Ending Pesticide Myopia: Broadening the Role of Alternatives in Assessing Dangerous Products Under FIFRA

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INTRODUCTION

The Hartz UltraGuard Plus Flea and Tick Collar is a tremendously convenient product. It provides seven months of protection for your pet, costs just a few dollars, and is sold everywhere from Walmart to Amazon.[1] Simply take the collar out of its package, fit it around your pet's neck, and trim off the excess—leaving a little extra for future adjustment.[2] Your dog or cat is now protected from fleas and ticks.

Hartz UltraGuard Spot Treatment is sold right next to the collars in those same stores, but it works a little differently.[3] The treatment comes in a single-use tube, and pet owners must squeeze a line of drops to a pet's back once per month.[4] The spot treatment also costs slightly more.[5]

On the surface, the choice is easy: use the collar. There is a catch, however. The collar works by gradually shedding a dust containing tetrachlorvinphos (TCVP) onto the pet's fur.[6] TCVP is extremely toxic to the fleas and ticks the collar targets, but it also has chronic effects for humans—especially children who pet the animal and then put their hands in their mouths.[7] By contrast, the active ingredients in the spot treatment (one of a class of products usually called "spot-ons") are at least somewhat less toxic,[8] and more importantly, the product's liquid formulation means the pesticide is not as easily transferred to a stroking hand as is the collar's dry dust.[9]

Despite the increased toxicity, for thirteen years EPA resisted a petition from the Natural Resources Defense Council (NRDC) to pull TCVP collars from

1. *See Hartz UltraGuard Flea and Tick Collar for Cats and Kittens*, AMAZON, https://www.amazon.com/Hartz-Ultra-Guard-Flea-Tick/dp/B0009F3MLA (last visited March 26, 2023); *Hartz UltraGuard Pro Reflective Flea And Tick Collar For Dogs And Puppies*, WALMART, https://www.walmart.com/ip/Hartz-UltraGuard-Pro-Reflective-Flea-And-Tick-Collar-For-Dogs-And-Puppies-7-Months-Protection-1ct/186639859?athbdg=L1100 (last visited March 26, 2023).

2. *Hartz UltraGuard Flea and Tick Collar for Dogs*, HARTZ, https://www.hartz.com/product/hartz-ultraguard-plus-flea-tick-collar-for-dogs/#directions-for-use (last visited March 23, 2023).

3. *Hartz UltraGuard Spot Treatment for Dogs and Puppies 15–30 lbs.*, HARTZ, https://www.hartz.com/product/hartz-ultraguard-plus-topical-flea-tick-prevention-dogs-puppies-15-30lb/#directions-for-use (last visited March 26, 2023).

4. *Id.*

5. DON ATWOOD & STEPHEN SMEARMAN, BIOLOGICAL AND ECON. ANALYSIS DIV., OFF. OF PESTICIDE PROGRAMS, EPA, ALTERNATIVES ASSESSMENT FOR TETRACHLORVINPHOS (TCVP) (PC CODE 083702) IMPREGNATED FLEA AND TICK COLLARS ON DOGS AND CATS (2017), https://www.regulations.gov/document/EPA-HQ-OPP-2008-0316-0087.

6. Nat. Res. Def. Council v. EPA (*NRDC v. EPA*), 31 F.4th 1203, 1205 (9th Cir. 2022).

7. *Id.*

8. See discussion *infra* Part IV.B.

9. *NRDC v. EPA*, 31 F.4th at 1205.

the market.[10] Fleas and ticks are vectors for a variety of human diseases,[11] and before canceling a pesticide with public health-promoting uses like controlling fleas and ticks, EPA considers the impact the action may have on the spread of disease.[12] While preventing the spread of disease is important, EPA's decision effectively perpetuated a situation where a pesticide with harmful effects stayed on the market despite the presence of less harmful alternatives.

In 2022, the Ninth Circuit found technical errors in EPA's response to the petition and ordered EPA to reconsider its decision. The court's holding resulted in the removal of a harmful pesticide, but it was based solely on those technical errors. *NRDC v. EPA* did nothing to address the larger issue of EPA's myopia toward pesticides: a system that does not take sufficient account of alternatives when considering whether a potentially harmful pesticide should reach or remain on the market.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) mandates that EPA register a pesticide before it can be sold.[13] FIFRA also mandates that EPA allow the sale of pesticides that do not cause "unreasonable adverse effects on the environment," taking into account "the economic, social, and environmental costs and benefits of the use of any pesticide."[14] The agency may cancel a pesticide's registration if it finds evidence of unreasonable adverse effects after initial registration.[15] Particularly in initial registration decisions, EPA currently bases its decisions on quantitative risk assessment criteria: if the pesticide meets the criteria, its adverse effects are *by definition* reasonable, and EPA will register the pesticide. Where there are no alternatives to the pesticide, EPA's current practice of comparing a pesticide's toxicity to a quantitative baseline provides a complete picture of the pesticide's reasonability. But when another pesticide can perform the same task with less risk, those same toxic effects can seem far less reasonable.[16]

This Note argues that EPA should consider the broader context of alternatives in initial registration decisions and lean on it more heavily in deciding whether to cancel already-registered pesticides. Doing so would increase EPA's ability to cancel pesticides shown to be more hazardous than their counterparts, and potentially allow EPA to decline to register such pesticides in the first place. Part I summarizes FIFRA and the process EPA uses to assess

10. EPA, AGENCY RESPONSE TO THE NATURAL RESOURCES DEFENSE COUNCIL'S (NRDC) APRIL 2009 TETRACHLORVINPHOS PETITION (2020 Denial) (2020), https://downloads.regulations.gov/EPA-HQ-OPP-2008-0316-0088/content.pdf; EPA, RESPONSE TO NATURAL RESOURCE DEFENSE COUNCIL'S APRIL 23, 2009 PETITION REQUESTING CANCELLATION OF ALL PET USES OF TETRACHLORVINPHOS (2014 Denial) (2014), https://downloads.regulations.gov/EPA-HQ-OPP-2009-0308-0010/content.pdf.

11. *See, e.g.*, *Vector-borne diseases*, WORLD HEALTH ORG. (Mar. 2, 2020), https://www.who.int/news-room/fact-sheets/detail/vector-borne-diseases.

12. *See* 2020 Denial, *supra* note 10, at 32.

13. 7 U.S.C. §§ 136–136y.

14. *Id.* § 136a.

15. *Id.* § 136d(b).

16. As discussed in Part IV, EPA does engage in such balancing under its Special Review process.

pesticides' risks. Part II relates the history of *NRDC v. EPA*—a useful case study and the litigation that spawned EPA's refusal to cancel TCVP pet collars. Part III discusses policy rationales for changing EPA's assessment of alternatives. Part IV offers a regulatory mechanism for EPA to effect change to better consider alternatives.

I. FIFRA AND COST-BENEFIT ANALYSIS

Minimizing harm from pesticides is a challenging task precisely because they are *designed to harm*—that is, to kill or deter pests.[17] That makes pesticide regulation a different challenge from, for instance, regulating auto emissions. In the case of auto emissions, the harm caused is a byproduct of a useful activity (driving), while in pesticides the harm *is* the useful activity.[18] As EPA puts it: "Pesticides may pose some risk because they are meant to kill or control insects, weeds, rodents, and other pests. But even though pesticide use entails some risk, pesticides provide substantial benefits to society."[19] The basic question that pesticide regulators must ask is one of costs and benefits: how much collateral damage are we willing to accept in exchange for a given pesticide's control of a target pest?

Congress crafted FIFRA with that balancing at its core, mandating that EPA "shall" register pesticides that perform their function without "unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."[20] EPA has interpreted this statutory language to require a relatively strict cost-benefit balancing.[21] The following Subpart examines how EPA approaches cost-benefit balancing in initially registering pesticides, and then discusses how that process differs from the more broad-based inquiry EPA undertakes when considering whether to cancel a pesticide's registration.

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17. FIFRA defines a pesticide (as relevant here) as follows: "The term "pesticide" means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest . . ." 7 U.S.C. § 136(u).

18. *See, e.g.*, Mary Jane Angelo, *Embracing Uncertainty, Complexity, and Change: An Eco-Pragmatic Reinvention of a First-Generation Environmental Law*, 33 ECOLOGY L. Q. 105, 109 (2006) (stating that "[P]esticide regulation is unique in that, unlike other areas of environmental protection where environmental laws can seek to eliminate or minimize hazardous releases that result as unintended consequences of manufacturing or other processes, pesticides are intentionally released into the environment for the express purpose of killing, injuring, or disrupting the behavior of living organisms in the environment.").

19. OFF. OF PESTICIDE PROGS., EPA, RISK/BENEFIT BALANCING UNDER THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (EPA FIFRA Risk Balancing Explainer) (1990).

20. 7 U.S.C. § 136a(a); *id.* § 136(bb) ("The term 'unreasonable adverse effects on the environment' means (1) 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. . .").

21. Angelo, *supra* note 18, at 182. *See also* Danica Li, *Toxic Spring: The Capriciousness of Cost-Benefit Analysis Under FIFRA's Pesticide Registration Process and Its Effect on Farmworkers*, 103 CAL. L. REV. 1405, 1422 (2015) ("[I]n considering whether to register, suspend, or cancel a pesticide, the EPA must perform a cost-benefit analysis that weighs the unreasonable adverse effects of the pesticide to humans or the environment against the beneficial commercial use of the pesticide in question.").

