CITIZEN PETITION TO THE
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

CENTER FOR FOOD SAFETY 660 Pennsylvania Ave., SE, Suite 302 Washington, DC 20003 Petitioner, ***Filed With:*** **SCOTT PRUITT** in his official capacity as, Administrator Environmental Protection Agency Ariel Rios Building 1200 Pennsylvania Ave., NW Washington, DC 20460	Docket Number _____

CITIZEN PETITION SEEKING REVISED TESTING REQUIREMENTS OF PESTICIDES PRIOR TO REGISTRATION

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INTRODUCTION

While the old toxicology adage states that the "dose makes the poison," it is increasingly clear that instead the "formulation makes the poison"[1] when it comes to the adverse effects of pesticides and their "inert" and adjuvant ingredients on non-target organisms. Pesticides are compositions of chemicals intended to be toxic to target organisms. Specifically, they are "intended for preventing, destroying, repelling or mitigating any pest."[2] Because they are designed to have biological activity, pesticides have the potential to be, and often are, toxic to non-target organisms as well. A growing body of research indicates that a pesticide's active ingredients in combination with its inert and adjuvant ingredients can increase pesticide toxicity, ecotoxicity, and exposure, both independently and through their synergistic effects with the pesticide's active ingredients. Nonetheless, in regulating and approving pesticide usage, the Environmental Protection Agency (EPA) focuses its testing and data collection on active ingredients alone, largely ignoring inerts and adjuvants, as well as the synergistic effects of the chemicals once combined. EPA's insufficient safety assessment of pesticides endangers the health of the public and the environment as a whole.

Through the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),[3] Congress charged EPA with the task of regulating pesticide usage "[t]o the extent necessary to prevent unreasonable adverse effects on the environment."[4] Underlying every pesticide registration, review, and reregistration is the requirement that EPA finds that use of the pesticide would not pose "unreasonable adverse effects on the environment."[5] In delegating to EPA the task of setting requirements for data in support of registration in FIFRA, Congress specified that the data should reflect a pesticide's *use in its entirety*.[6] Yet, EPA's regulations implementing FIFIRA only require testing and data on some of a pesticide's *components*.

The majority of EPA's regulations only require toxicological data on a pesticide's active ingredients in isolation, and thus do not concern the environmental impact of the whole pesticide formulation.[7] EPA's data requirements largely ignore inert and adjuvant ingredients in a given formulation, as well as synergistic effects. Without testing of the whole pesticide formula to account for the toxicological effects of inert and adjuvant ingredients and the interactions between different pesticide ingredients, EPA cannot possibly determine with accuracy whether a given pesticide formulation will have unreasonable adverse effects to the environment. As EPA itself stated: "[t]he safety of the formulation, *including all its ingredients*, is a *critical* factor in

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[1] Christopher A. Mullin, Jing Chen, Julia D. Fine, Maryann T. Frazier, James L. Frazier, *The formulation makes the honey bee poison*, 120 Pesticide Biochemistry and Physiology May 2015, at 27, https://doi.org/10.1016/j.pestbp.2014.12.026.
[2] 7 U.S.C. § 136(u)(1) (2012).
[3] *Id.* §§ 136-136y.
[4] *Id.* § 136a(a).
[5] *E.g.*, *id.* § 136a(a), 136a(c)(2)(E)(ii), 136a(c)(3)(B)(i)(I), 136a(c)(5), 136a(c)(7)
[6] *See id.* § 136a(c)(2)(A).
[7] *See generally*, 40 C.F.R. § 158.

whether the pesticide 'will perform its intended function without unreasonable adverse effects on the environment.'"[8]

Therefore, EPA has violated the congressional mandates of FIFRA, and its interpretation of FIFRA and regulatory action under FIFRA are unacceptable. EPA can and should act to address this serious error under its existing regulatory authority.[9] EPA must revise its regulatory regime to fully assess whole pesticide formulations and tank mixtures in all parts of its pesticide registration process.

ACTIONS REQUESTED

Petitioner requests the following actions:

(1) Revise pesticide registration regulations to take into account all pesticide ingredients (active, inert and adjuvant) and their effects on the environment.

(2) Revise pesticide registration regulations to require whole pesticide formulation and tank mixture testing to take into account synergistic effects.

(3) Revise pesticide registration regulations to require inert ingredients and whole pesticide formulations testing for chronic toxicological effects and degradation.

(4) Revise pesticide registration regulations to require Endangered Species Act (ESA) consultation on the effects of whole pesticide formulations and tank mixtures on threatened and endangered species.

(5) Comply with the above requirements in conducting statutorily mandated registration reviews of pesticides.

To implement requests (1) through (4), Center for Food Safety petitions EPA to amend its regulations as follows:

I. **40 C.F.R. § 152.3 and 40 C.F.R. § 158.300**. Amend the definition of "End-use product" by adding the language in italics:

> End-use product means a pesticide product *being registered, including all active and inert ingredients (including adjuvants and surfactants) in the formulation,* whose labeling:
>
> (1) Includes directions for use of the product (as distributed or sold, or after combination by the user with other substances) for controlling pests or

[8] Public Availability of Identities of Inert Ingredients in Pesticides, 74 Fed. Reg. 68215, 68222 (Dec. 23, 2009) (to be codified at 40 C.F.R. § 156) (citing 7 U.S.C. § 136a(c)(5)(C)) (emphasis added).

