

**Case Note: *League of United Latin Am. Citizens v. Regan***  
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**I. INTRODUCTION**

Agencies have the power of self-governance under the limited powers statutorily provided by Congress.<sup>2</sup> Agency decisions can be easily overturned by Congressional order, but when should the judiciary get involved?<sup>3</sup> The answer may lie in the Ninth Circuit Court of Appeals case, *League of United Latin Am. Citizens v. Regan*.<sup>4</sup>

The fate of chlorpyrifos pesticide came to a head in the recent 2019 Ninth Circuit of Appeals case, *League of United Latin Am. Citizens v. Regan*.<sup>5</sup> Chlorpyrifos pesticides have been at the center of no fewer than six disputes brought before the United States Court of Appeals for the Ninth Circuit during the twenty-first century.<sup>6</sup> Chlorpyrifos is an organophosphate insecticide employed for the eradication of various pest species like termites, mosquitoes, and roundworms.<sup>7</sup> It was initially registered as a pesticide in 1965 and underwent re-registration by the Environmental Protection Agency (“EPA”) in 2006.<sup>8</sup> Since then, the EPA has

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<sup>2</sup> Michael Rappaport, *A Stronger Separation of Powers for Administrative Agencies*, The Regulatory Review (Dec. 18, 2019), <https://www.theregreview.org/2019/12/18/rappaport-stronger-separation-powers-administrative-agencies/>.

<sup>3</sup> 5 U.S.C. § 706

<sup>4</sup> *Id.*; see generally *League of United Latin Am. Citizens v. Regan*, 996 F.3d 673 (9<sup>th</sup> Cir. 2021).

<sup>5</sup> *League of United Latin Am. Citizens*, 996 F.3d at 677.

<sup>6</sup> *Id.*

<sup>7</sup> Christensen, K.; Harper, B.; Luukinen, B.; Buhl, K.; Stone, D. *Chlorpyrifos General Fact Sheet*. National Pesticide Information Center, Oregon State University Extension Services (2009), <http://npic.orst.edu/factsheets/chlorpgen.html>, (last visited Sep. 24, 2023).

<sup>8</sup> *Id.*

been repeatedly hailed into court as an increasing number of governmental agencies, states, state officials, and private citizens implore it to prohibit the utilization of chlorpyrifos pesticide because of its possible harmful effect on humans.<sup>9</sup> Within the past decade, the EPA has officially recognized that residues of chlorpyrifos pesticide are likely to cause harm to fetuses when pregnant mothers are exposed.<sup>10</sup> In the face of the acknowledged risks, there is debatable evidence substantiating the safety of chlorpyrifos pesticide, and the EPA has steadfastly refused to ban the usage of chlorpyrifos pesticide or to, at a minimum, reduce the legal tolerance levels.<sup>11</sup>

The commencement of such legal proceedings date back to 2007, when two nonprofit organizations, the Pesticide Action Network North America (“PANNA”) and the Natural Resources Defense Council, Inc. (“NRDC”), jointly submitted a “Petition” to the EPA.<sup>12</sup> Their Petition requested a complete ban on all foods containing any trace of chlorpyrifos residue.<sup>13</sup> If enacted, this plea would overturn the then existing EPA policy that permitted varying “tolerance” levels depending on the type of food.<sup>14</sup>

Even with such a petition, the permitted tolerance levels must meet the EPA’s mission to “protect human health and the environment.”<sup>15</sup> Part of the EPA’s

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<sup>9</sup> *League of United Latin Am. Citizens*, 996 F.3d at 677, 690.

<sup>10</sup> *Id.* at 677.

<sup>11</sup> *Id.* at 677-8, 680. The use of chlorpyrifos was banned in California and the European Union in February 2021, prior to the decision in this case. SEE *infra* Section IV Analysis.

<sup>12</sup> *League of United Latin Am. Citizens*, 996 F.3d at 677.

<sup>13</sup> *Id.*

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

<sup>15</sup> *Our Mission and What We Do*, U.S. Environmental Protection Agency, <https://www.epa.gov/aboutepa/our-mission-and-what-we-do>, (last visited Sep. 24, 2023).

work is to ensure that “National efforts to reduce environmental risks are based on the best available scientific information . . . [and] Chemicals in the marketplace are reviewed for safety.”<sup>16</sup> The EPA was granted authority to regulate the use of pesticide chemicals under the Federal Food, Drug and Cosmetic Act (“FFDCA”). The statute mandates that the EPA ensures, with a “reasonable certainty,” that pesticide residue will not cause harm to infants and toddlers due to their special susceptibility to harm, including neurological effects.<sup>17</sup> The EPA is further obligated to issue a “specific determination” addressing these safety concerns.<sup>18</sup> It is the EPA’s duty to review and stay current on studies about safety, particularly to children and infants, to ensure compliance with the “reasonable certainty” requirement and publish their specific determinations regarding those findings.<sup>19</sup>

Starting in 2007, two categories of studies began to generate evidence suggesting that chlorpyrifos pesticides pose a risk to children and infants: experimental studies conducted with rats and mice and epidemiological studies tracking human exposure to chlorpyrifos from in-utero onwards.<sup>20</sup> Such studies prompted the two non-profit organizations (PANNA and NRDC) to file a petition for review of the EPA’s chlorpyrifos registration determination.<sup>21</sup>

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<sup>16</sup> *Our Mission and What We Do*, *supra* note 15.

<sup>17</sup> 21 U.S.C. § 346a(b)(2)(C)(i)–(ii).

<sup>18</sup> *Id.* § 346a(b)(2)(C)(i)(II).

<sup>19</sup> *Id.* § 346a(b)(2)(C)(ii).

<sup>20</sup> *League of United Latin Am. Citizens*, 996 F.3d at 677.

<sup>21</sup> *Id.*

In the 2021 case of *League of United Latin Am. Citizens v. Regan*, the court intervened in the EPA's responsibility to assess the chemical chlorpyrifos.<sup>22</sup> Between 2007 and 2016, the EPA published Human Risk Assessments and met with its Scientific Advisory Board (“SAB”) multiple times to evaluate chlorpyrifos and its effects.<sup>23</sup> Using the information gathered, the EPA began to acknowledge the heightened proposed risk associated with chlorpyrifos.<sup>24</sup>

Furthermore, in 2015, the EPA issued a Notice of Proposed Rulemaking suggesting the revocation of all chlorpyrifos tolerances.<sup>25</sup> In 2016, it released a Revised Human Health Risk Assessment, asserting that the EPA could not adequately determine if the current tolerances were deemed safe.<sup>26</sup> Nevertheless, the EPA deliberately refrained from ruling on the 2007 Petition until the court was required to impose a deadline in 2017.<sup>27</sup> In its court-imposed ruling, the EPA denied the 2007 petition and subsequently rejected all objections to that decision in 2019.<sup>28</sup>

Upon reviewing the EPA's actions, the Ninth Circuit Court of Appeals determined that the second denial in 2019 was an attempt to postpone a decision on the 2007 petition further until the safety of chlorpyrifos underwent a separate registration re-review under a statute expected to take place around 2022.<sup>29</sup> The court held that such a delay, despite the EPA's awareness that it could not affirm

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<sup>22</sup> See generally *League of United Latin Am. Citizens*, 996 F.3d 673.

<sup>23</sup> *Id.* at 667.

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

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

<sup>26</sup> *League of United Latin Am. Citizens*, 996 F.3d at 667-668.

<sup>27</sup> *Id.* at 678.

<sup>28</sup> *Id.*

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

the safety of chlorpyrifos, constituted a violation of the EPA's authority under the FFDCA.<sup>30</sup> In light of the EPA's conduct, the court granted the petitions for review and imposed a 60-day order on the EPA to either amend chlorpyrifos tolerances and publish findings affirming the chemical's safety or revoke all chlorpyrifos tolerances.<sup>31</sup> Additionally, the court instructed the EPA to promptly modify or rescind Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") regulations pertaining to food use.<sup>32</sup>

This case has paved the way for increased judicial intervention in the EPA's tolerance review process. It has reaffirmed the EPA's ongoing responsibility to regulate and ensure the safety of current tolerances. The court in its decision highlighted the need for this responsibility particularly when such tolerances are suspected of causing harm to all individuals, especially harm to infants and children.

## II. BACKGROUND: LEAGUE OF UNITED LATIN AM. CITIZENS v. REGAN

### A. *History: The EPA and Pesticide Chlorpyrifos Tolerances*

In response to rising public concern over the environment, President Nixon sent Congress a plan to create a federal agency to address environmental responsibilities – which resulted in the formation of the EPA.<sup>33</sup> Congress created

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<sup>30</sup> *League of United Latin Am. Citizens*, 996 F.3d at 668.