A. Registration Procedures under FIFRA

When a manufacturer applies to register a new pesticide, EPA requires submission of data on the pesticide's toxicity.[22] "EPA may require data from any combination of more than 100 different tests, depending on the potential toxicity of active and inert ingredients and degree of exposure."[23] EPA then performs a risk assessment to determine whether the pesticide should be registered, and if so, whether to place any restrictions on its use.[24]

1. Risk Assessment under FIFRA

The EPA human health risk assessment process consists of four steps: hazard identification, dose/response assessment, exposure assessment, and risk characterization.[25]

Hazard identification asks, as an initial matter, whether some harm from the substance is plausible. In the case of TCVP, that answer is quite clear: yes. TCVP is an organophosphate (OP), a class of chemicals first synthesized in the mid-1800s, but perhaps best known from its incarnations as Sarin and other World War II-era nerve agents.[26] All OPs interfere with the functioning of acetylcholine, a neurochemical essential for muscle control.[27] Acetylcholine

22. This Part lays out the default registration process under FIFRA. It is important to note, however, that in some ways it represents the most rigorous end of a spectrum of potential pathways to registration. FIFRA grants EPA authority to develop a number of simplified processes to register pesticides in circumstances where the agency feels less rigorous examination is necessary. *See, e.g.* 7 U.S.C. § 136a(c)(2)(E) (authorizing EPA to waive certain data requirements when an already-registered pesticide is being registered for a new "minor use"); *see also* 7 U.S.C. § 136a(c)(7) (allowing EPA to "conditionally register" a pesticide that "meets the standard for registration," but for which certain data is lacking). These special procedures have become more commonly used in recent years, prompting criticism. *See, e.g.*, GOV. ACCOUNTABILITY OFF., PESTICIDES: EPA SHOULD TAKE STEPS TO IMPROVE ITS OVERSIGHT OF CONDITIONAL REGISTRATIONS (2013). A fulsome discussion of these important procedures is beyond the scope of this Note.

23. EPA FIFRA Risk Balancing Explainer, *supra* note 19.

24. CONG. RSCH. SERV., RL31921, PESTICIDE LAW: A SUMMARY OF THE STATUTES 6 (2012) (noting that restricted-use pesticides may only be applied by specially trained applicators). Because "new scientific information can come to light at any time and change . . . understanding of potential effects from pesticides," EPA reviews the registration of each pesticide at least every fifteen years. EPA, REGISTRATION REVIEW PROCESS (2022), https://www.epa.gov/pesticide-reevaluation/registration-review-process. It should be noted that beginning in 2008—and continuing for the entirety of the *NRDC v. EPA* litigation saga (see *infra* Part II)—EPA was engaged in such a registration review for all TCVP products. *See* 2020 Denial, *supra* note 10, at 7–9 (noting that "[w]hile EPA has completed the revised residential exposure assessment in order to expedite its response to the NRDC Petition, TCVP remains under registration review pending completion of a full revised human health risk assessment (including an aggregate assessment together with all TCVP uses) and registration review decision"). An appreciation of how responding to NRDC's petition may have helped or hindered the more structured registration review process is beyond the scope of this Note. *But see* discussion, *infra* note 49.

25. *See generally Human Health Risk Assessment*, EPA, https://www.epa.gov/risk/human-health-risk-assessment (last visited Aug. 19, 2023).

26. Lucio G. Costa, *Organophosphorus Compounds at 80: Some Old and New Issues*, 162(1) TOXICOLOGY SCI. 24, 25 (2018), https://doi.org/10.1093%2Ftoxsci%2Fkfx266.

27. *Id.*

function is also the target of potent natural toxins such as black widow and cobra venom.[28] There is a large body of evidence linking TCVP in particular to carcinogenicity[29] and to neurodevelopmental issues in children.[30] TCVP toxicity led the industry to voluntarily cancel all *crop* uses of TCVP as long ago as 1987.[31]

Second, once EPA identifies some plausible toxicity, the agency attempts to quantify and qualify that toxicity. In the case of TCVP, toxicity data comes from studies conducted on animals such as rats.[32] By exposing animals to specific amounts of TCVP under controlled conditions and observing the effects, researchers can identify harmful effects, creating a so-called dose-response assessment. Mammal physiology is similar enough across species that a harmful dose calculated from rats or rabbits applies—with uncertainty, as discussed in the description of risk characterization below—to humans. In addition, researchers can identify the *type* of harm a pesticide causes—for example: cancer, chronic neurological issues, or acute toxicity (poisoning).[33]

Third, once EPA has information on the harmful effects that will result from contact with a pesticide, the agency must assess how much of a dose someone would likely receive from a given product containing that pesticide.[34] The real world is a far different place than the lab, and exposure from a product such as a pet collar is subject to innumerable variables. TCVP pet collars kill fleas and ticks by gradually sloughing off the active ingredient onto the pet's fur, where pests contact it.[35] Some TCVP sloughs off the collar as dust, while some of it

28. *See* generally, Akemichi Baba & Jack R. Cooper, *The Action of Black Widow Spider Venom on Cholinergic Mechanisms in Synaptosomes*, 34 J. NEUROCHEMISTRY 1369 (1980); Ayaulym Bekbossynova et al., *Venom-Derived Neurotoxins Targeting Nicotinic Acetylcholine Receptors*, 26 MOLECULES 3373 (2021).

29. EPA classifies TCVP as a group C "possible carcinogen" while the International Agency for Research on Cancer (IARC) classifies it as a group 2B, which is a more hazardous category. Costa, *supra* note 26, at 30.

30. MIRIAM ROTKIN-ELLMAN & GINA SOLOMON, NAT. RES. DEF. COUNCIL, POISON ON PETS II - TOXIC CHEMICALS IN FLEA AND TICK COLLARS (2009), https://www.nrdc.org/sites/default/files/poisonsonpets.pdf; EPA, THIRD REVISION: HUMAN HEALTH DRAFT RISK ASSESSMENT FOR REGISTRATION REVIEW (Human Health Risk Assessment) 32 (2022), https://www.epa.gov/system/files/documents/2022-10/TCVP%20Third%20Revision%20Human%20Health%20DRA.pdf.

31. EPA, TETRACHLORVINPHOS (TCVP), https://www.epa.gov/ingredients-used-pesticide-products/tetrachlorvinphos-tcvp (last visited Nov. 9, 2022). Though beyond the scope of this Note, TCVP is still used for pest control on livestock, and EPA lists allowable residue limits for a variety of products such as beef fat. *See* 40 C.F.R. § 180.252.

32. EPA, REREGISTRATION ELIGIBILITY DECISION FOR TETRACHLORVINPHOS (TCVP) 24 (2006), https://archive.epa.gov/pesticides/reregistration/web/pdf/tcvp_red.pdf.

33. *See generally* Human Health Risk Assessment *supra* note 30.

34. EPA separately assesses dermal, inhalation, and ingestion exposure. Further, in the case of TCVP pet collars it differentiated between handlers who apply the collar to the animal and persons who subsequently come in "incidental" contact with the pesticide through, for example, petting the animal. *See generally id*. EPA determined that incidental oral contact, such as a child placing their fingers in their mouth after petting the animal, was the most hazardous category of exposure, and throughout this Note it is that category I refer to with the general label "exposed."

35. *Id.* at 48.

comes off as a liquid. The liquid tends to stick more tightly to pet fur than does the dust and is therefore less likely to transfer to a child's hand.[36] But how much dust comes off the collar each day? How much is transferred from fur to hand with each stroke? How many strokes per day will the pet receive? Will the child sleep with the animal? How much TCVP is in the collar to begin with? Similarly, collars are generally sold as "trim to fit," and the total amount of TCVP that can slough off is also dependent on whether pet owners do in fact trim their collars.[37] None of these questions have uniform answers, but EPA must make reasonable assumptions for each one.[38] Once all these assumptions are factored in, EPA arrives at an estimate for the amount of the pesticide it expects a person to be exposed to in interacting with the product.

The final step, risk characterization, effectively asks how much risk the expected exposure poses.[39] Because of the uncertainty inherent in translating laboratory studies on animals into estimates of the risk products containing a pesticide pose to humans in the real world, EPA applies uncertainty factors to create a "level of concern."[40] In the case of TCVP, EPA decided that to be "safe," the expected exposure had to be less than 1/1000 the minimum harmful dose. EPA arrived at that level of concern by applying a 10x factor because the results were being extrapolated from another species, a second 10x factor because of the variation in response expected among humans, and a third 10x factor because of the evidence of neurodevelopmental harm caused by OP pesticides.[41] In its final

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36. *NRDC v. EPA*, 31 F.4th 1203, 1205 (9th Cir. 2022).

37. EPA, STANDARD OPERATING PROCEDURES FOR RESIDENTIAL PESTICIDE EXPOSURE ASSESSMENT (SOPs) 8–3 (2012), https://www.epa.gov/sites/default/files/2015-08/documents/usepa-opp-hed_residential_sops_oct2012.pdf. EPA publishes standard, research-based answers to these questions and more in its residential pesticide standard operating procedures (SOPs) for risk assessment. *See generally id*.

38. As example of the difficulty: Based on past data, EPA had considered all pet collars "liquid formulations" and therefore subject to a certain set of risk assessment assumptions. *See* Human Health Risk Assessment, *supra* note 30, at 48. In the midst of TCVP litigation, NRDC challenged that assumption, bringing forward data that TCVP collars, at least, should be considered solid formulations, which are subject to a different set of risk assessment assumptions. *Id.*

39. EPA, CONDUCTING A HUMAN HEALTH RISK ASSESSMENT, https://www.epa.gov/risk/conducting-human-health-risk-assessment#tab-5 (last visited Nov. 9, 2022) ("A risk characterization conveys the risk assessor's judgment as to the nature and presence or absence of risks, along with information about how the risk was assessed, where assumptions and uncertainties still exist, and where policy choices will need to be made.").

40. 2020 Denial, *supra* note 10, at 12.

41. *Id.* The final 10x safety factor is the result of the Food Quality Protection Act (FQPA), which directed EPA:

> [I]n setting pesticide tolerances, to use an additional tenfold margin of safety to protect infants and children, taking into account the potential for pre- and postnatal toxicity and the completeness of the toxicology and exposure databases. The statute authorizes EPA to replace this tenfold "FQPA safety factor" with a different FQPA factor only if reliable data demonstrate that the resulting level of exposure would be safe for infants and children.