[9] FIFRA grants EPA broad discretion in determining data requirements for pesticide registration. 7 U.S.C. §136a(c)(2).

defoliating, desiccating or regulating growth of plants, or as a nitrogen stabilizer, and

(2) does not state that the product may be used to manufacture or formulate other pesticide products.

II. **Part 158, Subpart C, 40 C.F.R. §§ 158.200 to .270.** Amend the test substance requirements from technical grade active ingredient (TGAI) or typical end-use product (TEP) to End-use product (EP).

III. **Part 158, Subpart F, 40 C.F.R. § 158.500.** Amend the test substance requirements from TGAI or TEP to EP, or End-use product.

IV. **Part 158, Subpart F, 40 C.F.R. § 158.510(a).** Expand the required data replacing the phrase "active ingredient" with "end-use product."

V. **Part 158, Subpart G, 40 C.F.R. § 158.630(d)**. Amend the test substance requirements from TGAI or TEP to EP, or End-use product.

VI. Add testing requirement for "Combination and tank mixtures" to **Part 158, Subparts C, F, and G** as "conditionally required" for all categories, with the following testing note:

This test is required if, as recommended by the pesticide manufacturer, indicated by the pesticide label, or in common practice, 1) the pesticide product will be mixed prior to application with any recommended vehicles or adjuvants or 2) if the pesticide product will be mixed prior to application with any other approved pesticide product or active ingredient.

PETITIONER'S AND THE PUBLIC'S INTERESTS

I. Petitioner's Interest

The **Center for Food Safety** (CFS) is a public interest, nonprofit membership organization, with offices in Washington, D.C., San Francisco, California, Portland, Oregon, and Honolulu, Hawaii. CFS's mission is to empower people, support farmers, and protect the earth from the harmful impacts of industrial agriculture. Through groundbreaking legal, scientific, and grassroots action, CFS protects and promotes the public's right to safe food and the environment. With more than 900,000 members throughout the country that support safe, sustainable agriculture, CFS has consistently supported comprehensive EPA review of registered pesticides and individual inert ingredients.[10]

[10] To this end, CFS joined Center for Biological Diversity's *Petition For Rulemaking to Evaluate Synergistic Effects of Pesticides During Registration and Registration Review* (July 28, 2016), *see* CFS Letter to Administrator McCarthy and Director Housenger (July 29, 2016).

II. Broader Public Interest

The massive use of pesticides in nearly all aspects of industrial agricultural production negatively impacts the environment and public health. Currently registered pesticide products have not been fully tested, and many of those products can severely damage agricultural land, human health, and threatened and endangered species. The use of pesticides impacts the broader public interest by impacting our food, water, land, and products.

EPA's failure to adequately assess the interactions amongst active ingredients, inerts, and adjuvants in the whole formula of pesticides is already having tangible harm. For example, as discussed more fully below, certain pesticide formulations can be more harmful to non-target invertebrates (including our nation's vital pollinator insects) and amphibians due to their particular adjuvants and inert ingredients, compared to toxicity of the active ingredients of those pesticides alone. *See infra* Statement of Legal Grounds, section II, pp. 13-18. These additive or synergistic effects are missed when pre-market testing of a pesticide's toxicological effects, including its chronic effects, are required only on the active ingredient, to the detriment of non-target species of plants, invertebrates, amphibians, and other wildlife, as well as humans. By ignoring these impacts, EPA fails to meet its statutory duty to assess and ensure that the pesticides it registers meet FIFRA's safety standard, i.e., do not have unreasonable adverse effects to the environment. Because FIFRA's safety standard exists to protect human health and the environment, the public interest lies in registration of only pesticides that meet this standard.

APPLICABLE LAW

(1) The Administrative Procedure Act, 5 U.S.C. § 551 *et seq.*

(2) The Endangered Species Act, 16 U.S.C. § 1531 *et seq.*

(3) The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*

(4) The Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. § 136 *et seq.*

(5) The Food Quality Protection Act, Pub. L. No. 104-170 (1996).

(6) Code of Federal Regulations, EPA, 40 C.F.R. Parts 152, 158 (2017).

RELEVANT REGULATORY BACKGROUND

I. FIFRA Terminology and Mandates.

FIFRA governs the sale, distribution, and use of pesticides. A pesticide is "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest …."[11] A pesticide may not be distributed or sold unless registered under FIFRA.[12] FIFRA's

[11] 7 U.S.C. § 136(u).
[12] *Id.* § 136a(a).

safety standard for pesticides requires that an approved pesticide use must not cause "unreasonable adverse effects on the environment."[13]

In enacting FIFRA, Congress understood that pesticides are generally comprised of active ingredients and inert ingredients.[14] An active ingredient is one that "will prevent, destroy, repel, or mitigate any pest."[15] An inert ingredient is "an ingredient which is not active."[16] While "adjuvant" is not a defined FIFRA term, it is an ingredient that is not active. Thus, the term "inert" will be used throughout this Petition to refer to both inerts and adjuvants, except where specifically noted.

