The Food Quality Protection Act: Empirical Evidence of a Thirty-Year Failure to Protect the Nation's Children from Pesticide Residues and What to Do About It

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Abstract:

In 1996, amid a worldwide proliferation of pesticide use, Congress passed the Food Quality Protection Act in light of scientific reports that called attention to the dangers that pesticides pose to children. Experts hailed the FQPA as "one of the most significant environmental and public health bills passed in 20 years." This paper assesses the Environmental Protection Agency's track record in enforcing the FQPA to protect children and finds that the Act has fallen short of what Congress intended and what experts believed was possible. The paper lays out new empirical evidence to document the EPA's record in child-related safety decisions. After examining the EPA's three-decade track record, we suggest future actions to improve the Agency's current approach to setting pesticide limits on foods. We also offer concrete suggestions for administrative actions to better protect children from pesticide exposures in food. This article intends to spur a critical shift in public and administrative policy and to serve as a clarion call to better align regulatory action with what Congress intended in passing the FQPA.

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INTRODUCTION

Congress passed the Food Quality Protection Act of 1996 (FQPA)[1] in light of scientific reports that called attention to the danger of pesticides for children[2] and amid a worldwide proliferation of pesticide use.[3] Experts hailed the FQPA as "one of the most significant environmental and public health bills passed in 20 years," which "indeed may distinguish itself in time as the most significant."[4] Almost 30 years later, there is enough evidence to assess whether the FQPA has addressed these dangers and lived up to expectations. The evidence shows that the Act has fallen short of what Congress intended and what experts believed was possible.

Legislators designed the FQPA to better protect children from pesticide residues on food.[5] For the first time, the FQPA required the United States Environmental Protection Agency (EPA) to consider children differently than adults when setting limits for pesticide residues on food. It also required the EPA to apply an additional safety factor in assessing the risk to children.[6] "Safety factors" are critical to the EPA's regulatory approach because applying these factors can often mean the "difference between the withdrawal of a pesticide from the market and its continued use."[7]

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1. Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489 (codified as amended in various sections of 7 U.S.C. and 21 U.S.C.). The FQPA amended the Federal Food, Drug, and Cosmetic Act ("FFDCA"), Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301-399).

2. NATIONAL RESEARCH COUNCIL, PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN 13 (1993) [hereinafter "NRC Report"].

3. Jorge Fernandez-Cornejo et al., *Pesticide Use in U.S Agriculture: 21 Selected Crops, 1960-2008*, U.S. DEPT. OF AGRIC. ERS (May 2014). Scientists called for a need for immediate "precautionary action" as to pesticides. *See* ROBERT REPETTO & SANJAY S. BALIGA, WORLD RESOURCES INST., PESTICIDES AND THE IMMUNE SYSTEM: THE PUBLIC HEALTH RISKS 59, 63 (1996), https://www.wri.org/research/pesticides-and-immune-system [https://perma.cc/A9JS-Z25B].

4. Frank B. Cross, *The Consequences of Consensus: Dangerous Compromises of the Food Quality Protection Act,* 75 WASH. U. L.Q. 1155, 1155 (1997) (quoting Letter from Charles Benbrook, Former Dir., Nat'l Acad. of Sci. Agric. Bd., to Mike Thompson, Cal. State Senator (July 31, 1996)).

5. *See* H.R. REP. No. 104-669, pt. 2 (1996) [hereinafter "Commerce Committee Report"]; 118. H.R. REP. No. 104-669, pt. 1 (1996) [hereinafter "Agriculture Committee Report").

6. 21 U.S.C. § 346a(b)(2)(C) (1994 & Supp. III 1997). Congress also required the EPA to consider vulnerable subpopulations when setting maximum contaminant levels ("MCLs") under the Safe Drinking Water Act, 42 U.S.C. § 300g-1(b)(3)(C)(i)(V) (2013). For a discussion of the FQPA and its initial implementation, *see generally* Valerie Watnick, *Risk Assessment: Obfuscation of Policy Decisions in Pesticide Regulation and the EPA's Dismantling of the Food Quality Protection Act's Safeguards for Children*, 31 ARIZ. ST. L.J. 1315 (1999). *See also* Exec. Order No. 13045, Protection of Children from Environmental Health Risks and Safety Risks, 62 Fed. Reg. 19885, § 2-202 (a)-(b) (Apr. 23, 1997).

7. Nat. Res. Defense Council v. EPA, 658 F.3d 200, 209 (2d. Cir. 2011).

The post-FQPA period has arguably coincided with a reduction in the use of some of the most dangerous, persistent, and bio-accumulative pesticides[8] and a decrease in the use of a toxic class of pesticides known as organophosphates.[9] A 2017 United Nations Report, however, still identifies pesticides as an international "human rights concern" in that children and other vulnerable communities bear a disparate disease and environmental burden related to pesticide use.[10]

Since the FQPA's passage, childhood cancer rates,[11] which are correlated with certain pesticide exposures,[12] have concomitantly risen,[13] along with other potentially related ill health effects such as asthma[14] and attention deficit disorders.[15] In particular, pesticides can increase cancer risk by acting as endocrine-disrupting chemicals (EDCs), damaging DNA, and causing

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8. CONSUMER REPORTS FOOD SAFETY & SUSTAINABILITY CENTER, FROM CROP TO TABLE: PESTICIDE REPORT 15 (2015), https://advocacy.consumerreports.org/wp-content/uploads/2015/08/CR_FSASC_FromCroptoTablePesticides_Mar2015-4.pdf [https://perma.cc/A9W8-VQJT] [hereinafter"Consumer Report"].

9. Irva Hertz-Picciotto et al., *Organophosphate Exposures During Pregnancy and Child Neurodevelopment: Recommendations for EssentialPolicyReforms*,15 PLOSMED e1002671 (2018) ("After passage of the FQPA, OP pesticide use across all market sectors declined by over 70%, from 70 million pounds per year (lbs/yr) in 2000 to about 20 million lbs/yr in 2012 . . .").

10. Press Release, United Nations Off. of the High Comm'r for Hum. Rts., PesticidesAre "GlobalHumanRightsConcern",Say UN Experts Urging New Treaty (March 7, 2017), https://www.ohchr.org/en/press-releases/2017/03/pesticides-are-global-human-rights-concern-say-un-experts-urging-new-treaty [https://perma.cc/H2XK-N6JS] (discussing *Report of the Special Rapporteur on the Right to Food*, U.N. Doc. A/HRC/34/48 (Jan. 24,2017).

11. David A. Siegel et al., *Counts, Incidence Rates, and Trends of Pediatric Cancer in the United States, 2003-2019*, 115 NCI: J. NATI'L CANCER INST. 1337-54 (2023).

12. Anna Novoselov, *These Pesticides May Increase Cancer Risk in Children*, U. OF CAL. (Sept. 15, 2022), https://www.universityofcalifornia.edu/news/these-pesticides-may-increase-cancer-risk-children [https://perma.cc/997J-BHJE]; *see also* U.S. ENVIRONMENTAL PROTECTION AGENCY, AMERICA'S CHILDREN AND THE ENVIRONMENT 224 (3d ed., 2013), https://www.epa.gov/sites/default/files/2015-06/documents/ace3_2013.pdf [https://perma.cc/KK5T-X4YG] (noting an association between pesticides and leukemia in children). "Besides an increased risk of childhood cancers, such as leukemia and neuroblastoma (the most common brain cancer), the latest research shows that exposure to environmental chemicals contributes to the rise in childhood disorders such as autism and ADHD." Claire Gervais, *Should Parents be Concerned About Their Kids and Lawn Chemicals?* UW HEALTH (June 6, 2012), https://www.uwhealth.org/news/lawn-chemicals-and-kids-should-parents-be-concerned [https://perma.cc/KTX9-JLLV].

13. Siegel et al., *supra* note 11, at 1338-54.

14. James R. Roberts & Catherine J. Karr, Council on Env't Health, *Pesticide Exposure in Children*, 130 PEDIATRICS e1765 (2012).

15. Jianghong Liu & Erin Schelar, *Pesticide Exposure and Child Neurodevelopment: Summary and Implications*, 60 WORKPLACE HEALTH & SAFETY 235 (2012); Maryse F Bouchard et al., *Attention-Deficit/Hyperactivity Disorder and Urinary Metabolites of Organophosphate Pesticides in U.S. Children 8-15 Years*, 125 PEDIATRICS e1270 (2010).

inflammation.[16] Exposure to EDCs at a young age may also cause latent or even intergenerational effects.[17]

Against this backdrop, we examine the EPA's near three-decade track record in enforcing the FQPA to protect children. We document the EPA's child-related safety decisions for the first time and suggest future actions to improve how pesticide limits on foods are set. Our research shows that the EPA has failed to work in accord with the FQPA's protective mandates, that it has at times acted as an advocate for less strict pesticide regulation, and that the trends show continuing reduction in precautionary measures for children. This article explores the policies underlying these trends and suggests ways in which the FQPA could be used to better protect children from pesticide exposure.

Part I of this article examines the history, context, and intent behind the FQPA. Part II discusses the empirical data regarding the EPA's application of the law to protect children from pesticide residues on food. Part III explores why the EPA has not acted in accord with the FQPA's strict mandates. The section discusses court challenges to EPA actions under the FQPA, noting that courts have generally allowed the EPA to reduce protections for children. This section also discusses the EPA's failure to involve children's health experts in decision-making, as well as a lack of transparency and urgency in implementing the FQPA. Part IV intends to spur a shift in administrative and public policy by calling for increased public awareness training and greater transparency related to food use pesticide decisions affecting children. Finally, this section makes an important call for reform in how the EPA tracks and makes such decisions.

I. LEGISLATIVE AND SCIENTIFIC BACKGROUND

A. History and Intent of the FQPA

In 1993, a widely publicized, groundbreaking report by the National Research Council (NRC) found that the practice of treating children and adults

16. Aris Ismanto et al., *Endocrine Disrupting Chemicals (EDCs) in Environmental Matrices: Occurrence, Fate, Health Impact, Physio-Chemical and Bioremediation Technology*, 302 ENV'T POLLUTION 119061 (2022); Eva Rahman Kabir et al., *A Review on Endocrine Disruptors and Their Possible Impacts on Human Health*. 40 ENV'T. TOXICOLOGY & PHARMACOLOGY 241 (2015). Wissem Mnif et al., *Effect of Endocrine Disruptor Pesticides: A Review,* 8 INT'L J. ENV'T RSCH. & PUB. HEALTH 2265 (2011).

17. Pilar Zamora-León, *Are the Effects of DES Over? A Tragic Lesson from the Past*, 18 INT'L J. ENV'T. RSCH. & PUB. HEALTH 10309 (2021); Linda Titus et al., *Reproductive and Hormone-Related Outcomes in Women Whose Mothers Were Exposed in Utero to Diethylstilbestrol (DES): A Report from the US National Cancer Institute DES Third Generation Study*, 84 REPROD. TOXICOLOGY 32 (2019) (finding risk of menstrual irregularity, amenorrhea, preterm birth, and possibly risk of ectopic pregnancy in third generation after exposure to DES).

alike for purposes of setting legal limits on pesticide residues did not take children's special susceptibilities into account.[18] The NRC report noted that children are not as able to ward off the dangers of pesticide exposure due to their developing bodies and smaller physical stature[19] and pressured Congress to legislate to protect children.[20] The NRC report urged Congress to implement an additional tenfold margin of safety for pesticide tolerance setting where data are incomplete and where evidence of developmental toxicity exists. It also recommended "a presumption of greater toxicity to infants and children."[21] Lawmakers and scientists viewed the NRC report as a wake-up call to the growing body of evidence showing that children are more susceptible to pesticide exposure.[22] Congress passed the FQPA against this backdrop.[23]

B. Why Pesticides Are More Dangerous to Children

The NRC report found that pesticides generally present a greater short-term and long-term risk to children than to adults.[24] This is because children have higher metabolic rates,[25] tend to eat a less varied diet,[26] and consume more food and water per pound of body weight than adults.[27] Additionally, children are likely to have more hand-to-mouth contact, which increases their exposure to toxic substances.[28] Children also spend more time nearer to the ground than

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18. NRC Report, *supra* note 2. Congress had asked the National Academy of Sciences in 1988 to convene a committee within the NRC to study the scientific and policy issues around pesticide exposures and children. The resulting report took five years to develop, and the NRC released the long-sought after study in 1993. *See* Watnick, *supra* note 6, at 1320 n.38.

19. NRC Report, *supra* note 2, at 9, 61.

20. Thomas O. McGarity, *Politics by Other Means: Law, Science, and Policy in EPA's Implementation of the Food Quality Protection Act*, 53 ADMIN. L. REV. 103, 111-17 (2001) (discussing the steps leading up to the enactment of the FQPA); James Smart, *All the Stars in the Heavens Were in the Right Places: The Passage of the Food Quality Protection Act of 1996*, 17 STAN. ENV'T L.J. 273, 305-09 (1998) ("The National Academy of Sciences report on pesticides in the NRC Report, the *Les* [*v. Reilly*, 968 F.2d 985, 990 (9th Cir. 1992)] decision, and EPA's response to it created unprecedented pressure to reform the law on pesticide residues.").

21. NRC Report, *supra* note 2, at 9.

22. *No Action Taken on Pesticide Regulation*, *in* CQ ALMANAC 1993, at 229, 230 (Neil Skene ed., 1994).

23. NRC Report, *supra* note 2, at 4.

24. *See id.* at 105-10.

25. *Id.* at 38; *accord* Cynthia. F. Bearer, *Environmental Health Hazards: How Children Are Different from Adults*, *5* FUTURE CHILD 11, 15.

26. NRC Report, *supra* note 2, at 192.

27. *Id*.

28. Marissa Hauptman & Alan Woolf, *Childhood Ingestions of Environmental Toxins: What Are the Risks?* 46 PEDIATRIC ANNALS e466 (2017); U.S. GOV'T ACCOUNTABILITY OFF., GAO-13-254, ENVIRONMENTAL HEALTH: EPA HAS MADE SUBSTANTIAL PROGRESS BUT COULD IMPROVE

adults,[29] putting them closer to where toxic chemicals may be applied or settle.[30]

The NRC report also considered differences between rats (upon which studies are conducted) and human children, noting that maturation rates at the time of exposure affect toxicity.[31] The NRC report noted that these differences complicated interspecies comparison, as the toxicity data available at the time were insufficient for extrapolating to children.[32]

C. Registration and "Tolerance" Setting under FIFRA and FQPA

1. Registration and Re-Registration

Every pesticide must be registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)[33] before sale.[34] FIFRA allows the EPA to register a pesticide only if that pesticide will not cause unreasonable adverse effects on the environment.[35] The statute defines "unreasonable adverse effects on the environment" 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."[36] In other words, the EPA may use a cost-benefit analysis when deciding whether to register a pesticide for sale. Under FIFRA, registration must be based on up-to-date scientific information about potential harms to human health and the environment.[37] FIFRA thus requires the EPA to periodically re-

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PROCESSES FOR CONSIDERING CHILDREN'S HEALTH 1, 37 (2013), https://www.gao.gov/products/gao-13-254 [https://perma.cc/6555-UBR2] [hereinafter "GAO Report"].

29. Hauptman & Woolf, *supra* note 28, at 2-3; *see also* Philip J. Landrigan et al., *Children's Health and the Environment: Public Health Issues and Challenges for Risk Assessment,* 112 ENV'T HEALTH PERSPECTIVES 259 (2004).

30. Minnesota Dep't of Health, *Chemicals of Special Concern to Children's Health* (October 3, 2022), https://www.health.state.mn.us/communities/environment/childenvhealth/chemicals.html [https://perma.cc/T7BU-PTNX].

31. NRC Report, *supra* note 2 at 25, 29; *see also* Pallav Sengupta and & Rajdeb Banerjee, *Environmental Toxins: Alarming Impacts of Pesticides on Male Fertility*, 33 HUMAN & EXPERIMENTAL TOXICOLOGY 1017, at nn.28-29 (2013).

32. NRC Report, *supra* note 2, at 25-43.

33. 7 U.S.C. § 136 et seq.

34. 7 U.S.C. § 136a(c)(5)(C).

35. 7 U.S.C. § 136a(c)(5)(D); U.S. Env't Prot. Agency, *About Pesticide Registration* (Nov. 6, 2024), https://www.epa.gov/pesticide-registration/about-pesticide-registration [https://perma.cc/L53C-X7GC].

36. 7 U.S.C. § 136(bb).

37. 40 C.F.R. § 155.40(a). *See also* 16 U.S.C. § 1536(a)(2) (EPA must also determine that any proposed action will not likely harm the continued existence of a threatened or endangered species or destroy or adversely modify a critical habitat).

register all pesticides.[38] In this re-registration process, the EPA must consider whether new regulations, data requirements, or scientific information warrant a new risk assessment, risk-benefit analysis, or other review of the pesticide.[39]

2. Tolerance Setting

In addition to registration under FIFRA, the FQPA requires the EPA to set either a legal limit—known as a tolerance—for a pesticide residue or an exemption from a tolerance before a user may register a pesticide for a food use.[40] The EPA generally makes tolerance determinations through an informal notice and comment rulemaking process.[41] The agency publishes a summary of the registrant's petition within thirty days determining that the registrant has met the requirements for filing.[42] The EPA does not evaluate the sufficiency of the data provided before publishing the summary in the Federal Register.[43] The FQPA then permits the Administrator to either issue a final rule without further opportunity for comment[44] or issue a proposed rule with opportunity for notice and comment.[45]

In making these determinations, the FQPA requires the EPA to establish a "safe"[46] tolerance or an exemption from a tolerance for each pesticide for each individual type of food use. The FQPA specifically requires the EPA to set the tolerance to ensure "reasonable certainty" that no harm will result from aggregate exposure to a pesticide through residues on food and all other exposures for which there is reliable information,[47] including exposures from air, water, and

38. 7 U.S.C. § 136a(a); 40 C.F.R. § 155.50(a). In completing a re-registration, the EPA may consider the registration status for the pesticide; a list of relevant and up to date registrations and registrants, any Federal Register notices documenting actions, or pending tolerances; risk assessment documents; bibliographies "concerning current registrations"; data regarding any negative incidents; and any other information it deems relevant. *Id.; see* CTR. FOR FOOD SAFETY, EPA-HQ-OPP- 2013-0266-1274, SIMAZINE (EPA-HQ-OPP- 2013-0251-0146), AND PROPAZINE (EPAHQ-OPP-2013-0250-009), at 3 (Mar. 2, 2020), https://centerforfoodsafety.org/files/cfs-atrazine-pirrd-comments--3-2-20_57806.pdf [https://perma.cc/KY96-L373].