EPA, DETERMINATION OF THE APPROPRIATE FQPA SAFETY FACTOR(S) IN TOLERANCE ASSESSMENT ii (2002), https://www.epa.gov/sites/default/files/2015-07/documents/determ.pdf. EPA declined to apply this factor to TCVP in its first (2014) denial of NRDC's petition but acknowledged the risks to children

denials of NRDC's petitions, EPA found that the amounts of TCVP sloughed off by the pet collars still on the market were less than this level of concern and therefore passed the risk assessment in EPA's eyes.[42]

2. The Preeminence of Quantitative Assessment in Registration

In initial registration actions, the risk assessment described above is arguably *the* key hurdle a pesticide applicant must clear, in part because EPA does not perform a benefits analysis in most initial registration proceedings.[43] First, FIFRA gives EPA authority to waive submission of data on the efficacy of most pesticides for which registration is sought.[44] EPA in fact waives this data requirement as a matter of course because, as one scholar has put it, it "assumes a manufacturer would not invest the resources necessary to support registration and commercialization of the pesticide unless the pesticide was efficacious and thus has benefits."[45]

Second, when *initially registering* a pesticide, EPA does not consider whether alternative pesticides already on the market might reduce the relative net benefits of the pesticide.[46] This Note suggests a path by which EPA *could* consider alternatives, as discussed in Part IV. At present in registration proceedings, however, "EPA will make a regulatory decision using risk assessments based on review of the [manufacturer-submitted] data, information and proposed label."[47] Those submissions do not include information on alternatives.[48]

B. Cancellation Procedures and Benefits Analysis

Standing in contrast to the relatively narrow inquiry of initial registration actions are what EPA regulations call Special Reviews—the precursor to canceling a pesticide.[49] The Special Review process implements FIFRA's

in its 2020 Denial. *See* 2014 Denial, *supra* note 10, at 6; Human Health Risk Assessment, *supra* note 30, at 12.

42. See 2020 Denial, *supra* note 10, at 40.

43. Angelo, *supra* note 18, at 163.

44. 7 U.S.C. §136a(c)(5).

45. Angelo, *supra* note 18, at 183 n.371. There are exceptions: for instance, when registering a pesticide specifically targeting vectors of human disease, EPA requires scientific data demonstrating that the pesticide is effective against those vectors. EPA, REGULATION OF PESTICIDES WITH PUBLIC HEALTH USES (2022), https://www.epa.gov/pesticides/regulation-pesticides-public-health-uses.

46. Angelo, *supra* note 18, at 163.

47. EPA, HOW TO REGISTER A PESTICIDE – A GUIDE FOR APPLICANTS NEW TO THE PROCESS (2023), https://www.epa.gov/pesticide-registration/how-register-pesticide-guide-applicants-new-process.

48. EPA, DATA REQUIREMENTS FOR PESTICIDE REGISTRATION (2022), https://www.epa.gov/pesticide-registration/data-requirements-pesticide-registration. The Special Review procedures discussed below allow EPA to consider factors including alternatives during both initial registration actions and cancellation procedures. 40 CFR §154.1(a).

49. 40 C.F.R. § 154. Note that EPA appears to have stopped using the term "Special Review"; it appears in few recent places on EPA's website, and EPA now places its emphasis on the newer "Registration Review" process, which requires reevaluation of every registered pesticide every fifteen years. *Id.* at § 155.40. *See* discussion of the process *supra* note 24 (noting that TCVP products have been under registration review for the last fifteen years). The registration review process essentially requires

provision that EPA may hold a hearing to determine whether to cancel the registration of or not register a pesticide if it "appears to [EPA] that a pesticide . . . generally causes unreasonable adverse effects on the environment."[50] EPA regulations identify a variety of triggers for a review, including risk of acute injury to humans or domestic animals, a risk of a "chronic or delayed toxic effect" to humans or "nontarget organisms," or any other risk to humans or the environment great enough to justify considering whether the risk outweighs whatever social, environmental, or economic benefits the pesticide provides.[51] According to EPA, issuing a Notice of Special Review means that "the Agency *expects* to initiate formal proceedings seeking to cancel [or decline to register] the registration of the product(s) in question *unless* it has been shown during the Special Review that the Agency's initial determination was erroneous . . . ."[52]

Once EPA initiates a Special Review, the agency performs a complete benefits assessment, considering both biological and economic factors. With regard to biological benefits, EPA considers what pests the pesticide targets, how the pesticide is used, and "the effectiveness of chemical and non-chemical alternatives"—all with the goal of determining how important the chemical really is to the production of any crop or to any other pesticide use.[53] On the economic side, the key questions are whether alternative pest control strategies will cost more and what impact that will have on the consumers or farmers who currently rely on the pesticide.[54] In some cases, EPA finds relatively minor impacts "because cost effective substitutes (chemical and non-chemical) exist and are readily available." In other cases, "equally effective alternatives do not exist."[55] However, even in this latter case EPA does not have formal criteria for assessing when the presence of an alternative should result in a cancellation

each pesticide to re-meet the initial registration criteria and provides an opportunity to introduce newly available scientific information on its effects. *Id.* at §155.40(a)(1). However, "[a]t any time, [EPA] may undertake *any other review* of a pesticide under FIFRA, irrespective of the pesticide's past, ongoing, scheduled, or not yet scheduled registration review." *Id.* at §155.40(c)(1) (emphasis added). The Special Review process codified in 40 C.F.R. § 154 appears to be the primary other applicable review process specified in FIFRA's implementing regulations. *See generally* 40 C.F.R. §§ 150–180. In addition, EPA's document *Pesticide Cancellation Under EPA's Own Initiative* directly follows the structure of the Special Review process outlined in 40 C.F.R. § 154. *See Pesticide Cancellation Under EPA's Own Initiative*, EPA (last updated Dec. 6, 2022), https://www.epa.gov/pesticide-tolerances/pesticide-cancellation-under-epas-own-initiative. For these reasons, I will refer to the cancellation process as the Special Review throughout this Note.

50. 7 U.S.C. § 136d(b); *see generally* 40 C.F.R. § 154. FIFRA actually gives EPA an option to either issue a notice of hearing or directly issue a notice of intent to cancel (NOIC). For purposes of this Note, I focus on the hearing option because if EPA simply issues the notice a registrant may still demand an evidentiary hearing—which history shows will inevitably occur.

51. 40 C.F.R. § 154.7(a).

52. *Id.* § 154.1(a) (emphasis added).

53. EPA FIFRA Risk Balancing Explainer, *supra* note 19, at 5.

54. *Id.*

55. *Id.*

decision.[56] The TCVP saga presents an excellent case study of lack of rigorous attention to alternatives.

II. NRDC'S EFFORT TO REMOVE TCVP COLLARS FROM THE MARKET

NRDC began its legal efforts to remove TCVP pet collars from the market in 2009. In late 2022, EPA granted NRDC's petition—before reversing that decision in late 2023.[57] This Part briefly relates the basis and history of NRDC's efforts and then discusses the Ninth Circuit ruling that led to NRDC's petition being granted.

A. Background

In 2009, NRDC published a report entitled *Poison on Pets II* that discussed research that NRDC had done into the potential harm to children from TCVP pet collars.[58] The results of the research suggested risk existed, particularly to children who "are more likely to put their hands in their mouths and ingest TCVP after petting an animal."[59] As permitted by EPA regulations, NRDC petitioned EPA to initiate cancellation of all TCVP pet collars then on the market, all of which were manufactured by Hartz.[60]

In 2020, after a series of delays by EPA that the court called "nothing short of egregious," the Ninth Circuit ordered EPA to respond to NRDC's petition.[61] In response, EPA concluded that all seven Hartz collars then on the market were unacceptably dangerous because their TCVP content exceeded EPA's level of concern.[62] But EPA did not attempt to cancel the collars; Hartz voluntarily withdrew one collar from the market and "mitigated the exposure" from the remaining six collars by amending the instructions, reducing the collars' TCVP content, and "implementing other design changes."[63] With these changes, EPA

56. *See* Li, *supra* note 21, at 1425 (noting, in the context of an agricultural pesticide, that beyond general guidelines "EPA lacks a formal procedure for weighing benefits against risks [when considering pesticide exposure]. . . . For example, the EPA does not have methods for evaluating how much additional worker risk is acceptable for every unit increase in grower revenue. . . .").

57. EPA, AGENCY RESPONSE TO THE NATURAL RESOURCES DEFENSE COUNCIL'S (NRDC) APRIL 2009 TETRACHLORVINPHOS PETITION (Grant of Petition) 44 (2022), https://downloads.regulations.gov/EPA-HQ-OPP-2009-0308-0028/content.pdf. In September 2023, EPA reversed this decision based on new data submitted by Hartz, and said it would allow TCVP collars to remain on the market. *See* EPA, AGENCY DETERMINATION NOT TO FURTHER PURSUE CANCELLATION OF TETRACHLORVINPHOS (TCVP) PET COLLARS (Reversal of Decision to Cancel) 14 (2023), https://downloads.regulations.gov/EPA-HQ-OPP-2009-0308-0032/content.pdf; *infra* Part IV.B.

58. The report also discussed other TCVP flea and tick products, and other pesticides. *See generally* ROTKIN-ELLMAN & SOLOMON, *supra* note 30.

59. *Id.* at 4.

60. *NRDC v. EPA*, 31 F.4th 1203, 1205 (9th Cir. 2022).

61. *Id.* at 1205–06.

62. *Id.* at 1206.

63. *Id.*

found that the remaining collars no longer exceeded EPA's level of concern and denied NRDC's petition.[64]

B. NRDC v. EPA *(Ninth Circuit, 2022)*

NRDC appealed and, in April 2022, the Ninth Circuit vacated EPA's denial and remanded to the agency for reconsideration.[65] The court found two errors in EPA's analysis, both of which concerned how the agency interpreted study data provided. The errors resulted in an underestimation of the amount of TCVP the collars would expose consumers to.[66]

First, EPA miscalculated the amount of TCVP that the collar would release during use. The agency relied on Hartz's data as to the total amount of dust that would be released, but it substituted its own lower—and erroneous—figure for the amount of that dust composed of TCVP.[67]

Second, EPA assumed that pet owners would trim an average of 20 percent off the collar after installation, thereby reducing the total amount of TCVP that *could* be released.[68] This reversed the position EPA had taken in an earlier risk assessment, where the agency had noted that "because it could not determine the amount of collars owners would trim, it assumed that owners would not trim any of the collar."[69] Further, the court noted the decision to assume a 20-percent trim was directly at odds with EPA's residential pesticide standard operating procedures (SOPs). The decision stated explicitly that because the agency cannot verify whether a customer will actually trim a collar or not, the maximum length of the collar should be used.[70]

Both errors had the effect of reducing EPA's assessment of the amount of TCVP the collars would expose humans to, bringing EPA's assessment of their risk below EPA's level of concern.[71]

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64. *Id.* EPA based its denial on data contained in two studies conducted by Hartz: one that tested the amount of TCVP released by twisting collars and another that tested how much TCVP the collars released in the course of normal use. *Id.*

65. *Id.* at 1211. In response to this ruling, in October 2022, EPA reversed itself and initiated the cancellation process for all six remaining collars. *See* Grant of Petition, *supra* note 57. In September 2023, EPA reversed itself again and ended its cancellation efforts in response to new data from Hartz. *See* Reversal of Decision to Cancel, *supra* note 57, at 14.