<sup>31</sup> *Id.*

<sup>32</sup> *League of United Latin Am. Citizens*, 996 F.3d at 678.

<sup>33</sup> *The origins of EPA* | US EPA - U.S. Environmental Protection Agency, <https://www.epa.gov/history/origins-epa> (last visited Oct 11, 2023).

the EPA with Order 1110.2 on December 4, 1970.<sup>34</sup> The EPA's rules were designed to remain perpetually until amendments were deemed necessary.<sup>35</sup> The EPA's creation included and continues to include notable offices: the Assistant Administrator (For Standards And Enforcement) And General Counsel and Pesticides Office.<sup>36</sup>

The Assistant Administrator (For Standards And Enforcement) acts as a principal advisor to the EPA Administrator and assists with establishing and enforcing environmental standards while acting as the agency's chief legal officer.<sup>37</sup> An additional office, the Office of Standards and Compliance, creates Agency guidelines for enforcing compliance standards and requires continuous performance reviews for each office.<sup>38</sup> The Office of General Counsel assists in the establishment of such standards and changes in legislation.<sup>39</sup>

The Pesticide Office is focused on handling pesticides, including chlorpyrifos, for the entire EPA. It establishes the level of tolerance for pesticide residues on or in food, pesticide registration, pesticide registration review, and research on effects on human health, among other duties.<sup>40</sup> Under applicable statutes, Congress provides the authority to act, the Pesticide Office established chlorpyrifos tolerances and continued to renew its registration until the decision in *League of United Latin Am.*

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<sup>34</sup> *EPA order 1110.2 -- initial organization of the EPA* (1970), <https://www.epa.gov/archive/epa/aboutepa/epa-order-11102-initial-organization-epa.html> (last visited Oct 11, 2023).

<sup>35</sup> *Id.*

<sup>36</sup> *Id.*

<sup>37</sup> *Id.*

<sup>38</sup> *Id.*

<sup>39</sup> *EPA order 1110.2, supra* note 34.

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

*Citizens v. Regan*.<sup>41</sup> Congress provided the EPA, particularly the Pesticide Office, the authority to act under the FIFRA and FFDCA.<sup>42</sup>

In *League of United Latin Am. Citizens v. Regan*, the civil suit seeking judicial review, is brought under and focuses on The Federal Food, Drug, and Cosmetic Act (“FFDCA”).<sup>43</sup> The FFDCA dates back to the Progressive era when it was signed into law on June 30, 1906, by President Roosevelt.<sup>44</sup> The Act’s focus was predominately on food, with a greater concern on chemical additives.<sup>45</sup> The Act was replaced on June 25, 1938, to address the prior act’s shortcomings.<sup>46</sup> Particularly, the Act mandated legal food standards and set tolerances for certain poisonous substances, like pesticide chemicals.<sup>47</sup> By the 1960s, the food standards expanded to cover half of the food supply.<sup>48</sup>

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<sup>41</sup> *EPA order 1110.2*, *supra* note 39.

<sup>42</sup> *Summary of the Federal Food, Drug, and Cosmetic Act | US EPA*, <https://www.epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act> (last visited Oct 16, 2023); *Summary of the Federal Insecticide, Fungicide, and Rodenticide Act | US EPA*, United States Environmental Protection Agency, <https://www.epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> (last visited Oct 17, 2023).

<sup>43</sup> *League of United Latin Am. Citizens v. Regan*, 996 F.3d at 678.

<sup>44</sup> Office of the Commissioner, *Part I: The 1906 Food and Drugs Act and its enforcement U.S. Food and Drug Administration* (2019), <https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/part-i-1906-food-and-drugs-act-and-its-enforcement#:~:text=Since%201879%2C%20nearly%20100%20bills,pillar%20of%20the%20Progressive%20era.> (last visited Oct 15, 2023).

<sup>45</sup> *Id.*

<sup>46</sup> Office of the Commissioner, *Part II: 1938, Food, Drug, Cosmetic Act U.S. Food and Drug Administration* (2018), <https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/part-ii-1938-food-drug-cosmetic-act> (last visited Oct 15, 2023).

<sup>47</sup> *Id.*

<sup>48</sup> Office of the Commissioner, *Part III: Drugs and foods under the 1938 act and its amendments U.S. Food and Drug Administration* (2018), <https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/part-iii-drugs-and-foods-under-1938-act-and-its-amendments> (last visited Oct 16, 2023).

Currently, the Federal Food, Drug, and Cosmetic Act<sup>49</sup> authorizes the EPA to set tolerances for pesticide residue limits.<sup>50</sup> If the residue is above the tolerated limit, the food is subject to seizure and triggers enforcement.<sup>51</sup> FFDCA states in relevant part:

Administrator may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.<sup>52</sup>

Tolerances must be determined as “safe,” meaning that there is a “reasonable certainty” that no harm will result from exposure over time, and one important consideration is the “special risks posed to infants and children.”<sup>53</sup> If there is no dietary risk under “reasonably foreseeable circumstances,” the EPA may grant an exemption to those pesticide residues.<sup>54</sup>

Challenges to current tolerances can be made by any person who files a petition that proposes the “issuance of a regulation establishing, modifying, or revoking a tolerance.”<sup>55</sup> The petition must assert a factual basis that establishes “reasonable grounds for the action sought” and show that they have a “substantial interest” in the tolerance or exemption.<sup>56</sup> Upon review of the petition and

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<sup>49</sup> 21 U.S.C. §301 et seq. (2002).

<sup>50</sup> *Summary of the Federal Food, Drug, and Cosmetic Act / US EPA*, <https://www.epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act> (last visited Oct 16, 2023).

<sup>51</sup> *Id.*

<sup>52</sup> 21 U.S.C. § 346a(b)(2)(A)(i).

<sup>53</sup> *Summary of the Federal Food, Drug, and Cosmetic Act / US EPA*, <https://www.epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act> (last visited Oct 16, 2023).

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

<sup>55</sup> 21 U.S.C. § 346a(d)(1). The EPA can further dictate requirements for what is included in the petition. *Id.* § 346a(d)(2)(B).

<sup>56</sup> “Evidence that a person has registered or has submitted an application for the registration of a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act will be regarded as evidence



determination that it meets the designated threshold, the EPA is subject to a notice requirement that requires publication of the petition within 30 days.<sup>57</sup>

The EPA only has three options once it considers the petition: issue a final regulation that establishes, denies, or revokes residue tolerance or exemption; issue a proposed regulation; or deny the petition.<sup>58</sup> Denial of the petition allows any person to file objections with the administrator.<sup>59</sup> If the case results in an actual controversy regarding the validity of the EPA's action in retaining tolerances or issues over filed objections to the EPA's denial of a properly filed petition, judicial action can be brought within 60 days by individuals adversely affected.<sup>60</sup>

The EPA is generally allowed to enforce pesticide use regulation through the Office of Pesticide Programs under the Federal Insecticide, Fungicide, and Rodenticide Act.<sup>61</sup> The EPA must register pesticides under FIFRA by showing that the use of the pesticide "will not cause unreasonable adverse effects on the environment."<sup>62</sup> "Unreasonable adverse effects on the environment" include human

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that the person has a substantial interest in a tolerance or exemption from the requirement of a tolerance for a pesticide chemical that consists in whole or in part of the pesticide." 40 C.F.R. § 180.32.

<sup>57</sup> 21 U.S.C. § 346a(d)(3). The published notice must include a description of the analytical methods available and measurement of residue available relating to the petition or include a statement on why the method is unnecessary.

<sup>58</sup> *Id.* § 346a(d)(4)(A).

<sup>59</sup> *Id.* § 346a(g)(2)(A).

<sup>60</sup> *Id.* § 346a(h)(1).

<sup>61</sup> 7 U.S.C. §136 et seq. (1996); *Summary of the Federal Insecticide, Fungicide, and Rodenticide Act / US EPA*, United States Environmental Protection Agency, <https://www.epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> (last visited Oct 17, 2023).

<sup>62</sup> *Id.*

dietary risks from pesticide residues on foods that are inconsistent with section 408 of the FFDCA.<sup>63</sup>

The Food Quality Protection Act (“FQPA”) amended FIFRA.<sup>64</sup> The FQPA focused on setting tolerances that would render a “reasonable certainty of no harm,” assess the harms to children and infants, and evaluate aggregate exposure from the pesticide under pesticide risk assessments.<sup>65</sup> One major factor of this law is the Registration Review Requirements for the EPA.<sup>66</sup> Under this program, pesticide registration would be completed every fifteen years to ensure it continues to meet FIFRA standards.<sup>67</sup>

“Registration” of pesticides permits the sale of the pesticides while asserting that such use will not cause harm to the environment or human health.<sup>68</sup> The EPA’s registration review process can be easily revisited prior to the fifteen-year deadline if there is an urgent environmental or human health risk that the EPA must

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<sup>63</sup> *Id.* Section 408 of the FFDCA is the particular section that authorizes the EPA to set tolerances and maximum residue limits for pesticide residues.