39. U.S. Env't Prot. Agency, *Registration Review Process* (Nov. 6, 2024), https://www.epa.gov/pesticide-reevaluation/registration-review-process [https://perma.cc/Z24G-C7G9]; 40 C.F.R. § 155.53(c).

40. 21 U.S.C. § 346a(a).

41. 21 U.S.C. § 346a(d).

42. 21 U.S.C. § 346a(d)(3).

43. U.S. Env't Prot. Agency, Notifying the Public about Pesticide Tolerances (Jan. 16, 2025), https://www.epa.gov/pesticide-tolerances/notifying-public-about-pesticide-tolerances [https://perma.cc/XT9S-CTNT].

44. 21 U.S.C. § 346a(d)(4).

45. 21 U.S.C. § 346a(d)(4); 21 U.S.C. § 346a(e).

46. 21 U.S.C. § 346a(b)(2)(A)(i).

47. 21 U.S.C. § 346a(b)(2)(A)(ii). *See also* 40 CFR § 180.7; 40 CFR § 152.50.

soil.[48]

Importantly, for the first time, the FQPA detailed specific factors the EPA must consider to account for children's special susceptibilities[49] when setting legal limits on the amount of pesticide residues allowable on food.[50] For example, Congress mandated that the EPA consider "dietary consumption patterns of consumers,"[51] available information concerning "aggregate exposure levels,"[52] and "common mechanisms" of toxicity between pesticides."[53] Aggregate and cumulative exposure factors are especially relevant to children because their less varied diets might mean more exposure to the same pesticide residues or to those with common mechanisms of toxicity.[54] Under the FQPA, the EPA must also consider whether a pesticide will affect children differently than adults[55] and whether the pesticide will affect the human endocrine system.[56] In furtherance of this mandate, the EPA created the Endocrine Disrupting Screening Program (EDSP).[57]

When setting tolerances, the EPA relies on data provided by the business entities that wish to market their pesticides. These entities are known in FQPA parlance as "registrants."[58] For pesticides for which the EPA can identify a

48. *See* 21 U.S.C. § 346a(b)(2)(A)(ii), (b)(2)(D)(vi). The SDWA regulates MCLs in the nation's drinking water, including pesticides. The EPA has established an MCL for the pesticide atrazine of three parts per billion. 56 Fed. Reg. 3594 (Jan. 30, 1991); *see also* 40 C.F.R. § 141.61(c).

49. 21 U.S.C. § 346a(b)(2)(C).

50. 21 U.S.C. § 346a(b)(2)(D). Past federal law did not consider tolerances for children but considered the effect a toxic chemical would have on an adult. In passing the FQPA, Congress responded in part to the NRC Report that found that children are not "little adults" and had special susceptibilities to toxic substances. *See* NRC Report, *supra* note 2, at 9.

51. 21 U.S.C. § 346a(b)(2)(D)(iv). The FQPA requires the Administrator to engage in surveys to determine dietary patterns. 21 U.S.C. § 346a(b)(2)(C)(ii)

52. 21 U.S.C. § 346a(b)(2)(D)(vi).

53. 21 U.S.C. § 346a(b)(2)(D)(v).

54. NRC Report, *supra* note 2, at 4; 21 U.S.C. § 346a(b)(2)(C)(D).

55. 21 U.S.C. § 346a(b)(2)(D)(vii), (b)(2)(D)(iv).

56. 21 U.S.C. § 346a(b)(2)(D)(viii), (b)(2)(A)(ii).

57. U.S. Env't Prot. Agency, *Endocrine Disruptor Screening Program Timeline* (Feb. 28, 2024), https://www.epa.gov/endocrine-disruption/endocrine-disruptor-screening-program-timeline [https://perma.cc/YQ8H-B956]. The SDWA also requires the EPA to consider endocrine effects of pesticides in the nation's drinking water. 42 U.S.C. § 300j-17. Under the SDWA "Estrogenic Substances Screening Program," the EPA can request additional testing if it believes a substantial population will be exposed to the substance. *Id.*

58. U.S. Env't Prot. Agency, *supra* note 57; *see also* NAT'L RSCH. COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS 126 (1983). "For example, EPA may establish a tolerance as part of a new use registration, such as when a pesticide manufacturer seeks approval for use of an existing pesticide on a different food crop. Similarly, EPA may amend a tolerance when a pesticide manufacturer completes studies that were not available at the time the existing tolerance was set. According to EPA officials, generally, in both of these instances, the

threshold effect, the agency determines a safe level of pesticide residue, known as the "no observed adverse effect level" or "NOAEL."[59] The agency then generally divides this number by ten to account for interspecies variability if the provided data are based on animal studies, then divides by ten again to account for intraspecies variability.[60] These uncertainty factors are necessary because humans may not be affected by a pesticide in the same way as nonhuman animals and not all humans will react similarly to the same exposures. This smaller, divided number becomes the reference dose (RfD) upon which the tolerance is set.[61] In this way, the EPA is said to, at the very least, set the tolerance at a level that is one hundred times safer than what the data suggest the safe exposure level to be.[62] Additionally, for every pesticide for which a threshold effect is identified, the EPA must consider the application of a third uncertainty factor or "margin of safety" that we call the "Child Safety Factor."[63]

For pesticides for which the EPA Administrator is not able to determine a safe exposure level or threshold effect—generally those involving cancer risks—the EPA is still required to set the tolerance so that it is "safe."[64] In these cases (where the EPA determines that a pesticide residue has a non-threshold effect), the FQPA allows the Administrator to consider the benefits of the substance and set the tolerance so that the yearly risks are limited to ten times the risks associated with a threshold risk pesticide and so that the lifetime risk is not more than twice the lifetime risk of pesticides with a threshold effect.[65]

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tolerance process would be initiated by a petition from the pesticide registrant." GAO Report, *supra* note 28, at 10-11. In establishing a tolerance, the EPA must engage in quantitative risk assessment involving four steps: toxicological hazard identification; determination of dose response, including the determination and application of safety factors; exposure pathways for humans; and an overall characterization of the risk. *See* Watnick, *supra* note 6, at 1332.

59. *See* William R. Reeves et al., *Assessing the Safety of Pesticides in Food: How Current Regulations Protect Human Health*, 10 ADVANCES IN NUTRITION 80 (2019).

60. *Id.* at 83 n.23.

61. *Id.* at 83.

62. *See* Olga V. Naidenko, *Application of the Food Quality Protection Act Children's Health Safety Factor in the U.S. EPA Pesticide Risk Assessments*, 19 ENV'T HEALTH, no. 16, at 2 (2020); U.S. Env't Prot. Agency, *Assessing Human Health Risk from Pesticides* (Feb. 20, 2024), https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides [https://perma.cc/3WSW-7S33]. *See* NAT'L RSCH COUNCIL, SCIENCE AND DECISIONS: ADVANCING RISK ASSESSMENT (2009).

63. 21 U.S.C. § 346a(b)(2)(C).

64. 21 U.S.C. § 346a(b)(2)(A)(i).

65. 21 U.S.C. *Id.* at § 346a(b)(2)(B)(iv).

1. Issues Relevant to Tolerance Setting

i. Tolerance Setting Methods

In toxicological tests conducted by registrants and submitted to the EPA, pesticides are generally tested on an individual basis. These results are submitted to the EPA to establish a threshold effect. In setting tolerances, the EPA considers "the toxicity of the pesticide and its breakdown products; how much pesticide is applied and how often; how much of the pesticide remains in or on food by the time the food is marketed and prepared; and all possible routes of exposure."[66] If a pesticide belongs to a broader class of similar chemicals, the EPA must consider the common mechanisms of toxicity of this class of chemicals and the cumulative exposures to the pesticide under consideration.[67] The sum of all exposures to pesticides in the class cannot exceed the RfD.[68] The EPA's tolerance-setting approach thus focuses on the consumer's aggregate exposure to one pesticide or one type of pesticide at a time.

In the real world, however, consumers are exposed to a wide range of pesticide residues.[69] Encountering pesticides within these mixtures may have different effects than encountering the same pesticides separately.[70] For example, different pesticides may have synergistic effects,[71] such that simultaneous exposure to two pesticides has a greater effect than each would have if encountered alone.

In addition to failing to account fully for the mix of pesticide residues that consumers encounter, the EPA uses an intraspecies factor of ten that treats all people identically. This one-size-fits-all intraspecies factor may not sufficiently account for the differing vulnerability of certain populations due to age, illness, or other conditions.[72]

Moreover, while testing is designed to find threshold levels of pesticide exposures, pesticides that act as endocrine disruptors may have significant endocrine effects even at minute levels of exposure.[73] Researchers have found

66. U.S. Env't Prot. Agency, *Setting Tolerances for Pesticide Residues in Foods* (Dec. 31, 2024).

67. 21 U.S.C. § 346a(b)(2)(D)(iv)(v).

68. Reeves et al., *supra* note 59, at 84.

69. Angelo Moretto, *Exposure to Multiple Chemicals: When and How to Assess the Risk from Pesticide Residues in Food*, 19 TRENDS IN FOOD SCI. & TECH. S56 (2008).

70. CONSUMER REPORTS, *supra* note 8, at 10.

71. *Id*.

72. NAT'L RSCH COUNCIL, SCIENCE AND DECISIONS, *supra* note 62, at 69.

73. NAT'L INST. OF ENV'T HEALTH SCI., ENDOCRINE DISRUPTORS AND YOUR HEALTH (2023), https://www.niehs.nih.gov/health/materials/endocrine_disruptors_508.pdf [https://perma.cc/BS2C-X7AR].

that endocrine effects may not follow traditional patterns where "the dose makes the poison." Rather, endocrine-disrupting chemicals may follow non-linear response curves, such that high-dosage animal testing cannot be used to extrapolate and show that a lower dose is safe.[74] In fact, for some endocrine-disrupting chemicals, scientists have observed a reverse bell curve, where effects at minute levels of exposure are more severe than those at higher exposures.[75] Setting tolerances based on the assumption that higher exposures result in greater impact and lower exposures are safe may thus fail to account for impacts at trace levels of exposure.[76]

ii. Data Input

The EPA's Office of Pesticide Programs (OPP) requires registrants to submit testing on acute, sub-chronic, and long-term effects of exposure to the pesticide for which the registrant seeks a tolerance.[77] The EPA promulgated these data requirements in 1984, prior to passage of the FQPA. But these tests do not consider—and EPA does not require them to consider— all potential endocrine or other toxic effects of pesticides.[78] To streamline pesticide registration and tolerance setting, the EPA has stated that "[i]t is important to only require data that *adequately* inform regulatory decision making and thereby avoid unnecessary use of time and resources, data generation costs, and animal testing."[79] This is the case even though, for example, commonly used agricultural pesticides in the United States have been linked to endocrine effects, including human infertility, impaired reproductive development, and abnormal hormone levels.[80]

In addition to relying on limited toxicology data, the EPA sometimes permits

74. Laura N. Vandenberg et al., *Hormones and Endocrine-Disrupting Chemicals: Low-Dose Effects and Nonmonotonic Dose Responses*, 14 ENDOCRINE REV. 378 (2012).

75. *Id.* at Figure 3.

76. Ismanto, *supra* note 16.

77. U.S. Env't Prot. Agency, *Data Requirements for Pesticide Registration* (Apr. 4, 2024) https://www.epa.gov/pesticide-registration/data-requirements-pesticide-registration [https://perma.cc/94WE-UKLP] (codified at 40 C.F.R. part 158). These data requirements were later amended with regard to antimicrobial pesticides. 40 C.F.R. part 158, subpart W.

78. *See, e.g.*, Reeves et al., *supra* note 59, at Table I; U.S. Env't Prot. Agency, *Data Requirements*, *supra* note 77. EPA has only required registrants to submit reproductive toxicity studies for about 20% of the food use pesticides currently in use. *See* Ken Cook, Alexis Temkin & Phillip Landrigan, *Protecting Children from the Risks of Pesticides*, KEN COOK IS HAVING ANOTHER EPISODE at 14:02 (July 30, 2024), https://podcasts.apple.com/us/podcast/ken-cook-is-having-another-episode/id1735379217?i=1000663779530 [https://perma.cc/3WS3-WNX6].

79. U.S. Env't Prot. Agency, *Data Requirements*, *supra* note 77 (emphasis added).

80. *See, e.g.*, CTRS. FOR DISEASE CONTROL & PREVENTION, ATRAZINE: RELEVANCE TO PUBLIC HEALTH, https://www.atsdr.cdc.gov/ToxProfiles/tp153-c2.pdf [https://perma.cc/R5XN-A26U].

registration of a pesticide when it lacks data about that pesticide. For example, the EPA may issue a conditional registration pending submission of additional data[81] or register and set a tolerance for the pesticide based on a "data call in."[82] This system, which allows later submission of data while a product continues to market, assumes that the pesticide is safe for use as intended and that it does not present unreasonable risks to people or the environment until proven otherwise.[83]

4. The 10X Child Safety Factor

To account for the differences between children and adults in setting pesticide tolerances, the FQPA added an additional "margin of safety" or Child Safety Factor.[84] Congress included the Child Safety Factor "to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children."[85] The FQPA thus requires the EPA to apply a tenfold (10X) Child Safety Factor as the default if data on the pesticide's effects on children are incomplete or if existing pre- or post-natal toxicological data shows adverse effects on children.[86] The Child Safety Factor is thus used to account for uncertainty about pesticides' impact on children. The

81. 7 U.S.C. § 136a(c)(7); U.S. Env't Prot. Agency, *Conditional Pesticide Registration* (Sept. 4, 2024), https://www.epa.gov/pesticide-registration/conditional-pesticide-registration [https://perma.cc/56NU-53XY]; 40 C.F.R. § 152.113.

82. U.S. Env't Prot. Agency, *Registration Review Process—Gathering Information: Data Call-In and Risk Assessments—Conduct New Assessments as Needed* (Nov. 6, 2024), https://www.epa.gov/pesticide-reevaluation/registration-review-process [https://perma.cc/Y3CH-QCZD].

83. U.S. regulation has long allowed the EPA to assume toxic chemicals are safe unless proven otherwise. Valerie J. Watnick, *The Lautenberg Chemical Safety Act of 2016: Cancer, Industry Pressure, and a Proactive Approach*, 43 HARV. ENV'T L. REV. 373, 380, 390 (2019). The Lautenberg Chemical Safety Act was the first U.S. toxic substances law to require that new non-pesticidal chemicals undergo safety testing before going to market. *Id.*; 15 U.S.C. §§ 2604(a)(3)(A), 2604(e)-(f). European law hews to a more protective approach in line with the precautionary principle. *See* COMM'N OF THE EUROPEAN COMMUNITIES, PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL CONCERNING THE PLACING OF PLANT PROTECTION PRODUCTS ON THE MARKET (July 12, 2006), https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2006:0388:FIN:EN:PDF [https://perma.cc/QE8V-527P] ("Regulation is to ensure a high level of protection of both human and animal health and the environment. Particular attention should be paid to the protection of vulnerable groups of the population, including pregnant women, infants and children. The precautionary principle should be applied and ensure that industry demonstrates that substances or products produced or placed on the market do not adversely affect human health or the environment.").

84. 21 U.S.C. § 346a(b)(2)(C).

85. *Id*. The FQPA also requires the EPA to publish its decision on the determination of the Child Safety Factor. *Id.*

86. *Id*.

FQPA only allows the EPA to use a different "margin of safety" or Child Safety Factor "if, on the basis of reliable data, such margin will be safe for infants and children."[87]

In the decades since Congress enacted the FQPA, the EPA has typically interpreted the Act to allow the use of any Child Safety Factor ranging from 1X (that is, no added stringency to account for children) to 10X.[88] A lower factor, such as 1X, results in a higher reference dose and higher pesticide tolerances, which in turn means more pesticide residues on consumer food.[89] Correspondingly, a higher factor means a lower reference dose and lower pesticide tolerances, which in turn means less pesticide residues on food.[90] In practical terms, a 10X Child Safety Factor means that all food of a certain type will be subject to the 10X Factor. Even though a 10X Factor may not be necessary to protect adults from pesticides, it would be difficult, if not impossible, for the EPA to allow different pesticide tolerances on different batches of the same food items.

II. Enforcement of the FQPA to Date

A. The EPA's Tolerance-Setting History

While initial policy guidance issued by the EPA appeared aligned with a presumption in favor of a 10X Child Safety Factor for all pesticide tolerance applications,[91] the EPA has never routinely applied a factor of 10X. Over the past three decades, our investigation and the work of other researchers show that the EPA has most often used a 1X Child Safety Factor.

