

## Note

### Should You Know About the Pesticides in Your Clothes? Nanosilver and the Treated Articles Exemption to FIFRA

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#### INTRODUCTION

Your gym shorts have pesticides in them.<sup>1</sup> Your yoga pants have pesticides in them, so does your sports bra, socks, microfiber running shirt, bed spread, pillow case, toothbrush, and your cutting board.<sup>2</sup> Or, at least they might have pesticides in them, and if they do, the manufacturer cannot print the name of the pesticide on the label or tell you about potential hazards or benefits.<sup>3</sup> If the pesticide-impregnated product was intended to be used as a pesticide—to be applied to an environment to prevent, mitigate, or destroy pests<sup>4</sup>—the United States Environmental Protection Agency (EPA) would require pre-market registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),<sup>5</sup> which only allows a pesticide to go to market after balancing the risks and benefits

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1. See, e.g., U.S. ENVTL. PROT. AGENCY, EPA-735-F-980-04, CONSUMER PRODUCTS TREATED WITH PESTICIDES 1 (1998), available at <http://nepis.epa.gov/Exe/ZyPURL.cgi?Dockkey=200002OE.txt>.

2. See *id.*

3. See *infra* Section III.

4. See definition of “pesticide” at 7 U.S.C. § 136(u) (2012).

5. 7 U.S.C. §§ 136–136y (2012).

involved with the product.<sup>6</sup> Registered pesticide products are not approved for sale like other consumer products; they can only be sold for specific intended uses in specific situations, and the product must be accompanied by its EPA-approved label that indicates the approved uses and hazard warnings.<sup>7</sup> Using a pesticide product in a manner inconsistent with the label violates federal law.<sup>8</sup> An odd outgrowth of this strict regulatory scheme is that consumer products, which might contain pesticides or have pesticidal activity because they are sprayed with, or are otherwise are treated with a pesticide, cannot carry these labels if these “treated articles” are not intended as pesticides themselves.<sup>9</sup> In an effort at regulatory efficiency, EPA exempted “treated articles” from the pesticide registration process,<sup>10</sup> and since the agency does not assess individual treated products, EPA argues that including the pesticide labels could be misleading to consumers—providing a false sense of regulatory oversight.<sup>11</sup> EPA allows some limited labeling disclosures and advertising about enhanced coatings on the product, but takes the stance that these products do not prevent the spread of bacteria and disease and cannot use public health pesticidal claims.<sup>12</sup>

This Note explores how a regulatory regime that fundamentally operates by requiring labeling, is currently being used to prevent labeling. For example, in an enforcement action involving a toothbrush marketed for children, EPA took issue with packaging text: “Reach Antibacterial for kids,’ ‘made with Microban antibacterial plastic—a material proven to inhibit the growth of germs.”<sup>13</sup> EPA required the company to remove the statements from packaging, and then attach stickers to every toothbrush already in stores.<sup>14</sup> The stickers read in part: “Microban antibacterial protection built in to

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6. *Id.* § 136(a).

7. *See infra* Section II.

8. § 136j(a)(2)(G).

9. *See infra* Section III.

10. 40 C.F.R. § 152.25(a) (2011).

11. *See* Erin M. Tesch, *The Regulation of Antimicrobials in Paints*, PAINT & COATINGS INDUSTRY, July 2004, at 64, 65.

12. U.S. ENVTL. PROT. AGENCY, *supra* note 1, at 1–3.

13. McNeil-PPC, Inc., No. FIFRA 98-H-08, 1998 WL 482777, at \*2 (E.P.A. July 31, 1998) (consent order).

14. *Id.* at \*3.

inhibit the growth of bacteria that may affect the plastic in the handle. Microban does not protect you against disease. As always, rinse your toothbrush.”<sup>15</sup> EPA was concerned that consumers would see the antibacterial claims and assume some level of public health protection is being provided when no public health benefit had been substantiated.<sup>16</sup> By preventing this partial labeling, consumers are left in the dark, and cannot take reasonable measures to receive the benefits provided by the pesticide or avoid the risks.

Pesticides are intentionally designed to be toxic and fatally disrupt essential biological function.<sup>17</sup> However, Americans tolerate increased health and environmental risks from consumer products all the time. Some consumer products, like motor vehicles, are extremely dangerous,<sup>18</sup> while others are known human carcinogens, like cigarettes.<sup>19</sup> Through the legislative process, Americans have expressed certain levels of tolerance for individual and collective risk, benefit, and choice in our regulation of dangerous products. For example, we mitigate the danger of vehicles by requiring seat belts, insurance, and regulating speed of travel, and for cigarettes we require health risk labeling, but we do not ban smoking. For pesticide products, this country has recognized that the economic benefits of pest reduction in agriculture, our homes, and yards can often leave us blind or indifferent to incredible ecological disruption. And so, we give significant power to EPA to ensure that our pursuit of agricultural efficiency, and bug-free suburbs, does not incidentally wipe out entire ecosystems and future generations of birds, bees, or humans.

This Note explores EPA’s statutory authority to regulate pesticides, and the policies EPA has adopted to regulate pesticides used to preserve consumer products. The use of

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15. *Id.*

16. *See id.* at \*2.

17. *See* 7 U.S.C. § 136(u) (2012).

18. 36,415 people were killed in the United States in 2012 from motor vehicle accidents. U.S. Ctrs. for Disease Control, *Deaths: Final Data for 2012*, 63 NAT’L VITAL STAT. REP., no. 9, 2014, at 1, tbl.10, available at [http://www.cdc.gov/nchs/data/nvsr/nvsr63/nvsr63\\_09.pdf](http://www.cdc.gov/nchs/data/nvsr/nvsr63/nvsr63_09.pdf).

19. Between the years 2005 and 2009, 480,000 deaths per year were attributable to cigarette smoking. *Annual Deaths Attributable to Cigarette Smoking—United States, 2005–2009*, CENTERS FOR DISEASE CONTROL, [http://www.cdc.gov/tobacco/data\\_statistics/tables/health/attrdeaths/](http://www.cdc.gov/tobacco/data_statistics/tables/health/attrdeaths/) (last updated Feb. 27, 2015).

nanosilver—small particles of silver under 100 nanometers (nm)—as an antimicrobial pesticide has brought some recent attention to EPA’s policies on articles treated with pesticides.<sup>20</sup> Some public health and environmental advocates have been critical of EPA for approving the use of nanosilver as an antimicrobial in textiles and other consumer products.<sup>21</sup> In general, advocates are concerned that nano-scale particles might have increased toxicity due to their size—that the tiny particles may pass through membranes and organs that ordinarily filter and block pollutants, and then accumulate in places that larger particles cannot.<sup>22</sup> There is a mixed scientific literature on the toxicity profile of nano-scale particles, but nanosilver has at least the same toxicity as non-nanosilver and there are some indications of greater toxicity.<sup>23</sup>

In Section I, this Note documents some of the toxicity issues with nanosilver. Section II discusses those concerns within the regulatory framework EPA uses to assess and regulate pesticide risks. Section III discusses the treated articles exemption to FIFRA and how the lack of hazard labeling under the exemption could run counter to the statutory provision that allows for regulatory exemptions to “carry out the purposes of [the Act].”<sup>24</sup> Section IV explores the

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20. AMRO EL-BADAWY ET AL., U.S. ENVTL. PROT. AGENCY, STATE OF THE SCIENCE LITERATURE REVIEW: EVERYTHING NANOSILVER AND MORE 1–2 (2010) [hereinafter EPA, STATE OF THE SCIENCE], available at [http://cfpub.epa.gov/si/si\\_public\\_record\\_report.cfm?dirEntryId=226785](http://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=226785).

21. Jennifer Sass, *NRDC Reveals Failed Safeguards for Pesticides*, SWITCHBOARD (Mar. 27, 2013), [http://switchboard.nrdc.org/blogs/jsass/nrdc\\_reveals\\_failed\\_safeguards.html](http://switchboard.nrdc.org/blogs/jsass/nrdc_reveals_failed_safeguards.html) (“Nanosilver was conditionally approved by EPA . . . without rigorous toxicity testing to evaluate risks. The small size of the nanoparticle means it can go places that the conventional silver cannot . . . . [The submitted rat studies] showed a dose-dependent increase in silver distribution in the liver, kidneys, stomach, brain, lungs, testes and blood . . . . [And it] has been reported in rodents to end up in the brain . . . . EPA should have required a complete set of reliable data on potential risks to people and wildlife, including studies of risks from long-term exposures, before making its registration decision.”).

22. See, e.g., *Nanosilver: Health Effects*, BEYOND PESTICIDES, <http://www.beyondpesticides.org/antibacterial/health/nano.php> (last visited Apr. 1, 2015) (“Preliminary research with laboratory rats has found that silver nanoparticles can traverse into the brain, and can induce neuronal degeneration and necrosis (death of cells or tissue) by accumulating in the brain . . . . Due to their size, these particles can readily penetrate the body and cells through various routes.”).

23. See *infra* Section I.

24. 7 U.S.C. § 136w(b)(2) (2012).

history of the treated articles exemption, and argues the exemption does not represent a statutory limitation and can be challenged with proposals to label downstream treated articles. This perspective prioritizes EPA's mandate to prevent adverse effects on human health and the environment, and does not prioritize society's interest in rapid technological advances in protection from pests. However, even if a reader would allow more benefits from new pesticide products despite increased risks, this Note hopes to satisfy all readers that the treated articles exemption is not a statutory limitation of FIFRA itself. This Note aims to provide historical context for the treated articles exemption to explain the exemption's statutory parameters. Hopefully, this Note will be helpful in efforts to allow more information to pass to consumers in the marketing and labeling of treated articles, and to help consumers better understand the technologies in our products, and the risks and benefits of pesticides in our products.

## I. NANOSILVER TOXICITY AND REGISTRATION

### A. REGISTRATION

In September 2008, the Swiss company HeiQ Materials AG (HeiQ) submitted a pesticide product application to EPA for "AGS-20" as an antimicrobial and preservative additive to treat fibers in textiles.<sup>25</sup> HeiQ listed the active ingredient in their product as silver and submitted an abbreviated application, commonly called a "me-too" registration, for a new use of a registered pesticide.<sup>26</sup> EPA had also recently received a petition for rule-making from a coalition of environmental organizations that alleged that some silver pesticides were being manufactured at the nano-scale, which gave them a different toxicity profile to non-nano particles, and thus EPA was allowing illegally-registered pesticides into the market.<sup>27</sup> When

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25. OFFICE OF PESTICIDE PROGRAMS, U.S. ENVTL. PROT. AGENCY, DECISION DOCUMENT: CONDITIONAL REGISTRATION OF HEIQ AGS-20 AS A MATERIALS PRESERVATIVE IN TEXTILES 1 (2011) [hereinafter EPA, HEIQ DECISION DOCUMENT], *available at* <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2009-1012-0064>.

26. *Id.*

27. *See* Petition for Rulemaking Requesting EPA Regulate Nanoscale Silver Products as Pesticides, 73 Fed. Reg. 69644 (Nov. 19, 2008) (providing notice of petition and opening docket for comments); Petition for Rulemaking from Int'l Ctr. for Tech. Assment to U.S. Env'tl. Prot. Agency (Mar. 1, 2008),

HeiQ submitted its “me-too” application, there were ninety-three registered pesticide products with silver as an active ingredient.<sup>28</sup> For the first time, EPA asked the petitioner to provide particle dimension to determine if the nano-scale of HeiQ’s pesticide required the full registration process for a new pesticidal active ingredient.<sup>29</sup> After requesting a report from its Scientific Advisory Panel in 2009,<sup>30</sup> and assessing the 1477 comments on the nanosilver petition for rulemaking,<sup>31</sup> EPA determined in 2010 that the application would be considered as a new active ingredient not currently in a registered product, rather than a new use of the existing registration for silver.<sup>32</sup>

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available at [http://www.centerforfoodsafety.org/files/cta\\_nano-silver-petition\\_final\\_5\\_1\\_08.pdf](http://www.centerforfoodsafety.org/files/cta_nano-silver-petition_final_5_1_08.pdf).

28. U.S. ENVTL. PROT. AGENCY, SILVER AND COMPOUNDS SUMMARY DOCUMENT (CASE 4082 AND CASE 5015): REGISTRATION REVIEW PRELIMINARY WORK PLAN 27 (2009) [hereinafter SILVER AND COMPOUNDS REVIEW SUMMARY], available at <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2009-0334-0005>.

29. See EPA, HEIQ DECISION DOCUMENT, *supra* note 25, at 1–2.

30. The Scientific Advisory Panel is an ad hoc scientific review board created by FIFRA to advise EPA on scientific decisions involved in regulatory issues. FIFRA Scientific Advisory Panel Notice of Public Meeting, 74 Fed. Reg. 47,575 (Sept. 16, 2009) (giving notice and opportunity to comment on the panel meeting). The meeting occurred on Nov. 3–6, 2009. *Id.* at 47,576. The review document *Evaluation of Hazard and Exposure Associated with Nanosilver and Other Nanometals* was released for review on Oct. 9, 2009. FIFRA SCIENTIFIC ADVISORY PANEL, U.S. ENVTL. PROT. AGENCY, EVALUATION OF HAZARD AND EXPOSURE ASSOCIATED WITH NANOSILVER AND OTHER NANOMETALS (2009), available at <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2009-0683-0004>. The meeting minutes were published on Jan. 26, 2010. U.S. ENVTL. PROT. AGENCY, MEETING MINUTES OF THE FIFRA SCIENTIFIC ADVISORY PANEL MEETING ON THE EVALUATION OF HAZARD AND EXPOSURE ASSOCIATED WITH NANOSILVER and Other Nanometal Pesticide Products (2010), available at <http://www.epa.gov/scipoly/sap/meetings/2009/november/110309ameetingminutes.pdf>. The review documents and comments submitted to EPA regarding the FIFRA SAP meeting are found in the EPA regulatory docket EPA-HQ-OPP-2009-0683. *Assessment of Hazard and Exposure Associated with Nanosilver and Other Nanometal Pesticides*, REGULATIONS.GOV, <http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2009-0683> (last visited Apr. 1, 2015).