<sup>64</sup> Public Law 104-170 (1996); *Summary of the Federal Insecticide, Fungicide, and Rodenticide Act / US EPA*, United States Environmental Protection Agency, <https://www.epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> (last visited Oct 17, 2023); *Summary of the Food Quality Protection Act / US EPA*, United States Environmental Protection Agency, <https://www.epa.gov/laws-regulations/summary-food-quality-protection-act> (last visited Oct 18, 2023).

<sup>65</sup> *Summary of the Food Quality Protection Act / US EPA*, United States Environmental Protection Agency, <https://www.epa.gov/laws-regulations/summary-food-quality-protection-act> (last visited Oct 18, 2023).

<sup>66</sup> *Id.*

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

<sup>68</sup> To determine that pesticides have a “reasonable certainty of no harm,” the EPA considers, through scientific exposure, the toxicity of the pesticide and its break-down products, how much and how often it is applied, how much residue remains in or on foods, and all routes of exposure from the pesticide. Particular pesticides may even qualify for an exemption for a tolerance upon this review. *Setting tolerances for pesticide residues in foods / US EPA*, United States Environmental Protection Agency, <https://www.epa.gov/pesticide-tolerances/setting-tolerances-pesticide-residues-foods> (last visited Oct 19, 2023).

address.<sup>69</sup> The review process starts with a public docket with a Preliminary Work Plan (PWP) that includes all the information the EPA has on the particular pesticide.<sup>70</sup> Next steps include arranging Focus Meetings for pesticides pending review to address uncertainties affecting the pesticide risk assessments.<sup>71</sup> The EPA gathers information by considering additional data collected since the last registration review, conducts its own studies as necessary, seeks public review on draft assessments,<sup>72</sup> and consults with other Regulatory partners and agencies if needed.<sup>73</sup>

Once the EPA comes to a decision, it must make available a proposed registration review decision available for public commentary for at least 60 days.<sup>74</sup> An Interim Decision can then be issued before a complete registration review explaining any proposed changes and responding to “significant comments.”<sup>75</sup> To

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<sup>69</sup> *Registration review process / US EPA*, United States Environmental Protection Agency, <https://www.epa.gov/pesticide-reevaluation/registration-review-process> (last visited Oct 18, 2023).

<sup>70</sup> *Id.* The PWP includes facts about the pesticide and its use, anticipated risks, and what data the EPA still needs, and the EPA must provide an estimated timeline for review. All information is opened for public comment for 60 days once notice is announced in the Federal Register. The EPA must further announce when a pesticide is no longer under registration review.

<sup>71</sup> *Id.* Such steps are used to narrow the EPA’s review focus to particulars that raise legitimate public concerns.

<sup>72</sup> The notification for public commentary is similar to that of a PWP. The notice will be announced in the Federal Register and will be open for public comment for 60 days. *Id.*

<sup>73</sup> *Registration review process / US EP; Setting tolerances for pesticide residues in foods / US EPA*, *supra* note 54.

<sup>74</sup> The notification for public commentary is similar to that of a PWP. The bases for the decision must also be posted for public review. Proposed Interim Decisions must include proposed findings regarding the FIFRA standard, modifications to pesticide use if risk is found, proposed label changes, and deadlines for completing required actions. *Registration review process / US EPA. supra* note 55.

<sup>75</sup> The EPA will file notice in the Federal Register. Further, if a registrant address newly identified risks or requirements, the EPA is authorized to take legal action. *Id.*

conclude the registration review process, the EPA must issue a final decision once all assessments and consultations are completed.<sup>76</sup>

The EPA first registered chlorpyrifos in 1965.<sup>77</sup> Originally, chlorpyrifos was used both for agriculture and non-agriculture purposes, including ant and roach baits, termiticides, fire ant mound treatments, and pesticides.<sup>78</sup> Because it was widely utilized throughout the United States, the EPA has reviewed the tolerances and application of chlorpyrifos several times.<sup>79</sup> The passage of the FQPA caused the EPA to review the tolerances of chlorpyrifos to ensure the safety of children.<sup>80</sup> In response, the EPA modified chlorpyrifos utilization to meet a new stringent standard.<sup>81</sup>

The registrant, Corteva, Inc. (formerly Dow Chemical Company),<sup>82</sup> went a step further in 2000 when it entered into another voluntary agreement that either eliminated or phased out all applications of chlorpyrifos that resulted in residential

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<sup>76</sup> The EPA is currently working to improve the ESA-FIFRA process. The registration process also considers Endocrine Disruptor Screening Program screening required under the FFDCFA. Similarly to the interim decision, if the registrant fails to act, the EPA may take legal action. *Id.*

<sup>77</sup> *Chlorpyrifos / US EPA*, United States Environmental Protection Agency, <https://www.epa.gov/ingredients-used-pesticide-products/chlorpyrifos> (last visited Oct 20, 2023).

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

<sup>79</sup> *Chlorpyrifos / US EPA; Reregistration Eligibility Decision (RED) for Chlorpyrifos*, U.S. Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances, Office of Pesticide Programs, U.S. Government Printing Office: Washington, DC: 2006, p 3.

<sup>80</sup> *Summary of the Food Quality Protection Act / US EPA*, surpa. note 41.

<sup>81</sup> *Chlorpyrifos / US EPA*, surpa. note 70; Registrants voluntarily entered into an agreement with the EPA to eliminate indoor uses in residential settings. Such uses included pet shampoos, paint additives, sprays, and pest dips. *Reregistration Eligibility Decision (RED) for Chlorpyrifos*, p. 3, surpa note 73.

<sup>82</sup> Ashley Dean and Dr. Erin Hodgson, *Corteva™ to End Chlorpyrifos Production: What Does this Mean for Iowa Farmers?* (Feb. 21, 2020), <https://crops.extension.iastate.edu/cropnews/2020/02/corteva%E2%84%A2-end-chlorpyrifos-production-what-does-mean-iowa-farmers>.

exposure.<sup>83</sup> Particular uses were allowed to remain but required new labels; some of these operations include indoor areas where children will not be exposed (different processing plants, ship holds, railroad boxcars), outdoor areas children will not be exposed (golf course turf, road medians), and other public health uses (fire ant mounds and mosquito control).<sup>84</sup> Due to these changes, the EPA began to express concerns that harm may be caused by mechanisms other than the established AChE (Acetylcholinesterase Inhibitors) inhibition.<sup>85</sup> For example, in 2002, the EPA provided risk mitigation factors for individuals exposed, specifically addressing occupational exposure.<sup>86</sup>

Nonetheless, in 2002, the EPA still found that residue chlorpyrifos food and water consumption exposure was safe, even for children and infants.<sup>87</sup> The EPA determined that dietary risks were “below the level of concern for the entire U.S. population.”<sup>88</sup> Further, the EPA determined that drinking water was not a concern

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<sup>83</sup> *Reregistration Eligibility Decision (RED) for Chlorpyrifos* at 3-6. The restrictions were separated by food uses and home uses. Chlorpyrifos pesticide uses were eliminated in apples and tomatoes, while other agricultural uses underwent a new classification system. Home and public uses for lawns or outdoor uses, termiticides, crack/crevice, or indoor uses were canceled, especially when exposure to children is high.

<sup>84</sup> *Id.* at 6.

<sup>85</sup> EPA, Office of Pesticide Programs, *Human Health Risk Assessment-Chlorpyrifos 4* (June 8, 2000), [https://archive.epa.gov/scipoly/sap/meetings/web/pdf/hed\\_ra.pdf](https://archive.epa.gov/scipoly/sap/meetings/web/pdf/hed_ra.pdf), p. 3 (“New data in the literature also gave rise to uncertainties such as...the suggestion that the inhibition of cholinesterase may not be essential for adverse effects on brain development...”).

<sup>86</sup> EPA, Office of Prevention, Pesticides, and Toxic Substances, EPA 738-R-01-007, *Interim Reregistration Eligibility Determination for Chlorpyrifos 2*, at 3 (Feb. 2002).

<sup>87</sup> *Id.* at 2.