In a 2006 study, the NRC noted that for the fifty-nine pesticides it reviewed,

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87. *Id*.

88. 21 U.S.C. § 346a(b)(1)(B) (allowing the Administrator discretion); *see, e.g.*, Northwest Coalition for Alternatives to Pesticides v. EPA, 544 F.3d 1043, 1053 (9th Cir. 2008) (holding that EPA had to justify using a Child Safety Factor between 1X and 10X).

89. Heidi Gorovitz Robertson, *How Many Times Do I Have to Tell You?!: EPA's Ongoing Struggle with Data from Third-Party Pesticide Toxicity Studies Using Human Subjects,* 28 WM. & MARY ENV'T L. & POL'Y REV. 205, 212.

90. *Id*.

91. U.S. Env't Prot. Agency, *Determination of the Appropriate FQPA Safety Factor(s) in Assessing Pesticide Tolerances* (Mar. 20, 2024), https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/determination-appropriate-fqpa-safety-factors [https://perma.cc/L2YU-B2A7]. The OPP also published guidance relevant to the 10X Child Safety Factor. U.S. ENV'T PROT. AGENCY, CONSIDERATION OF THE FQPA SAFETY FACTOR AND OTHER UNCERTAINTY FACTORS IN CUMULATIVE RISK ASSESSMENT OF CHEMICALS SHARING A COMMON MECHANISM OF TOXICITY (Feb. 28, 2002), https://www.epa.gov/sites/default/files/2015-07/documents/apps-10x-sf-for-cra.pdf [https://perma.cc/8GVS-SY7Z]; *see also* GAO Report, *supra* note 28, at 37.

the EPA used a 1X Child Safety Factor in all but eleven cases.[92] Of the remaining eleven cases, the agency used a 3X Child Safety Factor in six cases and a 10X Factor in five cases. In the five cases where it used a 10X Child Safety Factor, the EPA had information on "*severe* developmental toxicity end points, such as multiple malformation and fetal death" in laboratory animals.[93]

Similarly, from 1996 to 2012, the Government Accountability Office (GAO) reported that the EPA made actual food use tolerance decisions for 412 pesticides, and in 308 of those cases, the Office of Pesticide Programs (OPP) applied a Child Safety Factor less than 10X.[94] In 61% of these decisions, or 251 cases, the EPA applied a 1X Child Safety Factor, choosing not to account for any special susceptibilities of children.[95]

Another study, published in 2020, showed that the EPA has continued to act without a presumption in favor of a 10X Child Safety Factor for most of the past two decades.[96] In that study, the EPA applied a 1X Child Safety Factor for eleven of the twelve most used pesticides by volume in the United States, considering both acute and chronic dietary exposures. The sole exception was in the case of the herbicide glufosinate.[97] For glufosinate, a key agricultural weed killer in the United States,[98] the EPA applied a 1X Child Safety Factor for acute dietary exposures and a 10X Child Safety Factor for chronic dietary exposures.[99]

B. Data as of July 2024

We chose to begin our study with published decisions starting in 2006, ten years after Congress passed the FQPA, because FIFRA requires all pesticides to be re-registered every fifteen years, and the FQPA required the EPA to reassess all existing pesticide tolerances within ten years.[100] At each ten-year tolerance reassessment, the EPA would thus consider the application of the Child Safety

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92. NATIONAL RESEARCH COUNCIL, TOXICITY TESTING FOR ASSESSMENT OF ENVIRONMENTAL AGENTS: INTERIM REPORT 130, 132 (2006).

93. *Id*. (emphasis added).

94. GAO Report, *supra* note 28, at 37.

95. *Id*. at 38.

96. *See* Naidenko, *supra* note 62, at 2; GAO Report, *supra* note 28.

97. *See* Naidenko, *supra* note 62, at Table 1.

98. Hudson Takano, *Glufosinate-Ammonium: A Review of the Current State of Knowledge*, 76 PEST MGMT. SCI. 3911 (2020).

99. *See* Naidenko, *supra* note 62, at Table 1.

100. U.S. Env't Prot. Agency, *Reregistration and Other Review Programs Predating Pesticide Registration Review* (Jan. 16, 2025), https://www.epa.gov/pesticide-reevaluation/reregistration-and-other-review-programs-predating-pesticide-registration [https://perma.cc/CG68-D7K4]; 7 U.S.C. § 136a(g); 21 U.S.C. § 346a(q). As of 2006, the EPA had reassessed over 99% of all tolerances since the passage of the FQPA.

Factor. The data reviewed from 2006 to 2024 confirms that the EPA has not used the 10X Child Safety Factor in most tolerance-related decisions. In addition, our research shows that in cases where a pesticide is exempt from a tolerance, Federal Register notices often neither mention the application of the FQPA Child Safety Factor nor acknowledge that the EPA has considered the special vulnerabilities of children. This is significant because even when it allows an exemption from a tolerance, the EPA must still show that the exemption is "safe" for children and that there exists a "reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information."[101]

1. Methods of Data Collection

To collect the latest data, we searched all Federal Register notices for the term "pesticide tolerance"[102] and reviewed each publication returned.[103] For search results containing "pesticide tolerance," we then searched for "FQPA," "child," and "safety." If the Federal Register notice did not state that a Child Safety Factor had been applied or considered, or contain references to either "FQPA," "child," or "safety," we searched the Federal Register for the name of the pesticide to clarify whether a Child Safety Factor had been applied in setting the tolerance or exemption. If none of the above search mechanisms yielded instructive information on the Child Safety Factor, we then turned to the EPA's publication of Interim Registration Eligibility Decisions to see if the EPA had issued an interim registration or reregistration decision or other publication. Our results thus also include interim and emergency decisions, as well as risk assessments, opinions, and exemptions published for public comment. These materials reflect the EPA's thinking on the application of the 10X Child Safety Factor to a particular pesticide and method of exposure.[104] We believe we have analyzed every tolerance decision related to the Child Safety Factor published since 2006. During this period, the EPA revoked and reinstated the registration for a widely used and controversial pesticide, chlorpyrifos.[105] We thus included

101. 21 U.S.C. § 346a(c)(2)(A); 21 U.S.C. § 346a(b)(2)(C).

102. We found that the title "pesticide tolerance" is routinely used as a heading when the EPA issues a tolerance decision or an exemption from a tolerance for a pesticide.

103. This search of Federal Register notices using the keyword "pesticide tolerance" and filtered by those published by the EPA since January 1, 2006, returned 728 documents.

104. For a similar approach to collecting and considering EPA action regarding the 10X Child Safety Factor, *see* Naidenko, *supra* note 62.

105. Gina Solomon, *The EPA is Banning Chlorpyrifos, a Pesticide Widely Used on Food Crops, After 14 Years of Pressure from Environmental and Labor Groups*, CONVERSATION (Aug. 24, 2021), https://theconversation.com/the-epa-is-banning-chlorpyrifos-a-pesticide-widely-used-on-

the EPA's responses to petitions to revoke chlorpyrifos tolerances in our data.

We reviewed over 700 Federal Register notices returned in our initial search for the term "pesticide tolerance." Many Federal Register notices refer to multiple crops, such that the EPA might be counting a single notice relating to many crops as "multiple tolerance decisions." For example, a decision published in the Federal Register on November 6, 2013, establishes tolerances for residues of spirotetramat "in or on corn, sweet, kernel plus cob with husks removed and persimmon and revises established tolerances in or on feijoa, papaya, and Spanish lime."[106] This inclusion of numerous crops in one notice, along with the lack of reference in many notices to the Child Safety Factor, may at least partially account for why the EPA says it has made thousands of tolerance related decisions[107] while we found far fewer. The GAO, in reviewing the EPA's record in a 2013 report, stated that it only reviewed a total of 412 pesticide food use tolerance decisions between 1996 and 2012 related to the Child Safety Factor.[108] The lack of clarity about how many tolerance decisions the EPA is making, and the inclusion of multiple crops in one notice, complicates efforts to understand the decisions and categorize them appropriately.

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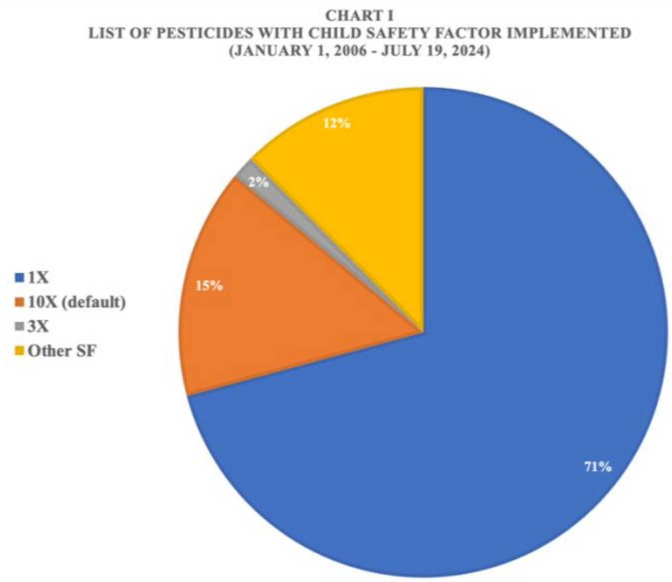
food-crops-after-14-years-of-pressure-from-environmental-and-labor-groups-166485 [https://perma.cc/4N8F-HVRK] (noting that 5.1 million pounds of chlorpyrifos was used on a wide range of U.S. crops between 2014 and 2018).

106. Spirotetramat; Pesticide Tolerances, 78 Fed. Reg. 66649, 66649-66651 (Nov. 6, 2013).

107. GAO Report, *supra* note 28, at 36.

108. *Id*. at 37.

CHART 1: STUDY RESULTS



2. Study Results

Chart I and Table I in the Supplementary Materials depict all cases where the EPA considered a Child Safety Factor since 2006.[109] Of those cases, the Agency applied a Child Safety Factor greater than 1X in ninety-six cases, or approximately 29% of the time. In 15% of notices implementing a Child Safety Factor, the EPA used the presumptive 10X Child Safety Factor.

In many instances where the EPA applied a Child Safety Factor greater than 1X, but less than 10X, it only applied the additional factor on a limited basis. Table I shows that in the ninety-six cases where the EPA applied an enhanced Child Safety Factor (greater than 1X and up to and including 10X), it limited its application to particular exposures in 15% of these cases.[110] For example, in five such cases, the EPA applied a 10X Child Safety Factor, but only for inhalation exposures, not for dietary exposures.[111] In two out of fifty cases in which the

109. *Id.*
110. *Id.*
111. Didecyl Dimethyl Ammonium Carbonate and Didecyl Dimethyl Ammonium Bicarbonate; Exemption From the Requirement of a Tolerance, 77 Fed. Reg. 50613, 50615 (Aug. 22, 2012); Naphthalene Acetates; Pesticide Tolerances, 80 Fed. Reg. 77255, 77258-59 (Dec. 14, 2015); Naphthaleneacetic acid; Pesticide Tolerances, 78 Fed. Reg. 30213, 30216-17 (May 22, 2013); Boscalid, 83 Fed. Reg. 52991, 52994 (Oct. 19, 2018); Trifloxystrobin; Pesticide Tolerances,

EPA applied a 10X Child Safety Factor, the agency only applied the 10X Child Safety Factor to residential exposures, not dietary exposures.[112] By limiting the application of the Child Safety Factor, the EPA stopped short of additional protection for children as to pesticide residues *on food*—the FQPA's main focus.

In another limiting example, the EPA used a 3X Child Safety Factor when it set a tolerance for the pesticide fenpropathrin for children less than six years old, but only a 1X Child Safety Factor for anyone over six years old. The EPA explained this difference by positing that the metabolic system of a child aged six or older is close to or on par with that of an adult.[113] In its decision, the EPA also stated that it had sufficient information to characterize toxic effects, including developmental and reproductive toxicity, neurotoxicity, and immunotoxicity.[114]

In other cases with limited application of the Child Safety Factor—for example, in the tolerance decision for azoxystrobin—the EPA only applied a 3X factor for "acute dietary risk" and a 1X Safety Factor for all other exposures.[115] In yet another case, the EPA applied a 3X Child Safety Factor for the pesticide isoxaflutole, but only for females aged thirteen to forty-nine.[116] This age range suggests a concern for those of child-bearing age, potentially to address increased in utero susceptibility and the lack of a NOAEL in developmental toxicity studies undertaken in the course of setting the tolerance.[117] Examples of child-protective tolerance setting do exist, but they are few and far between. The EPA has twice used a Child Safety Factor of 30X during the period we studied, once for propyzamine[118] and once for mesotrione.[119] But these may be the exceptions that prove the rule.

Finally, it is worth noting that the EPA keeps a list of pesticides about which

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87 Fed. Reg. 1363, 1365 (Jan. 11, 2022); Trifloxystrobin; Pesticide Tolerances, 88 Fed. Reg. 39770, 39773 (June 20, 2023). Deltamethrin; Pesticide Tolerances, 88 Fed. Reg. 19873, 19877 (Apr. 4, 2023).

112. [alpha]-(p-Nonylphenol)-[omega]-hydroxypoly(oxyethylene) Sulfate and Phosphate Esters; Time-Limited Exemption from the Requirement of a Tolerance, 75 Fed. Reg. 27434, 27440-41 (May 17, 2010); [alpha]-[p-(1,1,3,3-Tetramethylbutyl)phenyl]-[omega]-hydroxypoly(oxyethylene); Time-Limited Exemption from the Requirement of a Tolerance, 75 Fed. Reg. 27443, 27448-49 (May 17, 2010).

113. Fenpropathrin; Pesticide Tolerances, 78 Fed. Reg. 69562, 69567 (Nov. 20, 2013)

114. Fenpropathrin; Pesticide Tolerances for Emergency Exemptions, 84 Fed. Reg. 70429, 70432-33 (Dec. 23, 2019).

115. Azoxystrobin Decision, 88 Fed. Reg. 16570, 16571 (Mar. 20, 2023).

116. Isoxaflutole: Pesticide Tolerances, 76 Fed. Reg. 76309, 76312-13 (Dec. 7, 2011).

117. Isoxaflutole: Pesticide Tolerances, 76 Fed. Reg. at 76311.

118. Propyzamide; Pesticide Tolerance for Emergency Exemptions, 84 Fed. Reg. 60937, 60939, 60941 (Nov. 12, 2019) (with emergency exemption for tolerance period extended to December 31, 2025; *see* Propyzamide; Extension of Tolerance for Emergency Exemption, 87 Fed. Reg. 76944 (Dec. 16, 2022).

119. Mesotrione; Pesticide Tolerance, 73 Fed. Reg. 9222, 9225 (Feb. 20, 2008).

outsiders to the agency frequently inquire.[120] The EPA lists these pesticides on its website but does not include specific information surrounding the application of the Child Safety Factor in related tolerance setting.[121] We sought information about the application of the Child Safety Factor to these pesticides and have included information on these frequently inquired-about pesticides in Table III.[122] Overall, Table III shows that for all twenty such pesticides, the EPA has either applied a 1X Child Safety Factor (potentially because the agency has not yet made a decision on the pesticide tolerance), the product is off the market, or the product is exempt from a tolerance requirement.

3. Trends in Application of the 10X Child Safety Factor

In addition to data showing a limited number of applications of the Child Safety Factor on a percentage basis, our research also highlights a trend in EPA decisions.[123] In the periodic tolerance reviews required under federal law,[124] the EPA has displayed a tendency to reduce its initial application of the Child Safety Factor over time. For example, as noted above, the EPA originally raised the Child Safety Factor for mesotrione from the default 10X in 2008 to 30X.[125] It did so owing to deficiencies in the toxicity database, including the failure to identify a NOAEL in a two-generation reproductive study and an outstanding EPA requirement to undertake a developmental neurotoxicity study.[126] In raising the Child Safety Factor to 30X, the EPA addressed safety concerns related to child health and the absence of reliable data. Nonetheless, in 2015, upon further review, the EPA reduced the Safety Factor to 3X for mesotrione in or on almonds, citrus, pome, stone fruits, and tree nuts.[127] Based on a comprehensive human health risk assessment, for corn and other uses, the EPA later further

120. U.S. Env't Prot. Agency, *Brief Overviews about Individual Pesticides* (Aug. 28, 2024), https://www.epa.gov/ingredients-used-pesticide-products/brief-overviews-about-individual-pesticides [https://perma.cc/EDF8-RP9W].

121. *Id.*

122. Table III in the Supplementary Materials shows pesticides and related tolerances for those most often inquired about by third parties.

123. Table IV in the Supplementary Materials shows pyrethroid pesticide tolerances since 2006 with downward trend in application of the Child Safety Factor.

124. 7 U.S.C. § 136a(g)(1)(A)(iii)-(iv); 21 U.S.C. § 346a(q).

125. *See* Mesotrione; Pesticide Tolerance, 73 Fed. Reg. 1508, 1511 (Jan. 9, 2008); Mesotrione; Pesticide Tolerance, 73 Fed. Reg. 9222, 9225 (Feb. 20, 2008) (the EPA raised the 10X FQPA Safety Factor to 30X in light of a data gap, the necessity of a reliance on a LOAEL to calculate the RfD, and the quantitative and qualitative evidence of increased susceptibility of the young).