31. EPA Response to ICTA Petition on Nanosilver, REGULATIONS.GOV, <http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2008-0650> (last visited Apr. 14, 2015).

32. See Notice of Antimicrobial Pesticide Products; Registration Applications, 75 Fed. Reg. 16,109, 16,109–10 (Mar. 31, 2010).

## B. TOXICITY

Silver and nanosilver emit individual silver ions, which have a well-documented antimicrobial effect on a variety of bacteria, fungi, and viruses; however, EPA has noted that “the effects of nanosilver on bacteria and the bactericidal mechanism are only partially understood.”<sup>33</sup> The most well understood mechanism suggests that nanosilver particles damage the cell wall and membrane of bacteria, allowing silver ions to enter the bacterial cell.<sup>34</sup> There are many theories about exactly how the cell membrane damage occurs<sup>35</sup> and how ions damage cells upon entry.<sup>36</sup> EPA notes that “it is reasonable to suggest” that a “synergistic toxic effect” occurs between the nanosilver-caused “increase in cell [wall/membrane] permeability” and ion-caused activity inside the cell, which leads to “uncontrolled transport through the” cell membrane leading to cell death.<sup>37</sup> To understand how this toxic effect on microbes translates to humans and the environment, EPA conducts a risk assessment that identifies toxic effects on cells, biological systems, and living animals, and then runs these toxic effects through an exposure estimate to assess potential harm to human health or the environment.<sup>38</sup>

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33. EPA, STATE OF THE SCIENCE, *supra* note 20, at 15–17.

34. *Id.* at 16 (citing Ee Taek Hwang et al., *Analysis of the Toxic Mode of Action of Silver Nanoparticles Using Stress-Specific Bioluminescent Bacteria*, 4 SMALL 746, 746, 748 (2008)).

35. See, e.g., M. Danilczuk et al., *Conduction Electron Spin Resonance of Small Silver Particles*, 63 SPECTROCHIMICA ACTA PART A 189, 189, 191 (2006); Jun Sung Kim et al., *Antimicrobial Effects of Silver Nanoparticles*, 3 NANOMEDICINE: NANOTECHNOLOGY BIOLOGY & MED. 95, 95–96, 100 (2007) (proposing that nanosilver leads to formation of free radicals that cause membrane damage); Jose Ruben Morones et al., *The Bactericidal Effect of Silver Nanoparticles*, 16 NANOTECHNOLOGY 2346, 2346–47 (2005); Ivan Sondi & Branka Salopek-Sondi, *Silver Nanoparticles as Antimicrobial Agent: A Case Study on E. coli as a Model for Gram-Negative Bacteria*, 275 J. COLLOID & INTERFACE SCI. 177, 177–80 (2004) (showing that silver nanoparticles anchor to and penetrate cell walls of Gram-negative bacteria).

36. E.g., David W. Hatchett & Henry S. White, *Electrochemistry of Sulfur Adlayers on the Low-Index Faces of Silver*, 100 J. PHYSICAL CHEMISTRY 9854, 9854, 9858 (1996); Morones et al., *supra* note 35, at 2347 (arguing that silver nanoparticles interfere with DNA replication potentially by interacting with vital enzymes in the cell).

37. EPA, STATE OF THE SCIENCE, *supra* note 20, at 16.

38. See generally *Overview of Risk Assessment in the Pesticide Program*, U.S. ENVTL. PROTECTION AGENCY, [http://www.epa.gov/pesticides/about/overview\\_risk\\_assess.htm](http://www.epa.gov/pesticides/about/overview_risk_assess.htm) (last updated Nov. 24, 2014).

The human health risk assessment EPA conducted in its registration of HeiQ's AGS-20 pesticide noted a range of potential toxicity issues, but concluded that anticipated exposure levels during the period of conditional registration did not raise human health concerns for acute or intermediate-term exposure.<sup>39</sup> Non-animal lab tests on cellular material indicated that nanosilver can cause depletion of neurotransmitters like dopamine,<sup>40</sup> neuronal toxicity,<sup>41</sup> and changes to inhibitory action of hippocampal neurons.<sup>42</sup> These cell-level tests also showed that nanosilver can cause alteration of "cellular morphology, decreased mitochondrial activity . . . and increased apoptosis" in mouse sperm cells, which would support the "conservative interpretation . . . that nanosilver which reach the testes may be able to cause decreased fertility due to toxicity to spermatogonia."<sup>43</sup> The toxicity review of studies on rats indicated that nanosilver "showed toxic effects in the liver . . . and lungs" from 90-day inhalation exposure,<sup>44</sup> increased ALP/AST/ALT production response in the liver from oral 28-day and 90-day exposures,<sup>45</sup> and potentially conflicting implications for human neurotoxicity.<sup>46</sup> The only human clinical observations of neurotoxicity potential that the EPA could review were in

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39. See EPA, HEIQ DECISION DOCUMENT, *supra* note 25, at 8–13.

40. Saber M. Hussain et al., *The Interaction of Manganese Nanoparticles with PC-12 Cells Induces Dopamine Depletion*, 92 TOXICOLOGICAL SCI. 456, 456–57 (2006).

41. *Id.* at 456, 462.

42. Liu Zhaowei et al., *Action Potential Changes Associated with the Inhibitory Effects on Voltage-Gated Sodium Current of Hippocampal CA1 Neurons by Silver Nanoparticles*, 264 TOXICOLOGY 179, 179 (2009).

43. EPA, HEIQ DECISION DOCUMENT, *supra* note 25, at 12; Laura Braydich-Stolle et al., *In Vitro Cytotoxicity of Nanoparticles in Mammalian Germline Stem Cells*, 88 TOXICOLOGICAL SCI. 412, 412, 414–16 (2005).

44. EPA, HEIQ DECISION DOCUMENT, *supra* note 25, at 9; Jae Hyuck Sung et al., *Subchronic Inhalation Toxicity of Silver Nanoparticles*, 108 TOXICOLOGICAL SCI. 452, 457, 458 tbl.9, 460–61 (2009).

45. Yong Soon Kim et al., *Subchronic Oral Toxicity of Silver Nanoparticles*, 7 PARTICLE & FIBRE TOXICOLOGY 20, 22 (2010) [hereinafter *Subchronic Oral Toxicity*]; Yong Soon Kim et al., *Twenty-Eight-Day Oral Toxicity, Genotoxicity, and Gender-Related Tissue Distribution of Silver Nanoparticles in Sprague-Dawley Rats*, 20 INHALATION TOXICOLOGY 575, 577–78, 581 (2008).

46. EPA, HEIQ DECISION DOCUMENT, *supra* note 25, at 11 (noting that the one available study of human exposures did not indicate nanosilver crossed the blood-brain barrier, but that animal studies do show nanosilver).



reviews of silver that included nanosilver exposures by patients receiving nanosilver burn wound bandages; those observations conclude that nanosilver, like silver, should not cause neurotoxicity issues.<sup>47</sup> However, those human observations are in conflict with acute exposure rat studies showing that nanosilver passes through the rats' blood-brain barrier and enters brain tissue after inhalation<sup>48</sup> and oral<sup>49</sup> administration. The rat studies also indicated sex-variable organ accumulation with two to three times more silver accumulation in kidneys of female rats compared to male rats.<sup>50</sup>

In general, a lack of findings in human studies is common for non-pharmaceutical chemicals new to commerce—as we do not intentionally dose human subjects with high levels of chemicals just to see the effects.<sup>51</sup> Any documented human exposures for new chemicals are likely to be short-term, and analysis of causation with any particular disease would likely be confounded by the multitude of low-level exposures to other toxins we experience in everyday life while pumping gas or picking up our dry cleaning.<sup>52</sup> Even well known toxic substances and pesticides often lack any human clinical studies, and regulatory decisions are made completely based on toxicity effects graphed and understood through lab tests on mammalian cells and animal studies.<sup>53</sup> Recently, researchers have replicated nanosilver toxicity observations from non-human cells in a variety of human cells finding stress on cell barriers that lead to programmed cell death.<sup>54</sup> The EPA risk

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47. See A. B. G. Lansdown, *Critical Observations on the Neurotoxicity of Silver*, 37 CRITICAL REVIEWS TOXICOLOGY 237, 237, 241, 243, 246 (2007).

48. See Sung et al., *supra* note 44, at 457, 460.

49. See *Subchronic Oral Toxicity*, *supra* note 45, at 29; Kim et al., *supra* note 45, at 580, 582.

50. EPA, HEIQ DECISION DOCUMENT, *supra* note 25, at 9–10 (citing Kim et al., *supra* note 45; Sung et al., *supra* note 44).

51. DAVID MICHAELS, DOUBT IS THEIR PRODUCT: HOW INDUSTRY'S ASSAULT ON SCIENCE THREATENS YOUR HEALTH 60–63 (2008).

52. *Id.*

53. *Id.* at 67–68.

54. See Jean-Christophe Simard et al., *Silver Nanoparticles Induce Degradation of the Endoplasmic Reticulum Stress Sensor Activating Transcription Factor-6 Leading to Activation of the NLRP-3 Inflammasome*, 290 J. BIOLOGICAL CHEMISTRY 5926, 5926–27, 5930–31, 5934 (2015) (reporting that silver nanoparticles can cause a type of rapid programmed cell death distinct from apoptosis, and that the observed dual effects of inflammation

assessment did note certain toxic effects of nanosilver, the most concerning being the potential for nanosilver buildup in the brain, liver, and reproductive organs and evidence that nanosilver can disrupt certain processes in those areas.<sup>55</sup> However, EPA did not have chronic exposure tests to review, and the agency was able to conclude that the overall toxicity risk for short-term exposures to humans was reasonable—a finding that was upheld on substantial evidence review in a subsequent legal challenge.<sup>56</sup>

### C. RISK AND EXPOSURE

EPA's environmental risk assessment for HeiQ's nanosilver pesticide used a standard EPA ecotoxicity model to develop risk quotients from the toxicity study results for nanosilver LC<sub>50</sub> concentrations<sup>57</sup> for ninety-six-hour acute exposure for invertebrates<sup>58</sup> and fish,<sup>59</sup> and one- and two-hour acute exposure for algae.<sup>60</sup> The lowest nanosilver concentration that caused an LC<sub>50</sub> among these indicator species was for freshwater invertebrates where fifty percent of the population died in one batch at 1.8µg/L.<sup>61</sup> Using this most sensitive group, EPA calculated a risk quotient of 0.016 using the most conservative toxicity model inputs—which assumed the nanosilver removal efficiency of wastewater treatment at eighty-five percent, and a 1:1 stream dilution factor—which is only three times lower than the lowest risk quotient EPA

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and toxicity beg for further study of the toxicity mechanism to limit undesired effects from nanosilver uses).

55. See EPA, HEIQ DECISION DOCUMENT, *supra* note 25, at 9–13.

56. See Lynn L. Bergeson & Timothy D. Backstrom, *Narrow Critique Does Not Alter EPA Nano Risk Assessment*, LAW360 (Nov. 26, 2013, 7:11 PM), <http://www.law360.com/articles/491849/narrow-critique-does-not-alter-epa-nano-risk-assessment>; see also *infra* notes 173–75 and accompanying text.

57. LC<sub>50</sub> is the concentration required to kill half the members of a tested population. Alan J. Kennedy et al., *Fractionating Nanosilver: Importance for Determining Toxicity to Aquatic Test Organisms*, 44 ENVTL. SCI. & TECH. 9571, 9571 (2010).

58. See *id.* at 9571–72.

59. Geoff Laban et al., *The Effects of Silver Nanoparticles on Fathead Minnow (*Pimephales promelas*) Embryos*, 19 ECOTOXICOLOGY 185, 185–86 (2010).

60. See generally Enrique Navarro et al., *Toxicity of Silver Nanoparticles to *Chlamydomonas reinhardtii**, 42 ENVTL SCI. & TECH. 8959 (2008).

61. EPA, HEIQ DECISION DOCUMENT, *supra* note 25, at 35–36 (quoting Kennedy et al., *supra* note 57).

allows for endangered species of 0.05.<sup>62</sup> This calculation means that the risk profile for nanosilver does not trigger closer scrutiny under EPA's ecotoxicity model,<sup>63</sup> but it is not far off, and EPA did require a pesticide label warning that nanosilver poses an acute toxicity risk to "avian, fish, and aquatic invertebrate[s]."<sup>64</sup>

The exposure estimate used in this calculation for nanosilver released to the environment was 4500 kg/year for total U.S. waters based on an assumption that each American would purchase one t-shirt containing 100ppm nanosilver.<sup>65</sup> EPA argued in the decision document that the 4500 kg/year figure was sufficiently conservative because the agency's confidential records showed the total mass of all forms of silver used as a material preservative in the United States to be less than 6800 kg in 2009.<sup>66</sup> The inhalation exposure estimate for consumers used in the human health risk assessment assumed exposure during laundry drying to one t-shirt containing 100ppm nanosilver.<sup>67</sup> The incidental oral exposure estimate for consumers in the human health risk assessment calculated nanosilver ingestion by a 3-year old from mouthing 100 cm<sup>2</sup> of fabric per day.<sup>68</sup> EPA did not have studies to assess how much nanosilver would be extracted from fabric by saliva and chewing, so they used factors from a general water leaching study that found maximum nanosilver loss of 1.5% when incorporated in the synthetic fibers, and loss of 35% when spray coated on the fibers.<sup>69</sup> Experiments of nanosilver leaching from other treated articles have found that some products will lose nearly 100% of the pesticide after a few washings.<sup>70</sup>

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62. *Id.* at 37–38.

63. *Endangered Species Effects Determinations, Technical Overview of Ecological Risk Assessment*, U.S. ENVTL. PROTECTION AGENCY [http://www.epa.gov/oppefed1/ecorisk\\_ders/toera\\_risk.htm#endangered](http://www.epa.gov/oppefed1/ecorisk_ders/toera_risk.htm#endangered) (last updated Mar. 25, 2014).

64. EPA, HEIQ DECISION DOCUMENT, *supra* note 25, at 38–39.

65. *Id.* at 37–38.

66. *Id.*

67. *Id.* at 25.

68. *Id.* at 26.