EPA is responsible for dictating what information must be submitted to support registration of a pesticide and assessing that data to make its determination of whether the pesticide will perform its intended function while meeting the safety standard under FIFRA.[17] A pesticide registration application must include, among other things, "the complete formula of the pesticide"[18] and "a full description of the tests made and the results thereof upon which [safety and efficacy] claims are based, or alternatively a citation to [relevant safety and efficacy] data …."[19] EPA requires a "confidential statement of formula" that includes all active and inert ingredients and impurities in a given pesticide formula or formulation.[20] FIFRA dictates that, in order to grant a pesticide's registration, EPA must find that a pesticide "perform[s] its intended function without unreasonable adverse effects on the environment; and [that] when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."[21] EPA has broad discretion to require supporting data for pesticide applications and to require additional data for registered pesticides to maintain registration.[22]

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[13] *See id.* ("To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under [FIFRA].").
[14] *See* 40 C.F.R. § 158.300, which defines "formulation" to mean the process of mixing active and inert ingredients to create a final pesticide product.
[15] 7 U.S.C § 136(a)(1).
[16] *Id.* § 136(m).
[17] *Id.* § 136a(c)(5)(C).
[18] *Id.* § 136a(c)(1)(D).
[19] 7 U.S.C. § 136a(c)(1)(F); *see also Pesticide Registration Manual*, EPA, http://www2.epa.gov/pesticide-registration/pesticide-registration-manual-introduction (last updated May 24, 2017) ("The purpose of these data requirements is to demonstrate that the product will not cause unreasonable adverse effects….").
[20] *Pesticide Registration Manual*, *supra* note 19, at Ch. 2, *available at* https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product#required (citing 7 U.S.C. § 136a(c)(1)(D)).
[21] 7 U.S.C. § 136a(c)(5).
[22] *Id.* § 136a(c)(2).

An application for registration is incomplete if it contains insufficient information for EPA to determine if a pesticide is safe.[23] Registration of a pesticide—conditional or otherwise—cannot continue on the basis of an incomplete application.[24] Once a pesticide is registered, FIFRA provides EPA with ongoing oversight authority, and EPA may at any time propose cancellation if it appears a pesticide does not meet FIFRA's safety standard.[25]

When deciding if there are unreasonable adverse effects on the environment, EPA must take into account "the economic, social and environmental costs and benefits of the use of [the] pesticide."[26] "Environment" "includes water, air, land, and all plants and man and other animals living therein, and the interrelationships which exist among these."[27] For pesticides used on food products, EPA must also consider the "human dietary risk from residues."[28] EPA must consider public health pesticides separately, including consideration of a standard of an overall improvement in public health.[29]

Pesticides may be sold as formulations, or technical grade ingredients. A pesticide formulation is a mixture of one or more active ingredients—the pesticide formula, along with other chemicals, statutorily defined and commonly known as inert ingredients.[30] The mixture of the pesticide formula and inert ingredients is often referred to simply as the pesticide or the pesticide formulation.[31] The term inert is used to distinguish certain ingredients from active ingredients. Though inerts may or may not have a direct effect on the target species, they can be toxic, biologically active and potentially hazardous.[32]

To apply a pesticide, the pesticide formulation is often added to a tank or other container containing adjuvants.[33] The difference between adjuvants and inerts is that adjuvants are added to a tank mixture in the field at the time a pesticide is applied rather than when it is formulated in the laboratory.[34] Adjuvants include surfactants, compatibility agents, antifoaming agents, dyes, and drift-control agents.

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[23] 40 C.F.R. § 152.104.
[24] *Id.* § 152.105.
[25] 7 U.S.C. § 136d(b).
[26] *Id*. § 136(bb).
[27] *Id.* § 136(j).
[28] *Id.* § 136(bb).
[29] *Id.*
[30] Committee on Ecological Risk Assessment under FIFRA and ESA, National Research Council, *Assessing Risks to Endangered and Threatened Species from Pesticides*, 65 (2013) [*hereinafter* NRC].
[31] *Id.*
[32] *Id.* at 66. *See also* Mullin *et al.* (2015), *supra* note 1, at 2 ("Numerous studies have found that pesticide active ingredients elicit very different physiological effects on nontarget organisms when combined with their formulation ingredients.")
[33] NRC (2013), *supra* note 30, at 65.
[34] *Id.* at 66.

Both "[i]nerts and adjuvants are comprised of an extremely broad array of chemicals, including carriers, stabilizers, sticking agents, and other materials added to facilitate handling or application."[35] The identity and concentration of the constituents are known in both pesticide formulations and tank mixtures, simplifying exposure analysis.[36] Despite this fact, along with EPA's admission that inerts and adjuvants are often toxic, EPA testing requirements of these chemicals remains elusive. EPA's guidance documents for developing new pesticide inerts do not contain a specific list or detail the required tests for approval; however, as detailed below, inerts and adjuvants can and should be subject to the same types of tests that are required for active ingredients.[37]

II. Current EPA Regulation of Pesticides.

According to EPA's website, "EPA performs a rigorous, comprehensive scientific assessment of the [pesticide] product" before making a registration decision.[38] "Under this review, [EPA] evaluates pesticides' active ingredient(s), other constituent substances (including inert ingredients), and the proposed use pattern(s)."[39] In a 2009 proposal concerning labeling inert ingredients, EPA described its pesticide safety review process: "[i]n order to determine if a pesticide product meets the unreasonable adverse effects standard, EPA conducts risk assessments for pesticide products [that] consist of four general steps: hazard identification, dose-response assessment, exposure assessment, and risk characterization."[40]