<sup>88</sup> *Id.*

at that time, even with the new literature and changes.<sup>89</sup> In 2006, the EPA reiterated these findings in the chlorpyrifos registration renewal memo.<sup>90</sup>

The continued affirmation of these concerning standards resulted in two organizations taking advantage of the petition option under the FFDCA: Pesticide Action Network North America (“PANNA”) and the Natural Resources Defense Council, Inc. (“NRDC”).<sup>91</sup>

PANNA is focused on “tackling” the pesticide use that adversely affects health, especially for children.<sup>92</sup> The organization was built out of the 1982 “Green Revolution” that increased the world’s use of pesticides.<sup>93</sup> PANNA began to engage in initiatives in North America in the 1990s in connection to its original mission in the Global South.<sup>94</sup> PANNA is focused on bringing legal action and working on behalf of farmers, their families, rural communities, indigenous people, and children both nationally and internationally.<sup>95</sup>

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<sup>89</sup> EPA, Office of Prevention, Pesticides, and Toxic Substances, EPA 738-R-01-007, *surpa* note 86 at 2.

<sup>90</sup> EPA, Office of Prevention, Pesticides and Toxic Substances, *Memo to Jim Jones from Debra Edwards, Finalization of Interim Reregistration Eligibility Decisions and Interim Tolerance Reassessment and Risk Management Decisions for the Organophosphate Pesticides, and Completion of the Tolerance Reassessment and Reregistration Eligibility Process for the Organophosphate Pesticides 2*, at 2 (July 31, 2006).

<sup>91</sup> *League of United Latin Am. Citizens*, 996 F.3d at 677.

<sup>92</sup> *Mission, Vision & Values: Pesticide Action Network (PAN)*, Pesticide Action Network North America (2023), <https://www.panna.org/about/mission/> (last visited Oct 20, 2023).

<sup>93</sup> *Our Story: Pesticide action network (PAN)*, Pesticide Action Network North America (2023), <https://www.panna.org/about/our-story/> (last visited Oct 20, 2023).

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

<sup>95</sup> *Core constituencies: Pesticide action network (PAN)*, Pesticide Action Network North America (2023), <https://www.panna.org/about/our-commitment-to-core-constituencies/> (last visited Oct 20, 2023); *Our work: Pesticide action network (PAN)*, Pesticide Action Network North America (2023), <https://www.panna.org/campaign/our-work/> (last visited Oct 20, 2023).

NRDC was started on January 1, 1970, by John H. Adams and became the first national environmental advocacy group.<sup>96</sup> These litigators came together to focus on legal action and to protect the environment and human health.<sup>97</sup> The organization works on behalf of non-profits, communities, and individuals in litigation matters that affect issues of wildlife, environment, clean water, and overall human health in the communities.<sup>98</sup>

Both agencies share the same goal as the EPA maintain human health and safety.<sup>99</sup> Nonetheless, it was the EPA's Pesticide Office's failure to continuously ensure the protection of human health and safety under the current chlorpyrifos tolerances as required by the FFDCA that put these agencies at odds.<sup>100</sup>

### *B. Factual Background*

In July 2006, the EPA renewed and enforced its historical safety findings regarding chlorpyrifos tolerances, stating it met the safety standards of Section 408(b)(2) of the FFDCA.<sup>101</sup> With growing scientific evidence of increased harm to infants and children, this finding prompted PANNA and NRDC to file an administrative petition with the EPA in September 2007.<sup>102</sup> This petition, known as

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<sup>96</sup> *About NRDC*, <https://www.nrdc.org/about#history> (last visited Oct 20, 2023).

<sup>97</sup> *Id.*

<sup>98</sup> *Litigation*, <https://www.nrdc.org/about/litigation> (last visited Dec 5, 2023).

<sup>99</sup> *About NRDC*, <https://www.nrdc.org/about#history> (last visited Oct 20, 2023); *Mission, Vision & Values: Pesticide Action Network (PAN)*, Pesticide Action Network North America (2023), <https://www.panna.org/about/mission/> (last visited Oct 20, 2023); *Our Mission and What We Do*, U.S. Environmental Protection Agency, <https://www.epa.gov/aboutepa/our-mission-and-what-we-do>, (last visited Sep. 24, 2023).

<sup>100</sup> *See generally League of United Latin Am. Citizens*, 996 F.3d.

<sup>101</sup> *Id.* at 681.

<sup>102</sup> *Id.* at 682.

the 2007 Petition, requested the EPA to revoke all chlorpyrifos tolerances under the FFDCFA and cancel all FIFRA registrations for chlorpyrifos.<sup>103</sup>

In support of their petition, PANNA and NRDC cited experiments on live mice and rats exposed in utero to levels below the current tolerance, which resulted in AChE inhibition.<sup>104</sup> The organizations also referred to an epidemiological study known as the “Columbia study,” which tracked pregnant women and their children, collecting data on maternal organophosphate (chlorpyrifos) exposure.<sup>105</sup> Both studies concluded that prenatal chlorpyrifos exposure correlated with declined neurological effects and cognitive impairments in early childhood, particularly in males.<sup>106</sup> These findings were further substantiated by additional studies, including the “Mount Sinai Study” and the “CHAMACOS Study,” which collaborated with the Columbia “Human Cohort Study.”<sup>107</sup>

In August 2008, the same year as the 2007 Petition was reviewed, the EPA published a Science Issue Paper that reviewed the aforementioned scientific studies.<sup>108</sup> In this paper, the EPA initially concluded that “chlorpyrifos likely played a role” in the observed low birth rates and delays in infant and childhood mental development.<sup>109</sup> However, the EPA later dismissed these findings by suggesting an alternative “mechanism of harm” that did not warrant a comprehensive

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<sup>103</sup> *League of United Latin Am. Citizens*, 996 F.3d. at 682.

<sup>104</sup> *Id.*

<sup>105</sup> *Id.*

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

<sup>107</sup> *League of United Latin Am. Citizens*, 996 F.3d at 682.

<sup>108</sup> See generally Health Effects Division, Office of Pesticide Programs, EPA, *Science Issue Paper: Chlorpyrifos Hazard and Dose Response Characterization 52* (Aug. 21, 2008).

<sup>109</sup> *Id.* at 40–41 & fig.5.



characterization or risk assessment, preventing them from making updates to the existing chlorpyrifos risk assessment.<sup>110</sup>

The following month, the EPA convened its Scientific Advisory Panel (SAP) to review its findings.<sup>111</sup> SAP concurred that “chlorpyrifos likely played a role” in the neurological defects found in the studies, yet noted that these results could not be solely attributed to chlorpyrifos exposure.<sup>112</sup> While the Columbia Study was acknowledged as having potential utility for revising chlorpyrifos's risk assessment, it was deemed insufficient to deviate from the current regulatory standard.<sup>113</sup>

In 2011, the EPA had not yet decided on the 2007 petition but instead released a Preliminary Human Health Risk Assessment.<sup>114</sup> This assessment reaffirmed the findings of the 2008 study and SAP analysis and viewed the Columbia Study favorably.<sup>115</sup> In this preliminary assessment, the EPA concluded that the “ongoing” analysis of “neurological toxicity” resulting from prenatal and postnatal exposure would continue to shape and alter the current “point of departure,” which is currently set at 10% AChE.<sup>116</sup>

In 2012, the EPA had still not responded to the 2007 Petition.<sup>117</sup> In April of that year, the EPA reconvened the Scientific Advisory Panel (SAP), which reported

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<sup>110</sup> Health Effects Division, Office of Pesticide Programs, EPA, *surpa* note 108 at 6.

<sup>111</sup> *League of United Latin Am. Citizens*, 996 F.3d at 683.

<sup>112</sup> *SAP Minutes No. 2008-04, A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: The Agency's Evaluation of the Toxicity Profile of Chlorpyrifos 13*, at 37, 43-44 (Sept. 16–18, 2008).

<sup>113</sup> *League of United Latin Am. Citizens*, 996 F.3d at 683.

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

<sup>115</sup> *Memo from Danette Drew et al. to Tom Myers re: Chlorpyrifos: Preliminary Human Health Risk Assessment for Registration Review*, EPA at 27-8 (June 30, 2011).

<sup>116</sup> *Id.* at 42-3.

<sup>117</sup> *League of United Latin Am. Citizens*, 996 F.3d at 684.

an increased certainty that AChE data might not be the most informative for assessing the neurological development risks associated with chlorpyrifos.<sup>118</sup> There was mounting evidence suggesting a correlation at levels lower than the currently tolerated AChE levels.<sup>119</sup>

The 2012 SAP reiterated the conclusions of the EPA's previous research and SAP findings from 2008, stating that “chlorpyrifos likely played a role” in the neurological deficiencies observed in children.<sup>120</sup> Notwithstanding the growing scientific support for the connection between chlorpyrifos and neurological development issues in infants and children, the EPA continued to delay taking final action on the 2007 Petition.<sup>121</sup>

In defiance of the EPA's claim of having a “firm date” to address the 2007 Petition in February 2014, as stated in a mandamus proceeding, the agency still failed to take final action.<sup>122</sup> Instead, in December 2014, the EPA published a Revised Human Health Risk Assessment, which expressed even greater certainty that chlorpyrifos caused neurological defects through a mechanism other than AChE inhibition.<sup>123</sup> In this assessment, the EPA concluded that the harm observed was below the established point of departure related to AChE inhibition and

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<sup>118</sup> *SAP Minutes No. 2012-04, A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding Chlorpyrifos Health Effects*, at 53 (Apr. 10–12, 2012).