69. *Id.* at 23–24, 26–27 (citing L. Geranio et al., *The Behavior of Silver Nanotextiles During Washing*, 43 ENVTL. SCI. & TECH. 8113, 8116 (2009)).

70. EPA, STATE OF THE SCIENCE, *supra* note 20, at 85–86 (citing Troy M. Benn & Paul Westerhoff, *Nanoparticle Silver Released Into Water from*

These estimated amounts of nanosilver released to the environment, and absorbed by consumers might have been overestimates based on what EPA knew of production before the approval of nanosilver,<sup>71</sup> but could easily be underestimates based on market demand for advanced textiles. One t-shirt per person would be impressive market penetration for any single apparel brand, but certainly does not take into account actual consumer statistics for individual consumption of apparel or home textiles, which suggest that American consumers buy more than one t-shirt per year.<sup>72</sup> It seems unlikely that every American consumer would buy more than one of the same t-shirt, but the registration itself does not limit the number of textile manufacturers that could apply the HeiQ pesticide to different fabrics or textile materials, nor the number of apparel companies that could use those materials, nor the number of different products an apparel company could make with those materials. There is evidence that competition in the apparel sector has led to exactly this type of widespread adoption of pesticide-treated articles, or enhanced fabrics, across product lines and across brands.<sup>73</sup> In 2011, estimates of raw nanosilver production in the United States ranged from 2800–20,000 kg

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*Commercially Available Sock Fabrics*, 42 ENVTL. SCI. & TECH. 4133, 4136 (2008).

71. See EPA, HEIQ DECISION DOCUMENT, *supra* note 25, at 38–39.

72. The Bureau of Labor Statistics notes that in 2013, the average American consumer spent approximately \$641 on apparel and about another \$38 on home textiles. BUREAU OF LABOR STATISTICS, CONSUMER EXPENDITURES SURVEY tbl.1300 (2013), available at <http://www.bls.gov/cex/2013/combined/age.pdf> (dividing mean spending per consumer unit by 2.5, the provided average number of people per consumer unit).

73. See generally Elizabeth A. Harris, *Workout Clothes with High-Tech Twist Sell Briskly*, N.Y. TIMES (July 28, 2014), <http://www.nytimes.com/2014/07/29/business/workout-clothes-with-high-tech-twist-sell-briskly.html> (“If everyone is using the same types of yarns and the suppliers, the one key thing you need to do is have a unique selling point, something simple to understand that provides a benefit the consumer really values.’ Lululemon has been using a technology it calls Silverescent for several years, which executives enthusiastically describe as ‘anti-stink.’ . . . [T]he company claims that materials in the thread kill odor-causing bacteria in the garment itself . . . . Lululemon will start selling anti-odor socks this fall. But anti-odor is no longer particularly unique. Retailers as diverse as Under Armour, Uniqlo, Athleta and the Duluth Trading Company offer lines of anti-odor clothing . . . . To lure customers back for the next, latest thing, retailers are speeding up the rate at which new fabrics appear and old ones are enhanced. For example, beginning this season, Lululemon’s men’s line will introduce something new in its fabrics every season . . .”).

per year.<sup>74</sup> Global estimates for nanosilver production reach 250–312 tons.<sup>75</sup> It is unclear how much would enter the United States for domestic apparel purchasing.<sup>76</sup>

These discussions of uncertainties in nanosilver toxicity and exposure estimates might be concerning to those who are skeptical of EPA risk assessment models, or who suspect the manufacturers are withholding information from the regulators. However, this discussion is designed to give readers a sense of where EPA has made science-based assessments and where EPA has made educated guesses. As discussed in Section II through the examples of the herbicide Imprelis<sup>77</sup> and insecticide-implicated birth defects among farmworkers,<sup>78</sup> EPA often has to make regulatory decisions when there are known data gaps and based on imperfect data. As discussed in Section III, the treated articles exemption compounds the imprecision of these risk estimates by preventing the flow of information to consumers and leaving consumers no way to modulate their exposure to these pesticides.

#### D. OTHER SILVER COMPOUNDS AND UNKNOWN EXPOSURES TO NANOSILVER

Since EPA made its decision to conditionally register nanosilver,<sup>79</sup> the agency has taken a closer look at other silver pesticide products, and a variety of exposure and toxicity assumptions now appear to be in flux or wildly incorrect. EPA is currently undergoing a re-registration review of registered pesticides using silver and silver compounds, which does not

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74. Christine Ogilvie Hendren et al., *Estimating Production Data for Five Engineered Nanomaterials as a Basis for Exposure Assessment*, 45 ENVTL. SCI. & TECH. 2562, 2566 (2011).

75. Nate Seltenrich, *Nanosilver: Weighing the Risks and Benefits*, 121 ENVTL. HEALTH PERSP. A220, A224 (2013).

76. *See id.* at A221, A224. In general, 97.5% of apparel sold in the United States is imported. However, specialty fabrics like silver-impregnated synthetics can be made in the United States then shipped abroad for dyeing and assembly. *See* Press Release, Am. Apparel & Footwear Ass'n, AAFA Releases ApparelStats 2013 and ShoeStats 2013 Reports (Jan. 5, 2014), available at <https://www.wewear.org/aafa-releases-apparelstats-2013-and-shoe-stats-2013-reports/>.

77. *See infra* notes 156–59 and accompanying text.

78. *See infra* notes 126–45 and accompanying text.

79. *See supra* note 32 and accompanying text.

include nanosilver pesticides.<sup>80</sup> One of EPA's stated concerns in its review is that in the 112 active registrations for different forms and compounds of silver,<sup>81</sup> there might be products that contain or emit nanosilver particles, and that the specific antimicrobial and aquatic toxicity issues with nanosilver particles were not assessed when those products were originally registered.<sup>82</sup> Among the companies that registered silver pesticide products before EPA made distinctions based on size are companies that expressly specialize in nanosilver production like American Biotech Labs,<sup>83</sup> and the inconspicuously named NanoHorizons.<sup>84</sup> Other companies holding silver pesticide registrations make no mention of the size of their silver compounds, or claim there is a distinction between their compound and nanosilver, like Noble Biomaterials Inc., which makes X-Static, the silver-impregnated fabric used in the vast majority of Lululemon apparel.<sup>85</sup>

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80. The re-registration review decision was originally scheduled to be open for public comment until December 2015, with a final decision expected in March 2016; since initial timelines have not been met this will likely be extended. See SILVER AND COMPOUNDS REVIEW SUMMARY, *supra* note 28, at 21.

81. There are currently 112 EPA-registered pesticide products with silver or silver compounds as their active ingredient; 93 of them are for silver. *Id.* at 27–28.

82. *Id.* at 7 (“The Agency is concerned that some existing registered silver products may contain extremely small particles (e.g., <500 nm) that may not have been appropriately evaluated during the registration and reregistration processes.”).

83. See *Next Generation Colloidal Silver*, AM. BIOTECH LABS, <http://ablsilver.com/colloidal-silver.php> (last visited Apr. 2, 2015) (“With the Ag<sub>4</sub>O<sub>4</sub> coating, the nano silver particle is attracted to the surrounding water molecules, and as such, becomes part of the structure of the water. This makes the silver much more stable and bioavailable than other forms of silver.”).

84. *Our History*, NANO HORIZONS, <http://www.nanohorizons.com/index-1.html> (last visited Apr. 2, 2015) (“NanoHorizons invents, designs, and manufactures advanced nanoscale silver additives that add permanent, cost-effective, and environmentally friendly antimicrobial and performance-enhancing characteristics to consumer, commercial, and industrial products.”).

85. Press Release, Noble Biomaterials Inc., EPA Requests Data on Silver Nano-Technologies (Oct. 2, 2009), available at [http://www.noblebio.com/pinewsarticles\\_www.asp?itemid=333&submit=getrecord&recordid=60](http://www.noblebio.com/pinewsarticles_www.asp?itemid=333&submit=getrecord&recordid=60) (“Our technology employs metallic silver in its common form and is not a nanotechnology . . . . By definition nano silver is different than metallic silver technologies . . . .”). But see *Next Generation Colloidal Silver*, *supra* note 83 (“Testing has uncovered multiple modes of action by which the ABL Metallic Nano-silver Particle functions.”). See also Harris, *supra* note 73 (“For

In response to EPA's pending re-review of silver registrations, four silver registrants have disclosed to EPA that their products contain nanosilver.<sup>86</sup> The silver pesticide manufacturers have also formed a new trade association, which is advancing the scientific argument that silver's antimicrobial properties are exclusively from silver ion emission, and that the size of the silver particle that the ion emits from, nano or not, does not justify categorization or attention in risk assessments.<sup>87</sup> After EPA levied a \$1,000,000 fine against The North Face for marketing seventy styles of shoes with the public health claim "inhibits the growth of disease-causing bacteria,"<sup>88</sup> the pesticide registration holder that supplied North Face shoe inserts changed its marketing material to say "Agion is an EPA registered ionic silver technology and is not a nanosilver technology."<sup>89</sup>

It is unclear if silver pesticide companies disclaiming the use of "nanosilver technology" are saying their silver pesticide only has particles larger than some nano-scale cutoff or if they are claiming the nano-scale particles were not made by some particular technology. In what looks like a regulatory science game-of-chicken, the silver pesticide lobbying association claims that if you measured silver pesticides based on their

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its Silverescent technology, Lululemon has an exclusive deal with Noble Biomaterials to use the company's proprietary X-Static technology in its athletic clothes. The way X-Static is made is a trade secret."); *Innovation in the Science of Stink*, LULULEMON, <http://www.lululemon.com/education/info/silverescent> (last visited Apr. 2, 2015) ("The X-STATIC technology embedded in Silverescent fabric bonds 99.9% pure silver to the surface of every fibre—which means that there's stink-conquering technology woven into the very fabric of your favourite workout clothes.")

86. U.S. ENVTL. PROT. AGENCY, EPA-HQ-OPP-2011-0370, NANOSILVER SUMMARY DOCUMENT REGISTRATION REVIEW: INITIAL DOCKET 5 (2012) [hereinafter NANOSILVER REVIEW SUMMARY], available at <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0370-0004>.

87. See SILVER TASK FORCE N. AM., POSITION PAPER ON REGISTRATION REVIEW OF SILVER COMPOUNDS 2, 8–9 (2012), available at <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2009-0334-0033>.

88. Press Release, U.S. Env'tl. Prot. Agency, 'The North Face' Clothing Parent Company Facing Nearly \$1M in Federal Fines Following Unsubstantiated Product Claims (Sept. 22, 2009), available at <http://yosemite.epa.gov/opa/admpress.nsf/0/bcbd9b468b9aaf67852576390055de2f>.

89. *Products*, SCIESENT, <http://www.sciessent.com/brands.html> (last visited Apr. 2, 2015).

particle size, eighty-two percent of silver registered products would be nano-scale.<sup>90</sup> Based on this argument, the silver pesticide lobbyists regularly state that “[w]e believe that silver and nano-silver are the same.”<sup>91</sup> EPA will need to determine in its silver and compounds registration review whether it will continue to require nanosilver and silver to be distinguished based on size, and if it will bring mislabeling enforcement actions against companies with registrations for silver, whose websites and product labeling refer to nanosilver or non-nanosilver when their pesticide registration is for a nano-compound. As part of this registration review, EPA is requesting data on the range and percentages of silver particle sizes found in registered products<sup>92</sup>—data that EPA has apparently not had for these pesticides or previous reviews of silver toxicity.

As long as EPA has determined that the risk profile of silver particles is different for nano-scale particles, the agency has an obligation to better police statements about those pesticides by those that sell and market treated textiles and pesticides for the apparel industry. Currently, EPA’s major enforcement actions have been to enforce its treated articles guidance when companies make marketing or labeling claims beyond pest mitigation and make public health claims.<sup>93</sup> The treated articles exemption, which is discussed in more detail in Section III, currently prevents apparel product manufacturers from communicating with consumers about the benefits, risks, or presence of pesticides in our products, and consumers cannot currently go to a store and determine which t-shirts or pillowcases do or do not have pesticides in them.<sup>94</sup> At most, a

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90. JAMES DELATTRE ET AL., SILVER NANOTECHNOLOGY WORKING GRP., COMMENTS OF THE SILVER NANOTECHNOLOGY WORKING GROUP FOR REVIEW BY THE FIFRA SCIENTIFIC ADVISORY PANEL 3-4 (2009), *available at* <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2009-0683-0117> (“Our analysis of particle sizes of EPA registered silver products reveals that approximately 82% of all silver products currently registered with EPA are estimated to be nanoscale or smaller, picoscale ions.”).

91. Sheila Kaplan, *Nanotechnology: Harmful or Benign? An Investigative Reporting Workshop Report*, IOWAWATCH.ORG (July 24, 2013), <http://iowawatch.org/2013/07/24/nanotechnology-harmful-or-benign-an-investigative-reporting-workshop-report/>.

92. NANOSILVER REVIEW SUMMARY, *supra* note 86, at 5-6.

93. *E.g.*, Press Release, U.S. Env’tl. Prot. Agency, *supra* note 88.

94. *See infra* Section III.



consumer could note which products claim to have “anti-stink” technology,<sup>95</sup> or a coating that makes the material last longer; however, these claims could indicate the presence of a number of preservative pesticides or even no pesticide. The lack of consumer information and uncertainty in the ubiquity of nanosilver treated products could be troubling to some consumers from a precautionary perspective; these uncertainties could also be a problem for EPA’s ability to fulfill its obligations under FIFRA, as discussed in the following section.

## II. FIFRA PURPOSE AND REGULATORY STANDARDS

### A. REGISTRATION DECISIONS UNDER FIFRA

At its original passage in 1947, FIFRA consisted primarily of a labeling requirement to protect users and the marketplace from misbranded pesticides that were either ineffective in killing pests or far more hazardous than understood for a particular use.<sup>96</sup> A major revision of FIFRA occurred in 1972 following a generally enhanced awareness of chemical pollution issues, and specifically Rachel Carson’s *Silent Spring*<sup>97</sup> brought enhanced awareness of potential implications of widespread lawful use of hazardous pesticides, which were often called “economic poisons.”<sup>98</sup> The pre-1972 FIFRA required pesticide manufacturers to register their product with the Secretary of the Department of Agriculture.<sup>99</sup> However, the Secretary could not refuse to register a chemical on hazard grounds, but could only register the pesticide “under protest,” which had no legal effect on the manufacturer’s ability to sell the product.<sup>100</sup> The current FIFRA framework gives the Administrator (of EPA) significantly more discretion to deny and modify registration

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95. See Harris, *supra* note 73.