In these assessments, however, EPA does not treat active ingredients, inert ingredients, and pesticide proposed uses equally. EPA has instead promulgated regulations requiring extensive data on pesticides' active ingredients and far less data on inert ingredients and whole formulations.[41] EPA's regulations include tables showing the potentially required tests, when they are required, and what substance must be tested. Nearly all of these require testing only of the "technical grade active ingredient" or a "typical end-use product," neither of which capture the actual pesticide formulation being registered.[42] Indeed, EPA provides: "[u]nlike active ingredients, inert ingredients do not have a 'required' data set[.]"[43] As a result, "[m]ost of the tests required to register a pesticide are performed with the active ingredient alone, not the full

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[35] *Id.*
[36] *Id.* at 65.
[37] *Id.* at 120.
[38] *Pesticide Registration Manual*, *supra* note 19.
[39] *Id.*
[40] Public Availability of Identities of Inert Ingredients in Pesticides, *supra* note 8, at 68216-17.
[41] Generally, EPA requires data on the toxicological significance of the active ingredients in pesticide products, but not necessarily of the whole formulas. *See* 40 C.F.R. § 158.130(e) (hazards to nontarget organisms); § 158.500 (toxicology data requirements); § 158.630 (data requirements for terrestrial and aquatic nontarget organisms); *see generally* 40 C.F.R. § 158.320.
[42] *Id.*
[43] Inert Ingredient Frequently Asked Questions, EPA, http://www2.epa.gov/sites/production/files/2014-05/documents/faqs.pdf (updated May 6, 2014).

pesticide formulation."[44] Regarding the pesticide risk assessment process, EPA explains: "[i]n the case of an inert ingredient, information on its hazard (the ability to cause adverse health and/or environmental effects) informs the risk assessment process but by itself is not sufficient to determine the risk [] associated with a particular product."[45]

EPA defines and dictates the particular test substance required for various tests. The test substances identified in the regulations could be one or more of the following: the end use product (EP), the manufacturing use product (MP), the technical grade active ingredient (TGAI), or the pure active ingredient (PAI).[46] Some tests may also be satisfied using a typical end-use product (TEP), which is not always clearly defined.[47] If the EP is used, the data will reflect the effects of the combination of the active and inert ingredients.[48] If the MP is used, the data may or may not reflect the effects of inert ingredients.[49] If the TGAI or PAI is used, inert ingredients will not be factored into the testing at all.[50] The TEP is undefined, but it does not represent the actual formulation that is being registered.

While acute toxicological effects tests require use of the EP, chronic toxicological effects tests require only the TGAI or the PAI.[51] Tests for toxicological effects on wildlife (both terrestrial and aquatic non-target organisms) or sediment also do not require the EP or the MP, but only the TGAI or TEP.[52] Tests for degradation effects and other tests only use the TGAI or the PAI.[53] Thus, neither the entire formulation, including its inert ingredients, are being tested for chronic toxicological effects, for degradation, or for toxicological effects on wildlife (including birds, mammals, aquatic organisms, and insect pollinators) or sediment. Importantly, most adverse effects to the environment and human health result from chronic exposure to pesticides.

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[44] Caroline Cox & Michael Surgan, *Unidentified Inert Ingredients in Pesticides: Implications for Human and Environmental Health* 114(12) Envtl. Health Persp. 1803, 1804 (2006) ("Of the 20 toxicologic tests required (or conditionally required) to register a pesticide in the United States, only 7 short-term acute toxicity tests use the pesticide formulation; the rest are done with only the active ingredient. The medium-and long-term toxicity tests that explore end points of significant concern (cancer, reproductive problems, and genetic damage, for example) are conducted with the active ingredient alone. The requirements for other types of tests are similar. Only half of the required (or conditionally required) tests of environmental fate use the formulated product, as do only a quarter of the tests for effects on wildlife and nontarget plants (U.S. EPA 2005a, Parts 158.290, 158.340, 158.490, and 158.540).").

[45] Public Availability of Identities of Inert Ingredients in Pesticides, *supra* note 8, at 68217 (emphasis added).

[46] *See, e.g.*, 40 C.F.R. § 158.500.

[47] *See e.g.* 40 C.F.R. § 158.630 ("TEP=Typical end-use product"); *but see* 40 C.F.R. § 158.300 (no definition of TEP).

[48] *See* 40 C.F.R. § 158.300.

[49] *Id.* § 158.300.

[50] *Id.*

[51] *Id.* § 158.630.

[52] *Id.* § 158.630.

[53] *Id.* § 158.1300.

As a result, EPA's current regulatory process cannot generate the data required to make pesticide safety determinations under FIFRA.

STATEMENT OF LEGAL GROUNDS

I. EPA Has Persistently Recognized the Potential Effects of Inert Ingredients in Pesticide Formulations.

EPA recognizes the potential harm of inert ingredients, and it has repeatedly indicated that reassessing their evaluation and testing requirements is necessary. In 1987, EPA created lists that divided inert ingredients existing at that time into four categories.[54] The purpose of these lists was to establish priorities for regulatory activities related to inert ingredients of highest concern.[55] Of primary concern were "List 1" inert ingredients, inert ingredients of toxicological concern.[56] "The criteria used to place chemicals on List 1 were carcinogenicity, adverse reproductive effects, neurotoxicity or other chronic effects, [] developmental toxicity (birth defects)[,] documented ecological effects[,] and the potential for bioaccumulation."[57] EPA required registrants to submit additional safety data on List 1 inert ingredients, and, ultimately, nearly all of these inert ingredients disappeared from pesticide formulations due to cancellation or voluntary removal.[58]

The 1987 policy also required that any new inert ingredients go through a new registration process.[59] In this new process, however, "[t]he minimal data generally required to evaluate the risks posed by the presence of a new inert ingredient in a pesticide product [was] a subset of the kinds of data typically required for active ingredients under 40 CFR Part 158."[60] Thus, despite recognizing the potential effects of inert ingredients, EPA's evaluation of inert ingredients remains cursory.

