethylene oxide and have banned imported spices that have been sterilized with ethylene oxide.<sup>110</sup>

## **2. EPA Must Propose Mitigation Measures to Reduce Risk from Healthcare Facilities and Warehouses that Use Ethylene Oxide**

EPA states that it is relying on the Office of Air and Radiation's ("OAR's") proposed mitigation to address residential bystander risks from inhalation exposure to ethylene oxide through the emissions reductions that would result from OAR's proposed updates to the emission standard for ethylene oxide under the Clean Air

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<sup>103</sup> Proposed Interim Decision at 45.

<sup>104</sup> *Id.* at 45, 47.

<sup>105</sup> *Id.* at 46, 47.

<sup>106</sup> *Id.* at 69.

<sup>107</sup> *Id.* at 29.

<sup>108</sup> *See* Proposed Interim Decision at 29.

<sup>109</sup> *Id.* at 32.

<sup>110</sup> Elliott Negin, *Ask a Scientist: EPA Failing to Protect Communities from Cancer-Causing Gas* (Feb. 9, 2023), <https://blog.ucsusa.org/elliott-negin/epa-failing-to-protect-communities/>.



Act.<sup>111</sup> EPA states that it believes that the emissions limits proposed by OAR would significantly reduce residential and non-residential bystander exposure without causing adverse impacts to the U.S. supply of sterilized medical devices needed for a variety of medical procedures.<sup>112</sup> Additionally, EPA states that its proposal for use rate reduction through reduced concentrations for all medical devices in all facilities will result in reduced emissions overall and would, therefore, be expected to reduce risk to residential bystanders.<sup>113</sup> However, OAR’s proposal only covers commercial sterilizers, and does not cover other facilities that use ethylene oxide as a pesticide such as healthcare facilities and warehouses. To fulfill its obligations under FIFRA, EPA cannot solely rely on the OAR commercial sterilizer proposal and must propose additional mitigation measures to reduce risk to acceptable levels.

### **3. For Registrations that EPA Does Not Cancel, EPA Must Reduce Risk to Acceptable Levels**

EPA states that its proposed mitigation measures would reduce risks to workers and residential and non-residential bystanders.<sup>114</sup> But EPA has not conducted a quantitative analysis of the risk reduction that would result from these measures.<sup>115</sup> EPA states that since the risk reduction is not quantitatively assessed, and since the air concentrations need to be very low to meet risk thresholds, EPA is taking an approach of “as low as reasonably achievable” (ALARA) for ethylene oxide use and application.<sup>116</sup> However, EPA acknowledges that it expects inhalation cancer risks of concern to remain for workers inside sterilization and healthcare facilities, and residential and non-residential bystanders, even after the implementation of the proposed mitigation.<sup>117</sup>

EPA must propose additional mitigation measures to reduce the risk of ethylene oxide to an acceptable level. As to an acceptable level of risk, EPA must use the lower cancer risk threshold. As EPA notes, OAR and OPP have different thresholds for when residential cancer risks are considered to be of concern.<sup>118</sup> For OAR that threshold is 100 in a million. For OPP, that threshold is 1 in a million.<sup>119</sup>

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<sup>111</sup> See *National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review*, 88 Fed. Reg. 22,790 (Apr. 13, 2023).

<sup>112</sup> Proposed Interim Decision at 53.

<sup>113</sup> *Id.*

<sup>114</sup> *Id.* at 69.

<sup>115</sup> *Id.*

<sup>116</sup> *Id.*

<sup>117</sup> *Id.*

<sup>118</sup> *Id.* at 69 n.138.

<sup>119</sup> *Id.*

#### IV. Conclusion

For the foregoing reasons, we urge EPA to revise the interim decision and draft risk assessment so that its registration of ethylene oxide fully complies with the agency's obligations under FIFRA.