96. Federal Insecticide, Fungicide, and Rodenticide Act of 1947, Pub. L. No. 80-104, 61 Stat. 190 (1947) (codified as amended at 7 U.S.C. §§ 136–136(y) (2012)); Marshall Lee Miller, *Pesticides*, in ENVIRONMENTAL LAW HANDBOOK 833, 834–35 (22d ed. 2014).

97. See generally RACHEL CARSON, *SILENT SPRING* (1962).

98. Miller, *supra* note 96, at 833–35.

99. *Id.* at 834–35.

100. *Id.*

petitions through a comprehensive pre-market approval and labeling regime.<sup>101</sup>

A pesticide product applicant submits a label that describes the proposed use of the pesticide and any claims about its efficacy, as well as a set of scientific studies about the pesticide.<sup>102</sup> The data requirements are promulgated in regulations and a number of agency guidance documents, and generally fall into five categories: product chemistry, environmental fate, residue chemistry, dietary and non-dietary hazards to humans, and hazards to domestic animals and nontarget organisms.<sup>103</sup> For different types of pesticides and the intended use of the pesticide, EPA regulations at 40 C.F.R. § 158 contain “data tables” that designate specific studies and methodologies with either an “R” for required, or a “CR” for conditionally required.<sup>104</sup> The original application for a new pesticide product must include all R studies or risk being disapproved outright, and through use of guidance, most registrants determine which CR studies will be triggered by the basic product chemistry and toxicity results.<sup>105</sup> Pesticide registrations are very specific; each new formulation or concentration of an active ingredient needs a new registration, as does applying a registered pesticide to a new crop or target pest.<sup>106</sup> EPA currently estimates the costs of data production and registration for a new active ingredient of an antimicrobial pesticide to be one to five million dollars.<sup>107</sup>

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101. ROGER W. FINDLEY & DANIEL A. FARBER, ENVIRONMENTAL LAW IN A NUTSHELL 193–94 (7th ed. 2008).

102. 7 U.S.C. § 136a(c)(1)(A)–(F) (2012) (“[A] complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use . . . [and] a full description of the tests made and the results thereof upon which the claims are based . . .”).

103. See Data Requirements for Pesticides, 40 C.F.R. § 158 (2012); *Data Requirements*, U.S. ENVTL. PROTECTION AGENCY, <http://www2.epa.gov/pesticide-registration/data-requirements> (last updated Mar. 10, 2015).

104. See 40 C.F.R. § 158.110.

105. *Id.*

106. Miller, *supra* note 96, at 839–40.

107. Data Requirements for Antimicrobial Pesticides 78 Fed. Reg. 26,936, 26,937 (May 8, 2013) (to be codified at 40 C.F.R. pt. 158) (estimating “average cost per registration of new antimicrobial active ingredient” at \$1 million to \$5 million, and for additional registration uses for existing chemicals at “\$588,000 for wood preservatives, \$284,000 for food and indirect food uses, and \$260,000 for other uses”).

EPA then either approves or denies the petition based on whether the pesticide will “perform its intended function without unreasonable adverse effects on the environment”<sup>108</sup> and when actually used “with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.”<sup>109</sup> The phrase “unreasonable adverse effects on the environment,” is defined by statute as “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>110</sup> In response to a petition, EPA can require a company to generate more scientific studies, or can reject submitted studies, and at any point can make similar requests for additional data from an already registered pesticide.<sup>111</sup>

Once EPA is satisfied with the identification of health or environmental hazards and chemical properties of the pesticide, EPA can restrict, or require additional, directions for uses on the pesticide label if the original use could pose an unreasonable adverse effect on the environment.<sup>112</sup> For instance, EPA can require that the pesticide only be sprayed when wind speed is below a certain level,<sup>113</sup> during certain times of the year,<sup>114</sup> that it cannot be sprayed if certain nontarget species live nearby,<sup>115</sup> or within so many feet of surface water.<sup>116</sup> EPA can additionally control the sale of the pesticide by classifying it as a restricted use pesticide that can only be purchased and applied by EPA-certified applicators.<sup>117</sup>

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108. 7 U.S.C. § 136a(c)(5)(C) (2012).

109. *Id.* § 136a(c)(5)(D).

110. *Id.* § 136(bb).

111. *Id.* § 136a(c)(2)(B).

112. Labeling Requirements for Pesticides and Devices, 40 C.F.R. § 156.10(i) (2009); *see, e.g.*, U.S. ENVTL. PROT. AGENCY, LABEL REVIEW MANUAL ch. 11 (2014) [hereinafter LABEL REVIEW MANUAL], *available at* <http://www2.epa.gov/sites/production/files/2015-03/documents/lrm-chap1-18-dec-2014.pdf>.

113. LABEL REVIEW MANUAL, *supra* note 112, at 11-14 to -17.

114. 40 C.F.R. § 156.10(i).

115. *Id.*

116. *Id.*

117. *See* 7 U.S.C. § 136a(d) (2012) (noting that restricted use classification is a finding of significant hazard and requires retailers to sell the product only to certified applicators, who then become the only legal user or applicator, whereas a general use pesticide can be purchased and applied by anyone within the limits of the label).

For agricultural pesticides, these specific restrictions on sale and use allow significant control and assessment over the downstream environmental fate of the pesticides including potential human and environmental exposures.<sup>118</sup> Some of these restrictions clearly regulate the spraying or use of the pesticide itself; however, others are about the pesticide applicators' continuing duty to control exposures to the pesticide even after the application.<sup>119</sup> One of the most important pesticide label restrictions is the statement on restricted entry intervals (REI).<sup>120</sup> For pesticides with potential toxicity to human health, people cannot enter the field following pesticide application during REI without specific protective equipment, which can be from a few hours to many days.<sup>121</sup>

Traditionally, courts have given EPA latitude on factual findings for placing restrictions on a proposed use of a pesticide. The standard for additional restriction is that the proposed use "when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment."<sup>122</sup> When construing the phrase "generally causes," the courts have not required substantial regularity of impacts or even actual impacts; instead the courts have required that EPA find a proposed use creates "significant probability" of "unreasonable risks" but "not necessarily actual adverse consequences."<sup>123</sup> The inherent toxicity of pesticides supports a significant precautionary need in regulatory oversight, and allows decisions to be made based on lab results of toxicity in cells and animals even when there is a lack of evidence that the same effect is certain in humans.<sup>124</sup> Often, the scientific demonstration of toxicity will exist for a pesticide—showing that an exposure will result in some cellular damage or disruption of biologic activities—while

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118. *See, e.g., id.*

119. *See, e.g., id.*; 40 C.F.R. § 156.10(i).

120. *See* 40 C.F.R. 156.208 (2011).

121. LABEL REVIEW MANUAL, *supra* note 112, at 10-21 to -26.

122. § 136a(c)(5) (requiring the standard "widespread practice generally causes" for approval of a new pesticide registration); § 136d(b) (requiring the standard "widespread practice generally causes" for a labeling change on an already registered pesticide).

123. *Ciba-Geigy Corp. v. EPA*, 874 F.2d 277, 279–80 (5th Cir. 1989).

124. *See supra* Section II.B.

a lack of data or a few early studies in human exposures will not demonstrate the same risk to human health with any epidemiological certainty.<sup>125</sup> This can lead to equally true but seemingly conflicting risk statements that “a chemical is toxic and can cause a disease,” but that the same chemical “has never been shown to cause the disease in humans.”

In a 2004 case, three fieldworkers at the same operation gave birth within eight weeks of each other and all three babies had significant malformations, one so severe the child died within a few days.<sup>126</sup> During the critical stages of their pregnancies, the workers had been exposed multiple times to fourteen pesticides, four of which had demonstrated teratogenicity—ability to cause birth defects—in animal studies but not in any human studies.<sup>127</sup> EPA’s registration of these pesticides had placed REIs between fourteen hours and four days for which workers could not enter the field after spraying without protective equipment.<sup>128</sup> One mother, age nineteen, entered fields in violation of REI up to four times during the two weeks of pregnancy where fetal limb formation occurs; her child was born without arms or legs.<sup>129</sup> Another mother, age thirty, entered fields in violation of REI on up to eight days of her six week gestational period, and her child was born with mild Pierre Robin syndrome (malformation of the jaw and palate); the father also had a malformed palate and the mother had three other children with no birth defects.<sup>130</sup> The third mother, age twenty-one, entered fields in violation of REI up to ten times<sup>131</sup> during her six-week gestational period and her child was born with a number of birth defects including a

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125. See, e.g., *infra* text accompanying note 127.

126. Geoffrey M. Calvert et al., *Case Report: Three Farmworkers Who Gave Birth to Infants with Birth Defects Closely Grouped in Time and Place—Florida and North Carolina, 2004–2005*, 115 ENVTL. HEALTH PERSP. 787, 787 (2007).

127. *Id.* at 787–90, tbl.2 (finding exposures to abamectin, mancozeb, methamidophos, and methylpyrrolidone during the maximal sensitivity days of pregnancy for birth defects and listing known birth defect impacts in animal studies).

128. *Id.* at 787–89; *Methamidophos Facts*, U.S. ENVTL. PROTECTION AGENCY, [http://www.epa.gov/pesticides/reregistration/REDS/factsheets/methamidophos\\_ired\\_fs.htm](http://www.epa.gov/pesticides/reregistration/REDS/factsheets/methamidophos_ired_fs.htm) (last updated Jan. 19, 2015).

129. Calvert et al., *supra* note 126, at 788.

130. *Id.*

131. *Id.*

missing kidney, malformed spine, lip, palate, and anus, and ambiguous genitalia; this child died three days after birth.<sup>132</sup> The third mother had previously miscarried a child with birth defects but also had one child with no birth defects.<sup>133</sup> All three mothers were undocumented workers from Mexico, and all three fathers worked in the same fields.<sup>134</sup>

The state health departments that investigated the birth abnormalities could not conclude there was a causal connection between pesticide exposure and the birth defects.<sup>135</sup> There are many causes and contributing factors to birth defects like nutrition deficits or genetic inheritance that can prevent a definitive causal conclusion.<sup>136</sup> In this case, uncertainties included background birth defect rates among agricultural workers generally,<sup>137</sup> date of conception,<sup>138</sup> exposure history for the fathers,<sup>139</sup> and whether the mothers had entered fields while REI was in effect or only on days where REI expired during the working day.<sup>140</sup> Civil penalties were initially assessed at \$185,000 against the operator for 200 alleged pesticide and worker safety violations;<sup>141</sup> however, the company disputed the violations and settled with the state for \$24,000.<sup>142</sup> The mother whose child was born without arms or legs filed a tort action against the operator.<sup>143</sup> The operator did not admit wrongdoing in the tort action, but the case was settled for an undisclosed sum that included full medical care

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132. *Id.*

133. *Id.*

134. *Id.*

135. *Id.* at 787, 790.

136. *Id.* at 788.

137. *See id.*

138. *Id.* at 788, tbl.1.

139. *Id.* at 788.

140. *Id.* at 787–89.

141. *State Fails to Protect Workers in Pesticide Lawsuit*, BEYOND PESTICIDES (Feb. 25, 2009, 7:51 AM), <http://www.beyondpesticides.org/dailynewsblog/?p=1322>.

142. Press Release, N.C. Dep't of Agric. & Consumer Servs., N.C. Pesticide Board Announces June Case Settlements (June 15, 2010), *available at* <http://www.ncagr.gov/paffairs/release/2010/Junepesticide.htm>; *Ag-Mart: The End of a Long, Sad Story*, TOXIC FREE NC (June 9, 2010), <http://toxicfreenc.blogspot.com/2010/06/ag-mart-end-of-long-sad-story.html>.

143. Complaint, *Herrera v. Ag-Mart Produce, Inc.*, No. 06–CA–001725 (Fla. Hillsborough County Ct. Feb. 28, 2006).

for the child for life.<sup>144</sup> The operator stopped using all four pesticides implicated for birth defects by this case, although the company's president noted during a deposition that "[i]t doesn't say on the label do not allow pregnant women to work in this, even though it has the warning that it might cause problems."<sup>145</sup>

For agricultural pesticides, EPA can generally assess what the risk of unreasonable adverse effects on the environment will be, but the agency often must rely on highly specific controls over the pesticide application to ensure exposures stay within the limits of their risk assessments.<sup>146</sup> For pesticides that operate in the consumer product environment, the pesticide often continues downstream in commerce and the environment in ways EPA may not be able to anticipate.<sup>147</sup> EPA could regain some of this control by allowing information to flow from the pesticide applicator to later exposed humans. Certainly, EPA could better ensure that pesticides in consumer products are not causing an adverse effect on the environment by letting information flow from pesticide applicator to product consumer. It might also be the case that EPA will need to allow increased information flow to meet its required statutory findings as treated articles become more ubiquitous in consumer products and higher cumulative exposures become possible from multiple products.

#### B. DATA PRODUCTION AND CONDITIONAL REGISTRATIONS

EPA does have the power to issue registrations prior to receiving the full set of data it requires to complete its determination of no adverse effect on the environment, by issuing a conditional registration.<sup>148</sup> The conditional registration allows the petitioner to market the pesticide product prior to fulfilling its data submission requirements, and requires the agency to support a finding that "use of the pesticide during such [conditional] period will not cause any

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144. Colleen Jenkins, *Lifelong Care for Limbless Boy, 3, Approved*, TAMPA BAY TIMES (Apr. 16, 2008, 9:36 PM), <http://mediakit.tampabay.com/news/courts/civil/lifelong-care-for-limbless-boy-3-approved/460186>.

145. *Ag-Mart Settles Birth Defect Case*, BEYOND PESTICIDES (Mar. 28, 2008, 8:53 AM), <http://www.beyondpesticides.org/dailynewsblog/?p=315>.