As a result of an ongoing review of inert ingredients, in 1999, EPA published a notice that it had removed certain chemicals from its approved inert ingredient lists.[61] EPA emphasized that these unapproved inert ingredients would not be registered until a "registrant satisfies all

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[54] These lists are no longer used. *See* Inert Ingredient Frequently Asked Questions, *supra* note 43, at http://www2.epa.gov/sites/production/files/2014-05/documents/faqs.pdf ("Now that reassessment of food tolerances/tolerance exemptions under the Food Quality Protection Act (FQPA) is complete, the approval determinations of inert ingredients are no longer classified as List 1, 2, 3, or 4A/4B and these lists are no longer being updated by the Office of Pesticide Programs.")

[55] Inert Ingredient in Pesticide Products Policy Statement (IIPS), 52 Fed. Reg. 13,305 (Apr. 22, 1987).

[56] *Id.*

[57] *Id.*

[58] *Categorized Lists of Inert Ingredients (Old Lists),* EPA, https://www.epa.gov/pesticide-registration/categorized-lists-inert-ingredients-old-lists (last updated Apr. 24, 2017).

[59] Inert Ingredient in Pesticide Products Policy Statement, *supra, n. 55.*

[60] *Id.*

[61] Inert Ingredients No Longer Used in Pesticide Products, 64 FR 31575, 31575 (June 11, 1999).

data requirements as identified by [EPA], and [EPA] is able to make a determination that the use of the inert ingredient will not pose unreasonable risk to human health or the environment."[62]

In 2006, Congress passed the Food Quality Protection Act (FQPA)[63], which "required the reassessment of inert ingredient tolerances and tolerance exemptions [for pesticides used on food] that were in place before August 3, 1996."[64] EPA completed this review, but to date has not reassessed inert ingredients used in pesticide formulations not used on food.

Then, in 2009, EPA proposed disclosing inert ingredients on pesticide labels, but in 2014 revoked that proposal.[65] Explaining its decision not to mandate inert ingredient labeling, EPA resolved to further categorize and prioritize inert ingredients for review and regulatory efforts; EPA also specified that non-food use inert ingredients were top priority, since they did not benefit from the reassessment conducted for food use inerts, and about 230 non-food-use inert ingredients remained for further consideration of potential risks.[66] More than two years later, in December 2016, EPA removed 72 inert ingredients from the list of approved inerts because they were no longer used as inert ingredients in any registered pesticide product.[67] EPA described this action as one of the action discussed in its May 22, 2014 letter discussing EPA's strategy towards inerts, stating that it would facilitate EPA's review of inert ingredients, by eliminating those not current used in pesticide formulations.[68] Nonetheless, EPA has not moved to strengthen its review of inert ingredients by requiring more stringent consideration of their potential effects in its pesticide review process.

Similarly, the synergistic effects of multiple active ingredients, or a pesticide's active ingredient(s) and its other ingredients (inerts, adjuvants) can boost a pesticide's toxicity to both target and non-target organisms including listed species, and must be evaluated accordingly. Nonetheless, despite the safety hazards of inerts and adjuvants and the potential synergistic effect of multiple ingredients, most EPA regulations require registrants to submit toxicity data on active ingredients in isolation.[69]

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[62] *Id.*
[63] Pub. L. No. 104-170 (1996).
[64] Inert Ingredients Overview and Guidance, EPA, http://www2.epa.gov/pesticide-registration/inert-ingredients-overview-and-guidance (last updated May 24, 2017).
[65] Public Availability of Identities of Inert Ingredients in Pesticides, *supra* note 8, at 68216-17.
[66] EPA Office of Chemical Safety and Pollution Prevention Letter to Attorney General of California, Northwest Coalition for Alternatives to Pesticides, and Western Environmental Law Center (May 22, 2014), EPA-HQ-OPP-2014-0558-0003.
[67] Removal of Certain Inert Ingredients From the Approved Chemical Substance List for Pesticide Products, 81 Fed. Reg. 90356 (December 14, 2016).
[68] *Id.*
[69] *See* 40 C.F.R. § 158.

II. Real World Examples of Pesticide Formulations and Tank Mixtures Make Clear That Whole Formulas Have Different and Potentially More Toxic Effects Than Active Ingredient Alone.

Pesticides are biologically active. They are designed to attack the specific pest a pesticide is designed to combat.[70] However, pesticides may have a variety of effects on non-target organisms as well, including listed species. Active ingredients are inherently toxic. Inert ingredients and adjuvants are by definition not active ingredients, but this does not mean they are biologically or chemically inert. As EPA explains, "inert" does not mean non-toxic.[71] EPA acknowledges that these chemicals can be harmful.[72] The potential harm of inert ingredients is clear in that hundreds of these chemicals have also been registered for use as active ingredients, and over half of these chemicals are considered hazardous air and water pollutants of at least moderate risk.[73]