FOR THE PEOPLE OF THE STATE OF  
NEW YORK

LETITIA JAMES  
Attorney General of New York

*/s/ Sarah Kam*

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SARAH KAM  
Assistant Attorney General  
MICHAEL MYERS  
Senior Counsel  
CHARLES SILVER  
Chief Scientist  
REBECCA DUBE  
Environmental Scientist  
New York State Office of the Attorney  
General  
Environmental Protection Bureau  
28 Liberty Street, 19th Floor  
New York, NY 10005  
(212) 416-8465  
sarah.kam@ag.ny.gov

FOR THE PEOPLE OF THE STATE OF  
CONNECTICUT

WILLIAM TONG  
Attorney General of Connecticut

*/s/ Scott N. Koschwitz*

---

MATTHEW I. LEVINE  
Deputy Associate Attorney General  
SCOTT N. KOSCHWITZ  
Assistant Attorney General  
Connecticut Office of the Attorney General  
165 Capitol Avenue  
Hartford, Connecticut 06106  
(860) 808-5250  
Scott.Koschwitz@ct.gov

FOR THE PEOPLE OF THE STATE OF  
ILLINOIS

KWAME RAOUL  
Attorney General of Illinois

*/s/ Jason E. James*

---

JASON E. JAMES  
Assistant Attorney General  
Illinois Attorney General's Office  
201 W. Pointe Drive, Suite 7  
Belleville, IL 62226  
(872) 276-3583  
jason.james@ilag.gov

FOR THE PEOPLE OF THE STATE OF  
MARYLAND

ANTHONY G. BROWN  
Attorney General of Maryland

*/s/ Steven J. Goldstein*

---

STEVEN J. GOLDSTEIN  
Special Assistant Attorney General  
200 Saint Paul Place  
Baltimore, Maryland 21202  
(410) 576-6414  
Sgoldstein@oag.state.md.us

FOR THE PEOPLE OF THE  
COMMONWEALTH OF  
MASSACHUSETTS

ANDREA JOY CAMPBELL  
Attorney General of Massachusetts

*/s/ I. Andrew Goldberg*

---

I. ANDREW GOLDBERG  
Assistant Attorney General  
Environmental Protection Division  
Office of the Attorney General  
One Ashburton Place, 18<sup>th</sup> Flr.  
Boston, Massachusetts 02108  
(617) 963-2429  
andy.goldberg@mass.gov

FOR THE PEOPLE OF THE STATE OF  
MICHIGAN

DANA NESSEL  
Attorney General of Michigan

*/s/ Elizabeth Morrisseau*

---

ELIZABETH MORRISSEAU  
Assistant Attorney General  
Environment, Natural Resources,  
and Agriculture Division  
6<sup>th</sup> Floor, G. Mennen Williams Building  
525 W. Ottawa Street  
PO Box 30755  
Lansing, MI 48909  
(517) 335-7664  
MorrisseauE@michigan.gov

FOR THE PEOPLE OF THE STATE OF  
NEW JERSEY

MATTHEW J. PLATKIN  
Attorney General of New Jersey

*/s/ Daniel Resler*

---

DANIEL RESLER  
Deputy Attorney General  
Special Litigation Section  
Richard J. Hughes Justice Complex  
25 Market Street  
Trenton, NJ 08625  
(609) 376-2789  
Daniel.Resler@law.njoag.gov

FOR THE PEOPLE OF THE STATE OF  
OREGON

ELLEN F. ROSENBLUM  
Attorney General of Oregon

*/s/ Paul A. Garrahan*

---

PAUL A. GARRAHAN  
Attorney-in-Charge  
STEVE NOVICK  
Special Assistant Attorney General  
Natural Resources Section  
Oregon Department of Justice  
1162 Court Street NE  
Salem, OR 97301  
(503) 947-4540  
Paul.Garrahan@doj.state.or.us  
Steve.Novick@doj.state.or.us  
FOR THE PEOPLE OF THE STATE OF  
RHODE ISLAND

PETER F. NERONHA  
ATTORNEY GENERAL

*/s/ Randelle L. Boots*

---

Randelle L. Boots  
Special Assistant Attorney General  
Rhode Island Office of the Attorney  
General  
150 South Main Street  
Providence, RI 02903  
(401) 271-4400 ext. 2122  
rboots@riag.ri.gov



FOR THE PEOPLE OF THE STATE OF  
VERMONT

CHARITY R. CLARK  
Attorney General of Vermont

*/s/ Nicholas Persampieri*

---

NICHOLAS F. PERSAMPIERI

Assistant Attorney General  
Office of the Attorney General  
109 State Street  
Montpelier, VT 05609  
(802) 828-3171  
nick.persampieri@vermont.gov

FOR THE PEOPLE OF THE STATE OF  
WISCONSIN

JOSHUA L. KAUL  
Attorney General of Wisconsin

*/s/ Tressie K. Kamp*

TRESSIE K. KAMP  
Assistant Attorney General  
State of Wisconsin Department of Justice  
17 W. Main Street  
Madison, WI 53703  
(608) 266-9595  
kamptk@doj.state.wi.us