146. See *supra* text accompanying notes 108–21.

147. See *supra* Section I.C.

148. 7 U.S.C. § 136a(c)(7) (2012).

unreasonable adverse effect on the environment, and that the use of the pesticide is in the public interest.”<sup>149</sup> The administrator may only grant a conditional registration for the period of time “reasonably sufficient for the generation and submission of required data” and that upon receiving the data, that the data meet and do not exceed risk criteria, or any other condition prescribed by the administrator.<sup>150</sup>

The use of conditional registrations at EPA has been criticized by the Natural Resources Defense Council (NRDC)<sup>151</sup> and from the Government Accountability Office (GAO).<sup>152</sup> Due to scrutiny by NRDC and GAO,<sup>153</sup> EPA conducted its own “in-depth internal analysis” and concluded that it had “at times misclassified the status of conditionally and unconditionally registered pesticides in its record-keeping”; however, the agency also maintained that these errors did not lead to any unlawful registration decisions or adverse effects on the environment.<sup>154</sup> The scientific data required under FIFRA is what allows EPA to assess how the pesticide will move in the

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149. *Id.* § 136a(c)(7)(C).

150. *Id.*

151. JENNIFER SASS & MAE WU, NATURAL RES. DEF. COUNCIL SUPERFICIAL SAFEGUARDS: MOST PESTICIDES ARE APPROVED BY FLAWED EPA PROCESS 1–2 (2013), *available at* <http://www.nrdc.org/health/pesticides/files/flawed-epa-approval-process-IB.pdf> (arguing that EPA cannot issue conditional registrations prior to complete toxicity and environmental fate data submissions); *see also id.* at 2 (“For pesticides registered between 2004 and 2010, the EPA’s own analysis found that it had misused the conditional registration provision for other registration activities such as ‘requiring label changes’ and other actions that are ‘beyond the scope’ of the conditional registration. In fact, according to the EPA’s analysis, they misused it 98 percent of the time.” (citations omitted)).

152. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-13-145, EPA SHOULD TAKE STEPS TO IMPROVE ITS OVERSIGHT OF CONDITIONAL REGISTRATIONS 13 (2013), *available at* <http://www.gao.gov/assets/660/656825.pdf> (finding that over 11,000 of the approximately 16,000 currently active pesticide registrations were conditionally registered, and concluding that significant numbers of these decisions exceed the obvious categories for use of conditional registration).

153. *See, e.g.*, SASS & WU, *supra* note 151, at 2 (“Soon after NRDC submitted its findings to the EPA, the agency conducted its own analysis, and confirmed NRDC’s findings.” (citations omitted)).

154. *Conditional Pesticide Registration, EPA Internal Reviews of Conditional Pesticide Registrations*, U.S. ENVTL. PROTECTION AGENCY, <http://www2.epa.gov/pesticide-registration/conditional-pesticide-registration#reviews> (last updated Feb. 17, 2015).



environment and quantify pathways and levels of human and environmental exposure.<sup>155</sup>

When the data on environmental fate and health impacts is insufficient or misrepresented to the agency, EPA's assessment of what pesticide uses pose unreasonable adverse effects on the environment are stymied, or worse, manipulated. Sometimes the pesticide registrant bears the brunt of these events, like for the herbicide Imprelis, for which EPA granted a conditional registration to DuPont despite eighteen missing studies on the herbicide's impact on nontarget plants and trees.<sup>156</sup> Imprelis was a useful herbicide for controlling weeds like dandelions, thistle, and ground ivy, but it also caused tree deaths, which it did at significant levels all across the country generating 34,000 claims for compensation—many of which became part of a class action lawsuit.<sup>157</sup> DuPont paid a \$1,853,000 civil penalty to EPA over the incomplete data submissions during registration,<sup>158</sup> and as of June 30, 2014 DuPont estimated its total costs in litigation and claim payment at \$1.175 billion.<sup>159</sup> For any pesticide, EPA can only meet its statutory requirement to ensure the benefits of using a pesticide is not unreasonable in light of adverse effects on human health and the environment when the agency has a robust set of scientific studies on the toxicity of the pesticide on a diversity of animal and plant species in a realistic variety of ecosystems and human environments.<sup>160</sup> Whether uncertainty stems from lack of required scientific data, lack of certainty in market adoption of a product, or lack of knowledge about how downstream users will be exposed to the pesticide, significant environmental, health, and financial harms can occur.

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155. See *Data Requirements*, *supra* note 103.

156. See Press Release, U.S. Env'tl. Prot. Agency, EPA Settles with DuPont over Violations of Federal Pesticide (Sept. 15, 2014), *available at* <http://yosemite.epa.gov/opa/admpress.nsf/0/C7B2B4F94C0F3A0285257D54005CA7DA>.

157. *E.g.*, Bob Shaw, *DuPont Herbicide Imprelis Doing a Number on Minnesota Trees*, PIONEER PRESS (Jan. 20, 2013, 12:01 AM), [http://www.twincities.com/ci\\_22415500/dupont-herbicide-imprelis-doing-number-minnesota-trees](http://www.twincities.com/ci_22415500/dupont-herbicide-imprelis-doing-number-minnesota-trees).

158. Press Release, U.S. Env'tl. Prot. Agency, *supra* note 156.

159. E. I. du Pont de Nemours & Co., Quarterly Report (Form 10-Q), at 12-13 (July 22, 2014), *available at* [http://investors.dupont.com/files/doc\\_events/DD-2014-6-30-10Q-Final-Filed.pdf](http://investors.dupont.com/files/doc_events/DD-2014-6-30-10Q-Final-Filed.pdf).

160. See *supra* Section II.A.

For consumer products impregnated with pesticides, the estimate of risk is often based on significant uncertainty in exposure models that require assumptions of market response to a product, and assumptions regarding post-application behaviors in use and disposal of the product.<sup>161</sup> For agricultural products, EPA can regulate the pesticide user with restrictions and hazard information on the product label.<sup>162</sup> EPA does use its misbranding and product restriction powers to prevent downstream consumer products from containing pesticidal claims, and health protective claims inconsistent with the registration label.<sup>163</sup> However, under the treated articles exemption, EPA has relinquished its ability to require affirmative labeling of pesticide-impregnated products that can pose risk to human and environmental health.<sup>164</sup>

### III. ANTIMICROBIALS AND THE TREATED ARTICLES EXEMPTION UNDER FIFRA

#### A. REGISTRATION OF HEIQ'S AGS-20 NANOSILVER PRODUCT

EPA conditionally registered nanosilver on December 1, 2011 for use as an antimicrobial and preservative in textiles.<sup>165</sup> The agency issued findings in its decision document that allowed registration prior to full data submittal: (1) The use of the product would “not cause unreasonable adverse effects on the environment during the period when newly required data are being developed;”<sup>166</sup> (2) “[i]nsufficient time has elapsed for HeiQ to generate and submit the newly required data;”<sup>167</sup> and (3) “[u]se of AGS-20 is in the public interest.”<sup>168</sup> The risk assessment accompanying EPA’s decision used acute toxicity endpoints for inhalation, oral, and dermal routes.<sup>169</sup> However, because of a near complete lack of any scientific literature, EPA could make no assessment of chronic reproductive toxicity,

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161. See EPA, HEIQ DECISION DOCUMENT, *supra* note 25, at 25, 33–34, 39, 45; see, e.g., *supra* text accompanying notes 65–74.

162. See *supra* notes 108–21 and accompanying text.

163. See *supra* notes 12–16, 88–89 and accompanying text.

164. See *infra* Section III.

165. See EPA, HEIQ DECISION DOCUMENT, *supra* note 25, at 1–2.

166. *Id.* at 2.

167. *Id.* at 1.

168. *Id.*

169. *Id.* at 8–9, 25.

developmental toxicity, or neurotoxicity, and could only consider one limited mutagenicity study.<sup>170</sup> The NRDC challenged the risk assessment in the Ninth Circuit on human health grounds.<sup>171</sup> The court did remand the decision document back to EPA to cure error, but on narrow grounds, agreeing with EPA on the substantive risk calculation aspects of the decision.<sup>172</sup>

When EPA determined that nanosilver was sufficiently different from silver, it triggered a suite of data requirements for registration.<sup>173</sup> EPA waited for its FIFRA Scientific Advisory Panel<sup>174</sup> to conduct a literature review and issue recommendations before EPA finalized a set of additional registration studies for HeiQ to complete, and had not made a final decision on required scientific data until it issued the conditional registration.<sup>175</sup> EPA determined that this late notice to the registrant of the data requirements gave HeiQ insufficient time to generate the data, and so was appropriate for the statutory requirements of a conditional registration.<sup>176</sup> While it is likely reasonable for EPA to determine that HeiQ had insufficient time to provide data the agency had not required until the issuance of the conditional registration, the findings of “in the public interest” and no “unreasonable adverse effects on the environment” can only be supported circularly by assuming the submitted studies represent the only risks.<sup>177</sup>

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170. *Id.* at 8–12; *see supra* Section I.B.

171. *Natural Res. Def. Council v. EPA*, 735 F.3d 873, 875–76 (9th Cir. 2013).

172. *Id.* at 880–81, 884, 886–87.

173. *See* Notice of Antimicrobial Pesticide Products; Registration Applications, 75 Fed. Reg. 16,109, 16,110 (Mar. 31, 2010); EPA, HEIQ DECISION DOCUMENT, *supra* note 25, at 3–7; Press Release, U.S. Env'tl. Prot. Agency, Pesticide News Story: EPA Announces Conditional Registration of Nanosilver Pesticide Product (Dec. 1, 2011), *available at* [http://www.epa.gov/oppfead1/cb/csb\\_page/updates/2011/nanosilver.html](http://www.epa.gov/oppfead1/cb/csb_page/updates/2011/nanosilver.html).

174. EPA, HEIQ DECISION DOCUMENT, *supra* note 25, at 3–7.

175. *Id.* at 41–42 (“[U]ntil today, EPA had not reached a final decision with regard to which types of data would be further required. This was due in large part to the need to understand and apply the advice provided in the report from the consultation with the FIFRA Scientific Advisory Panel.”).

176. *Id.* at 42–43.

177. *See supra* notes 166, 168 and accompanying text.

The HeiQ conditionally-approved pesticide label<sup>178</sup> accompanies packages of the nanosilver active ingredient to textile manufacturers, but does not go on to accompany the end-use products.<sup>179</sup> The label contains precautionary statements for “hazard to humans and domestic animals” for “moderate eye irritation,” and harm “if inhaled, swallowed, or absorbed through the skin.”<sup>180</sup> The label requires that workers handling the AGS-20 powder during application to a textile have covered arms, legs, and torso, chemically resistant gloves, and full-face respirators with NIOSH “P100 or equivalent filter cartridges.”<sup>181</sup> The environmental hazards statements note the aquatic toxicity environmental hazard—“[t]his pesticide is toxic to fish, aquatic invertebrates, oysters, clams, and shrimp”—and that the pesticide should not be discharged to surface water or sewer systems.<sup>182</sup> The label’s directions for use stipulate that end-use products may not advertise “public health claims relating to antimicrobial activity” without a specific “EPA registration for the manufactured product,” and further specifies that the product does not protect users from “food-borne or disease-causing bacteria, viruses, germs or other disease-causing organisms.”<sup>183</sup> The only approved use is for “non-food contact uses,” and the product cannot be used in “food contact, food packaging, or drinking water” applications.<sup>184</sup>

#### B. WHEN IS IT A PESTICIDE? WHEN IS IT A TREATED ARTICLE?

Treated products do contain pesticides, however, they are not themselves pesticides. Pesticide is defined as “any substance or mixture . . . intended for preventing, destroying, repelling, or mitigating any pest.”<sup>185</sup> By interpretive rule, EPA has further defined pesticides requiring registration as those “intended for a pesticidal purpose” by meeting either of two

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178. U.S. ENVTL. PROT. AGENCY, EPA-HQ-OPP-2009-1012, HEIQ AGS-20 REVISED LABEL (2010) [hereinafter HEIQ AGS-20 REVISED LABEL], available at <http://www.regulations.gov#!documentDetail;D=EPA-HQ-OPP-2009-1012-0017>.

179. See generally 40 C.F.R. § 152.25(a) (2010) (exempting the treated article end-use products from regulation under FIFRA).

180. HEIQ AGS-20 REVISED LABEL, *supra* note 178, at 1.

181. EPA, HEIQ DECISION DOCUMENT, *supra* note 25, at 42.

182. HEIQ AGS-20 REVISED LABEL, *supra* note 178, at 1.

183. *Id.* at 2.

184. *Id.*

185. 7 U.S.C. § 136(u) (2012).

definitional tests:<sup>186</sup> whether “pesticidal claims” are made for the substance, or even in the absence of such claims, if the substance is “intended to, or will have, a pesticidal use.”<sup>187</sup> Under this scheme, some products that might in fact kill or mitigate pests can fall outside the definition. A product can avoid the pesticidal claims test if the sale of the pesticide is done without any claim, statement, or implication “[t]hat the substance . . . can or should be used as a pesticide.”<sup>188</sup> And a product can avoid the pesticidal use definition if despite an active pesticidal ingredient, the product has a “significant commercially valuable use as distributed or sold other than . . . use for pesticidal purpose,” and the seller has no “actual or constructive knowledge that the substance will be used, or is intended to be used, for a pesticidal purpose.”<sup>189</sup> EPA has often successfully asserted jurisdiction to regulate nearly any use of a substance with pesticidal action under the intended or actual pesticidal use test, or upon even a hint of labeling indicating a similarity to pesticidal action.<sup>190</sup> In response to one of the first marketed commercial products containing nanosilver, EPA classified a Samsung washing machine as a pesticide because the machine dispensed nanosilver ions into the water during the washing process.<sup>191</sup> However, even if EPA could successfully bring a substance under its definition of pesticide, the agency has excluded some

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186. See 40 C.F.R. § 152.15 (2010).

187. LYNN L. BERGESON, FIFRA: FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT 3–6 (2000); see 40 C.F.R. §§ 152.10, .15.

188. 40 C.F.R. § 152.15(a).

189. *Id.* § 152.15(b)–(c).