66. *NRDC v. EPA*, 31 F.4th at 1207–08. The "Torsion Study" examined the amount of TCVP dust released when the collar was twisted, while the "Normal Wear Study" examined the amount released during the course of normal use. The court noted no issues with the studies themselves—only with the way that EPA used the data.

67. *Id.* at 1208. As the Ninth Circuit noted, "This . . . assumption, which directly contradicted the results of the Torsion Study . . . was unexplained . . . ." *Id.*

68. *Id.* at 1207.

69. *Id.* at 1210.

70. *Id.*; EPA Pesticide SOPs, *supra* note 37, at 8-3. In October 2022, EPA released an update to its SOPs that provides evidence for the decision EPA made that it could in fact assume owners would trim collars. *See generally* EPA, PET COLLAR TRIMMING FACTOR FOR USE IN EXPOSURE AND RISK ASSESSMENTS: A REFINEMENT OF THE TREATED PET SOP (2022), https://downloads.regulations.gov/EPA-HQ-OPP-2009-0308-0023/content.pdf.

71. 2020 Denial, *supra* note 10, at 12.

The Ninth Circuit overturned EPA's decision based on the agency's technical errors. The decision was correct, but it did not address the fact that EPA's myopic focus on quantitative risk assessment has drifted from the intent of FIFRA. The original House version of FIFRA used the term "*significant* adverse effects on the environment" in describing unacceptable pesticides, and in proposing the change to FIFRA's final "*unreasonable* adverse effects on the environment" language, the Senate Commerce Committee stated the change was "intended [to show] that any adverse effect ought not to be tolerated unless there are overriding benefits from the use of a pesticide."[72] Professor Mary Jane Angelo has taken this to mean that the balancing of costs and benefits "would not be a simple accounting of dollars and cents on each side of the equation, with the pesticide winning the right to registration as long as the scale was tipped, no matter how slightly, in favor of the benefits provided by the pesticide."[73] Similarly, another commentator has noted that "on its face FIFRA incorporates a rebuttable presumption against registration of pesticides."[74]

The Senate Agriculture Committee's own report on the legislation did not adopt the "overriding benefits" language the Commerce Committee used, yet at the same the Agriculture Committee took a maximalist position on the sorts of benefits the EPA should consider in its decision-making: "[T]he balancing of benefit against risk is supposed to take every relevant factor that the Administrator can conceive of into account. The question he must decide is 'Is it better for man and the environment to register this pesticide, or is it better that this pesticide be banned?'"[75]

Regardless of the differences demonstrated by the records of these two committees, it seems clear that the Senate intended that EPA undertake a thorough examination of costs and benefits before registering a pesticide—an approach that I do not see reflected in EPA's strict focus on quantitative risk assessment as the primary tool for assessing whether to register a pesticide. This myopia—and the path to reducing it—can be seen more clearly when we consider the analysis of alternatives to TCVP that EPA undertook in 2017.[76]

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72. S. REP. NO. 92-970, at 11 (1972).

73. Angelo, *supra* note 18, at 177.

74. Joan M. Ferretti, *Looking for the Big Picture – Developing A Jurisprudence for A Biotechnological Age*, 10 PACE ENV'T L. REV. 711, 720 (1993).

75. S. REP. NO. 92-838, at 10 (1972) ("He must consider hazards to farmworkers, hazards to birds and animals and children yet unborn. He must consider the need for food and clothing and forest products, forest and grassland cover to keep the rain where it falls, prevent floods, provide clear water. He must consider aesthetic values, the beauty and inspiration of nature, the comfort and health of man. All these factors he must consider, giving each its due.").

76. *See generally*, ATWOOD & SMEARMAN, *supra* note 5. Note that EPA undertook the Alternatives Assessment as part of the ongoing registration review for all TCVP products (discussed *supra* note 24), rather than directly in response to NRDC's petition. However, the two proceedings are not altogether separate; for instance, EPA referenced the Alternatives Analysis repeatedly in its 2020 Denial. *See* 2020 Denial, *supra* note 10, at 30–31.

III. THE ROLE OF ALTERNATIVES

In 2017, EPA's Biological and Economic Analysis Division (BEAD) canvassed registered alternatives to TCVP pet collars. Its report found that spot-ons were the most popular option in all regions and demographics of the United States, reaching 50 percent market share in 2012.[77] Pill treatments—called "veterinary medicines" because they are generally available only at vets' offices—came next with about 27 percent. Collars held 26 percent market share.[78] None of the alternative products check all the same boxes as TCVP collars: some prevent only fleas, some are only appropriate for use on dogs (or only on cats), some are far more expensive, and some require more frequent application.[79]

Two types of alternatives deserve attention: collars utilizing either deltamethrin or a cocktail of flumethrin and imidacloprid (collectively, alternative collars) and spot-on treatments using etofenprox. The alternative collars last as long as—or longer than—TCVP collars, but cost five to six dollars more per month.[80] Etofenprox spot-ons are similarly priced to TCVP collars but must be applied every month.[81] By at least some metrics, the alternatives—particularly etofenprox— are less toxic.[82] However, EPA felt that reduced toxicity did not outweigh the convenience offered by TCVP collars, writing: "If EPA were to cancel all TCVP pet collars, there would likely be some increased costs for consumers, either monetarily due to the higher cost of alternative collars or through additional time and effort required for topical spot-on products."[83]

Again, it is squarely in the interest of public health to prevent proliferation of fleas and ticks because of the diseases they carry.[84] Given that, EPA is right to consider whether removing products like TCVP pet collars will lead to less effective control of these pests.[85] But it appears uncertain whether canceling

77. ATWOOD & SMEARMAN, *supra* note 5, at 6 (using 2012 data).

78. *Id.* BEAD canvassed other TCVP-based products and their alternatives as well, including shampoos, dips, and powders. *See generally id.* Those options are beyond the scope of this Note.

79. *Id.*

80. *Id.* at 19. The alternative collars also lack the ability to kill flea eggs, something that TCVP collars do because the latter include methoprene in their formulations. *Id.* at 13. However, in one of the few nods toward innovation seen in the entire TCVP saga, BEAD noted "the remaining available products could potentially be formulated to include methoprene." *Id*. Further, at least some of the alternative collars have their own toxicity intrigues. *See, e.g.* EPA, EVALUATION AND REGULATION OF PET FLEA COLLAR PRODUCTS, https://www.epa.gov/pets/epa-evaluation-and-regulation-pet-collar-products (last accessed Dec. 15, 2022) (documenting the agency's response to a petition from the Center for Biological Diversity to cancel the Seresto collar—the key flumethrin and imidacloprid collar—due to toxicity concerns). For these reasons, I will not discuss the alternative collars as more than a data point.

81. ATWOOD & SMEARMAN, *supra* note 5, at 19.

82. *See infra* Part IV.

83. 2020 Denial, *supra* note 10 at 31.

84. *See generally Fleaborne Diseases of the United States*, CTRS. FOR DISEASE CONTROL AND PREVENTION, (August 13, 2020), https://www.cdc.gov/fleas/diseases.html; CTRS. FOR DISEASE CONTROL AND PREVENTION, TICKBORNE DISEASES OF THE UNITED STATES: A MANUAL FOR HEALTHCARE PROVIDERS (6th ed. 2022), https://www.cdc.gov/ticks/tickbornediseases/TickborneDiseases-P.pdf

85. *See* 2020 Denial, *supra* note 10, at 31.

TCVP collars would in fact lead to less tick and flea control: in the same document which contains the above passage about increased costs, EPA also wrote that "[o]ther pet pest control options are available that perform comparably to TCVP and *it is unlikely that consumers would forego pest treatments due to the increase in costs*."[86] EPA appears to have written the latter passage specifically in the context of the effect of cancellation on pet owners with lower socioeconomic status,[87] but the already-growing share of people using spot-on treatments suggests that EPA's concern about the effect of collar cancellation may be unfounded across the market. More to the point, the abundance of alternatives, the market opinion that they are viable, and the expert opinion that they are not too expensive suggest to me that there are relatively few benefits to keeping TCVP collars on the market, especially when compared to their potential for adverse health impacts on children. Certainly, there do not appear to be the "overriding benefits" that Professor Angelo pointed to as Congress's intent in drafting FIFRA.[88]

The presence of an Alternatives Assessment for TCVP points to EPA's capacity to consider the pros and cons of a potentially dangerous pesticide in the broader context of the market.[89] The weak link in EPA's analysis is the connection between that broader market context and the "unreasonable adverse effects" standard. EPA could strengthen that link by implementing a rule stating that when EPA finds viable, less hazardous alternatives, that means the more hazardous product is *per se* unreasonable.[90] As discussed in Part IV, EPA has authority to make that determination. Such a rule would push the pesticide industry to develop less harmful pesticides.[91]

Using the example of TCVP pet collars, the next Subparts will suggest three principal arguments in support of the idea that EPA should take more explicit account of alternatives in considering whether to cancel or deny registration to a pesticide. First, if the cancellation of a product like TCVP collars leaves an important void in the market, manufacturers will likely innovate to fill that void, for example by reducing the price of alternative collars or figuring out ways to put chemicals like etofenprox into longer-lasting formulations. Second, in some ways, EPA's current practice, encapsulated in the statement "If EPA were to

86. *Id.* at 32 (emphasis added).

87. *See id.*

88. Angelo, *supra* note 18, at 177.

89. *See generally* ATWOOD & SMEARMAN, *supra* note 5 ("Pesticide impregnated pet collars have been identified as a risk driver for the TCVP occupational and residential exposure assessment. BEAD was asked . . . to determine TCVP pet collar use patterns, identify alternative insecticides used in pet collars, and provide an overview of the pet flea and tick control market.").

90. The environmental group Beyond Pesticides has advocated for similar changes based on the unreasonable adverse effects standard. *See* BEYOND PESTICIDES, TELL EPA AND CONGRESS THAT THE FAILED PESTICIDE PROGRAM NEEDS A NEW START, https://secure.everyaction.com/-GXkDZSV9E-7ephksB1G_g2 (last visited March 23, 2023).