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

<sup>120</sup> *Id.* at 18.

<sup>121</sup> *League of United Latin Am. Citizens*, 996 F.3d at 685.

<sup>122</sup> *Id.*

<sup>123</sup> *Id.*

proposed a new method for determining this point. The EPA still did not act on the 2007 Petition.<sup>124</sup>

In November 2015, the EPA went a step further by publishing a Notice of Proposed Rulemaking in the Federal Register, proposing revoking all tolerances for insecticide chlorpyrifos residues.<sup>125</sup> The EPA explained that it could not currently determine the safety of aggregate exposure to chlorpyrifos residues, especially when combining exposures from food, residential sources, and estimated exposure from drinking water.<sup>126</sup> While the EPA acknowledged uncertainties regarding actual exposure levels experienced by mothers and infants in reported studies, measured exposures were likely low enough that the adverse effects were unlikely to result from AChE inhibition.<sup>127</sup>

In April 2016, the EPA convened another SAP to conduct a peer review of its 2014 Revised Human Health Risk Assessment.<sup>128</sup> The SAP concurred that there was evidence suggesting adverse health outcomes correlated with chlorpyrifos exposure levels below the current AChE inhibition point of departure but found an issue with the EPA's calculation for point of departure calculation.<sup>129</sup> The 2016 SAP recommended that the new measure should be based on the “determination and

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<sup>124</sup> *League of United Latin Am. Citizens*, 996 F.3d at 685.

<sup>125</sup> *Id.*

<sup>126</sup> *Chlorpyrifos: Tolerance Revocations*, 80 *Fed. Reg.* at 69,080, 69,081 (Nov. 6, 2015).

<sup>127</sup> *Id.* at 69,093.

<sup>128</sup> *League of United Latin Am. Citizens*, 996 F.3d at 686.

<sup>129</sup> *SAP Minutes No. 2016-01, A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: Chlorpyrifos: Analysis of Biomonitoring Data*, at 25 (Apr. 19–21, 2016).

characterization of time-weighted average blood concentrations for different exposure scenarios.”<sup>130</sup>

As a result of this recommendation, the EPA made an additional revision to its Human Health Risk Assessment in November 2016, the most recent assessment of chlorpyrifos.<sup>131</sup> This assessment acknowledged that the absence of established mechanisms to explain the neurological defects from chlorpyrifos exposure did not undermine the persistent scientific evidence supporting the relationship.<sup>132</sup> The EPA concluded that to protect against AChE inhibition and negative effects occurring at lower doses, a new approach needed to be established.<sup>133</sup>

Following the 2016 SAP's suggestion, the EPA began using the Physiologically Based Pharmacokinetic (PBPK) model developed by a chlorpyrifos registrant to estimate blood concentrations.<sup>134</sup> Using this measure, the EPA determined that the current chlorpyrifos tolerances were unsafe, even from food alone, and published these findings in a Notice of Data Availability in the Federal Register.<sup>135</sup>

The EPA had planned to proceed with its proposal to revoke all chlorpyrifos tolerances, citing the absence of a currently identified set of “currently registered uses that meet FFDCA safety standards” because the tolerances were limited to

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<sup>130</sup> *SAP Minutes No. 2016-01*, *supra* note 129 at 70.

<sup>131</sup> *League of United Latin Am. Citizens*, 996 F.3d at 687.

<sup>132</sup> *Memo from Wade Britton to Dana Friedman re: Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review*, EPA, at 12 (Nov. 3, 2016).

<sup>133</sup> *Id.* at 13.

<sup>134</sup> *Id.* at 14.

<sup>135</sup> *Chlorpyrifos: Tolerance Revocations; Notice of Data Availability and Request for Comment*, *supra* note 126 at 81,050.

some foods alone. When combined with exposure to drinking water, it did not meet the safety standard.<sup>136</sup>

Upon a court-mandated deadline, the EPA finally issued a ruling on the 2007 Petition in April 2017, which resulted in the denial of the 2007 Petition.<sup>137</sup> The EPA justified this denial by citing the court order and stating that in spite of years of studies, the issue of neurodevelopmental effects from chlorpyrifos exposure remained “unresolved.”<sup>138</sup>

The EPA's denial of the 2007 Petition prompted objections from PANNA, NRDC, and others, who also sought relief from the United States Court of Appeals for the Ninth Circuit.<sup>139</sup> The EPA's response to these objections did not occur until fourteen months later when the court heard oral arguments regarding the petition to review the 2017 Order.<sup>140</sup> In July 2019, the EPA denied the objections raised by PANNA, NRDC, and others, finalizing the required administrative denial for the original 2007 Petition in its final order, known as the “2019 Order.”<sup>141</sup>

### *C. Procedural Posture*

In April 2012, Petitioners PANNA and NRDC petitioned the United States Court of Appeals for the Ninth Circuit for a writ of mandamus because the EPA had not responded to their 2007 Petition.<sup>142</sup> During the mandamus proceeding, the EPA

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<sup>136</sup> *Chlorpyrifos; Tolerance Revocations; Notice of Data Availability and Request for Comment*, *supra* note 135.

<sup>137</sup> *League of United Latin Am. Citizens*, 996 F.3d at 669.

<sup>138</sup> *Id.*

<sup>139</sup> *Id.*

<sup>140</sup> *Id.* at 690.

<sup>141</sup> *Id.*

<sup>142</sup> *Id.* at 684.

claimed to have a set deadline in February 2014 to address the 2007 Petition.<sup>143</sup> This led to the court denying PANNA and NRDC's petition in July 2013.<sup>144</sup> Nonetheless, the EPA still did not address the 2007 Petition as it had represented to the court, resulting in PANNA and NRDC filing another writ of mandamus petition, which the court granted in August 2015.<sup>145</sup> The court found the EPA's lack of a ruling nine years later to be “too little too late” and egregious, ordering the EPA to issue a “full and final response” to the 2007 Petition by October 31, 2015.<sup>146</sup> Regardless of this order, the EPA failed to take any action by the court-set deadline.<sup>147</sup>

In 2014, the EPA published a proposed revocation rule, but it failed to fully address the 2007 petition, which consequently resulted in the court ordering the EPA to take “final action by December 30, 2016” on the proposed revocation rule and 2007 Petition.<sup>148</sup> In June 2016, the EPA informed the court that it could not meet the extended deadline and sought an additional six months in August of that year, which the court denied.<sup>149</sup> Instead, the court granted a “final” three-month extension.<sup>150</sup>

Upon the EPA's denial of the 2007 Petition in 2017 in accordance with the 2016 court order, PANNA, NRDC, and others objected to the EPA's denial and

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<sup>143</sup> *League of United Latin Am. Citizens*, 996 F.3d at 685.

<sup>144</sup> *Id.*

<sup>145</sup> *Id.*

<sup>146</sup> *Id.*

<sup>147</sup> *Id.*

<sup>148</sup> *Id.* at 686.

<sup>149</sup> *League of United Latin Am. Citizens*, 996 F.3d at 687.

<sup>150</sup> *Id.*

sought relief again from the United States Court of Appeals for the Ninth Circuit for a writ of mandamus.<sup>151</sup> The court denied the petition for mandamus relief, stating that the EPA had complied with the court order by issuing a decision, and any objections must first be completed through the administrative process.<sup>152</sup> Nevertheless, the EPA failed to rule on the objections until fourteen months later when the court heard oral arguments on the petitioner’s petition for review.<sup>153</sup>

A panel of the court found that it had jurisdiction over the EPA’s objections despite the EPA’s delay tactics.<sup>154</sup> The court also found that, based on the EPA’s failure to establish with “reasonable certainty” that chlorpyrifos tolerances are safe, it *must* be revoked.<sup>155</sup> The panel vacated the 2017 Order and remanded the case back to the EPA with a directive to revoke or modify all chlorpyrifos tolerances within 60 days.<sup>156</sup>

A majority of active non-recused judges voted to rehear the case en banc. The court issued a writ of mandamus requiring the EPA to rule on the 2017 objections within a 90-day period, which resulted in the EPA denying the 2017 objections and completing the entire administrative process for the 2007 Petition. Subsequently, the same Petitioners immediately petitioned the court again to review the EPA’s 2017 and 2019 Orders, and many states moved to intervene. The court sitting en

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<sup>151</sup> *League of United Latin Am. Citizens*, 996 F.3d at 689.