190. Miller, *supra* note 96, at 839 & n.29 (citing an unpublished California case, *Hahn v. Dep’t of Pesticide Regulation*, No. CO66493, 2012 WL 5360910 (Cal. Ct. App. Nov. 1, 2012)) (upholding a fine for selling worm poop without a pesticide registration due to claims that the poop made the plants healthier and thus less susceptible to pests); see e.g., *N. Jonas & Co. v. U.S. Env’tl. Prot. Agency*, 666 F.2d 829, 833 (3d Cir. 1981) (“In determining intent objectively, the inquiry cannot be restricted to a product’s label and to the producer’s representations. Industry claims and general public knowledge can make a product pesticidal notwithstanding the lack of express pesticidal claims by the producer itself.”).

191. See Notice of Pesticide Registration; Clarification for Ion-Generating Equipment, 72 Fed. Reg. 54,039, 54,040 (Sept. 21, 2007).

pesticide products from needing to register with the agency—most importantly treated articles.<sup>192</sup>

The treated articles exemption provides an exemption “from all provisions of FIFRA” for “[a]n article or substance treated with, or containing, a pesticide to protect the article or substance itself,” as long as the pesticide is already “registered for such use.”<sup>193</sup> The treated articles exemption has real regulatory-efficacy gains, as it means that a registered pesticide can be applied to materials, and every permutation of those materials does not have to go through the FIFRA registration process. In 2000, EPA expressly determined that non-public health uses of antimicrobial pesticides meet this exemption and published guidance to that effect.<sup>194</sup> The guidance specifically lists consumer products, including “cutting boards, kitchen sponges, cat litter, toothbrushes, and juvenile toys,” as examples of those within the exemption, as long as these products are distinguished in the marketplace from pesticide products by an “appropriate clarifying statement” that lacks any public health claim, and the “absence of the EPA’s pesticide registration number . . . of the registered pesticide.”<sup>195</sup> EPA has enforced the treated articles exemption

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192. 40 C.F.R. § 152.25 (2011) (“The pesticides or classes of pesticides listed in this section have been determined to be of a character not requiring regulation under FIFRA, and are therefore exempt from all provisions of FIFRA when intended for use, and used, only in the manner specified . . . . An article or substance treated with, or containing, a pesticide to protect the article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation), if the pesticide is registered for such use.”).

193. *Id.*

194. *See generally* U.S. ENVTL. PROT. AGENCY, PR NOTICE 2000-1, NOTICE TO MANUFACTURERS, FORMULATORS, PRODUCERS, AND REGISTRANTS OF PESTICIDE PRODUCTS: APPLICABILITY OF THE TREATED ARTICLES EXEMPTION TO ANTIMICROBIAL PESTICIDES (2000) [hereinafter EPA, PR NOTICE 2000-1], available at <http://www2.epa.gov/sites/production/files/2014-04/documents/pr2000-1.pdf>. A subsequent 2003 factsheet largely reiterates the 2000 guidance. *See Consumer Products Treated with Pesticides*, U.S. ENVTL. PROTECTION AGENCY, <http://www.epa.gov/pesticides/factsheets/treatart.htm> (last updated Jan. 8, 2013).

195. *See Consumer Products Treated with Pesticides*, *supra* note 194 (providing examples of appropriate language such as “[t]his product does not protect users or others against food-born [sic] bacteria. Always clean and wash this product thoroughly before and after each use,” and “[a]ntimicrobial properties are built-in to inhibit the growth of bacteria that may affect this product. The antimicrobial properties do not protect users or others against bacteria, viruses, germs, or other disease organisms”).

with civil fines, stop sale orders, and confiscations of non-conforming products and labeling.<sup>196</sup>

Prior to HeiQ's conditional registration of nanosilver, treated articles containing nanosilver could have been on the market as long as they did not meet the definition of pesticide by avoiding pesticidal claims in any labeling and maintaining non-pesticidal intended uses.<sup>197</sup> Now that there is a registered pesticidal use of nanosilver, any manufacturer can sell products containing the HeiQ nanosilver and make claims about incorporated pesticidal activity that protects the treated article from fungi and microorganisms, but only as long as the company does not make public health claims.<sup>198</sup> Any new pesticidal formulation of nanosilver would need to apply for a supplemental or "me-too registrations" under HeiQs registration.<sup>199</sup> This process preserves the competitive advantage of the original registrant by requiring cost-sharing among registrants for data production, and allows EPA to ensure that new products are not significantly altering the risk assessment exposure scenarios or are otherwise incompatible with the agency's previous findings on adverse effects to the environment.<sup>200</sup>

EPA recently clarified its position on how nanosilver is treated under the definition of pesticide and the treated articles

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196. See 7 U.S.C. §§ 136k(a)–(b), 136l(a) (2012) (describing the civil penalty authority of the EPA Administrator, and the "stop sale, use, removal, and seizure" powers of the EPA Administrator and state agencies for nonconforming products); see, e.g., Lynn L. Bergeson & Timothy D. Backstrom, *EPA Issues Stop Sales Order for Unregistered Food Containers Containing Nanosilver: What Are the Implications?*, 11 NANOTECHNOLOGY L. & BUS. 219, 223 (2014) (describing the withdrawal of "Kinetic Go Green" food containers labeled with the claim that "the nanosilver would protect food within the [food] containers by 'allowing food to stay fresh up to 3 times longer' and would 'kill over 650 types of bacteria'"); see also Bonni F. Kaufman, *Pesky Pesticide Product Claims—Bugs and Bacteria vs. FIFRA*, 26 NAT. RESOURCES & ENV'T 10–11 (2012) ("[Samsung] claimed in advertising material that its computer keyboards, notebooks, and computer laptops were antimicrobial and inhibited germs and bacteria. Samsung ultimately paid a \$205,000 fine . . .").

197. See *supra* notes 185–92 and accompanying text.

198. See EPA, HEIQ DECISION DOCUMENT, *supra* note 25, at 1, 5.

199. 7 U.S.C. § 136a(c)(3)(B) (2012) (providing expedited review for new products that are substantially similar to an existing formulation and use); see EPA, HEIQ DECISION DOCUMENT, *supra* note 25, at 1, 3.

200. See § 136a(c)(3)(B).

exemption in a response to a 2008 rulemaking petition.<sup>201</sup> The 2008 petition<sup>202</sup> was litigated for EPA's failure to respond,<sup>203</sup> which generated an action from EPA to grant in part and deny in part the petition.<sup>204</sup> Fundamentally, EPA did not change course in its response, but did clarify how nanosilver pesticides fit into its enforcement regime.<sup>205</sup> In the petition response EPA clarified that it does not consider all products containing nanosilver to be pesticides, and that some products containing nanosilver will be outside the definition if they do not have a pesticidal purpose through labeling claims or intended use as a pesticide.<sup>206</sup> EPA also noted that the treated articles exemption would remain in effect for articles that otherwise fit the exemption but were treated with pesticides registered as silver even if they are now known to the registrant and agency to contain nanosilver.<sup>207</sup> One EPA statement in the response may require the agency to expand its enforcement investigations, as the agency noted that "[t]o the extent that any unregistered pesticide articles are being sold or distributed in the United States, EPA will address them, as appropriate, through its

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201. Response to Petition for Rulemaking from U.S. Env'tl. Prot. Agency to Int'l Ctr. for Tech. Assessment, 4-8 (Mar. 19, 2015), *available at* <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0650-1406>.

202. Petition for Rulemaking from Int'l Ctr. for Tech. Assment to U.S. Env'tl. Prot. Agency, *supra* note 27.

203. Complaint for Declaratory and Injunctive Relief, Ctr. for Food Safety v. McCarthy, No. 14-2131 (D.D.C. Dec. 16, 2014).

204. Response to Petition for Rulemaking, *supra* note 201, at 2.

205. Lynn L. Bergeson & Carla N. Hutton, *EPA Issues Response to ICTA Petition Regarding Nanosilver*, NANO & OTHER EMERGING CHEMICAL TECH. BLOG (Mar. 26, 2015), <http://nanotech.lawbc.com/2015/03/articles/united-states/federal/epa-issues-response-to-icta-petition-regarding-nanosilver/> ("In general, the response does not alter EPA's legal position with regard to nanosilver . . . or otherwise contribute any new interpretations of existing EPA pesticide registration or enforcement policy.").

206. Response to Petition for Rulemaking, *supra* note 201, at 5 ("While EPA agrees with Petitioner that silver and nanosilver ingredients have inherent bactericidal properties, other well-known but non-pesticidal attributes of silver and nanosilver may instead be the intended use of such ingredients.").

207. *Id.* at 8 ("[T]he treated article exemption is available if a registered pesticide is used, consistent with any terms and conditions for use of the registered pesticide. Thus, pesticide products registered as containing silver but later found to contain nanosilver are nonetheless registered and as long as a registered silver product is used to treat an article . . . the treated article exemption may apply.").



general FIFRA enforcement program.”<sup>208</sup> It is consistent with FIFRA that EPA only has jurisdiction over products sold or distributed in the United States,<sup>209</sup> but it is unclear that EPA had been assessing treated articles in the market that stay within the exception to determine if the particular nanosilver pesticide was the HeiQ product. EPA’s recent statements on its enforcement policies re-iterate that the agency is still enforcing the parameters of the pesticide definition and the treated articles exemption, but do not address the real imprecision in exposure assessments and toxicity discussed in Section I of this Note.

The ability of EPA to accurately estimate the potential exposure to pesticides used in treated articles is diminished compared to the agricultural pesticides discussed in Section II where high levels of control can be exerted on each exposure event. The way EPA has construed the treated articles exemption to prevent the flow of information from pesticide applicators (in this case treated articles manufactures) to those possibly affected by the pesticide application (consumers), prevents any attempt to control exposure and risk after the pesticide is applied. Thus, even if EPA can use conservative exposure models to estimate risk initially, when they are not notified of new articles entering the market, EPA’s initial attempt at exposure and risk controls can quickly become outdated and irrelevant as usage patterns and exposures change. In the following Section, this Note explores the history of the treated articles exemption to illustrate why it exists, and what role it plays in EPA’s regulation of pesticide risks under FIFRA.

#### IV. THE TREATED ARTICLES EXEMPTION IS NOT REQUIRED BY FIFRA

##### A. THE ORIGINAL TREATED ARTICLES

The treated articles exemption represents an EPA policy shift that was a byproduct of the railroads’ and electric utilities’ desire to avoid regulation of use and disposal of railroad ties and power line poles, which are treated with preservative

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208. *Id.*

209. 7 U.S.C. § 136j(a)(1) (2012) (making it a violation of FIFRA to sell or distribute an unregistered pesticide within any state of the United States).

pesticides.<sup>210</sup> As discussed above in Section II, FIFRA labels accompany the pesticide when it leaves the manufacturing plant, and informs transporters, and ultimately the pesticide applicator, of the chemical's legally permissible and restricted uses. If the applicator follows the label, the adverse effect on the environment that EPA has approved is mitigated to the level the statute requires. However, for treated power poles and railroad ties, the application of pesticides occurs far upstream of human and environmental exposures, which continue to occur as pesticide-impregnated wood moves downstream in commerce, the environment, and waste disposal systems.<sup>211</sup> Because EPA realized these downstream exposures posed a significant cancer and disease risk, the agency began a registration cancellation proceeding in the early 1980's that sought to require labeling to accompany the treated wood, and to impose wood disposal and recycling programs on the manufacturers.<sup>212</sup> FIFRA requires EPA to conduct rulemaking by formal evidentiary hearing to add restrictions on a registered pesticide product.<sup>213</sup> As an outcome of one of these hearings, EPA gave up its attempted downstream labeling regulations in a settlement with the pesticide registrants after an administrative judge ruled that "downstream labeling" was 'beyond [the] authority conferred upon EPA by FIFRA.'<sup>214</sup>

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210. See Brian S. Tomasovic, *The Fate of Treated Wood Infrastructure*, 30 VA. ENVTL. L.J. 28, 35–40, 51–53, 67–68 (2012).

211. See *id.* at 35–42, 61–62.

212. Notice of Intent to Cancel Registrations of Pesticide Products Containing Creosote, Pentachlorophenol (including its Salts), and the Inorganic Arsenicals, 49 Fed. Reg. 28,666, 28,666 (July 13, 1984) (noting substantial concerns with oncogenicity (tumor causation), mutagenicity (DNA mutations), teratogenicity (fetal malformation), and reproductive and fetotoxic effects (fetal mal-development)).

213. See Tomasovic, *supra* note 210, at 53 ("[R]egulatory decision-making under FIFRA is an administrative law anomaly in that pesticidal restricted uses are established and upheld not through notice-and-comment rulemaking, but rather through protracted, formal evidentiary hearings.").

214. *Id.* at 54 (quoting Decision on Threshold Legal Issues at 28–29, *In re Chapman Chem. Co.*, FIFRA Docket No. 529 (ALJ June 11, 1985) (on file with author)) ("The Consumer Awareness Program insofar as it requires labeling of pressure-treated wood, which is not a pesticide, is not authorized by FIFRA and may not be required as a condition of the registration of the pesticides at issue."); *Chapman Chem. Co.*, *supra*, at 1.

The treated articles exemption was promulgated in 1988<sup>215</sup> as part of the first comprehensive reorganization and restructuring of the original 1975 regulations relating to pesticide product registration.<sup>216</sup> Promulgation of the treated article exemption was a complete about-face from EPA's position noticed in the 1984 draft proposal.<sup>217</sup> In the draft regulatory proposal, EPA asserted that FIFRA gave the agency authority to require "downstream labeling of consumer products treated with pesticides," and that articles with "repeated or regular human contact should bear statements of the potential hazard of the product."<sup>218</sup> The proposal invited comment on "how best to delineate . . . the universe of consumer products for which labeling statements would be appropriate," and specifically listed some products the agency might consider appropriate for imposing labeling requirements, such as products incorporated into "fabrics and textile goods intended for human clothing (diapers and socks for example), wood articles having substantial human contact (toilet seats), indoor paints, mattresses and rugs."<sup>219</sup> EPA argued that labels were needed to regulate the type of pesticide use, not the downstream products themselves.<sup>220</sup> EPA abandoned this interpretation in the final regulations presumably "to include policy and procedural changes that had evolved" since the original 1975 regulations<sup>221</sup>—like the downstream regulations on wood preservatives the agency gave up to settle a cancellation hearing.<sup>222</sup>

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215. Pesticide Registration Procedures; Pesticide Data Requirements, 53 Fed. Reg. 15,952, 15,977 (May 4, 1988) (to be codified at 40 C.F.R. pt. 152.25(a)).