91. *See, e.g.*, Michael Ollinger & Jorge Fernandez-Cornejo, *Innovation and Regulation in the Pesticide Industry*, 27(1) AGRIC. & RES. ECON. REV. 15 (1998) (finding that regulation of pesticides increases costs but leads to the development of pesticides with fewer side effects).

cancel all TCVP pet collars, there would likely be some increased costs for consumers,"[92] assumes that consumers have perfect knowledge about the hazards of TCVP and choose to use those collars anyway for the sake of the unquestioned convenience they provide. That is an unreasonable assumption because consumers do not have perfect knowledge of the risks of products they use. Finally, often in environmental law a key barrier to action is a lack of detailed information on a problem or an inability to connect data to real-world impacts. In the case of FIFRA, EPA already collects the rigorous scientific data needed to compare pesticide toxicity and has demonstrated an ability to use those data to compare alternatives. We will examine these arguments in turn.

A. The Role of Innovation

FIFRA does not charge EPA with encouraging innovation in pesticides in the same way as technology-forcing statutes such as the Clean Air Act (CAA) and Clean Water Act (CWA). The requirements of the CAA's stationary source permitting program, for example, "are expressly designed to force regulated sources to develop pollution control devices that might at the time appear to be economically or technologically infeasible."[93] Similarly, the CWA requires "effluent limitations for point sources [requiring] the application of the best practicable control technology currently available."[94] The CAA has been remarkably successful in improving air quality through technological innovation, in spite of vociferous pushback from industry on the supposed unreasonableness of EPA's decisions.[95] By contrast, FIFRA is silent on the subject of developing new technology.

EPA *has* taken steps to encourage companies to market safer pesticides through the Design for the Environment (DfE) pesticide program.[96] The voluntary program "helps consumers and purchasers find antimicrobial products, like disinfectants and sanitizers, that have been reviewed by EPA and found to meet both" FIFRA registration requirements and EPA's Safer Choice

92. 2020 Denial, *supra* note 10, at 31.

93. Union Elec. Co. v. EPA, 427 U.S. 246, 257 (1976).

94. 33 U.S.C. §1311(b)(1)(A).

95. *See generally* Nat. Res. Def. Council v. EPA, 655 F.2d 318 (D.C. Cir. 1981). *See also* HOLLY DOREMUS, *et al.*, ENVIRONMENTAL LAW POLICY 10–73 (6th ed. 2012) ("[F]ederal tailpipe emission standards have produced dramatic decreases in automobile pollution. Between 1970 and 2000, NOx and VOC emissions per mile from new cars were reduced more than 95%. Additional reductions of roughly 90% from those levels were phased in for model years 2004–2009."); *see also* NAT'L COMM'N ON PROD. SAFETY, FINAL REPORT PRESENTED TO THE PRESIDENT AND CONGRESS (1970) ("Manufacturers have it in their power to design, build, and market products in ways that will reduce if not eliminate most unreasonable and unnecessary hazards. . . . The capacity of individual manufacturers to devise safety programs, without undue extra cost, has been demonstrated repeatedly in the course of . . . history").

96. *Learn About Design for the Environment (DfE) Certification (DfE-Certified Disinfectants)*, EPA (last updated May 2, 2023), https://www.epa.gov/pesticide-labels/learn-about-design-environment-dfe-certification.

certification.[97] Safer Choice sets criteria for human health and environmental impacts, allowing "only those ingredients that pose the least concern among chemicals in their class."[98] In the case of antimicrobial pesticides, those ingredients include citric acid and ethanol.[99] Products that meet the criteria can display the DfE logo and be listed on the EPA website.[100]

The DfE pesticide program, while valuable, covers only one small slice of the pesticide market and imposes no mandates on manufacturers. Aside from this step, FIFRA's lack of innovation mandate has effects on the rate of pesticide innovation; for instance, according to one commentator, "no new herbicide mode of action . . . has been developed for the last 30 years . . . . A lack of meaningful regulation means these companies feel less pressure to create safer chemical pesticides."[101]

But as the undeniable success of the CAA and CWA shows, innovation can be a useful tool to improve the state of the planet, and only inertia prevents EPA from implementing a form of innovation mandate in FIFRA.[102]

EPA unambiguously claims the mandate to assess alternatives once an already-registered pesticide is shown to have potentially adverse environmental effects, and EPA could both strengthen that consideration and expand it to initial registration actions. Defining a pesticide's harmful effects as unreasonable when there are viable alternatives on the market will enable EPA to force companies to develop new products if they wish to retain market share.

B. Consumer Knowledge

One potential response to the idea that EPA should unilaterally remove dangerous products, when less dangerous alternatives are present, is that this

97. *DfE-Certified Disinfectants*, EPA (last updated Aug. 9, 2023), https://www.epa.gov/pesticide-labels/dfe-certified-disinfectants.

98. EPA describes the Safer Choice label this way:

> The Safer Choice label offers a readily identifiable way to know that a product is as safe as possible for people and the environment. When you see the Safer Choice label on a product it means that the Safer Choice scientific review team has screened each ingredient for potential human health and environmental effects and that—based on the best available experimental data and EPA predictive models—the product contains only those ingredients that pose the least concern among chemicals in their class.

EPA, EPA'S SAFER CHOICE STANDARD (2015 Revision) (2015), https://www.epa.gov/sites/default/files/2013-12/documents/standard-for-safer-products.pdf.

99. *See DfE-Certified Disinfectants*, *supra* note 96.

100. *Id.*

101. Nathan Donley, *How the EPA's Lax Regulation of Dangerous Pesticides is Hurting Public Health and the US Economy*, THE BROOKINGS INST. (Sept. 29, 2022), https://www.brookings.edu/research/how-the-epas-lax-regulation-of-dangerous-pesticides-is-hurting-public-health-and-the-us-economy/.

102. *See* EARL R. SWANSON, NAT'L RSCH. COUNCIL COMM. ON SCI. & REGUL. ISSUES UNDERLYING PESTICIDE USE PATTERNS & AGRIC. INNOVATION, REGULATING PESTICIDES IN FOOD: THE DELANEY PARADOX 226–27 (1987) (noting that "if [an] expanded benefit analysis by the EPA is perceived by industry to be reasonably stable, pesticide manufacturers may be expected to respond by increasing production of registered substitutes and/or developing new pesticides for a changed market").

would be too drastic—consumers can make the decision of what product works best for them by voting with their wallets. That requires, however, that customers have complete knowledge about the risks and costs of the products they use.[103] At least in this case, that seems like a dubious assumption. The Hartz UltraGuard TCVP collar label contains the following warnings: "DO NOT LET CHILDREN PLAY WITH THIS COLLAR. SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS." The back panel states that the product is "[h]armful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet."[104] The packaging does not warn of the potential for indirect pesticide transfer from the animal's hair. Nor does the package mention the potential neurodevelopmental effects the pesticide may have on children. It is just another in a sea of products with non-specific warnings of harm.[105]

Professor Angelo has argued that warning labels such as these do not in fact mean that customers have perfect knowledge of the risks of various pesticides, and that "the time and thought required to sort out technical risk assessment information may be more than the average consumer can, or desires to, commit."[106] Research suggests that the continuing prevalence of emergency room visits for pesticide-related incidents means that warning labels are ineffective in preventing illness and injury.[107] NRDC made a similar point in

103. *See generally* NAT'L COMM'N ON PROD. SAFETY, *supra* note 95; *See also* Walter Oi, *The Economics of Product Safety*, 4(1) BELL J. OF ECON. & MGMT. SCI. 3, 23 (1973) (summarizing the NCPS final report as finding that informational issues lie at the heart of many product safety issues: "[C]onsumers are unaware of the risks of using increasingly complex products, unable to cope with these risks even if they knew about them, unable or unwilling to get accurate product information, or misled by questionable advertising practices."); *cf.* Mostafa Purmehdi et al., *The Effectiveness of Warning Labels for Consumers: A Meta-Analytic Investigation into Their Underlying Process and Contingencies*, 36(1) J. PUB. POL'Y & MKTG. 36 (2017) (finding that the effectiveness of warning labels at changing consumer behavior is dependent on a variety of factors, including the type of behavior change desired and other contextual clues).

104. Photograph of packaging, *in* Hartz UltraGuard Plus Flea & Tick Collar for Dogs, https://www.hartz.com/product/hartz-ultraguard-plus-flea-tick-collar-for-dogs/#precautionary-statements (last visited Nov. 20, 2022).

105. Proposition 65 is an example of where the overabundance of vague warning labels may cause people to simply stop reading the labels. *See* Geoffrey Mohan, *You See the Warnings Everywhere. But Does Prop. 65 Really Protect You?* L.A. TIMES (July 23, 2020), https://www.latimes.com/business/story/2020-07-23/prop-65-product-warnings ("More than three decades into California's right-to-know revolution, consumers today don't know much about the health risks posed by consumer goods. It's nearly impossible to tell whether to put down a product bearing a warning and choose one without it — either one may present a high risk, a low risk or no risk. The deepest internet dive is unlikely to surface an answer before consumers reach the checkout or finalize their order online.")

106. Angelo, *supra* note 18.

107. *See, e.g.*, N. Clayton Silver et al., *Warnings and Purchase Intentions for Pest-Control Products*, FORENSIC REPS. 4.1, 17, 18 (1991) ("On the basis of a sample of representative hospitals in the United States, the National Electronic Injury Surveillance System estimated that in 1988, 14,736 people were admitted to emergency rooms for pesticide product-related injuries. . . . Of these injuries, 88.3 % were released after medical treatment, whereas 11.7 % resulted in hospitalization. Most pest-control products contain warnings and instructions for the purpose of warning consumers against misuse and

Poison on Pets II, writing "many consumers are unaware of the dangers posed by these products."[108] Because consumers arguably do not possess perfect knowledge of the risks of various pesticides, it makes sense for those who do—like EPA—to remove dangerous products from the market when they can do so without significant detriment to consumer convenience or ultimately to public health.[109]

Comparing etofenprox spot-ons to other TCVP collar alternatives further emphasizes that removing TCVP collars from the market would not cause significant detrimental effects to customer convenience. In the Alternatives Assessment, EPA noted that collars based on geraniol, peppermint oil, and almond oil (hereafter essential oil collars) are available on the market, but that these products only repel—rather than control—fleas and ticks.[110] Further, these products "have activity against target pests which is substantially less than TCVP based products and the other identified alternatives."[111] Some advocates of using essential oil flea control products suggest combining their use with other techniques.[112] For example, in *Poison on Pets II*, NRDC suggested that rather than using any traditional pesticide, pet owners should use alternative methods such as "regular combing" to reduce fleas.[113] The report also noted that cats "that are not allowed to roam outdoors will not get fleas,"[114] though that technique has been questioned by at least one study.[115] Were etofenprox not on the market, consumers could choose a less-toxic alternative to TCVP collars by using a combination of combing, essential oil collars, or other non-pesticide flea control

accidents. Despite the presence of warnings and widespread publicity in the media, the number of injuries involving pesticides suggests that people may not be adequately aware of the potential hazards and misuses.").