When active ingredients are combined with "inert" ingredients, the effects of these pesticide formulations may be different, and in fact are intended to be different, then the active ingredient in isolation. While the effects of a mixture of chemicals may be additive—predicted on the basis of the expected responses to the individual components of a mixture—they may also be toxic, creating a response that is either antagonistic (less than additive) or synergistic (more than additive).[74] Synergy is the interaction of two or more ingredients in a mixture in such a way as to enhance their toxic effects beyond the effects of each individual ingredient.[75] Active ingredients may have increased synergistic effects when combined with other chemicals including other active ingredients,[76] inerts, or adjuvants. These synergistic effects can increase a pesticide's toxicity, ecotoxicity, and exposure (bioavailability or potency) to both target and non-target organisms by a factor of 100.[77] One recent study testing the toxicity of active ingredients compared to whole formulations found that 8 out of 9 formulations were "several hundred times

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[70] 7 U.S.C. § 136(u).
[71] Inert Ingredients Overview and Guidance, *supra* note 64.
[72] Office of Pesticide Programs, EPA, *Methodology for Determining the Data Needed and the Types of Assessments Necessary to Make FFDCA Section 408 Safety Determinations for Lower Toxicity Pesticide Chemicals* 6 (June 7, 2002), *available at* https://web.archive.org/web/20030413194437/http://www.epa.gov/oppfead1/cb/csb_page/updates/lowertox.pdf
[73] Cox & Surgan, *supra* note 44, at 1804; Holly Knight, *Worst Kept Secrets: Toxic Inert Ingredients in Pesticides* (1998).
[74] NRC (2013), *supra* note 30, at 110, 112.
[75] Nathan Donley, *Toxic Concoctions* (July 2016), https://www.biologicaldiversity.org/campaigns/pesticides_reduction/pdfs/Toxic_concoctions.pdf
[76] The 2013 NRC report notes three examples of known synergistic interactions between pesticide active ingredients including: *organophosphates and carbamates*; *pyrethroids and organophosphates*; and, *ergosterol biosynthesis-inhibiting fungicides and pyretheroids*. NRC, *supra*, n. 30 at 113-14; *See also id.*
[77] NRC, *supra*, n. 30 at 112 (citing Sahay & Agarwall 1997).

more toxic than their active principle."[78] Indeed, it is well documented that pesticide "[f]ormulations are generally more toxic than active ingredients, particularly fungicides, by up to 26,000-fold based on published literature."[79] Consequently, the potential synergistic effects among a mixture of chemicals contained in a pesticide formulation or tank mixture is critical when assessing whether the mixture poses an unreasonable adverse effect to the environment or a listed species. As a recent literature review concluded, "[i]t is clear that agrochemical risk assessment that takes into account only pesticide active ingredients and their formulations in absence of the spray adjuvants commonly used in their application will miss important toxicity outcomes that may prove detrimental, even to humans."[80] Both the National Marine Fisheries Service (NMFS) and the Fish and Wildlife Service (FWS) express substantial concern for these potential synergistic effects in their Biological Opinions (BiOp) while EPA's risk assessments misguidedly focus on single active ingredients.[81]

Notably, these synergistic effects are not accidental. Inerts are often specifically "designed to affect the behavior of an active ingredient after application."[82] Surfactants and penetrating agents have a powerful ability to enhance absorption and efficacy and are used intentionally for this purpose.[83] Furthermore, the synergistic effects of active ingredients and inerts are often the subject of chemical company patent applications (see case studies below).[84]

A. Monsanto's Patent: Novel Surfactants and Formulations.[85]

Monsanto filed a patent application relating to surfactants specifically chosen for the potassium salt of glyphosate, the active ingredient behind its pesticide product commonly known as Roundup. According to the patent application, "surfactant" includes a wide range of adjuvants added to herbicidal glyphosate compositions to enhance the herbicidal efficacy, i.e. to make glyphosate more toxic to plants.[86] Glyphosate salts need a surfactant for best herbicidal performance.[87] Interestingly, the surfactant can be provided in the pesticide formulation or added by the user in the tank mixture. [88] The herbicidal formulations of the subject patent may contain

[78] Mesnage, R et al., *Major Pesticides are More Toxic to Human Cells than their Declared Active Principles*, 2014 Biomedical Res. Int'l (Feb. 2014).
[79] Mullin *et al*., *Toxicological Risks of Agrochemical Spray Adjuvants: Organosilicone Surfactants May Not Be Safe*, 4 Frontiers in Pub. Health 92 (2016), http://journal.frontiersin.org/article/10.3389/fpubh.2016.00092/full.
[80] *Id.*
[81] NRC (2013), *supra*, n. 30 at 118-19.
[82] *Id.* at 67.
[83] *Id.*
[84] *See* Donley (2016) *supra*, n.75.
[85] U.S. Patent Application Publication, Lennon et al., Pub. No. US2010/0234228, Sep. 16, 2010.
[86] *Id.* at 1-2.
[87] *Id.* at 2.
[88] *Id.*

one or more additional surfactants, one or more additional herbicides, and/or other adjuvants or ingredients. [89] It may also be prepared onsite or supplied on a "ready to use" basis.[90]

As Monsanto's patent application demonstrates, herbicidal effectiveness, the control of plant growth such as killing, inhibiting growth, reproduction or proliferation, is one of the biological effects that can be enhanced through surfactants. However, "[b]eyond some broad generalizations, the relative ability of different surfactants to enhance the herbicidal effectiveness of glyphosate is highly unpredictable."[91] The application includes several tables that illustrate the increased efficacy of various surfactants combined with glyphosate.[92]

Several takeaways can be gleaned from the extensive data provided in Monsanto's patent application. One is that surfactants increase the percentage of plants killed while using lower concentrations of glyphosate. However, depending on the surfactant, the increased efficacy varies dramatically. Additionally, depending on the plant, the increased efficacy provided by the surfactant composition varies dramatically. This data supports the argument that EPA must require that the actual pesticide formulations as well as the tank mixtures be evaluated for unreasonable effects to the environment and listed species in any risk assessment. Surrogate formulations do not capture the wide variation in pesticide efficacy, and testing of active ingredients in isolation certainly do not.