216. *Id.* at 15,952 (finalizing proposals at 49 Fed. Reg. 37,916 (Sept. 26, 1984) and 50 Fed. Reg. 40,408 (Oct. 3, 1985) to reorganize and update regulations to "conform to legislative changes since 1975, and to include policy and procedural changes that had evolved in that period").

217. *See* Labeling Requirements for Pesticides and Devices, 49 Fed. Reg. 37,960, 37,969 (Sept. 26, 1984).

218. *Id.*

219. *Id.*

220. *See id.*

221. Pesticide Registration Procedures; Pesticide Data Requirements, 53 Fed. Reg. 15,952, 15,952–54 (May 4, 1988) (to be codified at 40 C.F.R. pt. 152.25(a)).

222. *See supra* note 214 and accompanying text.

## B. FIFRA SECTION 6 CANCELLATION PROCEEDINGS

The administrative hearing in the wood preservatives cancellation proceeding was requested by chemical companies with registered uses of three wood preservative pesticides after EPA issued a Notice of Intent to Cancel for the non-industrial uses of those pesticides.<sup>223</sup> EPA's Notice of Intent to Cancel was the culmination of a FIFRA section 6 process initiated in 1978<sup>224</sup> to review the registrations of wood preservative pesticides for continued compliance with the registration standard.<sup>225</sup> FIFRA gives EPA the ability to cancel, amend, or suspend the registration of a product upon finding that "additional factual information regarding unreasonable adverse effects on the environment"<sup>226</sup> or the "pesticide or its labeling . . . does not comply with the provisions of this [Act],"<sup>227</sup> or that the product's use "in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment."<sup>228</sup> EPA must first issue notice of the intent to cancel, the proposed action, and the "reasons (including the factual basis)" for the action.<sup>229</sup> Cancellation actions become final thirty days after notice to the public unless the registrant complies with conditions to avoid cancellation provided in the intended action notice, or a party "adversely affected by the notice" requests a

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223. Notice of Intent to Cancel Registrations of Pesticide Products Containing Creosote, Pentachlorophenol (including its Salts), and the Inorganic Arsenicals, 49 Fed. Reg. 28,666, 28,666 (July 13, 1984); see OFFICE OF PESTICIDES & TOXIC SUBSTANCES, U.S. ENVTL. PROT. AGENCY, WOOD PRESERVATIVES: A CHRONOLOGY OF REGULATORY ACTION & BIBLIOGRAPHY 48-50 (1985), available at <http://nepis.epa.gov/Exe/ZyPURL.cgi?Dockkey=2000V02M.txt>.

224. See Wood Preservatives Pesticides: Initiation of Schedule for Review and Notices of Rebuttable Presumption Against Registration of Certain Pesticides, 43 Fed. Reg. 48,154, 48,154-55 (Oct. 18, 1978).

225. See Notice of Intent to Cancel Registrations of Pesticide Products Containing Creosote, Pentachlorophenol (including its Salts), and the Inorganic Arsenicals, 49 Fed. Reg. at 28,667.

226. 7 U.S.C. § 136d(a)(2) (2012).

227. *Id.* § 136d(b).

228. *Id.*

229. *Id.* § 136d(b)(1) (providing notice to the Secretary of Agriculture or Secretary of Health, depending on end-uses of the pesticide, for comment sixty days prior to notice to the public, and must give notice to all registrants as well as the public in the Federal Register).

hearing.<sup>230</sup> Registrants of the pesticides have clear rights to request hearings, and reach settlement agreements on the terms of cancellation or continued registration under altered conditions.<sup>231</sup> The statute allows for “interested parties” to submit evidence and material to the hearing.<sup>232</sup> Non-registrants, however, are not always required to be noticed of cancellation actions,<sup>233</sup> and do not have full rights to initiate hearings when registrants take no action,<sup>234</sup> nor to continue a hearing after registrants have settled the issues with the agency.<sup>235</sup> By contrast to cancellation proceedings under FIFRA section 6, when EPA sets the conditions of registration through the original registration process of FIFRA section 3, adversely affected parties have the same broad rights to seek judicial review as registrants.<sup>236</sup>

FIFRA section 6 hearings are for purposes of evaluating evidence and material relevant to the objections of an adversely affected party.<sup>237</sup> Hearing examiners, who are often EPA

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230. *Id.* § 136d(b).

231. *See id.*

232. *Id.* § 136d(d).

233. *Id.* § 136d(c) (requiring notification of the registrant, but not the public, prior to accelerated cancellation’s allowable upon a finding of “imminent hazard,” and granting immediate hearing and appeal rights to registrants, but not the public, when EPA issues an “emergency order”).

234. *Pesticide Cancellation Under EPA’s Own Initiative*, U.S. ENVTL. PROTECTION AGENCY, <http://www.epa.gov/opp00001/regulating/cancellations.htm> (last updated Feb. 4, 2014) (“[I]f no registrant is interested in retaining a registration, and no other person wishes to become a registrant, a hearing is not convened.”).

235. *See* McGill v. EPA, 593 F.2d 631, 636–37 (5th Cir. 1979); Accelerated Decision at 4–6, *In re* Chapman Chem. Co., FIFRA Docket No. 590 (ALJ Mar. 14, 1988), available at <http://www.epa.gov/oalj/orders/fifra-590-031488.pdf> (holding that non-registrants—trade associations and environmental organizations—could not compel a hearing to go forward when registrant companies reached a settlement with EPA that canceled pesticide registrations but allowed for continued sale of existing stocks for two more growing seasons); *see also* Cedar Chem. Co., 2 E.A.D. 584, 585–86 (ALJ 1988) (holding that FIFRA requires non-registrants to have limited hearing rights that are concurrent with the registrant, which cannot persist when registrant settles a cancellation action).

236. *See* § 136a(d)(1)(C)(ii); *see, e.g.*, Decision on Threshold Legal Issues at 30 n.30, *In re* Chapman Chem. Co., FIFRA Docket No. 529 (ALJ June 11, 1985) (noting that parties had rights to seek judicial review under § 3 that they lacked in an action under § 6).

237. *See* § 136d(d).

Administrative Law Judges (ALJs),<sup>238</sup> have the power to grant subpoenas for relevant testimony or take discovery from any person; these powers are “guided by the principles of the Federal Rules of Civil Procedure,” and enforceable by a U.S. district court.<sup>239</sup> The hearing examiner does not have power to issue a final action regarding the registration cancellation or amendment—that power rests with the Administrator of EPA.<sup>240</sup> However, the Administrator must issue the final action “based only on substantial evidence” of the hearing record, and with detailed findings of fact.<sup>241</sup> Final actions are reviewable by a U.S. court of appeals within sixty days, to determine if the action of the EPA Administrator is supported by “substantial evidence when considered on the record as a whole.”<sup>242</sup> In general, “substantial evidence” review is governed by *Universal Camera Corp. v. NLRB* and the Administrative Procedure Act, 5 U.S.C. § 706(2)(E), which both require court review of all actions, findings, and conclusions, but would not require the ALJ’s conclusions to be given more weight than deserved.<sup>243</sup> This principle would uphold a decision by the EPA Administrator that runs counter to the ALJ’s conclusion as long as a reasonable person would find the evidence adequate to support the conclusion even if the court would have reached the opposite conclusion.<sup>244</sup>

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238. 40 C.F.R. § 164.40 (1999) (using Administrative Law Judges in hearings other than expedited hearings).

239. *Id.*

240. *Id.* § 136d(b)(1).

241. *Id.* § 136d(d).

242. *Id.* § 136n(b).

243. *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 488, 496 (1951) (holding that a reviewing court may set aside an Agency’s decision “when it cannot conscientiously find that the evidence supporting the decision is substantial, when viewed in the light that the record in its entirety furnishes, including the body of evidence opposed to the [Agency’s] view”); see 5 U.S.C. § 706(2)(E) (2012).

244. See *Universal Camera Corp.*, 340 U.S. at 495–97. This approach has been specifically applied by the D.C. Circuit when reviewing a final decision to cancel a pesticide registration from the Administrator that runs contrary to the ALJ’s initial hearing determination in a pesticide cancellation adjudication under FIFRA. *Env’tl. Def. Fund, Inc. v. EPA*, 489 F.2d 1247, 1253 (D.C. Cir. 1973).

## C. IN THE MATTER OF CHAPMAN CHEMICAL CO.

The *Chapman Chemical Company* hearing over the intent to cancel wood preservative registrations was resolved by two separate settlement agreements between EPA and parties to the hearing.<sup>245</sup> Both agreements were implemented by amendments to the notice of cancellation in the federal register.<sup>246</sup> On initial motion to the hearing, the chemical companies requested that the ALJ narrow the focus of the hearing by providing initial determinations on issues of law.<sup>247</sup> Administrative Law Judge Nissen determined that when the pesticides were pressure-treated into the wood, labeling the wood products was “beyond EPA’s authority under FIFRA and may not be required as a condition of registration of the pesticides here at issue.”<sup>248</sup> However, the ALJ also considered whether the same labeling statements could be required on the pesticide labels even if they were regulating downstream uses and disposal of the treated products.<sup>249</sup> All three pesticides

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245. Memorandum from the U.S. Env’tl. Prot. Agency, Final Compliance Monitoring Strategy for the Wood Preservative Uses of Creosote, Pentachlorophenol, and Inorganic Arsenicals 3–4 (Oct. 23, 1986) (on file with author) (“On September 30, 1985, EPA entered into a settlement agreement with many of the parties who requested a hearing pursuant to the July 13, 1984 Notice. The settlement agreement modified the terms of the July 13, 1984 Notice. As a result of the settlement agreement, on January 10, 1986, the Agency published an amended Notice of Intent to Cancel which incorporated the terms of the settlement agreement.”); Amendment of Notice of Intent to Cancel Registrations of Creosote, Pentachlorophenol, and Inorganic Arsenicals 51 Fed. Reg. 1334, 1334–35, 1337–38, 1345–47 (Jan. 10, 1986) (describing responsibilities for implementing a voluntary consumer awareness program on two wood treatment associations, AWPI and SAWP, resulting from EPA amending the mandatory consumer information sheet program originally proposed in the cancellation proceedings); Amendment of Notice of Intent to Cancel Registrations of Pentachlorophenol, 52 Fed. Reg. 140, 142–43 (Jan. 2, 1987) (noting a second settlement agreement between other parties to the *Chapman* hearing resolving issues on levels of permissible dioxin levels in pesticide treatments).

246. See Amendment of Notice of Intent to Cancel Registrations of Creosote, Pentachlorophenol, and Inorganic Arsenicals 51 Fed. Reg. at 1334–36; Pentachlorophenol; Amendment of Notice of Intent to Cancel Registrations, 52 Fed. Reg. at 140.

247. See Decision on Threshold Legal Issues at 2, *In re Chapman Chem. Co.*, FIFRA Docket No. 529 (ALJ June 11, 1985) (“At the prehearing conference, held February 5, 1985, the ALJ agreed to rule on these issues prior to commencement of the hearing.”).

248. *Id.* at 30.

249. See *id.* at 30–34.

could be impregnated in the wood by placement in a closed cylinder and subjected to high pressure to infuse the chemicals into the wood fibers, or they could be sprayed or brushed on to the wood by the end user or a commercial wood processor.<sup>250</sup> As a consumer product, the non-pressure-treated wood, like the pressure-treated wood, was still not a pesticide subject to FIFRA or the attempted mandatory labeling.<sup>251</sup> However, the ALJ decided that “EPA’s authority under FIFRA over labeling content of pesticides in order to prevent unreasonable adverse effects on the environment is extremely broad,” and held that the “label restrictions [restricting residential and farming end-uses] are more closely connected to pesticide application, which EPA clearly has authority to regulate, and thus more closely analogous to the field reentry requirements, crop rotational restrictions, etc.,” which are commonly required post-application restrictions for agricultural pesticides.<sup>252</sup>

Only if the EPA Administrator had issued a final order that conformed to the ALJ’s interpretation of FIFRA would the interpretation in *Chapman Chemical* become the position of the agency.<sup>253</sup> Following the Supreme Court’s unanimous opinion in *Immigration & Naturalization Serv. v. Yang*, an agency can issue a decision that is inconsistent with its precedents, whether by “rule or . . . settled course of adjudication” if the agency acknowledges it is changing course and provides

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250. *See id.* at 30 (distinguishing methods of high pressure treatment from “[n]on pressure methods . . . primarily involv[ing] brushing or spraying preservatives onto wood”).

251. *Id.* at 33–34.

252. *Id.* at 33; *see* ELIZABETH BOSAK & VINCE DAVIS, UNIV. OF WIS.-EXTENSION, HERBICIDE ROTATION RESTRICTIONS IN FORAGE AND COVER CROPPING SYSTEMS, UNIV. OF WIS.-EXTENSION (n.d), *available at* [http://wcws.cals.wisc.edu/wp-content/uploads/sites/4/2013/03/WCWS\\_201\\_Herbicide\\_Rotation\\_Restrictions\\_WEB.pdf](http://wcws.cals.wisc.edu/wp-content/uploads/sites/4/2013/03/WCWS_201_Herbicide_Rotation_Restrictions_WEB.pdf); *Restrictions After Pesticide Applications Under the Current WPS*, U.S. ENVTL. PROTECTION AGENCY, <http://www.epa.gov/oppfead1/safety/workers/restrictions-after-application.html> (last updated Feb. 20, 2014).