126. Mesotrione; Pesticide Tolerance, 73 Fed. Reg. at 1511; Mesotrione; Pesticide Tolerance, 73 Fed. Reg. at 9225.

127. Mesotrione; Pesticide Tolerances, 80 Fed. Reg. 30625, 30627-28 (May 29, 2015).

reduced the Child Safety Factor for mesotrione to 1X.[128]

Similarly, in 2019, the EPA reduced the Child Safety Factor for all pyrethroids, which were used to treat 200 million acres of crops from 2009 to 2012.[129] Until 2019, the Safety Factor for pyrethroids had been 3X for children under six years old,[130] making tolerances for pyrethroids three times safer for young children than they would have been without a Child Safety Factor. In 2019, however, the EPA, on the advice of the Council for the Advancement of Pyrethroid Human Risk Assessment (CAPHRA)—a group spearheaded by Bayer CropScience and other industry groups[131]—found that the Child Safety Factor for pyrethroids could be reduced across the board to 1X.[132] Following this advice, on July 1, 2019, the EPA announced a blanket reduction of the Child Safety Factor to 1X for all pyrethroids.[133] Table IV in the Supplementary Materials illustrates this trend.

In another, more recent example, in April 2024, the EPA reduced the Child Safety Factor for cyclaniliprole from 10X to 1X for uses on food crops.[134] By

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128. The EPA stated in its assessment of mesotrione in 2015: "The RAB1 risk assessment team for mesotrione determined that the FQPA SF should be reduced to 1X. The toxicological database is adequate for FQPA assessment, there is no evidence of neurotoxicity, evidence of offspring susceptibility/sensitivity is protected for by the selected endpoints, and there is no uncertainty in the exposure database." U.S. ENV'T PROT. AGENCY, MESOTRIONE, HUMAN HEALTH RISK ASSESSMENT FOR AMENDED USES ON CORN (May 20, 2015), https://www3.epa.gov/pesticides/chem_search/hhbp/D427385.pdf [https://perma.cc/E8AV-E2JB].

129. U.S. ENV'T PROT. AGENCY, COUNCIL FOR THE ADVANCEMENT OF PYRETHROID HUMAN RISK ASSESSMENT (CAPHRA) SCIENCE LEAD SLIDE PRESENTATION ADDRESSING POTENTIAL AGE-RELATED SENSITIVITY TO PYRETHROIDS AND PYRETHRINS 7 (May 27, 2015), https://www.regulations.gov/document/EPA-HQ-OPP-2015-0130-0008 [https://perma.cc/7U7M-MDDM].

130. U.S. ENV'T PROT. AGENCY, USEPA OFFICE OF PESTICIDE PROGRAMS' RE-EVALUATION OF THE FQPA SAFETY FACTOR FOR PYRETHROIDS: UPDATED LITERATURE AND CAPHRA PROGRAM DATA REVIEW 2 (July 1, 2019), https://www.epa.gov/sites/default/files/2019-08/documents/2019-pyrethroid-fqpa-caphra.pdf [https://perma.cc/7TXT-NUE2].

131. *See, e.g.*, U.S. ENV'T PROT. AGENCY, THE COUNCIL FOR THE ADVANCEMENT OF PYRETHROID HUMAN RISK ASSESSMENT (CAPHRA) BAYER CROPSCIENCE SLIDE PRESENTATION INTRODUCTION: INVESTIGATION OF AGE-DEPENDENT PHARMACODYNAMIC SENSITIVITY TO PYRETHROIDS (May 27, 2015), https://www.regulations.gov/document/EPA-HQ-OPP-2015-0130-0009 [https://perma.cc/8LNX-G6RF]; *EPA Proposes to Reduce Protections from Neurotoxic Pyrethroids*, BEYOND PESTICIDES (Nov. 14, 2019), https://beyondpesticides.org/dailynewsblog/2019/11/epa-proposes-to-reduce-protections-from-neurotoxic-pyrethroid-insecticides [https://perma.cc/26C9-GD4K] (calling CAPHRA a "weighty group of industry companies").

132. U.S. ENV'T PROT. AGENCY, *supra* note 130, at 11.

133. U.S. Env't Prot. Agency, *Evaluation of the FQPA Safety Factor for Pyrethrins and Pyrethroids* (Mar. 28, 2024), https://www.epa.gov/ingredients-used-pesticide-products/evaluation-fqpa-safety-factor-pyrethrins-and-pyrethroids [https://perma.cc/M392-CJ26].

134. *See* Cyclaniliprole; Pesticide Tolerance, 89 Fed. Reg. 30277 (Apr. 23, 2024)

comparison, cyclaniliprole is currently "not approved" for use in Europe.[135] Finally, in a controversial and heavily contested matter involving approval of chlorpyrifos, the EPA has, since 2006, lowered[136] the Child Safety Factor from 10X to 1X,[137] revoked all registrations,[138] and then raised the Child Safety Factor again to 10X.[139] The initial decision to lower the Child Safety Factor in 2006 was based on an industry study on rats,[140] which contradicted several peer-reviewed studies showing adverse effects of exposure to chlorpyrifos in children.[141] The protracted litigation regarding chlorpyrifos and its significance is discussed in Part III.F.

III. EPA'S FAILURE TO ABIDE BY THE FQPA'S MANDATE

The EPA's own strategic plan makes child health a "top priority."[142] In light of this plan and the data we found, we set out to analyze how the EPA has avoided the FQPA's strict mandate to protect children from toxic pesticides on

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135. *See Search Active Substances, Safeners and Synergists*, EUROPEAN COMM'N, https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/active-substances (last visited Apr. 8, 2025).

136. U.S. Env't Prot. Agency, *Organophosphorus Cumulative Risk Assessment 2006 Update* 61, 67 (July 31, 2006) https://www.regulations.gov/document/EPA-HQ-OPP-2006-0618-0002 [https://perma.cc/2ND4-8LZ5]; Chlorpyrifos; Final Order Denying Objections to March 2017 Petition Denial Order, 84 Fed. Reg. 35555, 35556, 35559-60 (July 24, 2019).

137. U.S. Env't Prot. Agency, *Organophosphorus Cumulative Risk Assessment 2006 Update* 61, 67 (July 31, 2006) https://www.regulations.gov/document/EPA-HQ-OPP-2006-0618-0002 [https://perma.cc/2ND4-8LZ5]; Chlorpyrifos; Final Order Denying Objections to March 2017 Petition Denial Order, 84 Fed. Reg. 35555, 35556, 35559-60 (July 24, 2019).

138. Chlorpyrifos; Tolerance Revocations, 86 Fed. Reg. 48315, 48319, 48333 (Aug. 30, 2021).

139. Chlorpyrifos; Reinstatement of Tolerances, 89 Fed. Reg. 7625 (Feb. 5, 2024).

140. Q. Zheng et al., *Comparative Cholinergic Neurotoxicity of Oral Chlorpyrifos Exposures in Preweaning and Adult Rats*, 55 TOXICOLOGICAL SCI. 124 (2000); Chlorpyrifos; Final Order Denying Objections to March 2017 Petition Denial Order, 84 Fed. Reg. at 35559-60 (citing EPA's reliance on the Zheng study for use of a 1X Child Safety Factor for the AChE inhibition endpoint used in EPA's Organophosphates Cumulative Risk Assessment 2006, *supra* note 137).

141. Hertz-Picciotto et al., *supra* note 9, at 1-5; Axel Mie et al., *Safety of Safety Evaluation of Pesticides: Developmental Neurotoxicity of Chlorpyrifos and Chlorpyrifos-methyl*, 17 ENV'T HEALTH 77 (2018) (noting the impact of chlorpyrifos exposure at all dose levels on brain dimension measure and adverse effects on children's cognitive development, in contravention to the industry-funded toxicity study results). Virginia A. Rauh, *Polluting Developing Brains - EPA Failure on Chlorpyrifos*, 378 N. ENG. J. MED. 1171, 1174 (2018) (noting that EPA's longtime failure to ban chlorpyrifos is "putting an entire generation of young brains in harm's way").

142. S*ee* GAO Report, *supra* note 28, at 20. Since our data look back from 2024, we cite the 2015 EPA Strategic Plan, which considers child health to be a priority. EPA's most recent Strategic Plan, for the years 2022-26, also notes that protecting children is key. U.S. Env't Prot. Agency, FY 2022-2026 EPA Strategic Plan 96 (Mar. 2022), https://www.epa.gov/system/files/documents/2022-03/fy-2022-2026-epa-strategic-plan.pdf [https://perma.cc/C2D3-4YYZ].

food. In this section, we discuss a combination of general and specific reasons for the EPA's failure to consistently apply the 10X Child Safety Factor.

A. Courts Have Generally Allowed the EPA to Reduce the Child Safety Factor

In addition to our empirical research on the EPA's tolerance-setting decisions, we studied lawsuits challenging EPA decisions to reduce the Child Safety Factor. In these cases, plaintiffs have urged that the agency is not moving quickly enough or doing enough to protect children. The EPA Inspector General has expressed concern that the EPA has long measured its progress not in how often it has acted to protect children's health but in how quickly it has acted to approve new pesticides.[143] FQPA-based claims by public interest groups have not, however, generally succeeded in forcing the EPA to act more protectively toward children.[144] Instead, public-interest challenges to EPA action demonstrate that courts typically uphold EPA decisions to reduce the 10X Child Safety Factor as long as those decisions are well explained.

For example, in 2011, the Natural Resources Defense Council (NRDC) challenged an EPA decision on the pesticide dichlorvos.[145] NRDC had previously petitioned the EPA to revoke all tolerances and cancel all registrations.[146] The agency denied the petition and instead reduced the Child Safety Factor[147] while acknowledging that the FQPA imposes a presumption in favor of the 10X Child Safety Factor.[148] In deciding to reduce the Child Safety Factor, the EPA relied on a human toxicity study involving nine adults that showed only a slight adverse effect from exposure to dichlorvos.[149] Based on the study, the agency concluded that it had "reliable data," as required by FQPA,[150] to justify the reduction of the

143. OFF. OF INSPECTOR GEN., U.S. ENV'T PROT. AGENCY, *Report: Measuring the Impact of the Food Quality Protection Act: Challenges and Opportunities* (Aug. 1, 2006), https://www.epaoig.gov/sites/default/files/2015-11/documents/20060801-2006-p-00028.pdf [https://perma.cc/QNY8-FTXG] at 4.

144. Alexandra B. Klass, *Pesticides, Children's Health Policy, and Common Law Tort Claims*, 7 MINN. J.L. SCI. & TECH. 146 (2005) ("[A]lthough the [FQPA] was heralded with great expectations . . . targeted lawsuits against EPA to improve implementation of the FQPA's key provisions have had little success as a result of procedural administrative law hurdles . . .").

145. *Nat. Res. Def. Council v. EPA*, 658 F.3d 200, 217 (2d Cir. 2011).

146. Dichlorvos (DDVP); Order Denying NRDC's Petition to Revoke All Tolerances, 72 Fed. Reg. 68662 (Dec. 5, 2007); Dichlorvos (DDVP); Order Denying NRDC's Objections and Requests for Hearing, 73 Fed. Reg. 42683, 42709-42711 (July 23, 2008).

147. Dichlorvos (DDVP); Order Denying NRDC's Objections and Requests for Hearing, 73 Fed. Reg. at 42696.

148. *Id.* at 42688.

149. *Nat. Res. Def. Council v. EPA*, 658 F.3d at 218.

150. 21 U.S.C. § 346a(a)(2)(C)(ii).

Child Safety Factor to 3X.[151]

The Second Circuit found, however, that the EPA had not sufficiently explained why a Child Safety Factor of less than 10X was sufficient to "take into account potential pre- and postnatal toxicity and completeness of data with respect to infants and children,"[152] as the FQPA requires.[153] The Court held that the EPA failed to provide a "reasoned basis" for the reduction in the Child Safety Factor from 10X to 3X and therefore had acted in an "arbitrary" and "capricious" manner.[154] The Second Circuit reversed and remanded the decision to the EPA.[155]

On reconsideration, the EPA again denied NRDC's petition, reaching the same decision to use a 3X Safety Factor. The EPA explained that its toxicity database was now complete, it had found no evidence of increased sensitively in the young in the completed database, and its exposure estimates were not understated.[156] NRDC again challenged the EPA's action, and the parties thereafter reached a settlement whereby the EPA agreed to reconsider its decision regarding dichlorvos.[157]

In another case, the Northwest Coalition for Alternatives to Pesticides sued the EPA for applying a reduced Child Safety Factor for the pesticides acetamiprid, mepiquat, and pymetrozine.[158] The Coalition argued that the EPA could not reduce the Child Safety Factor because it had not yet received the results of a developmental neurotoxicity study that it had required the registrant to provide. The Coalition also argued that the EPA had not adequately justified its reduction of the 10X Child Safety Factor.[159]

The Ninth Circuit agreed with the EPA's claim that it could decide that it no longer needed a developmental neurotoxicity study to determine the pesticides' safety.[160] The Court, however, remanded the matter in part and ordered the EPA to issue a more thorough explanation of why it had selected a reduced uncertainty multiplier rather than the "presumptive" 10X Child Safety Factor for the three pesticides.[161] In so doing, the court explained that it did not understand how the

151. *Nat. Res. Def. Council v. EPA*, 658 F.3d at 217.

152. *Id*. In setting tolerances for dichlorvos, a chemical that may disrupt the functioning of the human nervous system, the EPA relied on human studies involving six paid adult participants who ingested one dose of chemical every day for three weeks. *Id.* at 201, 209.

153. 21 U.S.C. § 346a(a)(2)(C) (1994 & Supp. III 1997).

154. *Nat. Res. Def. Council v. EPA,* 658 F.3d at 217-18.

155. *Id*. at 217.

156. U.S. Env't Prot. Agency, Dichlorvos (DDVP); Order Denying NRDC's Objections on Remand, 77 Fed. Reg. 54402. 54410 (Sept. 5, 2012).

157. GAO Report, *supra* note 28, at 43.

158. *Nw. Coal. for Alternatives to Pesticides v. EPA*, 544 F.3d at 1047.

159. *Id*. at 1050.

160. *Id*. at 1051.

161. *Id*. at 1046.

EPA chose a particular Safety Factor and that this lack of clarity was not acceptable.[162]

The above cases demonstrate that, while courts do impose some guardrails on EPA action, especially by requiring the agency to explain its decisions, the courts have generally allowed a reduction in the 10X Child Safety Factor if the agency explains why it believes "reliable data" exists to support its position.

The U.S. Supreme Court's recent decision in *Loper Bright Enterprises v. Raimondo*, which overturned the doctrine of *Chevron* deference, under which courts deferred to agencies' reasonable interpretation of statutory text,[163] may further impact judicial review of EPA tolerance decisions. *Loper Bright* will likely limit the EPA's powers of statutory interpretation and implementation and increase challenges to agency action under the FQPA. While *Loper Bright*'s effects on the EPA are yet to be determined, some predict that challenges to EPA action will see greater success in a post-*Chevron* world, where there will be less deference to agency decision-making.[164] In the short term, it seems likely that the repudiation of Chevron will generate more litigation under the FQPA and more media scrutiny, which might encourage registrants to act in a more health-protective manner to avoid lawsuits and consumer backlash. In the face of such challenges, Loper Bright might lead the EPA to forego application of the Child Safety Factor or to pause tolerance decision-making entirely for fear of adverse judicial fallout. Such paralysis could lead to a backlog in EPA's decision-making process, resulting in failure to update tolerances or older, more toxic pesticides remaining in use. Another concern is that the repudiation of the Chevron doctrine could generate more litigation,[165] which could overwhelm the courts with highly technical cases and thereby increase regulatory uncertainty. In the face of such uncertainty, it is hard to predict whether children will be more or less protected.

B. Lack of Transparency in the EPA's Published Decisions

Our results show that the EPA has both failed to regularly apply the 10X Child Safety Factor and exhibited a lack of transparency with regard to how it

162. *Id*. at 1052.

163. Brief of Professor Thomas W. Merrill as Amicus Curiae in Support of Neither Party, *Loper Bright Enterprises*, No. 22-451 (citing Smiley v. Citibank (South Dakota), N.A., 517 U.S. 735, 740-41 (1996).

164. Karen Zraick, *How a Trump Win Would Upend Major Climate Court Fights*, N.Y. TIMES (Nov. 2, 2024) https://www.nytimes.com/2024/11/02/climate/trump-climate-courts-lawsuits.html [https://perma.cc/HKM2-S6F8].

165. *Professor Thomas W. Merrill on the Future of the Chevron Doctrine,* COLUMBIA L. SCH. (Jan. 11, 2024) https://www.law.columbia.edu/news/archive/professor-thomas-w-merrill-future-chevron-doctrine [https://perma.cc/EHP3-EW82].

conveys and reports its decisions. This lack of transparency makes it difficult to find information on tolerance setting decisions, to understand what pesticide residues may remain on food, and for individuals and public interest groups to challenge such decisions.

In conducting our study, we were only able to retrieve data on pesticide tolerance decisions related to the Child Safety Factor by individually reviewing hundreds of Federal Register notices using relevant search terms. While these decisions are "publicly available" in the most rudimentary sense, the aggregate data are not readily accessible, even to subject-matter experts.[166] The most relevant search terms may not yield all relevant results, and the EPA does not maintain a comprehensive list of all its child-related tolerance decisions.[167] Sometimes, these decisions do not mention the Child Safety Factor at all. Additionally, the EPA does not uniformly identify tolerance decisions as decisions related to child health, and the decisions are not typically broken down by crop or pesticide. At times, the Federal Register notice lists multiple pesticides for use on many different crops, while at other times, only one pesticide is listed.