108. ROTKIN-ELLMAN & SOLOMON, *supra* note 30, at 6. A fulsome discussion of warning labels is beyond the scope of this Note.

109. *See generally* ATWOOD & SMEARMAN, *supra* note 5 (explaining the landscape of alternative flea and tick control products).

110. *Id.* at 13.

111. *Id*. Further, switching to an essential oil collar does not *necessarily* create a healthier home. *See* Allison G Genovese et al., *Adverse reactions from essential oil-containing natural flea products exempted from Environmental Protection Agency regulations in dogs and cats,* 22(4) J. VET. EMERGENCY & CRITICAL CARE 470, 470 (2012).

112. *See, e.g.*, Jean Hofve, *Natural flea control treatment & repellent methods for dogs & cats*, ONLY NAT. PET (May 28, 2020), https://www.onlynaturalpet.com/blogs/holistic-healthcare-library/natural-flea-control-methods.

113. ROTKIN-ELLMAN & SOLOMON, *supra* note 30, at 16. The recommendation does not address ticks.

114. *Id.* And many cat owners do keep their cats indoors. *See* Rachael Foreman-Worsley et al., *Indoors or Outdoors? An International Exploration of Owner Demographics and Decision Making Associated with Lifestyle of Pet Cats.* 11(2) ANIMALS: AN OPEN ACCESS JOURNAL FROM MDPI 253, 270 (2021) (noting that more than 60 percent of domestic cats in the United States live completely indoors).

115. *See, e.g.*, Robert Lavan et al., *Flea and tick treatment satisfaction, preference, and adherence of US cat owners prescribed topical fluralaner*, 11(1) OPEN VETERINARY J. 80, 87 (2021) ("Cat owners confirm . . . that all environments, whether indoor or outdoor, carry flea and tick exposure risk. An exclusively indoor cat is not guaranteed ectoparasite avoidance.").

methods.[116] However, adopting any of these methods would also create larger convenience costs to consumers than the relatively minor difference in inconvenience of applying a spot-on treatment once per month versus a collar twice per year.[117]

Of course, there are whole classes of dogs and cats that live outdoors and have relatively infrequent contact with humans of any age—the mousing barn cat of yore, for example—and even with perfect knowledge the owners of these animals might well make a rational decision that a TCVP product would pose little risk.[118] Further, if faced with a choice between using the cheap, tremendously convenient product and a product more costly in either time or money, that person might well choose to forgo treatment entirely.[119] In the same way, there is likely a class of consumer fully prepared to devote the extra time for combing their pet rather than using any traditional pesticide.[120] However, I submit that both groups represent relatively small portions of the population and that most consumers fall somewhere in the middle: willing to sacrifice a small amount of convenience for a real decrease in risk, but unwilling to undertake more wholesale changes in behavior.

C. EPA's Existing Access to the Required Data

Often in environmental law, a key problem to comparing alternatives is a lack of specific knowledge about either the dangers posed by a product or the relative benefits of other options.[121] Here, refreshingly, that is not the case.

First, even if EPA does not currently believe it can decline to register a new pesticide because there are less harmful alternatives (discussed below in Part IV), it takes notice of the reverse—sometimes celebrating a new pesticide that is significantly *less harmful* in some regard than current options. For instance, sulfoxaflor is an agricultural pesticide EPA calls "highly effective" against difficult pests such as aphids and tarnished plant bugs, protecting a variety of

116. *See generally* Hofve, *supra* note 112.

117. For instance, when using a flea comb as a primary flea control tool, one vet recommends brushing at least once per week when in flea season. *See* Sarah Wooten, *How to Use a Flea Comb for Dogs*, PETMD (Nov. 16, 2018), https://www.petmd.com/dog/parasites/how-use-flea-comb-dogs.

118. *See, e.g.*, BEST OUTDOOR DOG BREEDS, PURINA, https://www.purina.com/dogs/dog-breeds/collections/best-outdoor-dog-breeds (last visited Mar. 26, 2023).

119. EPA implicitly acknowledges this possibility—without discussing how much time or money might be "enough" to make that happen—in the line: "Other pet pest control options are available that perform comparably to TCVP and *it is unlikely that consumers would forego pest treatments due to the increase in costs*." *See* 2020 Denial, *supra* note 10, at 32.

120. *See* Karen L. Smith-Janssen, *Non-Toxic Ways to Protect Your Pet*, NAT. RES. DEF. COUNCIL: STORIES (Jan. 22, 2016), https://www.nrdc.org/stories/nontoxic-ways-protect-your-pet.

121. *See, e.g.*, Wendy Wagner, *Using Competition-Based Regulation to Bridge the Toxics Data Gap*, 83 IND. L. J. 629, 634 (2008) (noting the Toxic Substances Control Act (TSCA) creates perverse incentives for manufacturers to avoid testing their products for toxicity and that as of 2008 EPA had "demanded testing or imposed regulatory restrictions on less than *two percent* of chemicals that were in the TSCA inventory as of 1979.").

crops from strawberries to cotton to cacao.[122] In a 2019 decision allowing sulfoxaflor's use in several new contexts, EPA wrote that a key benefit of the compound was its extraordinary *lack* of toxicity against non-target species, sometimes "many orders of magnitude lower" than existing compounds.[123] "It is very unusual for an insecticide to pose no acute or chronic risk of concern to aquatic invertebrates. Sulfoxaflor is truly unique in this regard."[124] Similarly, when EPA registered the new pesticide active ingredient cyantraniliprole for use on crops like citrus and turfgrass, the agency touted its benefits, including that it is "generally less toxic towards mammals, birds and fish [and honey bees] than the leading alternatives. . . ."[125] Indeed, in both these cases EPA specifically noted that these pesticides could reduce the use of more hazardous pesticides and thus the risk to non-target species.[126]

FIFRA has robust data reporting requirements,[127] and the examples of sulfoxaflor and cyantraniliprole illustrate that EPA (1) has the capacity to judge the relative risks posed by the pesticides it registers and (2) sometimes registers new pesticides at least acknowledging that doing so may help reduce reliance on more toxic pesticides. As one commentator has noted, the problem is that EPA continues to allow the sale of older pesticides as well, and in fact continues to register new products containing the harmful chemicals that products like sulfoxaflor and cyantraniliprole are intended to replace.[128] As an illustration of this phenomenon in the OP context, a 2020 study by the Center for Biological Diversity found that during 2017 and 2018 alone EPA registered fifteen new

122. EPA, SULFOXAFLOR, https://www.epa.gov/ingredients-used-pesticide-products/sulfoxaflor (last visited Mar. 26, 2023).

123. EPA, DECISION MEMORANDUM SUPPORTING THE REGISTRATION DECISION FOR NEW USES OF THE ACTIVE INGREDIENT SULFOXAFLOR ON ALFALFA, CACAO, CITRUS, CORN, COTTON, CUCURBITS, GRAINS, PINEAPPLE, SORGHUM, SOYBEANS, STRAWBERRIES AND TREE PLANTATIONS AND AMENDMENTS TO THE LABELS 19–22 (2019), https://www.regulations.gov/document?D=EPA-HQ-OPP-2010-0889-0570 (hereinafter SULFOXAFLOR MEMORANDUM).

124. *Id.*

125. EPA, REGISTRATION OF THE NEW ACTIVE INGREDIENT CYANTRANILIPROLE 14 (2014), https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0668-0057.

126. *See id.* ("[C]yantraniliprole may also replace multiple or repeated applications of these other [more hazardous] compounds, which expose non-target organisms many times and present greater risks to a wider range of non-target species."); SULFOXAFLOR MEMORANDUM, *supra* note 123, at 22 ("The importance of honey bees and other pollinators to the U.S. food supply, and the significant value of pollination services warrants the registration of crop protection pesticides that improve the existing risk situation for bees. EPA believes that sulfoxaflor is better for bees than the registered alternatives."). This discussion of cyantraniliprole should not be mistaken for a benediction; cyantraniliprole has been implicated in toxicity controversy of its own. *See generally* In re Ctr. for Biological Diversity, 53 F.4th 665 (D.C. Cir 2022) (finding that in registering cyantraniliprole, EPA failed to perform an assessment on the pesticide's potential effects on endangered species, as required under the Endangered Species Act).

127. *But see* discussion *infra* Part I.A.2 about EPA's ability to grant waivers in certain circumstances, and discussion about conditional registrations and other simplified procedures, *supra* note 22.

128. NATHAN DONLEY, TOXIC HANGOVER: HOW THE EPA IS APPROVING NEW PRODUCTS WITH DANGEROUS PESTICIDES IT COMMITTED TO PHASING OUT, CTR. FOR BIOLOGICAL DIVERSITY (Jan. 2020), https://www.biologicaldiversity.org/campaigns/pesticides_reduction/pdfs/Toxic-Hangover.pdf.

products containing OPs and the related neurotoxins carbamates despite the availability of alternatives like sulfoxaflor.[129]

It seems clear from the above examples that EPA is not averse to the idea of reducing the use of harmful pesticides. Unusually in environmental law, EPA already gathers the specific, rigorous data to translate that general support into specific action. But EPA uses data myopically and needs a regulatory mechanism to enable it to use that information to actively cleanse the market of old and outdated pesticides.

IV. A LEGAL AVENUE TO CONSIDER THE PRESENCE OF VIABLE ALTERNATIVES IN REGISTRATION AND CANCELLATION DECISIONS

FIFRA states EPA "shall" register a pesticide that, among other requirements, "will perform its intended function without unreasonable adverse effects on the environment."[130] Unreasonable adverse effects, in turn, are defined 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."[131] EPA does not currently consider the presence of alternatives in registering pesticides.[132] Why it does not is unclear, but one possibility is language in FIFRA stating "[EPA] shall not make any lack of essentiality a criterion for denying registration of any pesticide."[133] Considering the presence of an alternative on the market arguably means considering whether a new pesticide is essential, thus violating the statute.[134] That stance has apparently not been directly tested by a court, but in dicta the Ninth Circuit has supported the interpretation.[135] The few academic papers that have addressed the question agree.[136]

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129. *Id.*; *see also* SULFOXAFLOR MEMORANDUM, *supra* note 119, at 21–22 (comparing sulfoxaflor's toxicity favorably to other pesticides, including the since-banned OP chlorpyrifos).