B. Pesticide Formulations with Organosilicone Adjuvants.

Organosilicones are a widely used and powerful class of nonionic surfactants used in tank mixtures for sprayed pesticides, as adjuvants that enhance penetration and spread of the active ingredient(s).[93] Worldwide, over 1.3 billion pounds of organosilicones were used in 2008, with increases every year after, and on California almond production alone, hundreds of thousands of pounds of this class of adjuvants are used every year, often during bloom.[94] Consequently, honey bees and other pollinators are readily exposed to organosilicones.[95] Despite their classification as "inerts" and the assumption that they are biologically inert, studies have found that they are toxic to bees in isolation and have synergistic effects when combined with insecticides and fungicides, including a class of insecticides known as neonicotinoids that is found to be harmful to honey bees and other pollinator species.[96]

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[89] *Id.* at 5.
[90] *Id.*
[91] *Id.* at 2.
[92] *Id.* at 69-102.
[93] Julia D. Fine, Diana L. Cox-Foster, & Christopher A. Mullin, *An Inert Pesticide Adjuvant Synergizes Viral Pathogenicity and Mortality in Honey Bee Larvae* 7 *Sci. Rep.* 1 (2017), https://www.nature.com/articles/srep40499.pdf.
[94] *Id.* at 1-2. *See also* Mullin *et al. (2015), supra*, n. 1.
[95] Mullin, et al. (2016), *supra*, n. 79.
[96] Fine, *et al.*, *supra*, n. 93; Mullin, *et al.* (2016), *supra*, n. 79; Mullin et al., (2015), *supra*, n. 1; Ciarlo TJ, Mullin CA, Frazier JL, Schmehl DR, *Learning Impairment in Honey Bees Caused by*

In 2012, researchers found for the first time that organosilicone adjuvants impaired learning in foraging honey bees, indicating severe, colony-level impacts from organosilicone adjuvants, despite their assumed inert nature.[97] The study found that oral ingestion of just 20 μg of the organosilicone adjuvants tested (Dyne-Amic, Syl-Tac, Sylgard 309, and Silwet L-77) significantly reduced honey bees' learning ability in the proboscis extension reflex assay (which simulates feeding events at flowers). *Id.* Further studies have shown that organosilicones are some of the most toxic adjuvants, both sublethally and acutely, to adult honey bees, both alone and in combination with active ingredients.[98] Combinations of organosilicones adjuvants and other stressors encountered by honey bees, like viruses, result in synergistic mortality to developing bee larvae.[99]

Not only are organosilicone adjuvants harmful to bees in isolation, but they have synergistic impacts with active ingredients, as they perform their *intended* function of increasing the efficacy of those pesticides.[100] Reviews of the use of organosilicone adjuvants with pesticides in California almond groves (where 80% of the nations managed bees are pollinating) show that the greatest increase in major agrochemical inputs before and after the onset of Colony Collapse Disorder in 2006 was the tripling of pesticide applications containing organosilicone adjuvants.[101] Researchers concluded that the use of these adjuvants in tank mixtures with fungicides may be associated with the recent USA honey bee declines. *Id.* By solely evaluating the active ingredients without the formulation ingredients and spray tank adjuvants, risk assessments relied on by EPA to register pesticides cannot fully address risk of pesticides to pollinators and other non-target species.[102]

C. Toxicity to Amphibians from Inerts/Adjuvants in Formulations of Glyphosate.

Frogs and other amphibians live and use water in or near farmlands, and as such are exposed to a wide range of the chemicals used in farming, including pesticides.[103] Amphibians are particularly susceptible to glyphosate, but the impact varies depending on the formulation containing glyphosate. In some cases, synergistic impacts from the adjuvants and active

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Agricultural Spray Adjuvants, 7 PLoS ONE 1 (July 16 2012), http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0040848.

[97] Ciarlo, *et al.* (2012), *supra*, n. 96 at 6.

[98] Mullin, *et al.* (2015), *supra*, n. 1 at 3-7.

[99] Fine, *et al.*, *supra*, n. 93 at 1 (Finding that synergistic mortality occurred during larval-pupal molt, demonstrating that organosilicone adjuvants, although considered inert, instead can lead to brood mortality especially in combination with other stressors).

[100] Mullin, *et al.* (2016), *supra*, n. 1 at 5.

[101] *Id.* at 3-4.

[102] *Id.* at 5-6.

[103] Reinier M. Mann, et al., *Amphibians and agricultural chemicals: review of the risks in a complex environment*, 157 Envtl. Pollution 2903-27 (2009).

ingredient are the factor that increases toxicity to amphibians; in other cases the increased toxicity may be attributable to the adjuvants alone.[104] In either case, the formulation is crucial.