In addition to the difficulty in locating the decisions relevant to the application of the Child Safety Factor, once identified, Federal Register notices related to tolerance decisions can be difficult to understand. While the EPA publishes explanations for its decisions, these decisions are lengthy, not uniform in their format and, at times, incomplete.[168] For example, the EPA has used inconsistent language in tolerance decisions, referencing the Child Safety Factor interchangeably as "reduced to 1X" or "removed."[169] Other decisions published in the Federal Register simply discuss the Child Safety Factor without setting a specific tolerance for a particular food crop.[170]

The EPA has acknowledged that at times it has used "short-hand" and that it has not been "transparent" in its tolerance-setting decisions.[171] This lack of transparency is ultimately detrimental to public health. The government, including the EPA, has a responsibility to protect Americans' wellbeing. Parents and families need accessible data to make informed decisions about how to

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166. *Id*.

167. *See* U.S. Env't Prot. Agency, HOW TO SEARCH FOR TOLERANCES FOR PESTICIDE INGREDIENTS IN THE CODE OF FEDERAL REGULATIONS (last updated September 18, 2023), https://www.epa.gov/pesticide-tolerances/how-search-tolerances-pesticide-ingredients-code-federal-regulations.

168. GAO Report, *supra* note 28, at 35.

169. DCPA; Pesticide Tolerance, 69 Fed. Reg. 51571, 51577 (Aug. 20, 2004).

170. *See, e.g.*, Butoxypolypropylene glycol, et al.; Exemption from the Requirement of a Tolerance, 87 Fed. Reg. 17013, 17015 (Mar. 25, 2022).

171. Dichlorvos (DDVP); Order Denying NRDC's Objections on Remand, 77 Fed. Reg. 54402, 54412 (Sept. 5, 2012).

reduce the risks of harmful chemicals entering their households. Current tolerance-related publications do not provide this information.[172]

Experts likewise agree that EPA tolerance decisions in the Federal Register are inordinately "complex" or "incomplete."[173] In an example of an incomplete decision, a tolerance publication for afidopyropen concerned two toxic substances with a different structure and mode of action, but only labeled one of the substances in its notice title.[174] Five academic experts interviewed by the GAO also stated that the EPA's explanations for why it chose not to apply a 10X Child Safety Factor lacked clarity.[175] All of the experts interviewed also expressed surprise at the frequent reduction in the Child Safety Factor and stated that the rationale provided by the EPA for such decisions could be difficult to understand.[176] A recent regulation on the pesticide afidopyropen demonstrates this lack of clarity. In that regulation, the EPA set tolerances using a Child Safety Factor of 1X and a tolerance for cyclopropane carboxylic acid, a metabolite of afidopyropen, using a Child Safety Factor of 10X, without clear explanation for this divergence.[177]

172. In 2015, for example, the EPA issued a Federal Register notice setting a tolerance for the use of etoxazole in or on pistachios. Etoxazole; Pesticide Tolerance, 70 Fed. Reg. 41619, 41623 (July 20, 2005). The agency later issued another notice removing the tolerance for residues of etoxazole in or on tree nuts excluding pistachios, without clearly explaining why pistachios were treated differently. Etoxazole; Pesticide Tolerances, 83 Fed. Reg. 51863, 51866 (Oct. 15, 2018). In another example showing how indiscernible these decisions can be, a set of Federal Register decisions on the pesticide cyclaniliprole from 2019 to 2024 do not mention the FQPA or Child Safety Factor at all. Cyclaniliprole; Pesticide Tolerance, 89 Fed. Reg. 30277 (Apr. 23, 2024); Cyclaniliprole; Pesticide Tolerances, 87 Fed. Reg. 69201 (Nov. 18, 2022); Cyclaniliprole; Pesticide Tolerances, 84 Fed. Reg. 50761 (Sept. 26, 2019) (no mention of the FQPA or Child Safety Factor). We had to search outside the Federal Register to find an internal EPA memorandum from an EPA Health Effects Division risk assessor and senior toxicologist to the branch chief indicating that the EPA had reduced the factor from 10X to 1X. *See* U.S. Env't Prot. Agency, *Memorandum: Cyclaniliprole: Human Health Risk Assessment for the Proposed New Uses on Bushberry Subgroup 13-07B; Caneberry Subgroup 13-07A; Citrus Fruit Crop Group 10-10; Low Growing Berry Subgroup 13-07G; Small Fruit Vine Climbing (except Grape) Subgroup 13-07E; and Tuberous and Corm Vegetables Crop Subgroup 1C*, at 14-15 (Aug. 22, 2019), https://downloads.regulations.gov/EPA-HQ-OPP-2018-0194-0005/content.pdf [https://perma.cc/FB7E-6WH7]. Other decisions published in the Federal Register simply discuss the Child Safety Factor without ever setting a specific tolerance for a particular food crop at all. *See, e.g.*, Butoxypolypropylene glycol, et al.; Exemption from the Requirement of a Tolerance, 87 Fed. Reg. 17013, 17015 (Mar. 25, 2022).

173. GAO Report, *supra* note 28, at 35, 41.

174. Afidopyropen; Pesticide Tolerance for Emergency Exemption, 89 Fed. Reg. 51843, 51846-47 (June 20, 2024),

175. GAO Report, *supra* note 28, at 41.

176. *Id.* at 41.

177. Afidopyropen; Pesticide Tolerance for Emergency Exemption, 89 Fed. Reg. 51843, 51846-47 (June 20, 2024),

Experts also noted that the EPA relies on confidential business information ("CBI") not subject to disclosure in making its decisions.[178] While registrants must submit information on their products when requesting registration and tolerance decisions, they are only generally required to identify the active ingredients in their pesticides. All other ingredients are considered trade secrets.[179] Additionally, registrants may request that submitted data be treated in a confidential manner, even if that data is relied on by EPA in its decision-making.[180]

In addition to incomplete information, obtuse language, and inconsistency in the format and content of Federal Register notices on child health-related pesticide decisions, the EPA has also never clearly laid out its overarching frameworks for tolerance-setting decisions in a manner understandable to the public. For example, the EPA has not fully explained what constitutes "reliable" information about a pesticide's safety and what metrics the agency uses to decide when to use a Child Safety Factor less than 10X. Because the agency has failed to publish such information, the public cannot fully understand how the EPA is protecting them from pesticide residues. Without such understanding, it is difficult for members of the public to challenge the agency's decisions or seek statutory or regulatory change.

In light of this lack of transparency and despite a trend toward lower Child Safety Factors in tolerance setting decisions in recent years, by the EPA's own account, tolerance decisions often receive little feedback from the public.[181] We could not, for example, find any media references to a recent decision to change the Child Safety Factor from 10X to 1X for the pesticide cyclaniliprole.[182] We surmise that trends and individual decisions in application of the Child Safety Factor are instead only noticeable to sophisticated petitioners such as public interest groups or legal researchers. Even the EPA's blanket reduction of the Child Safety Factor for the widely used class of pesticides known as pyrethroids[183] received little attention from the public or the media.[184] This was so even though scientists have found that pyrethroids pose a danger to fish and

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178. GAO Report, *supra* note 28, at 40-41.

179. 7 U.S.C. § 136h; 7 U.S. Code § 136e(a)(d).

180. 7 U.S.C. § 136h(a); 7 U.S.C. § 136h(d)(3).

181. GAO Report, *supra* note 28, at 36.

182. *See* Cyclaniliprole; Pesticide Tolerance, 89 Fed. Reg. 30277, 30279 (Apr. 23, 2024)

183. U.S. Env't Prot. Agency, *Evaluation of the FQPA Safety Factor for Pyrethrins and Pyrethroids* (Mar. 28, 2024), https://www.epa.gov/ingredients-used-pesticide-products/evaluation-fqpa-safety-factor-pyrethrins-and-pyrethroids [https://perma.cc/M392-CJ26].

184. The authors searched pyrethroid safety and pyrethroid tolerance and found little notice in the general media regarding tolerance decisions and changes in safety factors relevant to these pesticides.

bees[185] and an increased risk of death from cardiovascular disease in humans.[186]

Likewise, a proposed July 2024 rule to revise tolerances to harmonize them with international standards where international standards were less strict than U.S. standards,[187] which would apply to hundreds of crops, also received little public attention. The proposed rule increased the tolerances for deltamethrin, cyfluthrin, isomer beta-cyfluthrin, cypronconazole, and etoxazole but only referred to a vague finding that there is a reasonable certainty that no harm will result to the general population or specifically to infants and children from each tolerance decision, without any reference to the Child Safety Factor.[188] Even though this proposed action reduced child-protective measures for hundreds of pesticides, the EPA received only six public comments[189] and little publicity regarding the proposal.

C. Lack of Notice to Experts

In addition to the way the EPA has written and published its child health-related tolerance decisions, it has also kept important child health experts out of its tolerance setting processes. After the FQPA's passage, the EPA established the Office of Children's Health Protection (OCHP) to integrate research on children's health into regulatory decision-making.[190] The OCHP, in turn, established the Children's Health Protection Advisory Committee (CHPAC) to advise the agency on regulatory decisions affecting children.[191] The GAO, however, found that the EPA had not fully utilized these bodies to guide its decisions.[192] The GAO's 2013 report on environmental health noted that the OCHP has often been unaware that the EPA is considering tolerance decisions that could affect children's health, since no mechanism exists within the EPA to

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185. NAT'L PESTICIDE INFO. CTR, PYRETHROIDS FACT SHEET (Nov. 2014), http://npic.orst.edu/factsheets/pyrethrins.pdf [https://perma.cc/79B4-XMDJ].

186. Wei Bao et al., *Association Between Exposure to Pyrethroid Insecticides and Risk of All-Cause and Cause-Specific Mortality in the General US Adult Population*, 180 JAMA INT. MED. 367 (2019).

187. Pesticide Tolerances; Implementing Registration Review Decisions for Certain Pesticides; Terbacil, et al., 89 Fed. Reg. 59012, 59016-19 (July 22, 2024).

188. *Id.* at 59016-17, 59019.

189. *Id.*

190. U.S. Env't Prot. Agency, *History of Children's Environmental Health Protection at EPA, EPA Establishes Children's Environmental Health Agenda* (June 13, 2024) https://www.epa.gov/children/history-childrens-environmental-health-protection-epa [https://perma.cc/4P5B-DCRA]; GAO Report, *supra* note 28, at 7. The purpose of the OCHP was to make children's health a fundamental goal of public and human health. *Id*.

191. U.S. Env't Prot. Agency, *Children's Health Protection Advisory Committee* (Jan. 28, 2025), https://www.epa.gov/children/chpac [https://perma.cc/3PJG-3ZFQ].

192. GAO Report, *supra* note 28, at 4-7.

notify the OCHP of such decisions.[193] The GAO further reported that the OCHP has no "regular involvement" in the OPP's decision-making processes regarding tolerances for foods under the FQPA.[194]

Our investigations into the OCHP's current operations do not reveal concrete or ongoing plans to involve the office in tolerance-related decisions involving the Child Safety Factor.[195] By excluding the OCHP and CHPAC, the OPP and EPA have failed to use all the resources available to best protect children from pesticide exposures under the FQPA.

D. Ambiguous Tracking of Child Health-Related Decisions

Experts have suggested that the lack of involvement of the OCHP and CHPAC in EPA tolerance-setting decisions occurs at least partially due to the tracking and rule development system used to log pesticide decisions, which is

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193. *Id*. at 10, 24, 35.

194. GAO Report, *supra* note 28, at 30, 37. While the EPA publishes work plans for pesticide registrations and tolerance decisions in the Federal Register, the OCHP has stated that it does not have the resources to scour these publications for actions that may impact children's health.

195. *See, e.g.*, U.S. Env't Prot. Agency, *Children's Health Protection Advisory Charter* (Sept. 6, 2023), https://www.epa.gov/system/files/documents/2023-09/2023%20CHPAC%20Charter%20Renewal%20Final.pdf [https://perma.cc/7VWR-PHLM] (the 2023 charter makes no mention of efforts to implement FQPA or oversea tolerance decisions); U.S. Env't Prot. Agency, *Children's Health Protection Advisory Committee (CHPAC) Comment Letters and Meeting Materials* (Jan. 15, 2025) https://www.epa.gov/children/childrens-health-protection-advisory-committee-chpac-comment-letters-and-meeting-materials [https://perma.cc/ZH6C-MGWL] (showing all CHPAC comments to EPA from 2013 to 2023). A 2014 recommendation letter suggests that: EPA "[re]quire OCHP review, guidance, and concurrence with the application of safety factors protective of prenatal, infant and child populations in all Agency rules and regulations, with a specific focus on pesticide registration/re-registration eligibility decision documents and other pesticide risk assessments. . . . We concur with the report's recommendation to establish procedures for OCHP involvement in OPP decisions that affect children's health." Letter from Sheela Sathyanarayana, Chair, Children's Health Prot. Advisory Comm., to Gina McCarthy, Administrator, Env't Prot. Agency (Aug. 28, 2014), https://downloads.regulations.gov/EPA-HQ-OA-2022-0566-0015/content.pdf [https://perma.cc/ZL3Z-EYMW]. In response, the EPA wrote almost one year later: "OCHP is continuing active engagement on the highest-priority rules and regulations related to children's health. In addition, OCHP has recently established a new memorandum of understanding with the EPA's Office of Pesticide Programs. As stated in the MOU, OCHP will provide review of new policies that apply to pesticide risk assessments and will review the individual assessments developed for registration review and tolerance decisions with greatest risk to children's health, including review of the [FQPA] safety factors." But the agency's response mentioned no specific plans to include OCHP. Letter from Gwendolyn Keyes Fleming, Chief of Staff, Off. of the Administrator, U.S. Env't Prot. Agency, to Dr. Sheela Sathyarayana, Chair, Children's Health Prot. Advisory Comm. (Apr. 17, 2015), https://downloads.regulations.gov/EPA-HQ-OA-2022-0567-0024/content.pdf [https://perma.cc/HKR3-KV4S].

known as the Action Development Process (ADP).[196] The OCHP only receives notice of a potential decision if the matter is entered into the ADP as potentially affecting children's health.[197]

At the outset of the ADP, the EPA tracking system asks the rule drafter to answer questions related to children's health, both as to effects in utero and after birth.[198] But the process of drafting rules and answering screening questions does not consistently put key decision in front of OCHP. For example, a rule drafter must answer whether the agency action is "likely to address an adverse impact on childhood lifestages including prenatal (via exposure to women of child-bearing age)?" and "[a]re these potential adverse impacts due to exposure and/or toxicity?"[199] Rule drafters answering these screening questions, however, may not realize that the rule they are drafting could have an impact on children's health. This is partly because drafters come with varying levels of expertise and training. Moreover, to the best of our knowledge,[200] drafters do not receive mandatory training on how to answer the screening questions regarding children's health and agency decisions.[201] Indeed, rule drafters have been known to incorrectly answer screening questions, producing a false negative. For example, one rule drafter reportedly answered that an air emissions rule would have "no effect" on child health.[202]

These questions are designed to help OCHP understand when to get involved in a rulemaking,[203] and when a rule drafter incorrectly specifies that a tolerance decision will have no effect on children's health, the rule does not enter the ADP as an action potentially affecting children's health, and the OCHP does not receive notice.[204] Without notice, the OCHP is unlikely to become involved and therefore will have no opportunity to provide input on the Child Safety Factor.

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196. GAO Report, *supra* note 28, at 35.

197. *Id*. at 24-25

198. *Id*. at 24.

199. *Id.* at 25.

200. The authors wrote to the EPA for clarification on training for rule writers on June 3, 2024, but have not yet received a response.

201. GAO Report, *supra* note 28, at 24-25. GAO also noted that the EPA did not have in place a mechanism to report on child-specific risk assessments under SDWA. *Id. a*t 25. SDWA sets maximum contaminant levels, including for pesticides. U.S. Env't Prot. Agency, *National Primary Drinking Water Regulations* (Dec. 12, 2024) https://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations [https://perma.cc/XVY3-CYDJ].

202. GAO Report, *supra* note 28, at 25.

203. *Id.* at 24.

204. *Id.* at 24.