130. 7 U.S.C. § 136(c)(5).

131. *Id.* § 136(bb).

132. This position does not appear to be affirmatively stated anywhere, but rather implied through an exclusive focus on data on the pesticide in question. *See, e.g.* DATA REQUIREMENTS FOR PESTICIDE REGISTRATION, *supra* note 48 (listing only data on the performance and hazards of the pesticide in question); *see also* HOW TO REGISTER A PESTICIDE *supra* note 47 (stating that "EPA will make a [registration] decision using risk assessments based on review of the submitted data, information and proposed label").

133. 7 U.S.C. § 136(c)(5).

134. Angelo, *supra* note 18, at 184 ("It is not until EPA considers whether to cancel the registration of a pesticide that it evaluates the benefits of the pesticide and whether there are viable alternatives available."); *see generally* ATWOOD & SMEARMAN, *supra* note 5.

135. *Merrell v. Thomas*, 807 F.2d 776, 781 (9th Cir. 1986), quoting S. REP. NO. 838, *as reprinted in* 1972 U.S.C.C.A.N. 3993, 4011 ("This means that 'registration cannot be denied simply because the existence of an alternate means of control makes the new pesticide not essential.'").

136. *See* Wagner, *supra* note 121, at 659 (noting that the "essentiality" language "support[s] an argument that FIFRA bars the consideration of substitutes and efficacy" in initial registration proceedings); *see also* Angelo, *supra* note 18, at 184 ("It is not until EPA considers whether to cancel the registration of a pesticide that it evaluates the benefits of the pesticide and whether there are viable alternatives available."); Mary Jane Angelo & Megan Lancaster, *The Insect Apocalypse: Legal Solutions*

However, apparently no court or scholar has considered the phrase as just one part of a larger passage in section 136(c)(5). In relevant part, the section reads:

> [EPA] shall register a pesticide if [EPA] determines that, when considered with any restrictions imposed under subsection (d)—
>
> . . .
>
> **(C)** it will perform its intended function without unreasonable adverse effects on the environment; and
>
> **(D)** when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.
>
> [EPA] shall not make any lack of essentiality a criterion for denying registration of any pesticide. Where two pesticides meet the requirements of this paragraph, one should not be registered in preference to the other. . . .

When read as a whole, arguably the final passage takes on a different meaning, suggesting that the clause is intended to mandate that when considering the registration applications of two similarly *non*-harmful pesticides, EPA may not choose between them *solely* on grounds of essentiality. That is apparently what Congress intended the provision to mean—the Conference Committee report on FIFRA's final version notes that the bill kept the House-initiated ban on essentiality and "add[ed] the Senate clarifying provision which states that 'Where two pesticides meet the requirements of this paragraph, one should not be registered in preference to the other,' *thus reflecting the conferees' intent that no difference between these provisions exists*."[137] What follows is a pathway by which EPA could show that a proposed pesticide is unreasonable *when compared to other already-registered pesticides*.

A. A Formal Role for Unreasonability in the Special Review Process

According to EPA, courts have held that "Congress intended any substantial question of safety to trigger the issuance" of a notice of intent to cancel a pesticide.[138] EPA assesses that question through the Special Review process, and

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for Protecting Life on Earth, 49 ECOLOGY L. Q. 1, 51 (2022) (noting that the essentiality language means that "FIFRA does not mandate a pesticide be deemed essential or better than other pesticides to obtain a registration."); *see generally* ATWOOD & SMEARMAN, *supra* note 5.

137. H. REP. NO. 92-1540, at 31 (1972) (emphasis added). The "essentiality" language was a source of controversy throughout the legislative process. The Senate Commerce Committee, for example, wanted to strike the language entirely because its members worried about a "danger of misconstruction" that would prevent EPA from considering alternatives to a pesticide in the registration process. "If 'pesticide A' is safer than 'pesticide B', this is certainly a relevant consideration in the evaluation of an application for the registration of 'B'. All things being equal, it argues forcefully against approval of the registration." S. REP. NO. 92-970, *supra* note 72.

138. Env't Def. Fund, Inc. v. Ruckelshaus, 439 F.2d 584, 593 (D.C. Cir. 1971) (quoting Nat'l Coal. Against the Misuse of Pesticides v. EPA, 867 F.2d 636, 643 (D.C.Cir.1989)). Further, the standard for finding such a "substantial question" of safety is rather low, "perhaps even less rigorous than the typical

if the review determines that such unreasonable adverse effects exist, EPA may issue a notice of intent to cancel (NOIC) the pesticide's registration.[139]

EPA should include in its list of triggers for Special Review evidence that a pesticide poses a substantially greater risk of harm to humans or the environment than other registered pesticides, and that those potential harms are not outweighed by significant social, economic, or environmental benefits. Adding such language to the Special Review trigger list would effectively define those harms as "unreasonable adverse effects" in the language of FIFRA, thus allowing EPA to issue a NOIC—or decline to register it in the first place.

In the case of TCVP, such language would have led much more quickly to a NOIC. As discussed above at the beginning of Part III, there are a wide variety of alternative products on the market, and etofenprox spot-ons in particular are less toxic than TCVP collars. EPA found "[n]o increased cost or socio-economic impact . . . from the use of etofenprox spot-ons."[140] The economic cost of canceling the registration of TCVP pet collars was therefore either minimal or zero, while there was substantial evidence that harm to children would be avoided by their removal from the market. Put together, these factors point to TCVP flea collars' continued presence on the market causing "unreasonable adverse effects" and therefore presenting a situation where EPA may reasonably proceed to cancel the pesticide, regardless of whether TCVP satisfies the absolute toxicity requirement embodied by EPA's "level of concern" calculations (discussed above in Part I.B.1).[141]

FIFRA does not set specific limits on toxicity for pesticides, instead only stating that EPA must register pesticides that do not cause an unreasonable adverse effect on the environment.[142] Through the level of concern, EPA has added absolute limits of toxicity to the process—effectively stating that toxicity

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'reason to believe' with which many agencies begin enforcement proceedings." Defs. of Wildlife v. Jackson, 791 F. Supp. 2d 96, 117 (D.D.C. 2011).

139. 7 U.S.C § 136d(b). EPA FIFRA Risk Balancing Explainer, *supra* note 19. Apparently, only the Fifth Circuit has considered the meaning of the word "generally" in section 136d(b). Ciba-Geigy Corp. v. U.S. E.P.A., 874 F.2d 277, 280 (5th Cir. 1989) (holding that the language "generally causes unreasonable adverse effects" requires EPA to determine that "the use of a pesticide in a particular application creates unreasonable risks, *though not necessarily actual adverse consequences*, with considerable frequency" in a particular use case) (emphasis added). In this case, the harm has the potential to occur each time a flea collar is used in a household where children are present, thus likely meeting the "considerable frequency" standard. *See id.*

140. ATWOOD & SMEARMAN, *supra* note 5, at 2. In its 2020 Denial, however, EPA did note that there would be costs through "additional time and effort required for topical spot-on products." 2020 Denial, *supra* note 10, at 31.

141. At least one group has urged EPA to take a still broader view of potential alternatives in such alternatives assessments, using the unreasonable adverse effects standard to be "more holistic and precautionary. . . When evaluating pesticide registrations, EPA should determine the full range of practices available to achieve submitters' goals of pesticide registration or reregistration, including chemical and nonchemical strategies." *Tell EPA That the Failed Pesticide Program Needs a New Start*, BEYOND PESTICIDES, https://www.beyondpesticides.org/action-of-the-week/tell-epa-that-the-failed-pesticide-program-needs-a-new-start (last visited Mar. 25, 2023).

142. *See generally* 7 U.S.C. § 136a.

below the level is OK, while toxicity above that level is not. But as EPA implicitly seems to recognize by considering alternatives in its Special Review process,[143] lack of reasonability is a fundamentally dynamic concept: If the alternative to a pesticide is a public health crisis, even fairly severe adverse effects are reasonable. But where the alternative to a pesticide is a different pesticide that may only be slightly more challenging to apply, those same adverse effects become far less reasonable.

B. From a Special Review to a Canceled Pesticide

Issuing a NOIC or declining to register a pesticide is merely the end of the beginning, as Winston Churchill might have put it.[144] Indeed, issuance of an NOIC can resemble the commencement of pitched battle, with "swift and fierce" opposition from manufacturers.[145] The process of unilateral cancellations is so cumbersome that in "the past two decades, pesticide makers have voluntarily removed around 60 pesticides from use in the U.S., while EPA has unilaterally removed only five."[146] EPA acknowledged this difficulty in denying NRDC's petition, writing that "EPA does not take lightly the steps required for initiating cancellation under FIFRA section 6(b). If any steps are hastily completed and ultimately result in a need to change the program's proposal, it may result in needing to begin the process afresh."[147]

And the process is a long one. Once EPA publishes a proposed NOIC in the Federal Register, the registrant may request an evidentiary hearing before an administrative law judge (ALJ).[148] Hearings typically involve discovery, depositions, and cross-examinations.[149] Interested parties may intervene.[150] The final decision of the ALJ is subject to appeal before EPA's Environmental Appeals Board.[151] Judicial review of the agency's final decision is available to parties adversely affected by the ruling.[152] In sum, given these procedures, "[i]f

143. *See generally* EPA FIFRA Risk/Benefit Explainer, *supra* note 19.

144. "This is not the end. It is not even the beginning of the end. But it is, perhaps, the end of the beginning." *Life of Churchill*, INT'L CHURCHILL SOC'Y, https://winstonchurchill.org/the-life-of-churchill/war-leader/1940-1942/autumn-1942-age-68/ (last visited Oct. 2, 2023).

145. Donley, *supra* note 101. And indeed, in the case of TCVP pet collars Hartz submitted new data in response to EPA's decision to draft a NOIC which caused the agency to reverse its decision to seek cancellation. *See* Reversal of Decision to Cancel, *supra* note 57, at 4, 14.