<sup>152</sup> *Id.*

<sup>153</sup> *Id.* at 690.

<sup>154</sup> *Id.*

<sup>155</sup> *Id.*

<sup>156</sup> *Id.* (emphasis added).

banc granted the states' motion, consolidated the cases, and established this case as a “comeback case.”<sup>157</sup>

#### *D. Issue/Holding*

In this case, the court addressed two central issues. First, whether the EPA had retained its current chlorpyrifos tolerance without determining with “reasonable certainty” that it was safe.<sup>158</sup> Second, whether the EPA's denial of the 2007 Petition was “arbitrary and capricious.”<sup>159</sup> These questions were considered under the Administrative Procedure Act (APA).<sup>160</sup> The APA grants the court the authority to “hold unlawful and set aside agency action, findings, and conclusions” if it is shown that such actions are capricious, arbitrary, an abuse of discretion, or unauthorized by law.<sup>161</sup> An action by an agency is considered “arbitrary and capricious” when the agency's explanation or decision contradicts the evidence before it.<sup>162</sup> Furthermore, under the APA, the court can compel the agency to take “unlawfully withheld or unreasonably delayed” action.<sup>163</sup>

This Panel of the Ninth Circuit Court of Appeals vacated the 2017 and 2019 Orders and remanded the case back to the EPA with specific instructions.<sup>164</sup> The court determined that the EPA had maintained chlorpyrifos tolerance without establishing its safety with “reasonable certainty,” the EPA's denial of the 2007

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<sup>157</sup> *League of United Latin Am. Citizens*, 996 F.3d at 690.

<sup>158</sup> *Id.* at 691.

<sup>159</sup> *Id.* at 695.

<sup>160</sup> *Id.* at 690.

<sup>161</sup> *Id.*

<sup>162</sup> *Id.*

<sup>163</sup> *League of United Latin Am. Citizens*, 996 F.3d at 690.

<sup>164</sup> *Id.* at 703-4.



Petition was deemed “arbitrary and capricious.”<sup>165</sup> In particular, the court instructed the EPA to (1) grant the 2007 Petition; (2) either revoke or modify the current chlorpyrifos tolerance, providing specific evidence to support any modification; and (3) modify or cancel FIFRA registrations for food use in a timely manner, in accordance with 21 U.S.C. section 346a(a)(1).<sup>166</sup>

### III. Rationale: *LEAGUE OF UNITED LATIN AM. CITIZENS V. REGAN*

Under the FFDCA, the EPA is allowed to maintain current chlorpyrifos or other pesticide tolerances for residues on or in foods only if the Administrator determines that the chemical tolerances are safe with “reasonable certainty,” particularly for infants and children.<sup>167</sup> The Administrator must also publish a specific determination regarding the safety of these tolerances.<sup>168</sup> In its analysis of the issues mentioned above, the court interpreted the statute by applying the ordinary public meaning at the time of enactment and using a liberal construction of the FFDCA, focusing on ensuring public health.<sup>169</sup>

The EPA argued that its duty of periodic registration review under FIFRA was distinct from its ongoing duty to ensure safety under the FFDCA, contending that it could leave current tolerances in place when a petition lacked “sufficient evidence” to warrant revoking or modifying the tolerance.<sup>170</sup> The court rejected the EPA’s argument for two reasons: (1) there remained a duty for the EPA to ensure

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<sup>165</sup> *League of United Latin Am. Citizens*, 996 F.3d at 695-6, 699-700.

<sup>166</sup> *Id.* at 703-4.

<sup>167</sup> *Id.* at 691.

<sup>168</sup> *Id.*

<sup>169</sup> *Id.*

<sup>170</sup> *Id.*

safety under FFDCA, especially if there was a notice of risk, and (2) there was adequate evidence, provided by the EPA itself, to establish that the evidence in the 2007 Petition was sufficient to act upon.<sup>171</sup>

*A. The EPA's Continuous Duty to Ensure Human Safety*

When the EPA denied the 2007 Petition, it did not make a determination regarding the safety of the tolerance levels and even concluded in its research that it could not do so with reasonable certainty.<sup>172</sup> This decision was a departure from Congress's intended focus in the FQPA, which prioritized human health and safety.<sup>173</sup> In its holding, the court emphasized the distinctions between the duties established in the FIFRA and FFDCA; under the FIFRA, the EPA has discretion to cancel the registration of a chemical pesticide for various reasons, but such discretion does not apply under the FFDCA.<sup>174</sup> The EPA's obligations under the FFDCA are mandatory and solely centered on the issue of safety.<sup>175</sup>

The court characterized the reading of the FFDCA requirement that “[t]he Administrator may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe” as straightforward.<sup>176</sup> The court's interpretation of this provision underscored the paramount priority of protecting human safety.<sup>177</sup> Tolerances could and should

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<sup>171</sup> *League of United Latin Am. Citizens*, 996 F.3d at 691.

<sup>172</sup> *Id.* at. 692.

<sup>173</sup> *Id.*

<sup>174</sup> *Id.* at. 692-3.

<sup>175</sup> *Id.* at 693.

<sup>176</sup> *Id.* at 693-4.

<sup>177</sup> *League of United Latin Am. Citizens*, 996 F.3d at 694.

only be maintained if the EPA determined them to be safe, especially for infants and children.<sup>178</sup> If not deemed safe, tolerances should be modified or revoked accordingly.<sup>179</sup> The majority found the EPA's interpretation of "only" inconsistent with the overarching goal of safety imposed by the FFDCA.<sup>180</sup>

The court also rejected the EPA's argument that the 2007 Petition failed to meet the necessary requirements by providing "reasonable grounds [or an assertion of fact to justify modification or revocation] for the action sought."<sup>181</sup> While the EPA has the authority to deny frivolous petitions, the court held that the 2007 Petition met the requirements, thus triggering the EPA's duty to ensure with "reasonable certainty" the safety of the current chlorpyrifos tolerance.<sup>182</sup> The EPA's subsequent actions further supported the court's interpretation. The EPA published a notice of filing of the 2007 Petition in accordance with FFDCA requirements and offered no explanation as to why the petition did not meet the necessary "reasonable grounds" for revocation.<sup>183</sup>

While the majority focused on the word "may" from the statutory language of the FFDCA, Judge Bybee's dissent focused on the interpretation of "only" by limiting the EPA to three scenarios to occur under its discretion.<sup>184</sup> Judge Bybee's interpretation would allow the EPA to exercise discretion if it determined the

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<sup>178</sup> 21 U.S.C. § 346a(b)(2)(C).

<sup>179</sup> *Id.*

<sup>180</sup> *League of United Latin Am. Citizens*, 996 F.3d at 693.

<sup>181</sup> *Id.* at. 694.

<sup>182</sup> *Id.*

<sup>183</sup> *Id.* at 694-5.

<sup>184</sup> *Id.* at. 707 (Bybee, J., dissenting).

tolerance levels as safe and it (1) “may” keep the current tolerances or (2) modify them, but if it could not determine the tolerance as safe, it (3) should modify or revoke the tolerance.<sup>185</sup>

Bybee's dissent focused on placing the burden of persuasion on the claimant who deems the current chemical pesticide tolerances unsafe.<sup>186</sup> Yet, the majority refuted this stance by finding it inconsistent with FQPA's health protection purpose, FFDCA's requirement of “reasonable certainty” that the tolerances were safe, and EPA's regulations that imposed the burden of persuasion on the party contending that the tolerances were safe.<sup>187</sup> Overall, the court held that the EPA's failure to make reasonably certain safety findings for the current chlorpyrifos tolerance was contrary to the FFDCA.<sup>188</sup>

*B. The EPA's Denial of the 2007 Petition was Arbitrary, and Capricious as Its Own Research Supported the Facts Alleged in the Petition*

The court emphasized that the EPA must provide a rational explanation with a clear connection between its choice and supporting facts when making decisions.<sup>189</sup> Nonetheless, in the denials of both the 2017 and 2019 Orders of the 2007 Petition, the EPA failed to do so.<sup>190</sup> These denials contradicted the EPA's own conclusions in the 2016 Revised Human Health Risk Assessment and studies

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<sup>185</sup> *League of United Latin Am. Citizens*, 996 F.3d at 707 (Bybee, J., dissenting).

<sup>186</sup> *Id.* at 713 (Bybee, J., dissenting).

<sup>187</sup> *Id.* at 695.

<sup>188</sup> *Id.*

<sup>189</sup> *Id.* at 696.