E. Classification of Tolerance Decisions as Routine

Compounding the issues related to screening questions and lack of notice to OCHP is the fact that individual tolerance decisions for foods are not routinely covered in the OPP's ADP at all.[205] This is because the ADP typically only tracks decisions initiated by the EPA. Pursuant to the FQPA, the EPA can initiate a tolerance setting rulemaking,[206] but most tolerance decisions result from petitions to the EPA by industry registrants.[207] Pursuant to a longstanding agreement with the Office of Information and Regulatory Affairs at the White House's Office of Management and Budget, which is in charge of reviewing certain agency rules, the EPA classifies tolerance-setting decisions on petition from a registrant as "routine."[208] When classified as routine, these decisions—though published in the Federal Register—are not included in the published regulatory agenda, signed by the Administrator, or tracked in the ADP.[209] The EPA has stated that the process of approving pesticide food tolerances is "relatively straightforward, generally receives few public comments, [and] has resulted in 'very few' lawsuits."[210] While it is true that interest groups have sued the EPA for failure to enforce the FQPA in issuing a tolerance or registration decisions in some limited instances, the EPA has said that it makes thousands of tolerance decisions per year, and most do not result in litigation.[211]

Given the complexity of the toxicological data and exposure analyses that the EPA must consider in making tolerance decisions, it is hard to see how tolerance decisions could be considered routine.[212] The treatment of tolerance decisions as routine may increase efficiency for the OPP, but without any regular tracking, given the volume of tolerance decisions published, it is difficult for the OCHP to advise on child-related tolerance decisions.[213] Of the food use decisions for 412 pesticides made between 1996 and 2012 that the GAO identified in its report, the EPA did not involve the OCHP in a single one.[214] This is so even though, by the EPA's own designation, the OCHP is supposed to take the lead in protecting children from environmental health hazards.[215]

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205. *Id*. at 35.
206. 21 U.S.C. § 346a(e).
207. GAO Report, *supra* note 28, at 35.
208. *Id*. at 35-36.
209. *Id.* at 35-36.
210. *Id*. at 36; 21 U.S.C. 346a(d)(4).
211. GAO Report, *supra* note 28, at 36.
212. *Id.* at 36.
213. *Id*. (noting thousands of tolerance decisions per year).
214. *Id.* at 37.
215. Memorandum from Lisa P. Jackson, Administrator, Env't Prot. Agency, to Assistant and Associate Administrators, General Counsel, and Regional Administrators (Jan. 12, 2010),

F. Lack of Final Agency Action

In addition to its ambiguous tracking system and failure to involve child health agencies in tolerance setting, under the Administrative Procedure Act, EPA often delays "final agency action," thereby thwarting public challenges to administrative action.[216] Under FIFRA and FQPA, the EPA must re-register all pesticides and assess all tolerances periodically.[217] The EPA has, however, proven unable to consistently meet deadlines[218] and deploys delaying tactics to avoid "final agency action." [219]

Courts have indeed dismissed actions brought by public interest groups for failure to establish standing because the agency has not taken final action[220] or because the public interest group has not first petitioned the EPA to modify or revoke tolerances before seeking judicial intervention.[221]

One particularly egregious case of EPA foot-dragging relates to litigation over the pesticide chlorpyrifos—a matter that first began to occupy the courts in 2007 and has continued to do so for almost twenty years. Two environmental non-profit groups petitioned the EPA to ban foods containing chlorpyrifos residues, claiming that the EPA had acted in violation of its obligations to continually monitor and ensure safety in the food system under the FFDCA.[222] In its 2021 ruling on the matter, the Ninth Circuit explained that the EPA has

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https://www.epa.gov/archive/epapages/newsroom_archive/newsreleases/bb39e443097b5df5852576a9006a5a86.html [https://perma.cc/M4FW-CQYD] (OCHP will take the lead on matters of children's health and protecting children's health is central to the work of EPA).

216. 5 U.S.C. § 704 (only final agency action reviewable in court).

217. *See, e.g.*, U.S. Env't Prot. Agency, *Reregistration and Other Review Programs*, *supra* note 100 (EPA's goal was to complete over 600 product registrations but the agency actually completed 483 product registrations during the designated period).

218. *See, e.g.*, *Nat. Res. Def. Council v. Whitman*, No. C-99-3701, 2001 WL 1456783 (N.D. Cal. 2001). In 2001, NRDC and multiple stakeholders sued the EPA, alleging it failed to meet FFDCA statutory deadlines for regulatory action, including the reassessment of pesticide tolerances and the implementation of an Endocrine Disruptors Screening and Testing Program.

219. *Nat. Res. Def. Council v. Johnson*, 422 F. Supp. 2d 105, 117 (D.D.C. 2006) (holding that plaintiffs had not exhausted judicial remedies and did not have standing to sue until the EPA had concluded its special reviews and re-registration decisions in relation to various pesticides).

220. *Physicians Comm. for Responsible Med. v. EPA,* No. C-05-04093, 2006 WL 3000657, at 4, 7 (N.D. Cal. 2006) (holding that consumers lacked standing to sue the EPA for failing to implement Endocrine Disruptor Screening Program ("EDSP") because plaintiffs had not shown injury in fact and statute does not require the EPA to share EDSP details with the public and only requires a progress report to Congress).

221. *Nat. Res. Def. Council v. Johnson*, 461 F.3d 164, 168-69 (2d Cir. 2006).

222. NAT. RES. DEF. COUNCIL & PESTICIDE ACTION NETWORK NORTH AMERICA, PETITION TO REVOKE ALL TOLERANCES AND CANCEL ALL REGISTRATIONS FOR THE PESTICIDE CHLORPYRIFOS (Sept. 12, 2007), https://www.nrdc.org/sites/default/files/hea_10072201a.pdf [https://perma.cc/99VA-JBQE].

recognized that maternal chlorpyrifos residue exposure is associated with harms to infants *in utero,*[223] and the agency has "spent a decade assembling a record of chlorpyrifos's ill effects."[224] Nevertheless, "the EPA failed to act, requesting extension after extension."[225] The court continued: "rather than ban the pesticide or reduce the tolerances to levels that the EPA *can* find are reasonably certain to cause no harm, the EPA has sought to evade, through one delaying tactic after another, its plain statutory duties."[226] The Ninth Circuit ruled that the EPA had acted in derogation of its statutory duties under the FQPA.[227] The Court required the EPA to modify or revoke tolerances for chlorpyrifos and modify or cancel the pesticide's registration within sixty days of the ruling.[228] In 2021, after more than a decade of litigation, the EPA finally revoked tolerances for chlorpyrifos, noting that it could *not* conclude that the risk from aggregate exposure would meet the safety standard required under the FFDCA.[229]

In 2023, Gharda Chemicals and other industry groups challenged the EPA's tolerance revocation rule for chlorpyrifos in the U.S. Court of Appeals for the Eighth Circuit.[230] The Eighth Circuit vacated the EPA's final rule revoking the chlorpyrifos tolerances, finding the agency's action arbitrary and capricious under the APA.[231] The Court reasoned that the EPA not considered a more limited rule involving modification of the tolerance, other than total revocation.[232]

Following the Eighth Circuit's remand, on February 5, 2024, the EPA reinstated tolerances for chlorpyrifos, this time using a 10X Child Safety Factor.[233] The pesticide is now again legally used on American crops. Though the EPA does now apply the mandatory FQPA 10X Child Safety Factor, this does not undo the effects the previous use of a 1X Child Safety Factor for fourteen years, which resulted in additional exposures to a generation of children. The European Union, by comparison, ended approval for chlorpyrifos in 2019 due to

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223. *League of United Latin American Citizens v. Regan*, 996 F.3d 673, 684-85 (9th Cir. 2021).
224. *Id.* at 678.
225. *Id.* at 677.
226. *Id*. at 678.
227. *Id*.
228. *Id*. at 703.
229. Chlorpyrifos; Tolerance Revocations, 86 Fed. Reg. 48315, 48319, 48333 (Aug. 30, 2021).
230. Red River Valley Sugarbeet Growers Ass'n v. Regan, 85 F.4th 881 (8th Cir. 2023).
231. 5 U.S.C. § 706(2)(A); *Red River Valley*, 85 F.4th at 886-87.
232. *Red River Valley v. Regan*, 85 F.4th at 890.
233. Chlorpyrifos; Reinstatement of Tolerances, 89 Fed. Reg. 7625 (Feb. 5, 2024).

concerns about neurotoxicity in developing children.[234]

Although not technically involving a food use tolerance, another litigation regarding the pesticide tetrachlorvinphos (TCVP) demonstrates the impact of the EPA's delays on obtaining judicial review of its decision-making. This case, brought by the NRDC, illustrates the extraordinary efforts a plaintiff must undertake to obtain final agency action and the extreme delay involved.[235] In 2009, the NRDC petitioned the EPA[236] to cancel TCVP's registration for use on pet products, urging that the chemical presented a significant risk to young children who would come into close contact with their pets.[237] Based on a 2008 peer-reviewed study,[238] the NRDC alleged that TCVP, used in flea and tick collars and shampoos, acted as a neurotoxin.[239]

For five years, the EPA did not act on the NRDC's petition, which prompted the NRDC in 2014 to seek a writ of mandamus in the D.C. Circuit to compel the EPA to respond.[240] Seven months after NRDC sought the writ of mandamus, the EPA denied the NRDC's 2009 petition, reasoning that the agency's recently completed risk assessment concluded that the risks posed by TCVP were below the threshold of concern.[241] The parties voluntarily dismissed the mandamus action after the EPA issued a final decision on the 2009 petition.[242]

NRDC then filed suit in the Ninth Circuit for review of the EPA's final decision on TCVP.[243] The EPA filed a motion for voluntary remand, stating that it was committed to finalizing a new risk assessment, and the court remanded the

234. *See* European Food Safety Auth., *Statement on the Available Outcomes of the Human Health Assessment in the Context of the Pesticides Peer Review of the Active Substance Chlorpyrifos* 8 (Aug. 28, 2019) (referencing studies on frontal and parietal cortical thinning in children exposed to chlorpyrifos while *in utero*).

235. *In re Nat'l Res. Def. Council, Inc.*, 956 F.3d 1134, 1138 (9th Cir. 2020).

236. NAT'L RES. DEF. COUNCIL, PETITION TO CANCEL ALL USES FOR THE PESTICIDE TETRACHLORVINPHOS (Apr. 23, 2009), https://downloads.regulations.gov/EPA-HQ-OPP-2009-0308-0002/content.pdf [https://perma.cc/K2RU-BMZR].

237. *In re* Nat'l Res. Def. Council, Inc., 956 F.3d at 1138.

238. M. Keith Davis et al., *Assessing Intermittent Pesticide Exposure from Flea Control Collars Containing the Organophosphorus Insecticide Tetrachlorvinphos*, 18 J. EXPOSURE SCI. & ENV'T. EPIDEMIOLOGY 564, 568–69 (2008).

239. *In re Nat'l Res. Def. Council, Inc.*, 956 F.3d at 1136.

240. *Id.* at 1137.

241. Jack E. Housenger, Dir., Off. of Pesticide Programs, Response to Natural Resources Defense Council's April 23, 2009, Petition Requesting Cancellation of All Pet Uses of Tetrachlorvinphos (Nov. 6, 2014), https://downloads.regulations.gov/EPA-HQ-OPP-2009-0308-0010/content.pdf [https://perma.cc/A2BJ-S4E4].

242. *In re* Nat'l Res. Ref. Council, Inc., No. 14-1017, 2014 WL 7366669 (D.C. Cir. Nov. 21, 2014).

243. *In re Nat'l Res. Def. Council, Inc.*, 956 F.3d at 1137.

matter without a deadline.[244] In 2016, the EPA issued its revised risk assessment, which found that TCVP used on pets put children at considerable risk and declared that it would take action within ninety days.[245] The EPA did not act within this time period, and NRDC sought another writ of mandamus to compel a final EPA response to its 2009 petition.[246] The EPA then ordered the sole remaining TCVP pet collar registrant to produce the data that the agency had requested in 2017, which the registrant had declined to provide voluntarily.[247] In granting the writ, the Ninth Circuit noted that this was "an extraordinary remedy justified only in exceptional circumstances," such as when a delay in action is "egregious."[248] The court noted four occasions[249] from 2015 to 2020 (including the TCVP case) with significantly similar circumstances, where it had granted writs of mandamus to compel action after the EPA had "unreasonably delayed its response to serious dangers to human health."[250] The Ninth Circuit explained: "[t]he EPA's years-long delay on this critical matter of public health has been nothing short of egregious. For more than a decade, the EPA frustrated NRDC's ability to seek judicial review by withholding final agency action, while endangering the wellbeing of millions of children and ignoring its 'core mission' of protecting human health and the environment."[251] This case illustrates the difficulty public-interest groups face in getting a dangerous pesticide pulled from the market and the difficulty EPA faces in obtaining negative toxicity data from registrants: EPA first received information suggesting that TCVP posed a serious risk to children in 2008 but did not revoke TCVP's registration until 2020.

In another matter in which the EPA struggled to obtain toxicity information from the registrant, the EPA finally issued a serious warning in April 2024[252] about the dangers to pregnant people and babies in utero exposed to the herbicide

244. *Id.*
245. *Id.* at 1137.
246. *Id.* at 1138.
247. *Id*.
248. *Id.*
249. League of United Latin American Citizens v. Wheeler, 922 F.3d 443, 445 (9th Cir. 2019) (mandamus petition in relation to chlorpyrifos); *In re* A Community Voice, 878 F.3d 779, 787-88 (9th Cir. 2017) (mandamus petition in relation to lead paint); *In re* Pesticide Action Network North America, Nat'l Res. Def. Council, Inc., 798 F.3d 809, 811-815 (9th Cir. 2015) (mandamus petition in relation to eight-year delay over chlorpyrifos).
250. *In re* Nat'l Res. Def. Council, Inc., 956 F.3d at 1136.
251. *Id*. at 1142-43.
252. The EPA "found concerning evidence of health risks associated with DCPA use and application, even when personal protective equipment and engineering controls are used. The most serious risks extend to the developing babies of pregnant individuals." Press Release, U.S. Env't Prot. Agency, EPA Warns Farmworkers About Risks of Dacthal: Agency Developing Next Steps to Address Risks (Apr. 1, 2024), https://www.epa.gov/newsreleases/epa-warns-farmworkers-about-risks-dacthal [https://perma.cc/H7TY-V9E7].

dimethyl tetrachloroterephthalate (DCPA). The agency had requested additional safety data from DCPA's manufacturer more than ten years prior.[253] Data from a comparative thyroid assay had identified harmful effects to developing babies even at low doses[254] and linked DCPA exposure in fetuses to low birth weight, decreased IQ, cognitive impairment, and motor deficiencies in later life.[255] The EPA announced that it intended to take steps "to address the serious, permanent, and irreversible health risks associated with the pesticide as quickly as possible."[256]

In response to the EPA's risk assessment,[257] the registrant, AMVAC, issued some risk management proposals[258] and voluntarily agreed to cancel the pesticide's use on turf and athletic and sporting grounds, meaning that it would no longer be sold for use on these surfaces, where it posed the greatest threat to human health.[259] Finally, in October 2024, after finding that the herbicide presented adverse occupational and residential risks to human health, especially to pregnant people handling DCPA,[260] the EPA announced that, pursuant to a

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253. The EPA's DCPA 2023 risk assessment was published following EPA's review of data that it compelled DCPA's registrant, AMVAC, to submit. *See* Richard P. Keigwin, Jr., Dir., Pesticide Re-evaluation Div., Off. of Pesticide Programs, Generic Data Call-In Notice (Jan. 31, 2013), https://downloads.regulations.gov/EPA-HQ-OPP-2011-0374-0009/content.pdf [https://perma.cc/WR2K-JVKW]. AMVAC submitted the complete data set for the comparative thyroid assay, as required by the data-call in notice, following EPA's issuance of a separate Notice of Intent to Suspend: Notice of Rescheduled Public Hearing Regarding Notice of Intent to Suspend Dimethyl Tetrachloroterephthalate (DCPA) Technical Registration, 87 Fed. Reg. 77105 (Dec. 16, 2022).

254. Letter from Ed Messina, Dir., Off. of Pesticide Programs, to Anne Turnbough, VP of Regulatory Affs., AMVAC Chemical Corp. (Mar. 27, 2024), https://downloads.regulations.gov/EPA-HQ-OPP-2011-0374-0112/content.pdf [https://perma.cc/R8JA-JP27].

255. *Id*.

256. U.S. Env't Prot. Agency, *supra* note 252.

257. Letter from Anne Turnbough, VP of Global Regulatory Affs., AMVAC Chemical Corp., to U.S. Env't Prot. Agency (Feb. 21, 2024), https://www.regulations.gov/document/EPA-HQ-OPP-2011-0374-0113 [https://perma.cc/22FT-7CVH].

258. EPA confirmed AMVAC's risk management proposals were insufficient, stating "unacceptable risks from agricultural use remained." U.S. Env't Prot. Agency, *supra* note 252; *see also* Letter from Ed Messina, *supra* note 254 (risks identified by EPA "not . . . mitigated adequately").

259. Notice of Receipt of Requests to Voluntarily Cancel Certain Pesticide Registrations and Amend Registrations to Terminate Certain Uses, 88 Fed. Reg. 71356, 71357-71358 (Oct. 16 2023).

260. *Id*.; DCPA Registration Review; Draft Occupational and Residential Risk Assessment; Notice of Availability, 88 Fed. Reg. 35869 (June 1, 2023); Memorandum, DCPA: Occupational and Residential Exposure Assessment for the Registration Review of DCPA (May 18, 2023), https://downloads.regulations.gov/EPA-HQ-OPP-2011-0374-0081/content.pdf [https://perma.cc/8SVQ-575P].

request by the registrant, it was canceling all registrations of DCPA.[261]

Although the EPA ultimately cancelled the registrations, delays in obtaining data and the leeway that the EPA granted the manufacturer allowed a pesticide with significant risks to remain on the market for over ten years after the EPA first sought toxicity information.[262] During this long delay, the EPA did not mitigate the harm or place any mandatory restrictions on DCPA or its registrant. Even though the lack of comparative thyroid assay data should have led the EPA to retain the default 10X Child Safety Factor,[263] the agency instead reduced the Child Safety Factor to 1X during this period.[264]

Collectively, these cases show an important pattern in pesticide tolerance and registration actions in which the EPA delays final agency action and allows registrants leeway in providing data, thus metaphorically "kick[ing] the can down the road."[265] The TCVP case illustrates EPA's willingness to engage in delay even in the face of multiple mandamus orders[266] and even when the agency itself has acknowledged the existence of unfavorable toxicity information.[267]

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261. Dimethyl Tetrachloroterephthalate; Final Cancellation Order for Pesticide Registrations, 89 Fed. Reg. 84574 (Oct. 23, 2024); *see EPA Issues Warning to Farmworkers Instead of Regulating a Highly Hazardous Weed Killer as an Imminent Threat,* BEYOND PESTICIDES (Apr. 15, 2024), https://beyondpesticides.org/dailynewsblog/2024/04/epa-issues-warning-to-farmworkers-instead-of-regulating-a-highly-hazardous-weed-killer-as-an-imminent-threat [https://perma.cc/V6YZ-42LT]. 7 U.S.C. § 136d(c) (FIFRA section 6(c)) provides for the immediate suspension of a pesticide registration if the EPA determines it necessary to prevent an imminent hazard).