146. *Id.*

147. See 2020 Denial, *supra* note 10, at 32. In the present case, EPA appears to have not even reached a formal NOIC before ending its efforts to cancel TCVP collars.

148. *Id*. at 33.

149. *Id.*

150. *Id.*

151. *Id*. at 34; 40 C.F.R. §164.100.

152. *See* Reckitt Benckiser, Inc. v. Jackson, 762 F. Supp. 2d 34, 36 (D.D.C. 2011) ("The statute gives EPA the option of either issuing a notice of intent to cancel or issuing a notice of intent to hold a hearing to determine whether or not a registration should be canceled. [Citation omitted]. If the first option is chosen, the registrant may demand a hearing. [Citation omitted]." In either case, once a final decision to cancel a pesticide has been made, "the registrant may seek judicial review of that decision by filing a petition for review in a court of appeals.").

every appeal opportunity were pursued, a final decision would be years off."[153] EPA laid out that lengthy process in 2020 in support of its position that working with Hartz toward voluntary cancellation of some products and relabeling or reformulating others would "resolve EPA's risk concerns more quickly than an adversarial cancellation proceeding under FIFRA . . . could have done." [154] Indeed, some of EPA's concerns appear to have been borne out, as in late 2023 EPA reversed its decision to initiate cancellation procedures for TCVP collars based on new information submitted by Hartz.[155]

However,EPA is wrong if it treats the length and difficulty of a fight as sufficient reasons to avoid it. Rather—acknowledging the unfortunate reality of EPA's constrained resources and the pesticide industry's demonstrated resistance to removal of its products[156]—the correct lesson is to focus unilateral cancellation efforts on instances where there is a substantial difference between the toxicity of a harmful pesticide and its less harmful alternatives. Where there is not a great difference in toxicity between pesticides, canceling the more toxic pesticide would not result in great enough public health gains to justify the undoubted resources the process would consume.[157] The myriad definitions of toxicity, discussed in the next Subpart, provide EPA flexibility in determining when to spend its resources on canceling a more toxic alternative.

C. Metrics of Toxicity and Their Application in Triaging Cancellation Fights

EPA defines many dimensions of chemical toxicity. For instance, in deciding to initiate a Special Review, EPA can consider evidence of "serious acute injury . . . oncogenic [cancer-causing], heritable genetic, teratogenic [causing fetal abnormalities], fetotoxic [toxic to fetuses], reproductive effect, or a chronic or delayed toxic effect."[158] Those effects can be either highly dangerous to individual humans or put a large number of humans at "some risk."[159] Certain risks need not be to humans at all: they can affect "domestic animals," other "nontarget organisms," or any endangered or threatened species

153. 2020 Denial, *supra* note 10, at 34.

154. *Id.* at 35. *See* Nat. Res. Def. Council v. EPA, 31 F.4th 1203, 1205–06 (9th Cir. 2022).

155. *See* Reversal of Decision to Cancel, *supra* note 57, at 4.

156. *See, e.g.*, Richard N. L. Andrews, *The EPA at 40: An Historical Perspective*, 21 DUKE ENV'T L. & POL'Y F. 223, 224 (2010) ("[T]he EPA has become confined to incomplete and variable implementation of a set of laws and policies that, with few exceptions, were put in place more than thirty years ago. It has been chronically underfunded and subjected to increasing burdens of proof, oversight, and litigation."); Craig L. Infanger, *Environmental Regulatory Reform and the Unholy Trinity: Unfunded Mandates, Risk Assessment, and Property Rights*, 28 J. AGRIC. & APPLIED ECON. 108, 109 (1996) (discussing EPA's lack of funding in the CWA context); *see also* Donley, *supra* note 101 (discussing the "swift and fierce" industry opposition to pesticide cancellation).

157. Defining what qualifies as a "substantial difference" in toxicity and what metrics will be used to calculate that difference is clearly a vital question, but such a fraught question is beyond the scope of this Note.

158. 40 C.F.R. §154.7(a)(1)–(2).

159. *Id.* § 154.7(a)(2).

or its critical habitat.[160] TCVP, for instance, is most dangerous for its chronic neurodegenerative effects, specifically to children, even though it has relatively little acute toxicity at the doses at issue.[161]

Rather than creating a maze that EPA must navigate, this complex landscape provides EPA flexibility. As previously discussed, FIFRA mandates no specific toxicity thresholds for EPA to hew to. In promulgating regulations this Note calls for, therefore, EPA should craft language focused on relative disparity in toxicity—regardless of the specific metric used. If it does so and pays due attention to explaining its rationale for cancellation in any given proceeding, FIFRA and court decisions suggest EPA will eventually prevail in canceling pesticides against strong opposition.

There are two provisions of FIFRA that make the task of cancellation a lighter lift for EPA. First, EPA need not initiate the cancellation process itself. Private parties may petition EPA to initiate the Special Review process,[162] may intervene in any subsequent cancellation hearings,[163] and may seek judicial review if adversely affected by the outcome.[164] That is precisely what occurred in the case of TCVP.[165] Second, while the proponent of cancellation—either EPA or a third party—must present an affirmative case for cancellation, in both the Special Review process and in subsequent cancellation hearings "the ultimate burden of persuasion" rests with the party advocating for continued registration.[166] In other words, "[t]he responsibility to demonstrate that the benefits outweigh the risks is upon the proponents of continued registration."[167] Further, in any subsequent judicial review, a cancellation order made under FIFRA "shall be sustained if it is supported by substantial evidence when considered on the record as a whole."[168]

CONCLUSION

The Hartz UltraGuard package clearly states: "DO NOT LET CHILDREN PLAY WITH THIS COLLAR" and further instructs users to wash hands thoroughly after handling the collar.[169] Those warnings do not address the

160. *Id.* § 154.7(a)(5).

161. 2020 Denial, *supra* note 10, at 8 ("In acute lethality studies, TCVP has low acute toxicity by the oral, dermal, and inhalation routes of exposure. . . . It is a slight dermal irritant, a moderate eye irritant, and a dermal sensitizer.").

162. 40 C.F.R. § 154.10.

163. *Id.* § 164.31.

164. 7 U.S.C. § 136n(b).

165. *See generally* Nat. Res. Def. Council v. EPA, 31 F.4th 1203 (9th Cir. 2022).

166. 40 C.F.R. § 154.5; *id.* § 164.80(a) and (b).

167. Env't Def. Fund, Inc. v. EPA, 510 F.2d 1292, 1302 (D.C. Cir. 1975); *see also* Env't Def. Fund, Inc. v. Ruckelshaus, 439 F.2d 584, 593 (D.C. Cir. 1971) ("Congress intended any substantial question of safety to trigger the issuance of cancellation notices, *shifting to the manufacturer the burden* of proving the safety of his product") (emphasis added).

168. 7 U.S.C. § 136n(b).

169. Photograph of packaging, *supra* note 104.

realities of pet ownership with children. First, it is nearly inevitable that children will be unsupervised with pets long before they can understand—let alone remember—the instruction to wash hands after petting the animal. Further, the warning does not address the main route for TCVP transfer discussed in the Ninth Circuit's opinion: dry dust transfer from fur to hand *without directly touching the collar*. Put simply, a product of known toxicity is still on the market, adorned with a warning label that sounds good but does not actually address a key danger the product poses.[170] I find that astonishing.

The *NRDC v. EPA* litigation has shown that the risks posed by TCVP are greater than the agency had previously believed. In addition, there are products such as etofenprox spot-ons that can provide similar levels of flea and tick protection with far lower risk of toxicity. Taken together, these facts suggest a situation where the use of the TCVP products themselves is unreasonable, and EPA should ban their use.

EPA faces tremendous challenges in its administration of FIFRA: constrained resources, onerous cancellation procedures, and determined industry resistance to attempts at regulation.[171] Those challenges are not to be minimized. Yet at the same time, EPA's mission "is to protect human health and the environment."[172] The simple truth is that TCVP pet collars should have been forced from the market many years ago, and EPA's failure to do so is troublesome.

Fortunately, FIFRA provides a tool EPA can wield to move more aggressively in future situations of this type. Even if courts hold that the "essentiality" language precludes EPA from considering alternatives in registration proceedings, there is no doubt that EPA may consider alternatives in the more wide-ranging inquiry the agency performs in cancellation proceedings.[173] FIFRA's bias toward continued registration of pesticides means

170. See, e.g., CONSUMER ALERT: Flea and Tick Prevention Pet Products Containing Dangerous TCVP, OFF. OF THE ATT'Y GEN. OF D.C (July 28, 2022), https://oag.dc.gov/release/consumer-alert-flea-and-tick-prevention-pet ("Just because a product is on the shelf at your favorite store does not necessarily mean it is always safe to bring home to your family. Labels that say, 'do not let children play with collar' or 'harmful if swallowed or absorbed through skin', but the labels do not specify the degree of danger and risk of playing with the pets themselves after they are treated with the product."). Though not directly relevant here, given the challenges of supervising children and pets, conceivably the only warning label that would actually be effective would be one that simply stated: "If children may contact the animal, do not use this collar."

171. For instance, in the agency's response finally granting NRDC's petition to cancel TCVP pet collars, EPA noted that Hartz intends to submit additional data supporting the safety of its collars in an attempt to keep the collars on the market. Grant of Petition, *supra* note 57, at 7. Hartz did submit additional data, and in September 2023 EPA responded to those data by reversing its decision to seek cancellation. *See* Reversal of Decision to Cancel, *supra* note 57, at 14.

172. EPA, OUR MISSION AND WHAT WE DO (last updated May 23, 2023), https://www.epa.gov/aboutepa/our-mission-and-what-we-do.

173. See generally 2020 denial, *supra* note 10.

a surfeit of pesticides inhabit the market. In the present case, some of those same products are demonstrably safer than TCVP pet collars. FIFRA's cancellation provisions are broad enough that they permit EPA to use that range of toxicity to highlight the unreasonable adverse effects of the more dangerous chemicals. EPA's unambiguous duty to consider alternatives can be a forceful tool to cancel duplicative, hazardous pesticides. EPA can further that duty by changing its definition of "unreasonable adverse effects" to include evidence that a pesticide poses a substantially greater risk of harm to humans or the environment than other registered pesticides, and that those potential harms are not outweighed by significant social, economic, or environmental benefits. EPA should take advantage of that authority to protect unsuspecting consumers from pesticides that can be easily replaced by less harmful ones.