<sup>190</sup> *Id.*

indicating harm to infants and children.<sup>191</sup> The court further rejected the EPA's claim that it had discretionary authority to deny the 2007 Petition based on separate and unrelated FIFRA registration review requirements for additional studies in 2022.<sup>192</sup> The EPA could not consider the widespread usage and significance of chlorpyrifos in its denial, as pointed out by the court.<sup>193</sup> Furthermore, the EPA did not provide statutory support for its 2017 Order denying the petition in question.<sup>194</sup>

In addition, the court found the EPA's denial of the 2019 Order to be “arbitrary and capricious” because the EPA improperly placed the burden of persuasion on the petitioners.<sup>195</sup> For the reasons mentioned earlier, the publication of the petition in the Federal Register before the EPA determined that the burden was met, and scientific support from the Columbia and live rat studies supported the court's conclusion that the denials were “arbitrary and capricious.”<sup>196</sup>

The court held that the EPA had limited legal discretion, resulting in either a complete revocation or modification of chlorpyrifos tolerances with reasonably certain supporting evidence.<sup>197</sup> The court's decision to remand the case with specific instructions to adhere to its limited legal discretion was considered reasonable and did not raise due process concerns, as raised by the dissent.<sup>198</sup> Remanding the case

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<sup>191</sup> *League of United Latin Am. Citizens*, 996 F.3d at 696.

<sup>192</sup> *Id.* at 696-7.

<sup>193</sup> *Id.* at 696.

<sup>194</sup> *Id.* at 696-7.

<sup>195</sup> *Id.* at 697.

<sup>196</sup> *Id.*

<sup>197</sup> *League of United Latin Am. Citizens*, 996 F.3d at 701.

<sup>198</sup> *Id.* at 702.

with instructions after the EPA's fourteen-year delay demonstrated the court's tolerance while still requiring the EPA to finally and completely take action.<sup>199</sup>

Contrary to the majority, the dissent argued that the denial was entirely reasonable, given the court's Order and the EPA's inability to find reliable and replicable raw data to support the cited studies.<sup>200</sup> Judge Bybee took the opposite viewpoint, asserting that the EPA could use its discretion to deny the FFDCA petition because the tolerance level at issue would be subject to a “more up-to-date and methodical” FIFRA registration review.<sup>201</sup> According to the dissent, the court’s intervention in the current debate was improper, as the majority was “second-guessing” the agency's expertise in interpreting scientific studies.<sup>202</sup> Yet again, the majority held that it is not unilaterally ordering the EPA to revoke existing tolerances, and based on the existing evidence on record, the only reasonable action would be the issuance of a final regulation.<sup>203</sup> In conclusion, the court vacated both the 2017 and 2019 Orders.<sup>204</sup> The court further remanded the case with instructions for the EPA to grant the 2007 Petition, issue a final regulation to modify or cancel chlorpyrifos tolerances, and modify or cancel FIFRA registrations for food usage within sixty days.<sup>205</sup>

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<sup>199</sup> *League of United Latin Am. Citizens*, 996 F.3d. at 703.

<sup>200</sup> *Id.* at 721-2 (Bybee, J., dissenting).

<sup>201</sup> *Id.* at 723 (Bybee, J., dissenting).

<sup>202</sup> *Id.* at 724 (Bybee, J., dissenting).

<sup>203</sup> *Id.* at 702.

<sup>204</sup> *Id.* at 703-4.

<sup>205</sup> *League of United Latin Am. Citizens*, 996 F.3d. at 703-4.

#### IV. ANALYSIS

While there is value in Executive Agency autonomy and self-governance, administrative law must allow various actors, such as the courts, to assist in monitoring and preventing agency abuse, as seen in the *League of United Latin Am. Citizen*.<sup>206</sup> In the case of *League of United Latin Am. Citizen*, where the EPA failed to act in addressing the Chlorpyrifos Petition for over twelve years, such deference of duty can reasonably be considered agency abuse. For that reason, in particular, and after multiple opportunities to redress such issues, the Ninth Circuit Court of Appeals properly intervened to force agency action. Such intervention promotes agency accountability, especially for areas concerning health and safety.

While the case was pending in December 2020, the EPA published a Proposed Interim Registration Review Decision and convened another SAP to review the proposal to modify specific chlorpyrifos tolerances.<sup>207</sup> This fact, in turn, resulted in the court's enforcement of a valid response to the 2007 Petition.<sup>208</sup> Furthermore, during the pendency of this case, chlorpyrifos use was banned in both California and the European Union starting in February 2020.<sup>209</sup> Even Corteva, Inc. announced on February 6, 2020, that it planned to stop all chlorpyrifos production

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<sup>206</sup> Christopher J. Walker, *Constraining bureaucracy beyond judicial review*, 150 *Daedalus* 158–159 (2021).

<sup>207</sup> EPA, Office of Pesticide Programs, *Chlorpyrifos Proposed Interim Registration Review Decision Case Number 0100* (December 3, 2020).

<sup>208</sup> *League of United Latin Am. Citizens*, 996 F.3d. at 703.

<sup>209</sup> Press Release, Cal. Env't Prot. Agency & Cal. Dep't of Pesticide Regul., *Agreement Reached to End Sale of Chlorpyrifos in California by February 2020* (Oct. 9, 2019), <https://calepa.ca.gov/2019/10/09/press-release-agreement-reached-to-end-sale-of-chlorpyrifos-in-ca-by-feb-2020/>; Kelly N. Garson, *European Union to Ban Chlorpyrifos after January 31, 2020*, Bergeson & Campbell, P.C (Jan 3, 2020), <https://www.lawbc.com/european-union-to-ban-chlorpyrifos-after-january-31-2020/>.

by 2021.<sup>210</sup> Additionally, there has been an increase in toxic tort litigation within California state courts.<sup>211</sup> With such initiatives taken by citizens, particular states, countries, and even the registrant itself, it would make any reasonable person ponder why the courts avoided intervention for such a long period of time.

Under the APA, the courts are granted the power to “compel agency actions unlawfully withheld or unreasonably delayed.”<sup>212</sup> The courts, however, favor deferring to agency actions, as the agency holds expertise that the court does not possess.<sup>213</sup> Nonetheless, the legal community may be moving away from unfettered deference to agency decisions. Such critics of agency deference discuss even reviving the non-delegation doctrine.<sup>214</sup> The non-delegation doctrine would remove all agency deference as it prohibits Congress from delegating powers to executive controlled administrative agencies.<sup>215</sup> There is increasing concern that administrative

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<sup>210</sup> Ashley Dean and Dr. Erin Hodgson, *Corteva™ to End Chlorpyrifos Production: What Does this Mean for Iowa Farmers?*(Feb. 21, 2020).

<sup>211</sup> All the notable cases against Corteva, Inc. in California state courts highlighted the increased risk to children and infants. The two most notable cases include *Avila v. Corteva Inc.*, No. 20C-0311 (Cal. Super. Ct., October 27, 2020) and *Calderon de Cerda v. Corteva Inc.*, No. 20C-0250 (Cal. Super. Ct., September 16, 2020). In all of the cases, the plaintiffs alleged negligence, failure to warn, and design defects. The plaintiff further brought suit against the city they reside, the City of Avenal, based on negligence in providing drinking water free of chlorpyrifos residue. Brigit Rollins, *Pesticide Litigation: Chlorpyrifos Under Fire* (Nov. 5, 2020), <https://nationalaglawcenter.org/pesticide-litigation-chlorpyrifos-under-fire/>.

<sup>212</sup> 5 U.S.C. § 706(1).

<sup>213</sup> Michael Rappaport, *A Stronger Separation of Powers for Administrative Agencies*, The Regulatory Review (Dec. 18, 2019), <https://www.theregreview.org/2019/12/18/rappaport-stronger-separation-powers-administrative-agencies/>. Justice Bybee emphasized the need for deference to agency decisions based on its expertise. *League of United Latin Am. Citizens*, 996 F.3d. at 724 (Bybee, J., dissenting) (“Deference to an agency’s technical expertise and experience is particularly warranted with respect to questions involving ... scientific matters.”, citing *United States v. Alpine Land & Reservoir Co.*, 887 F.2d 207, 213 (9th Cir. 1989)).

<sup>214</sup> For a survey of such criticisms, see Christopher J. Walker, “Attacking Auer and Chevron Deference: A Literature Review,” *Georgetown Journal of Law and Public Policy* 103 (1) (2018).