262. *See EPA Issues Warning to Farmworkers Instead of Regulating*, *supra* note 261 ("The delays associated with this one pesticide [DCPA] exemplifies concerns that advocates have raised as endemic to EPA's pesticide registration process, resulting in serious harm that is not adequately prevented or managed by the agency.").

263. Memorandum, DCPA (Chlorthal Dimethyl): Human Health Assessment Scoping Document in Support of Registration Review 4 (May 27, 2011), https://downloads.regulations.gov/EPA-HQ-OPP-2011-0374-0004/content.pdf [https://perma.cc/U7TX-P633]. FQPA requires the application of a 10X Child Safety Factor where data are incomplete. *See* 21 U.S.C. § 346a(b)(2)(C)(ii)(II).

264. DCPA; Pesticide Tolerance, 69 Fed. Reg. 51571, 51578 (Aug. 20, 2004); *see also* EWG, EWG COMMENTS TO THE EPA ON THE DRAFT OCCUPATIONAL AND RESIDENTIAL EXPOSURE ASSESSMENT FOR REGISTRATION REVIEW OF PESTICIDE DCPA 3 (July 3, 2023), https://www.ewg.org/sites/default/files/2023-07/EWG_DCPA_comments_070323.pdf [https://perma.cc/E4J6-M5VR].

265. "Repeatedly, the EPA has . . . betrayed its prior assurances of timely action, even as it has acknowledged that the pesticide poses widespread, serious risks to the neurodevelopmental health of children." *In re Nat'l Res. Def. Council, Inc.*, 956 F.3d 1134, 1136 (9th Cir. 2020).

266. *See, e.g.*, *id.* at 1137-38.

267. *See, e.g.*, *League of United Latin American Citizens v. Regan*, 996 F.3d 673, 677 (2021) (EPA acknowledging risk to the developing brain); *In re Nat'l Res. Def. Council*, 956 F.3d at 1136, 1142-43.

G. A Wider Trend Towards Deregulation

In the context of several decades of deregulation and growing hostility to the administrative state, the EPA's inadequate implementation of key safety measures, including the FQPA's Child Safety Factor, is merely a symptom of a wider pattern of under-enforcement of consumer protection legislation. A detailed discussion of this pattern is beyond the scope of this paper, but pesticides are not the only issue on which the EPA has been insufficiently vigilant. To give a few current examples, the EPA has failed to enforce the Clean Air Act[268] and the Clean Water Act[269] to protect communities surrounding large agricultural operations.[270] Likewise, the GAO has criticized the EPA for failing to assess chemicals for their potential human health effects in a timely manner under the so-called Integrated Risk Information System.[271]

This deregulatory behavior is bolstered by a judicial presumption that an agency's failure to enforce the law is presumptively "unreviewable" under the APA.[272] This presumption has made challenges more difficult for those seeking child-protective action under the FQPA. Lackluster enforcement has in turn led the United States food safety system to lag behind other nations, hurting not only public health but also the wider economy.[273] This is not only morally embarrassing but also problematic for U.S. producers seeking to export agricultural products that contain residues of pesticide banned in the importing country.[274]

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268. *See* Valerie J. Watnick, *Climate Change, Marginalized Communities, and Pandemics: A New Paradigm for Transforming Industrial Agriculture Through ESG*, 54 ENV'L. L. 381, 404-06 (2024).

269. *Id.* at 398-401.

270. *See* JoAnn Burkholder et al., *Impacts of Waste from Concentrated Animal Feeding Operations on Water Quality*, 115 ENV'T HEALTH PERSPECTIVES 308, 308 (2007).

271. U.S. GOV'T ACCOUNTABILITY OFF., GAO-12-42, CHEMICAL ASSESSMENTS, CHALLENGES REMAIN WITH EPA'S INTEGRATED RISK INFORMATION SYSTEM PROGRAM 1-2, 16-17 (2011), https://www.gao.gov/products/gao-12-42 [https://perma.cc/TN98-MJ6X].

272. Heckler v. Chaney, 470 U.S. 821 (1985).

273. Nathan Donley, *How the EPA's Lax Regulation of Dangerous Pesticides Is Hurting Public Health and the US Economy*, BROOKINGS INST. (Sept. 29, 2022), https://www.brookings.edu/articles/how-the-epas-lax-regulation-of-dangerous-pesticides-is-hurting-public-health-and-the-us-economy [https://perma.cc/W285-6VGR].

274. *Id*. at nn.37, 38 (Thailand will not allow imported produce to contain the pesticide chlorpyrifos and this hurts U.S. agricultural suppliers).

IV. Moving Forward: Making Child-Protective Tolerance Decisions

A. EPA Should Fully Use the Expertise of OCHP and CHPAC

Since the passage of the FQPA, the EPA has not established a regular process to consult with expert groups such as OCHP and CHPAC in making tolerance decisions that affect child health.[275] Going forward, the EPA should engage in consultation with these groups to enable it to best protect child health.

To improve its tolerance-setting process and increase its access to expert advice, the EPA must reform how it uses the ADP tracker. Currently, since pesticide tolerance decisions are classified as routine and typically initiated by registrants, agency officials responsible for child health do not receive notice of proposed action. The EPA should incorporate industry-generated tolerance petitions and decisions into the ADP to ensure OCHP is informed when a tolerance decision could impact child health. This includes any tolerance decision where the EPA is evaluating the need for or a reduction in the Child Safety Factor.

If tolerance petitions and decisions were included in the ADP tracker, then EPA could implement mandatory training for rule drafters, enabling them to identify cases where the EPA is evaluating the need for a Child Safety Factor due to insufficient data or evidence of potential pre- or post-natal toxicity.[276] Once identified, the ADP tracker would automatically notify the OCHP and CHPAC and trigger their involvement. If too cumbersome to include all tolerance petitions and decisions in the ADP, at the very least, the EPA's OPP could establish a regular communication channel with the OCHP and CHPAC to specifically list and notify them about upcoming tolerance setting decisions that involve consideration of a reduction or addition of the Child Safety Factor.

B. EPA Should Not Rely on Industry Studies Alone

The EPA most often uses a Child Safety Factor of 1X rather than the presumptive 10X. In many instances, the agency chooses a factor of 1X because it lacks evidence of adverse toxicological consequences from use of the pesticide. But the pool of evidence on which the agency draws is supplied almost entirely by industry. A good example of this pattern is the interim registration decision

275. GAO Report, *supra* note 28, at 10, 24, 35.
276. 21 U.S.C. § 701(a)(2)(C)(ii).

currently in place for atrazine,[277] a chemical that is currently banned in over forty other countries.[278] In the United States, atrazine remains the second most used pesticide by volume.[279]

Yet, in issuing its draft human health risk assessment for atrazine in 2018, the EPA discounted epidemiological studies showing potential human harm when reducing the Child Safety Factor under FQPA from 10X to 1X.[280] The EPA issued a proposed interim registration decision on atrazine in 2020.[281] In addition to the two-year delay, EPA favored industry over health, declaring that "atrazine is an important herbicide for warm-season grass crops, such as corn, sorghum and sugarcane, because it is economical, has a flexible use pattern, has a long residual period, has good crop safety, and is highly effective against a broad spectrum of weeds."[282] The agency did this despite the 2018 assessment concluding that exposure to atrazine in water, food and from residential uses presented "reproductive and developmental risks to humans, particularly children."[283]

In excluding key studies, and giving undue weight to industry benefits, EPA has delayed child protective action as to atrazine, seeking information on causation and definitive proof of harm, even when information already suggests harm to children and when the FQPA does not require definitive proof of harm.[284] Significant evidence already exists that atrazine acts as an EDC and contributes to the development of certain cancers.[285] Despite this evidence,

277. CTR. FOR FOOD SAFETY, *supra* note 38, at 9 ("Peer-reviewed literature did not have any impact on EPA's human health risk assessment of atrazine or in particular the evaluation of epidemiological studies related to atrazine and atrazine's carcinogenic potential.").

278. Ctr. for Food Safety, *Atrazine*, https://www.centerforfoodsafety.org/issues/6459/pesticides/atrazine [https://perma.cc/FP7C-UGB3] (noting that atrazine is an endocrine disruptor associated with impaired fetal growth, behavioral abnormalities, and reproductive dysfunction and that there is evidence that atrazine contributes to breast and prostate cancer and non-Hodgkin lymphoma).

279. U.S. ENV'T PROT. AGENCY, PESTICIDES INDUSTRY SALES AND USAGE: 2008-2012 MARKET ESTIMATES, at 14 (2017), https://www.epa.gov/sites/default/files/2017-01/documents/pesticides-industry-sales-usage-2016_0.pdf [https://perma.cc/3T7Z-84WN].

280. CTR. FOR FOOD SAFETY, *supra* note 38, at 9, 14.

281. U.S. ENV'T PROT. AGENCY, ATRAZINE INTERIM REGISTRATION REVIEW DECISION CASE NUMBER 0062 (Sept. 2020), https://downloads.regulations.gov/EPA-HQ-OPP-2013-0266-1605/content.pdf [https://perma.cc/GF5L-3PGB].

282. *Id.* at 25.

283. Jason R. Rohr, *The Atrazine Saga and its Importance to the Future of Toxicology, Science, and Environmental and Human Health*, 40 ENV'T TOXICOLOGY & CHEMISTRY 1544, 1552 (2021).

284. *See* 21 U.S.C. § 346a(b)(2)(C)(ii)(II) (standard for when EPA must apply a 10X Child Safety Factor).

285. Mikaela Conley, *Atrazine, an Endocrine-Disrupting Herbicide Banned in Europe, Is Widely Used in the U.S.*, U.S. RIGHT TO KNOW (May 4, 2024), https://usrtk.org/pesticides/atrazine

atrazine has been found in drinking water across the United States,[286] and the EPA refuses to ban the chemical. Industry has gone to great lengths to discredit evidence that atrazine is dangerous to human health. As David Michaels, a former Assistant Secretary of Labor for Occupational Safety and Health, explains: "Industry has learned that debating the science is much easier and more effective than debating the policy . . . [I]n field after field, year after year, conclusions that might support regulation are always disputed. Animal data are deemed not relevant, human data not representative, and exposure data not reliable."[287] The fact that atrazine sales continue despite serious concerns within the EPA about the pesticide's safety points to problems in the regulatory approach. While the FQPA requires the application of the 10X Child Safety Factor absent reliable data that a different factor will be safe for infants and children,[288] the EPA has placed too great an import on industry studies. As the Ninth Circuit has noted, what constitutes "reliable" data is up to agency discretion.[289] But when the EPA uses industry data to conclude that it is safe to lower the Child Safety Factor below 10X, without regard to the other side of the story, as it did in the case of atrazine, it creates unnecessary hazards for child health.

Industry has little incentive to make regulators aware of robust toxicological data showing dangerous endpoints associated with their pesticide products and every incentive to downplay negative evidence from independent researchers. Pesticide producers have instead funded their own studies, which they have used to show that their products do not present human health concerns.[290] The EPA should reevaluate how it uses and evaluates toxicological data to account for possible funding bias of scientists and to ensure that its registration and tolerance-setting decisions are based on objective toxicological studies. For example, the EPA could require a mandatory communication barrier between scientists conducting studies and industry representatives, even where pesticide manufacturers or industry groups have funded a study. The EPA could also require industry registrants to submit, as part of any registration or tolerance

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[https://perma.cc/7LKV-2NEM]; Tyrone Hayes et al., *Herbicides: Feminization of Male Frogs in the Wild*, 419 NATURE 895 (2002).

286. Agency for Toxic Substances and Disease Registry, Ctrs. for Disease Control and Prevention, *Public Health Statement for Atrazine* (Nov. 28, 2011), https://wwwn.cdc.gov/TSP/PHS/PHS.aspx?phsid=336&toxid=59 [https://perma.cc/4KPV-96KP].

287. Rachel Aviv, *A Valuable Reputation*, NEW YORKER (Feb. 2, 2014), https://www.newyorker.com/magazine/2014/02/10/a-valuable-reputation [https://perma.cc/LQA4-YV5A].

288. 21 U.S.C. § 346a(b)(2)(C)(ii)(II).

289. Nw. Coal. for Alternatives to Pesticides, 544 F.3d at 1048-51 (allowing the EPA wide latitude as to what constitutes reliable data under FFDCA); 21 U.S.C. § 346a(b)(2)(C)(ii).

290. Mie, *supra* note 141.

petition, some number of independent studies not funded by the registrant.

C. EPA Should Increase Use of Epidemiological Evidence

In addition to the disincentive for industry to provide unbiased or negative toxicity information and the fact that the EPA does not presumptively apply a 10X Child Safety Factor, the EPA has not used epidemiological evidence to its full advantage to protect child health. Epidemiological information provides evidence on human impact in the real world.[291] While the World Health Organization has said that epidemiological evidence has a valid place in environmental health assessment and agency decisions related to human health, alongside toxicological studies on animals,[292] the EPA makes most of its decisions based on animal study data provided by registrants.[293]

Instead, epidemiologic data could round out the information on which EPA acts as extrapolating from animal studies to humans is complex and difficult to do in assessing danger to children. This difficulty in extrapolation is partly due to the differences in rates of maturation *in utero* and after birth in animals and humans.[294] Life stage is a crucial factor in susceptibility, as "critical windows of development" vary for different organs and tissues.[295] For example, a chemical may impact an organism's liver at an earlier point than it might affect development of the heart. Additionally, rats and other animals upon which studies are conducted have different rates of growth before and after birth than human children, and a matter of a day or more in exposure could result in different effects from the same chemical.[296] Additionally, lab animals possess

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291. WHO European Centre for Environment and Health, *Evaluation and Use of Epidemiological Evidence for Environmental Health Risk Assessment: WHO Guideline Document*, 108 ENV'T HEALTH PERSPS. 997, 997 (2000).

292. *Id.*

293. Naidenko, *supra* note 62, at n.2.

294. See U.S. ENV'T PROT. AGENCY, PROPOSED APPROACH TO EFFICIENTLY DEVELOP PHYSIOLOGICALLY BASED PHARMACOKINETIC (PBPK) & PHYSIOLOGICALLY BASED PHARMACOKINETIC-PHARMACODYNAMIC (PBPK-PD) MODELS FOR PESTICIDES, https://www.epa.gov/sites/default/files/2015-09/documents/pbpk.pdf [https://perma.cc/354Z-G857]; NRC Report, *supra* note 2, at 25-43; Rebecca Ram, *Extrapolation of Animal Research Data to Humans: An Analysis of the Evidence*, *in* ANIMAL EXPERIMENTATION: WORKING TOWARDS A PARADIGM CHANGE 341, 358 (Kathrin Herrmann & Kimberley Jayne eds., 2019).

295. U.S. ENV'T PROT. AGENCY, GUIDANCE FOR APPLYING QUANTITATIVE DATA TO DEVELOP DATA-DERIVED EXTRAPOLATION FACTORS FOR INTERSPECIES AND INTRASPECIES EXTRAPOLATION 9 (2014), https://www.epa.gov/sites/default/files/2015-01/documents/ddef-final.pdf [https://perma.cc/5LKA-QJDH].

296. NRC Report, *supra* note 2, at 25-43; *see also* Sengupta & Banerjee, *supra* note 31, at 1019 n.28 ("An issue of critical importance is the timing of exposure, since damage is age sensitive.")

different hormones and hormone receptors than children[297] and are studied in highly controlled environments. These differences in environment, development, and effects complicate interspecies comparison.[298]

While epidemiological data do not always offer definitive proof of a pesticide's danger, such evidence can still prove instructive.[299] For example, on the whole, epidemiological evidence tends to show relationships between exposures and harmful outcomes that may suggest a lack of safety.[300] Epidemiological studies of the widely used pesticide glyphosate, for example, have shown that exposure to the pesticide is linked to the development of non-Hodgkins lymphoma.[301] Since the FQPA does not require the EPA to have proof of harm to protect children, epidemiologic studies that show associations between exposure and disease can prompt the agency to apply an additional Safety Factor or otherwise modify or revoke a tolerance.[302]

D. EPA Should Update Testing Requirements and Operationalize Its Endocrine Disruptor Screening Program

The FQPA required the EPA to screen pesticides for endocrine effects and consider these effects in setting tolerances that are safe for children.[303] Yet, the EPA continues to rely on data requirements developed years ago that do not account for a broad range of endocrine effects.[304] This failure to update required testing is a serious lapse in progress given our increasing knowledge about substances that cross the placenta,[305] and our knowledge that endocrine-disrupting substances can act at extraordinarily low levels.[306]

In addition to updating its basic data requirements for pesticides, the EPA must operationalize its Endocrine Disruptor Screening Program, which the FQPA

297. Vandenberg, *supra* note 74, at n.58.

298. NRC Report, *supra* note 2, at 25-43.

299. Naidenko, *supra* note 62, at n.111 (citing U.S. ENV'T PROT. AGENCY, OFFICE OF PESTICIDE PROGRAMS' FRAMEWORK FOR INCORPORATING HUMAN EPIDEMIOLOGIC & INCIDENT DATA IN RISK ASSESSMENTS FOR PESTICIDES 43 (Dec. 28, 2016), https://downloads.regulations.gov/EPA-HQ-OPP-2008-0316-0072/content.pdf [https://perma.cc/RY5T-4UTB].

300. Luoping Zhang et al., *Exposure to Glyphosate-Based Herbicides and Risk for Non-Hodgkin Lymphoma: A Meta-Analysis and Supporting Evidence*, 781 MUTATION RSCH.: REVIEWS IN MUTATION RSCH. 186 (2019).

