LULAC v. Regan—Ninth Circuit directs EPA, after 14 years of litigation, to publish a "legally sufficient final response" under Federal Food, Drug and Cosmetic Act either ending the use of the pesticide chlorpyrifos or making requisite safety findings

Chlorpyrifos is a widely used pesticide. However, studies have indicated that prenatal human exposure may result in early childhood cognitive impairment. As a pesticide, the Environmental Protection Agency is charged under FFDCA, as well as under the Federal Insecticide, Fungicide and Rodenticide Act, to regulate its use. Only the former is directly relevant here. FFDCA provides, in part, 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. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe." 21 U.S.C. § 346a(b)(2)(A)(i). In 2007, two environmental groups filed a petition before EPA challenging a 2006 chlorpyrifos safety finding, which allowed distribution of foods containing the chemical so long as the residue in the particular food did not exceed a tolerance level specified as safe, and "asking the EPA to prohibit foods that contain any residue of the insecticide chlorpyrifos." Over the next decade, EPA's delay in resolving the petition prompted substantial litigation before the Ninth Circuit. *PANNA v. EPA (In re PANNA)*, 532 F. App'x 649 (9th Cir. 2013); *PANNA v. EPA (In re PANNA)*, 798 F.3d 809, 811 (9th Cir. 2015); *PANNA v. EPA (In re PANNA)*, 808 F.3d 402 (9th Cir. 2015); *NRDC v. EPA (In re PANNA)*, 840 F.3d 1014 (9th Cir. 2016); *LULAC v. Wheeler*, 922 F.3d 443 (9th Cir. 2019) (en banc); *LULAC v. Wheeler*, 940 F.3d 1126 (9th Cir. 2019) (en banc). In response to the first 2019 en banc decision, EPA finally issued a decision finding that "'despite several years of study, the science addressing neurodevelopmental effects remains unresolved'" and that, consequently, "'further evaluation of the science during the remaining time for completion of [FIFRA] registration review is warranted to achieve greater certainty as to whether the potential exists for adverse neurodevelopmental effects to occur from current human exposures to chlorpyrifos.'" The agency then denied the petition (as opposed to continuing analysis) "'only because [the Court of Appeals] had ordered it to make a decision.'"

A majority of the comeback-case three-judge panel, at last able to address the petition's merits, held that EPA's decision violated FFDCA. *LULAC v. Regan*, Nos. 19-71979 & 19-71982, 2021 WL 1682251 (9th Cir. Apr. 29, 2021). Although the majority and dissenting opinions are extensive, the nub of their disagreement lay in competing interpretations of § 346a(b)(2)(A)(i). In the majority's view,

> [t]he FFDCA [in § 346a(b)(2)(A)(i)] imposes a continuous duty upon the EPA by permitting it to "leave in effect" a tolerance "only" if it finds it is safe. To "leave" something in effect means "to cause or allow [it] to be or remain in a specified condition." Denying the 2007 Petition caused the chlorpyrifos tolerances to remain in place; as the EPA itself wrote in its brief, it "le[ft] the existing tolerances in place pending ... registration review." But in so doing, the EPA did not "determine[] that the tolerance is safe." Rather, the EPA's own pronouncements show that it has already concluded that it can no longer be reasonably certain that chlorpyrifos is safe at current tolerances.

In the dissent's view,

> [t]he[] standards [in § 346a(b)(2)(A)(i)] are consistent with the presumption against the use of pesticides in food. *If* EPA determines a pesticide is safe, then EPA may establish a new tolerance or leave in place a tolerance previously established. However, *if* EPA determines a tolerance is not safe, *then* EPA *shall* modify or revoke the tolerance. Establishing or leaving a tolerance in place is not mandatory, even if EPA determines that a pesticide is safe; but if EPA determines a tolerance is not safe, it must modify or revoke the tolerance.

Consequently, as the majority explained, under the dissent's interpretation:

> [T]here are three possible scenarios, one in which the EPA "determines that a tolerance is safe," one in which the EPA "determines it is not safe," and one in which the EPA is unwilling or unable to make a safety determination at this time. In this latter, middle world, the Dissent continues, the statute is silent as to the EPA's obligations, leaving the EPA with the discretion to leave in effect a tolerance based on its *prior* safety finding (here, the 2006 safety finding).

The majority and the dissent also disagreed over who bore the burden concerning whether an existing tolerance level was unsafe. The majority argued that once EPA, notwithstanding its "gatekeeping authority" to decline to publish notice of "a petition that fails even to 'furnish reasonable grounds for the action sought[,]'" actually publishes the notice, the agency's "duty to ensure a reasonable certainty of no harm" is triggered. The dissent, in contrast, contended that "[u]nder the FFDCA, EPA must modify or revoke the tolerance if it is 'not safe.' The majority would require EPA to prove that the tolerance 'safe.'" That, it reasoned, is "not how administrative law usually works."

As to remedy, the court directed EPA "to publish a legally sufficient final response to the 2007 Petition within 60 days of the issuance of the mandate. That response must be a final regulation that either revokes all chlorpyrifos tolerances or modifies chlorpyrifos tolerances and makes the requisite safety findings based on aggregate exposure, including with respect to infants and children."

Decision link: https://cdn.ca9.uscourts.gov/datastore/opinions/2021/04/29/19-71979.pdf