<sup>215</sup> *Nondelegation doctrine*, Legal Information Institute, [https://www.law.cornell.edu/wex/nondelegation\\_doctrine#:~:text=The%20non%2Ddelegation%20doctrine%20stands,agencies%20or%20to%20private%20organizations.](https://www.law.cornell.edu/wex/nondelegation_doctrine#:~:text=The%20non%2Ddelegation%20doctrine%20stands,agencies%20or%20to%20private%20organizations.) (last visited Nov 6, 2023).



agencies, like the EPA, violate the Separation of Powers doctrine. Still, the benefits of agencies providing specialized expertise and low-cost decision-making that Congress cannot meet in our modern society may make such an adoption unrealistic.<sup>216</sup> Either way, it is doubtful that a blanket exclusion removing any and all delegation, such as the non-delegation doctrine, will be applied at this time.

Recently, the Supreme Court has attempted to limit court intervention in agency decisions by adopting the Major Questions Doctrine. In *Biden v. Nebraska*, the Supreme Court held that agencies are not delegated decision-making power for issues of “economic and political significance.”<sup>217</sup> Yet, the actions of the EPA would not meet this less-than-defined doctrine because Congress expressly allows them to approve, set, and remove chemical tolerances through FIFRA and FFDCA. The court must assess when the actions of the EPA align with the requisite criteria, allowing for the provision of judicial review.

The EPA’s deferral from acting on the 2007 Petition was so egregious that such agency abuse did not necessarily require courts to consider scientific research and evidence.<sup>218</sup> In cases like this one, deference to agency action should be extremely reduced or eliminated, which the court did here.<sup>219</sup> Although deference based on the safety of chlorpyrifos tolerances would typically be within the agency’s

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<sup>216</sup> Rappaport, *supra* note 211.

<sup>217</sup> *Biden v. Nebraska*, 600 US \_\_, 20 (2023) (citing *West Virginia*, 597 U. S., at \_\_\_ (slip op., at 17) (quoting *Brown & Williamson*, 529 U. S., at 160).

<sup>218</sup> *League of United Latin Am. Citizens*, 996 F.3d. at 701, 703. The majority held that the actions of the EPA were egregious as all the evidence presented could only reach the reasonable conclusion that the current tolerances of chlorpyrifos are unsafe.

<sup>219</sup> Rappaport, *supra* note 211.

wheelhouse and expertise, the court's independent involvement is necessary to stop such abuses like the thirteen-year deferral period seen here.<sup>220</sup> There may even be a need to create more efficient means of court intervention that balances the independence of administrative agencies while addressing abuses before they reach this level.

Justice Bybee is a proponent of agency deference, as seen in his dissent as he favors EPA fact-finding.<sup>221</sup> Yet, even he could not deny that the EPA dithered too long before addressing the 2007 Petition.<sup>222</sup> Although Justice Bybee reframed the issue as the EPA needed to answer the sufficiency of scientific evidence to modify the current chlorpyrifos tolerances, the overall issue of the “unlawful withholding” of the EPA’s action addressing the Petition would still require reasonable court intervention.<sup>223</sup> Failure to address Petitions deemed to pass muster, exemplified when the EPA published the 2007 Petition within the thirty-day required period, does not require deferring to Agency decisions.<sup>224</sup> The lack of agency decision is at issue, thus requiring a de novo-like review of the agency’s action based on the factual record provided.

Court intervention in such abuses can become extremely important as an agency’s inaction prohibits redress to health-related harms that could have been

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<sup>220</sup> Walker, *supra* note 204 at 156.

<sup>221</sup> *League of United Latin Am. Citizens*, 996 F.3d. at 705 (Bybee, J., dissenting).

<sup>222</sup> *Id.* at 704 (Bybee, J., dissenting).

<sup>223</sup> 5 U.S.C. § 706(1); *League of United Latin Am. Citizens*, 996 F.3d. at 705 (Bybee, J., dissenting).

<sup>224</sup> *League of United Latin Am. Citizens*, 996 F.3d at 694-5.

avoided if actions were taken within a reasonable time.<sup>225</sup> The requirement for the EPA to “revoke or modify” all chlorpyrifos tolerances removed the burden on public health and, predominately, the health of farmworkers and their families.<sup>226</sup> The court’s ruling opens the door to require the EPA to address additional petitions on other harmful pesticides and prompts them to revisit their current chemical tolerances.<sup>227</sup> The court in *League of United Latin Am. Citizens* established a willingness to intervene if the EPA fails to act with reasonable evidence available. As more tolerances come under review, it is a waiting game on whether the EPA’s actions or failure to act will be egregious enough to address.

Furthermore, the court’s decision in *League of United Latin Am. Citizens* prompted members of Congress to propose legislation to update and strengthen FIFRA by banning more dangerous pesticides.<sup>228</sup> Section 3(b)(3)(B) of the proposed *Protect America’s Children from Toxic Pesticides Act of 2023* (PACTPA) states:

(B) FAILURE TO REVIEW PETITION.—If the Administrator fails make a finding on a petition by the date required under subparagraph (A), the active ingredient or pesticide product that is the subject of the petition shall be deemed to be a dangerous pesticide.<sup>229</sup>

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<sup>225</sup> *League of United Latin Am. Citizens*, 996 F.3d at 703 (“The EPA has had nearly 14 years to publish a legally sufficient response to the 2007 Petition. During that time, the EPA’s egregious delay exposed a generation of American children to unsafe levels of chlorpyrifos.”).

<sup>226</sup> Reynard Loki, *Pesticide Linked To Brain Damage In Children May Finally Be Banned*, The Trial Lawyer (2021), <https://thetriallawyeromagazine.com/2021/07/pesticide-linked-to-brain-damage-in-children-may-finally-be-banned/>.

<sup>227</sup> *Id.*

<sup>228</sup> *Booker announces legislation aimed at banning dangerous pesticides from our agriculture system: U.S. senator Cory Booker of New Jersey*, Cory Booker (Nov. 23, 2021), <https://www.booker.senate.gov/news/press/booker-announces-legislation-aimed-at-banning-dangerous-pesticides-from-our-agriculture-system>.

<sup>229</sup> *Protect America’s Children from Toxic Pesticides Act of 2023*, S. \_\_\_\_, 118<sup>th</sup> Congress, §3(b)(3)(B).

The additional provision would avoid later court intervention based on the EPA's failure to act under concerns of registration under FIFRA. If the EPA fails to address any petition within 90 days under section 3(b)(3)(A), the chemical or pesticide in general will automatically be deemed dangerous and be addressed appropriately.<sup>230</sup> Section 4 of the proposed bill would also require an emergency review of registered pesticides banned in other countries, requiring a review of all pesticides currently banned in the EU and beyond.<sup>231</sup>

The action, like PACTPA, is a step towards improving administrative agency's self-governance. Once the desired level of self-governance is attained, court intervention will be unnecessary, except in cases of egregious offenses, like significant delays. Eventually, agencies will be able to govern effectively enough to no longer require court intervention except to adjust behaviors to improve the agency's actions.<sup>232</sup> Maybe one day, Justice Bybee's conclusion that the Majority's intervention and requirement that the EPA responds to the 2007 Petition and 2019 Order within sixty days were in error and an overstep as more agencies are required to act independently.<sup>233</sup> Judicial intervention is the most suitable check on agency actions in order to avoid any internal abuses if the legislature allows the agency to remain unchecked.

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<sup>230</sup> *Protect America's Children from Toxic Pesticides Act of 2023*, S. \_\_\_\_, 118<sup>th</sup> Congress, §3(b)(3)(A).

<sup>231</sup> *Id.* §4.

<sup>232</sup> Walker, *supra* note 204 at 156.

<sup>233</sup> *League of United Latin Am. Citizens*, 996 F.3d. at 727-8 (Bybee, J., dissenting).

## V. CONCLUSION

The Ninth Circuit of Appeals' holding in *League of United Latin Am. Citizens v. Regan* was a proper use of judicial intervention in order to address and correct procedural agency abuse. The EPA's inaction to address the 2007 Petition for thirteen years was beyond egregious, and any judicial intervention was not an overstep over executive decision-making. There is value in an agency's self-governance, especially involving scientific or research-based decisions. However, if agencies prove to be ineffective, the judiciary has every right to intervene without any deference to agency decisions. Until legislative action is taken to force agencies to act on areas of great concern, like human health and safety, it is left to the judiciary to force their hand.

Progress, such as the proposed PACTPA legislative, can gain traction based on the actions of the Ninth Circuit Court of Appeals. The passing of such legislation would necessitate a more attentive eye from the EPA and other administrative agencies to ensure compliance with the power it grants. The passage of PACTPA will require the EPA to review chemical registrants with greater scrutiny and within a "reasonable time" to avoid cases as aforementioned. A willingness for both judicial and congressional oversight will pave the way for a brighter future of self-governance from the EPA without jeopardizing citizen health.