301. Zhang et al., *supra* note 300, at part 6.

302. Ctr. for Food Safety, *supra* note 278.

303. 21 U.S.C. § 346a(b)(2)(D)(viii).

304. *See* U.S. Env't Prot. Agency, *supra* note 77; Cook et al., *supra* note 78.

305. *See* Line Mathiesen et al., *Placental Transfer of Pesticides Studied in Human Placental Perfusion*, 127 BASIC & CLINICAL PHARMACOLOGY & TOXICOLOGY 505 (2020).

306. *Id.*; NAT'L INST. OF ENV'T HEALTH SCI., *supra* note 73.

called for almost thirty years ago.[307] A 2021 report on the progress of the EDSP found that twenty-four years after the FQPA's passage, the EPA has not implemented the Program and that EPA action is inconsistent with its obligation to protect public health.[308] While EPA had completed initial screening of 52 pesticide chemicals, and finalized its second level of testing guidelines—known as Tier 2—as of 2023, the agency has not restricted any chemicals under the program and has not posted a public update to its work since October 2023.[309]

E. EPA Should Not Consider Pesticide Studies Done on Humans

Prior to the passage of the FQPA, registrants rarely submitted studies based on intentional human exposure to pesticides.[310] In the wake of the FQPA, the number of human studies submitted by registrants increased,[311] even though studies of pesticides' effects on humans present ethical challenges and dangers to human health.[312] Human subjects studies test pesticides by intentionally exposing humans to a pesticide through ingestion, inhalation, or skin contact.[313] Epidemiological studies, in contrast, investigate the relationship between incidental human exposures and potential health effects over time.[314]

Human studies may be of interest to registrants because results can obviate the need for the interspecies 10X factor in tolerance setting. In this way, registrants seeking a food use pesticide tolerance may seek a higher reference dose based on a human study, thereby allowing more pesticide residue on consumer food.[315] Such practices, however, subject study participants to deleterious substances not to seek advancements in human health or science, but to avoid an interspecies safety factor and gain less health protective tolerances.

The federal rule regarding use of human subjects, which sets standards for all federal agencies conducting human studies, is known as the "Common

307. U.S. Env't Prot. Agency, *supra* note 57.

308. U.S. ENV'T PROT. AGENCY, OFF. OF INSPECTOR GEN., 21-E-0186, EPA'S ENDOCRINE DISRUPTOR SCREENING PROGRAM HAS MADE LIMITED PROGRESS IN ASSESSING PESTICIDES (2021), https://www.epaoig.gov/sites/default/files/documents/2021-07/_epaoig_20210728-21-e-0186.pdf [https://perma.cc/GQ9G-YFQX].

309. U.S. Env't Prot. Agency, *supra* note 57.

310. Robertson, *supra* note 89, at 213-14

311. *Id*. at 214.

312. *Id*. at 207, 217.

313. *Id*. at 213.

314. *See, e.g.*, Anneclaire J. De Roos et al., *Cancer Incidence Among Glyphosate Exposed Pesticide Health Applicators in the Agricultural Health Study*, 113 ENV'T HEALTH PERSPECTIVES 49 (2005); NATIONAL RESEARCH COUNCIL, TOXICITY TESTING FOR ASSESSMENT OF ENVIRONMENTAL AGENTS: INTERIM REPORT 5 (2006).

315. Robertson, *supra* note 89, at 212.

Rule."[316] The Common Rule requires review by an Institutional Review Board (IRB) where a study involves human subjects.[317] To receive IRB approval, researchers must commit to minimizing risk for study participants[318] and obtain informed consent from all participants.[319] Investigators also cannot be released from liability for their negligence.[320] Studies undertaken by pesticide registrants, which are not federal government entities, had not historically been subject to the Common Rule, but such studies were subject to regulation under FIFRA, which requires that participants give informed consent.[321]

In 2001, in light of increased use of human studies for pesticides after the FQPA's enactment,[322] the EPA requested advice from the National Academy of Sciences (NAS) on how to regulate such studies.[323] While awaiting NAS's response, the EPA issued a moratorium on human studies for use in regulatory decision-making.[324] Pesticide manufacturers sued the EPA, urging that the agency violated the APA by issuing the rule without an opportunity for notice and comment. The challengers also argued that the moratorium violated FIFRA's existing rules on human studies[325] and the FFDCA's requirement that the EPA consider all relevant data.[326] The D.C. Circuit Court agreed and vacated the rule.[327] The Court required the EPA to revert to its former practice of accepting

316. 45 C.F.R. § 46. Twenty agencies are either signatories to the Common Rule or follow it pursuant to an Executive order. *See* U.S. DEP'T OF HEALTH & HUMAN SERVS., FEDERAL POLICY FOR THE PROTECTION OF HUMAN SUBJECTS ('COMMON RULE') (Mar. 27, 2024), https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html [https://perma.cc/5VUL-DMA9].

317. *Id*. (federal agencies' adoption of the Common Rule through rulemaking); *see,* e.g., 7 C.F.R. § 1c.101 (2003) (Department of Agriculture); 6 C.F.R. § 46 (Department of Homeland Security).

318. 40 C.F.R. § 26.102(i).

319. 40 C.F.R. § 26.116.

320. *Id.*

321. 7 U.S.C. §§ 136-136y; 7 U.S.C. §§ 136j(a)(2)(p).

322. Christopher Oleskey et al., *Pesticide Testing in Humans: Ethics and Public Policy*, 112 ENV'T HEALTH PERSPECTIVES 915 (2004).

323. Press Release, U.S. Env't Prot. Agency, Agency Requests National Academy of Sciences Input on Consideration of Certain Human Toxicity Studies; Announces Interim Policy (Dec. 14, 2001), https://www.epa.gov/archive/epapages/newsroom_archive/newsreleases/c232a45f5473717085256b2200740ad4.html [https://perma.cc/9WF4-84G7].

324. *Id.*; *see also* EPA Sci. Advisory Panel, *EPA Statement on Human Testing* (July 27, 1998), https://archive.epa.gov/scipoly/sap/meetings/web/html/epastmt.html [https://perma.cc/NEQ9-9ACY].

325. 7 U.S.C. § 136a-1(g)(1); CropLife America v. Env't Prot. Agency*,* 329 F.3d 876, 878 (D.C. Cir. 2003).

326. 21 U.S.C. § 346a(b)(2)(D); *CropLife America,* 329 F.3d at 878.

327. *CropLife America,* 329 F.3d at 879.

human studies on a case-by-case basis, using high ethical standards and applying all relevant statutory mandates.[328]

The EPA has since issued final rules on third-party human studies,[329] implementing recommendations contained in the NAS report.[330] These rules apply the Common Rule to *all* studies submitted to the EPA[331] and adopt the NAS's main ethical recommendations.[332] The rules allow the EPA, when regulating under FIFRA and the FFDCA, to use the results of human pesticide studies conducted by third parties where research sponsors have adhered to strict requirements.[333] These requirements include fully informed consent, safeguards to protect against undue influence of economically disadvantaged persons, and prohibiting participation for individuals who cannot consent for themselves.[334]

Though the EPA final rules require participants in third-party studies to receive notice of the potential dangers of pesticides to which they will be exposed and to give informed consent,[335] these studies still present ethical challenges. Human studies in this area intentionally expose human subjects to poisonous substances. These studies are designed not for the betterment of human health but rather to procure registration and tolerance decisions that will allow continued or increased commercial use of a pesticide. These studies are also typically done on limited sample sizes as small as nine persons, [336] and are conducted only on adults, which means that the results may not easily extrapolate to children.[337] In the long term, more extensive use of such studies could resurface as a way for registrants to avoid the 10X interspecies uncertainty factor in the tolerance setting process. To avoid the ethical dilemma inherent in intentionally dosing humans with a pesticide, and because such studies provide only limited use in assessing risks to children under FQPA, the EPA should

328. *Id*.

329. *See* Protections for Subjects in Human Research Involving Pesticides, 78 Fed. Reg. 10538 (Feb. 14, 2013) (strengthening the standards for human research involving pesticides submitted by third parties for consideration in EPA decision-making but not amending the Common Rule).

330. NAT'L RSCH. COUNCIL (US) COMM. ON THE USE OF THIRD PARTY TOXICITY RSCH. WITH HUMAN RSCH. PARTICIPANTS, INTENTIONAL HUMAN DOSING STUDIES FOR EPA REGULATORY PURPOSES: SCIENTIFIC AND ETHICAL ISSUES (2004).

331. Protections for Subjects, 78 Fed. Reg. at 10538.

332. *Id*. at 10540.

333. *Id.* at 10540.

334. *Id*. at 10540, 10543.

335. *See* Requirements for Protection of Human Subjects, 40 C.F.R. part 26, subpart A; General Requirements for Informed Consent, 40 C.F.R. § 26.116.

336. *See, e.g.*, EWG, THE ENGLISH PATIENTS: HUMAN EXPERIMENTS AND PESTICIDE POLICY 1, 1 (1998), https://archive.epa.gov/scipoly/sap/meetings/web/pdf/english.pdf [https://perma.cc/P288-WYV4].

337. EWG, THE ENGLISH PATIENTS: HUMAN EXPERIMENTS AND PESTICIDE POLICY 1, 13 (1998), https://archive.epa.gov/scipoly/sap/meetings/web/pdf/english.pdf [https://perma.cc/P288-WYV4].

consider entirely ending its reliance on human studies to set pesticide tolerances.

F. EPA Should Make Final Decisions More Expeditiously

Given the time that has lapsed since the FQPA's enactment, the EPA must act expeditiously in making pesticide child-protective tolerance decisions where it has evidence of serious or widespread toxicity. Whole generations have lived without the full protection possible under the FQPA. For example, as noted above, the EPA has had information available for years suggesting that atrazine, the second-most widely used pesticide in the United States by volume,[338] acts as a potent endocrine disruptor.[339] In September 2020, the EPA issued its latest interim registration review decision for atrazine.[340] Environmental justice groups challenged the decision, claiming that the EPA had violated its duties under FIFRA by issuing the decision without sufficient supporting evidence.[341] The EPA subsequently sought and obtained a voluntary partial remand from the Ninth Circuit, which allowed the agency to re-evaluate certain policy decisions and propose risk mitigation solutions.[342] The agency's proposed revision to the atrazine interim registration decision, published in 2022, is currently open for public comment.[343]

Despite this recent progress toward mitigating the dangers of atrazine, years of regulatory battles have kept this profitable pesticide in use without child-protective measures.[344] Children who were babies when the chemical first gained widespread use are now young adults, many of childbearing age, and effects from atrazine's use may surface later in life or as intergenerational effects.[345]

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338. U.S. ENV'T PROT. AGENCY, PESTICIDES INDUSTRY SALES AND USAGE: 2008-2012 MARKET ESTIMATES, at 14 (2017), https://www.epa.gov/sites/default/files/2017-01/documents/pesticides-industry-sales-usage-2016_0.pdf [https://perma.cc/3T7Z-84WN].

339. *See* U.S. Env't Prot. Agency, *Atrazine* (Jan. 24, 2025), https://www.epa.gov/ingredients-used-pesticide-products/atrazine [https://perma.cc/KU2M-9JCM] (listing twelve consultations with FIFRA's Scientific Advisory Panel on atrazine since 2003).

340. U.S. ENV'T PROT. AGENCY, ATRAZINE INTERIM REGISTRATION REVIEW DECISION CASE NUMBER 0062 (Sept. 2020), https://downloads.regulations.gov/EPA-HQ-OPP-2013-0266-1605/content.pdf [https://perma.cc/GF5L-3PGB].

341. Petition for Review, Rural Coal. v. U.S. Env't Prot. Agency, No. 20-73220 (9th Cir. 2020).

342. U.S. Env't Prot. Agency, *supra* note 339.

343. Memorandum: U.S. Env't Prot. Agency, Proposed Revisions to the Atrazine Interim Registration Review Decision, Case Number 0062 (June 23, 2022), https://downloads.regulations.gov/EPA-HQ-OPP-2013-0266-1625/content.pdf [https://perma.cc/L9E2-R3CS].

344. *Id.*

345. Margaux McBirney et al., *Atrazine Induced Epigenetic Transgenerational Inheritance of Disease, Lean Phenotype and Sperm Epimutation Pathology Biomarkers*, 12 PLOS ONE e0184306 (Sept. 20, 2017) ("Ancestral environmental exposures to a variety of environmental toxicants and

G. EPA Should Publish Tolerance Decisions in a Uniform and Understandable Manner and Educate Communities About Pesticide Use and Risks

The EPA must publish an overarching policy on tolerance decisions, write in a more transparent manner, and work to increase public awareness of its tolerance decision-making methods. The EPA's overarching mission is to protect people and the environment from significant health risks.[346] With regard to pesticide residues on food, its specific mission is to set tolerances so that they are "safe" for children.[347] To further its mandate, the EPA could organize training programs to educate the public about pesticide use and exposure. Currently, the OCHP gives little indication that educating and involving the public in protecting children from pesticides is a high priority.[348] Implementing new public education programs would further OCHP's stated goal of coordinating "programs to eliminate threats to children's health in places where they live, learn and play."[349]

Additionally, the EPA should revamp how it publishes tolerance decisions. First, it should keep a running list of tolerance decisions in which it has considered, applied, reduced, or removed a Child Safety Factor. As detailed in Part III above, EPA pesticide regulatory decisions are unnecessarily obtuse and confusing. To increase transparency, the EPA should adopt a standardized form for all tolerance decisions. Adopting a consistent structure for pesticide tolerance decisions similar to the standardized form we propose and ensuring clear and consistent language—especially when the decision may impact children's health—will significantly enhance transparency and accessibility.

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other factors have been shown to promote the epigenetic transgenerational inheritance of adult onset disease . . . across generations [even] in the absence of any continued direct environmental exposure.").

346. *Environmental Protection Agency (EPA)*, USAGOV, https://www.usa.gov/agencies/environmental-protection-agency [https://perma.cc/XZJ7-TP2X].

347. 21 U.S.C. § 346a(b)(2)(C).

348. U.S. Env't Prot. Agency, About the Office of Children's Health Protection (OCHP) (Mar. 22, 2025) https://www.epa.gov/aboutepa/about-office-childrens-health-protection-ochp [https://perma.cc/69K3-9D5R]; *see also* U.S. Env't Prot. Agency, *Children's Health Protection Advisory Committee (CHPAC) Comment Letters and Meeting Materials* (Jan. 15, 2025), https://www.epa.gov/children/childrens-health-protection-advisory-committee-chpac-comment-letters-and-meeting-materials [https://perma.cc/W46D-5EZT] (no specific actions noted to ensure coordination with OPP on tolerance decisions that may affect children's health).

349. U.S. Env't Prot. Agency, About The Office Of Children's Health Protection (OCHP) (Oct. 4, 2024) https://www.epa.gov/aboutepa/about-office-childrens-health-protection-ochp [https://perma.cc/69K3-9D5R].

CONCLUSION

In September 2023, New York Congresswoman Nydia Velázquez re-introduced the federal Ban All Neurotoxic Organophosphate Pesticides from Our Food Act,[350] and in December 2023, the state of New York banned all neonicotinoid pesticide-treated seeds for agricultural use on wheat, soy, and corn.[351] These pesticides are believed to interfere with bee colony growth,[352] and scientists have opined that if pollinators decline, human diets would be "greatly impoverished."[353] The public surge in concern for bees and the passage of state legislation to ban these pesticide-treated seeds demonstrates that discussion, advocacy, and media coverage can achieve important regulation of and reductions in pesticide use.

Alongside changes in overarching policy towards pesticides, this paper urges the EPA to set pesticide tolerances for food residues in line with the presumptions of the FQPA. Over the past three decades, the EPA has shied away from applying the FQPA's presumptive 10X Child Safety Factor, which would make pesticide tolerances safer for children and other vulnerable groups. The EPA has done so through a combination of vague and unclear tolerance publications, delaying tactics, weak internal tracking practices, and failure to involve major child health experts within the agency. These practices must be reversed. This paper does not call for a new law but rather argues for a change in policy requiring the EPA to enforce existing law and educate the public about its efforts to protect the environment and human health. The EPA must reclaim its role as a protector of human health and the environment, instead of as an advocate for less strict regulation for pesticide registrants.

Generations have been exposed to large quantities of synthetic pesticides—substances that Rachel Carson first described six decades ago as "elixirs of death."[354] The ensuing health and environmental effects can be hard to pinpoint, but Carson's assertion that effects from synthetic pesticides will be extreme and ever present[355] rings as true today as it did in the 1960s. The wait has been long,

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350. Press Release, Congresswoman Nydia Velázquez, Rep. Velázquez Re-introduces a Bill to Ban All Neurotoxic Pesticides (Sept. 19, 2023), https://velazquez.house.gov/media-center/press-releases/rep-velazquez-re-introduces-bill-ban-all-neurotoxic-pesticides [https://perma.cc/NR2Z-CQZA].

351. S. 1856-A, 2023-24 Gen. Assemb. (N.Y. 2023).

352. Chia-Hua Lin et al., *Honey Bees and Neonicotinoid-Treated Corn Seed: Contamination, Exposure, and Effects*, 40 ENV'T TOXICOLOGY & CHEMISTRY 1212 (2021).

353. Alexandra-Maria Klein, *Importance of Pollinators in Changing Landscapes for World Crops*, 274 PROC. ROYAL SOC'Y B 303 (2006).

354. RACHEL CARSON, SILENT SPRING 15 (1962).

355. *Id.* at 226-27, 230-31, 234-42.

but the time to act is now, and the FQPA provides essential tools for a much-needed policy shift to better protect children from the dangers of pesticides in food.