253. Miller, *supra* note 96, at 860 (“The administrator is also not bound by findings of the ALJs. This conclusion follows the longtime general principle of administrative law that a hearing examiner’s decision should be accorded only the deference it merits . . . Only if the decision-maker arbitrarily and capriciously ignored the findings of an examiner . . . would a different conclusion be indicated.”).



adequate explanation for its new policy preference.<sup>254</sup> In any cancellation adjudication under FIFRA section 6 or initial registration decision under FIFRA section 3, EPA could interpret its duty to place conditions on pesticide uses to mitigate adverse effects on the environment to require that the agency regulate end-uses of a treated article through exchange of information between the pesticide registrant and the end-user. While the agency did subsequently promulgate the treated articles exemption, the agency did not give up on downstream labeling as a way to control adverse impacts on human health and the environment.<sup>255</sup>

In the settlement agreement that resolved the *Chapman Chemical* hearing, EPA and the wood treating registrants agreed to a voluntary program for labeling.<sup>256</sup> As part of the settlement, the trade associations were supposed to “notify the entire treating industry of the necessity to participate in the [program]”<sup>257</sup> and distribute “signs and placards to their retailers, wholesalers, and distributors” including the consumer information sheets to be disseminated at sale to the end user.<sup>258</sup> Only upon the trade associations’ agreement that they would significantly promote the voluntary program did EPA determine that the non-mandatory labeling could mitigate unreasonable adverse effects on the environment from unregistered home uses of treated wood.<sup>259</sup> Seven years later in 1993, the South Dakota Department of Agriculture conducted a state-wide survey to determine if the voluntary program was being implemented, and found that only three of the six wood treating operations recognized the voluntary program, and less than 10% of retail lumber yards and locations were giving consumer information sheets at sale and purchase of treated wood.<sup>260</sup> EPA then pressured the industry associations to

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254. See *Immigration & Naturalization Serv. v. Yang*, 519 U.S. 26, 32 (1996).

255. See *supra* Section IV.A–B.

256. Amendment of Notice of Intent to Cancel Registrations of Creosote, Pentachlorophenol, and Inorganic Arsenicals 51 Fed. Reg. 1334, 1335 (Jan. 10, 1986).

257. *Id.* at 1347.

258. *Id.* at 1337.

259. See *id.* at 1337–38, 1345–48.

260. SFIREG, ELIMINATION OF MANDATORY CONSUMER AWARENESS PROGRAM FOR CREOSOTE, PENTACHLOROPHENOL, AND INORGANIC ARSENICAL TREATED WOOD (1994), available at <http://www.aapco.org/doc/min1994>

implement the settlement agreement,<sup>261</sup> but rather than comply with the labeling program, the pesticide registrants sent EPA a request to cancel the remaining non-industrial uses of wood preservative pesticides.<sup>262</sup>

#### D. WHAT IS THE LEGAL STATUS OF IN RE CHAPMAN CHEMICAL CO. AND LABELING?

The registration cancellation hearing *Chapman Chemical* led to an initial opinion of law by the hearing examiner, who determined that EPA could not regulate the use of a pesticide by requiring hazard and use labeling on products treated with the pesticide that were not pesticides themselves.<sup>263</sup> The agency decided not to proceed through the hearing process to a final agency action and instead achieved its goals through a settlement agreement it thought would compel broad adoption of a voluntary downstream labeling program.<sup>264</sup> Later, in a separate rulemaking, EPA promulgated the treated articles

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/attach/94jul11/att\_min07111994.html (follow “New Regional & Working Committee Issue Papers: Attachment A” at 36–38).

261. See *Minutes of Meeting Working Group Committee – Pesticide Operations & Management*, SFIREG WC/PESTICIDE OPERATIONS & MGMT. (May 18–19, 1998), <http://www.aapco.org/doc/min1998/sfireg598.html> (noting that distribution of Consumer Information Sheets had not increased in two years, and EPA’s Office of Pesticide Products staff noting that risk with treated wood pesticides would need to be dealt with in upcoming Reregistration Eligibility Decision (RED)); *Minutes of Meeting Working Group Committee – Pesticide Operations & Management*, SFIREG WC/PESTICIDE OPERATIONS & MGMT. (Oct. 10–11, 1996), <http://www.aapco.org/doc/min1996/min10101996.html> (noting that EPA had pressured American Wood Preservers’ Institute to better implement the settlement agreement in 1994 and trade association had agreed to spend more money on distributing the Consumer Information Sheets).

262. See Notice of Receipt of Requests to Cancel Certain Chromated Copper Arsenate (CCA) Wood Preservative Products and Amend to Terminate Certain Uses of CCA Products, 67 Fed. Reg. 8244, 8224–25 (Feb. 22, 2002); Response to Requests to Cancel Certain Chromated Copper Arsenate (CCA) Wood Preservative Products and Amendments to Terminate Certain Uses of other CCA Products, 68 Fed. Reg. 17,366, 17,366–67 (Apr. 9, 2003) (finalizing request noticed on Feb. 22, 2002 to cancel non-industrial uses of CCA treated wood).

263. See Decision on Threshold Legal Issues at 11–14, 25–30, *In re Chapman Chem. Co.*, FIFRA Docket No. 529 (ALJ June 11, 1985).

264. See *supra* text accompanying notes 256–59.

exemption,<sup>265</sup> which showed the Reagan Administration's policy adoption of the spirit of the *Chapman Chemical* initial opinion of law, in that such treated articles were not required to go through FIFRA registration as long as they did not deviate from authorized uses in the pesticide's registration.<sup>266</sup>

In a FIFRA section 6 cancellation hearing, the hearing examiner can limit the issues of the hearing or otherwise make rulings of decision that apply the facts to law for the purposes of focusing the hearing when agreed by parties to a preconference hearing.<sup>267</sup> After the hearing, and based on the record of the hearing, the Administrator must issue an order to revoke the notice of intent to cancel, or an order canceling the registration or requiring modification of the labeling.<sup>268</sup> As a resolution of the cancellation hearing, the Administrator's order is reviewable by a district court for support of substantial evidence in the hearing record.<sup>269</sup> EPA would only be bound to use the ALJ's interpretation of FIFRA, if the Administrator had gone against the ALJ's initial opinion and required labeling of end-user pressure-treated wood products through the Consumer Awareness Program and a reviewing district court then found there was no substantial evidence in the *Chapman Chemical* hearing record.<sup>270</sup>

The ALJ upheld the same regulatory warnings on the pesticide labeling that accompanies shipments to the person applying the pesticide, but struck down the requirement that the pesticide applicator further label the treated product.<sup>271</sup> The decision did not find that the restricting and regulating downstream users and products offended the statute, only that labeling non-pesticides offended the statute.<sup>272</sup> The pesticide applicator that brushes, sprays, or pressure-treats the wood cannot use the wood for a restricted use, and has a duty to not

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265. See Pesticide Registration Procedures; Pesticide Data Requirements, 53 Fed. Reg. 15,952, 15,977 (May 4, 1988) (to be codified at 40 C.F.R. pt. 152.25(a)).

266. See *Chapman Chem. Co.*, at 30–33; Pesticide Registration Procedures; Pesticide Data Requirements, 53 Fed. Reg. at 15,977.

267. 40 C.F.R. § 164.50(a) (1999) (describing scope and purpose of prehearing conferences).

268. 7 U.S.C. § 136d(d) (2012).

269. *Id.* §§ 136d(h)–136n.

270. See Section IV.B–C.

271. See *Chapman Chem. Co.*, at 28–30.

272. See *id.* at 25–30.

allow an impermissible end-use when they sell that wood to another person.<sup>273</sup> Neither wood preservative pesticides nor antimicrobial pesticides applied to textiles are registered for food contact uses.<sup>274</sup> If Home Depot sells treated wood for non-residential uses, how can it restrict the purchaser from later sawing the wood and making an apple-storage crate or a cutting board? How can an apparel company restrict someone wearing a nanosilver-treated jacket from carrying an apple in their jacket pocket? It is the responsibility of the pesticide applicator to not sell the product for a restricted end use, and class actions have been tried by home owners who used treated lumber for home decking, and had to remediate soil in their backyards due to arsenic pesticide leaching.<sup>275</sup> If treated wood is buried on site, that land becomes a brownfield subject to CERCLA remediation due to the hazardous characteristics of the soil.<sup>276</sup>

Under any future petition to label downstream treated articles, or on its own, EPA can still use the argument it advanced in its original notice of intent to cancel registrations of wood preservatives.<sup>277</sup> While EPA does not actively review downstream products using approved treated material, EPA can still come to a factual finding that the use of the pesticide would create an unreasonable adverse effect on man or the environment unless consumers and downstream users of the

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273. See Tomasovic, *supra* note 210, at 53 n.136, 54 (noting that regulation of permitted uses of treated articles falls on EPA controlling manufactures and applicators through the registered pesticide uses not on the end user of the article); see also *Chapman Chem. Co.*, at 30–33 (discussing application methods).

274. See Notice of Intent to Cancel Registrations of Pesticide Products Containing Creosote, Pentachlorophenol (including its Salts), and the Inorganic Arsenicals, 49 Fed. Reg. 28,666, 28,675 (July 13, 1984) (noting label restrictions for any use whereby pesticides could become component of food); HEIQ AGS-20 REVISED LABEL, *supra* note 178, at 2 (“This product may not be used for any applications involving food contact, food packaging, or drinking water.”).

275. See, e.g., *Jacobs v. Osmose, Inc.*, No. 01-944-CIV, 2002 WL 34241682, at \*1 (S.D. Fla., Jan. 3, 2002) (class action brought against manufacturers and retailers of chromated copper arsenate treated wood).

276. *Bank Midwest*, MINN. BROWNFIELDS, <http://mnbrownfields.org/case-studies/bank-midwest/> (last visited Feb. 19, 2015) (“A total of 6,883.21 tons of treated wood and contaminated fill were removed from the site . . .”).

277. See *supra* text accompanying notes 217–19.

treated product are informed of the hazards of certain uses.<sup>278</sup> EPA would need to determine that an authorized use of a preservative pesticide was not being mitigated to a level compatible with the statute, and require a downstream labeling regime implemented by the pesticide manufacturers or applicators. Notably, since EPA had not allowed any food contact uses of treated wood, EPA wanted a customer information sheet to accompany the wood at the point of sale that would inform the end-user not to use the treated wood at sites for food silage or storage, or where the preservatives may become a component of food or animal feed.<sup>279</sup> EPA's notice of intent to cancel specifically held that incidental exposures to an end-user who uses treated wood in food contact was sufficiently high to outweigh the benefits of preserving the wood.<sup>280</sup> However, other benefits from preserving the wood may support continued registration so long as incidental consumer behavior exposures could be avoided. These use mitigation findings are the kind that initially led EPA to consider downstream labeling regulations, and very similar findings would be supported for antimicrobial preservatives widely approved for use in apparel.

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278. See Notice of Intent to Cancel Registrations of Pesticide Products Containing Creosote, Pentachlorophenol (including its Salts), and the Inorganic Arsenicals, 49 Fed. Reg. at 28,666–68; see also *Chapman Chem. Co.*, at 11–12. (“Respondent says that FIFRA grants EPA authority to take a broad range of actions to assure that the risks of the use of a pesticide do not exceed the benefits of such use and that to reduce risks to an acceptable level the Agency may address through labeling any risks attendant to pesticide use, whether those risks occur before, during, or after the application process. Respondent argues that the Agency must consider risks to all potentially exposed individuals, including applicators and others who may have contact with the pesticide or its residues, e.g., the general public exposed to residues in food and drinking water and farmworkers exposed to residues in the field.” (citations omitted)).

279. Notice of Intent to Cancel Registrations of Pesticide Products Containing Creosote, Pentachlorophenol (including its Salts), and the Inorganic Arsenicals, 49 Fed. Reg. at 28,675 (“Do not use treated wood under circumstances where the preservative may become a component of food or animal feed. Examples of such sites would be structures or containers for storing silage or food. Do not use treated wood for cutting boards or countertops . . . Do not use treated wood for construction of those portions of beehives which may come into contact with the honey. Treated wood should not be used where it may come into direct or indirect contact with public drinking water . . .”).

280. See also *id.* at 28,668–71 (summarizing the risks associated with “wood preservative chemicals”).

## CONCLUSION

FIFRA is one of the only statutes EPA administers where the agency has significant power to require regulated industries to generate health and safety data on unknown chemical toxicity issues.<sup>281</sup> EPA promulgated the treated articles exemption to provide a blanket exemption from FIFRA registration and labeling for companies that use pesticides to preserve materials, like the railroad industry and apparel companies that use fabrics and advanced textiles impregnated with pesticides. While there is a general regulatory efficiency gained by allowing companies to create new and different uses in the market for approved pesticides, EPA should not give up its ability to protect consumers through information exchange, and the generation of new toxicity information on technological innovations. EPA has taken the enforcement position that affirmative labeling of treated articles identifying the registered pesticide creates a misbranding problem that would give consumers a false sense of protection, and would lead to negative public health impacts. This policy has turned a labeling law that communicates information about pesticide risks and benefits, into a law that prevents the flow of information about pesticide risks and benefits.

The treated articles exemption is not a statutorily imposed limit on EPA's power, and EPA's implementation of the exemption has never been directly challenged or litigated. Any statutory argument that treated articles cannot be labeled because they are not pesticides would be in significant tension with EPA's broad statutory power and overriding duty to mitigate adverse effects on the environment and human health from any pesticide use the agency registers. On silver and nanosilver registrations specifically, the use of nanosilver in consumer products is likely a much larger exposure pathway than EPA calculated in their risk assessment for HeiQ's nanosilver pesticide; and EPA should use its broad statutory power to force more scientific research and information on this emerging technology to be transmitted to the public. In the ongoing re-registration decision for silver compounds and

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281. Miller, *supra* note 96, at 839 (noting the FIFRA registration process can take "years and millions of dollars of testing, and the submittal to and approval by EPA . . . more akin to FDA drug registration than the simple notification required for nonpesticidal chemicals under the Toxic Substances Control Act (TSCA).").

nanosilver, EPA should consider allowing labeling of both pesticide names, hazards, and usages—specifically that treated articles are not approved for food-contact uses. An interested party could outline the case for labeling restrictions against food-contact uses in a regulatory petition, which could be put before a court should EPA decline to attempt some affirmative labeling program. At the very least, EPA needs to find a better way for information to flow between pesticide manufacturers and consumers exposed to those pesticides through treated articles.

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