Both glyphosate and formulation "inerts" find their ways into water, even if they are not approved for direct spraying over water.[105] Relyea has conducted many studies on formulations of Roundup, containing glyphosate and various adjuvants (POEA in older formulations, and other trade-secret adjuvants in newer formulations), and found that these formulations are highly toxic to amphibians. *Id.* Recent studies have confirmed that the addition of "inerts" in formulations of glyphosate affect amphibians differently than the active ingredient alone, with serious implications for mitigation measures on labels, including buffer zones around water.[106]

D. Increased Toxicity to Pollinators from Synergy Between Certain Neonicotinoids and Fungicides

Neonicotinoids and fungicides are commonly mixed before being applied, in commercial and farmer tank mixtures, leading to pollinator exposure of these two classes of active ingredient simultaneously.[107] Studies in the last few years have demonstrated the potential for synergistic effects to pollinators from this common combination of neonicotinoid insecticides and fungicides.[108] Because the toxicity to neonicotinoids may be increased synergistically by the presence of fungicide active ingredients, information on the interaction of these active ingredients must be collected to determine the safety of a given active ingredient (or product containing that active ingredient).[109]

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[104] Cox & Surgan, *supra* note 44.

[105] Rick A. Relyea, *The Impact of Insecticides and Herbicides on the Biodiversity and Productivity of Aquatic Communities: Response,* 16 Ecological Applications 2027-2034 (2006); Rick A. Relyea. & Devin K. Jones, *The Toxicity of Roundup Original MAX® to 13 Species of Larval Amphibians, 28* Envtl. Toxicology and Chemistry 2004-2008 (2009); Rick A. Relyea, *Amphibians Are Not Ready for Roundup*, Emerging Topics in Ecotoxicology 267-300 (2011).

[106] Norman Wagner, Hendrik Müller & Bruno Viertel, *Effects of a commonly used glyphosate-based herbicide formulation on early developmental stages of two anuran species*, 24 Envtl. Sci. and Pollution Res. Int'l 1496-1508 (2016); Rafael Zanelli Rissoli, et al., *Effects of glyphosate and the glyphosate based herbicides Roundup Original® and Roundup Transorb® on respiratory morphophysiology of bullfrog tadpoles,* 156 Chemosphere 37-44 (2016).

[107] David J. Biddinger, et al., *Comparative Toxicities and Synergism of Apple Orchard Pesticides to Apis mellifera (L.) and Osmia cornifrons (Radoszkowski)*, 8 PLoS ONE 1-6 (2013), http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0072587.

[108] *Id.* at 3; *see also* Thomas James Wood & Dave Goulson, *The Environmental Risks of neonicotinoid pesticides: a review of the evidence post-2013*, *Envtl. Sci. Pollution Res.* 1-41 (2017), https://link.springer.com/content/pdf/10.1007%2Fs11356-017-9240-x.pdf (collecting and summarizing post-2013 studies on synergistic impacts to bees from combination of certain neonicotinoids and fungicides).

[109] Tjeerd Blacquie`re, et al., *Neonicotinoids in bees: a review on concentrations, side-effects and risk assessment*, 21 Ecotoxicology 973–992, 989 (2012) (citing Takao Iwasa, et al., Mechanism for the differential toxicity of neonicotinoid insecticides in the honey bee, *Apis*

As these case study examples show, formulations and tank mixtures have different and often more toxic effects to non-target wildlife, including essential pollinators and sensitive amphibians, due to the effect of their inert ingredients and the synergistic effects of different ingredients, both active and inert. By not requiring ecological toxicity testing with the whole pesticide formula and with known common tank mixtures, EPA's assessment of pesticide products is lacking the data necessary to determine the full range and impact of adverse effects to the environment.

III. FIFRA Requires Testing of Whole Formulations and Tank Mixtures. EPA Has the Authority to Mandate Such Data.

By its plain language, FIFRA requires that EPA consider the whole pesticide and whether it will have unreasonable adverse environmental impacts when used in accordance with widespread and commonly recognized practice.[110] Nothing in FIFRA limits "pesticide" to active ingredients only; to the contrary, the statute's requirement that EPA consider a pesticide's common use indicates that Congress intended EPA to look at the full formulation and any tank mixtures. Indeed, Congress's intent is unambiguous: it wanted EPA to approve a pesticide's registration when "it will perform its *intended* function without unreasonable adverse effects on the environment."[111] As described above, inerts and adjuvants in tank mixtures are intentionally added to increase the efficacy of pesticides, and synergistic effects of different pesticide ingredients are even patented. Fundamentally, pesticide formulations that act differently may have different effects on the environment (including humans). Thus, EPA must require enough testing data for every whole pesticide formulation and tank mixture to capture all synergistic effects and potential unreasonable effects on the environment.[112]

A. The Definition of Pesticide Supports Whole Formula and Tank Mixture Testing.

FIFRA's definition of "pesticide" is "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest," and plainly does not refer exclusively active ingredients.[113] Rather, the specific words "any substance or *mixture* of substances" indicates that whole formulations are the "pesticides" and not merely those ingredients deemed

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mellifera, 23 Crop Protection 371–378, 377 (2003) (finding that in laboratory studies, certain fungicides increased the toxicity of acetamiprid and thiacloprid by as much as 114-fold)).

[110] 7 U.S.C. § 136a(c)(5)(D).

[111] *Id.* (emphasis added).

[112] While EPA's regulations contain specific requirements for registering alternate formulations that put limits on the quantity of inerts, to the extent they have "toxicological significance," it is unclear how this significance will be shown when most pesticide testing ignores the particular mix of inerts in a given formulation, and many inerts (particularly those for non-food uses) have never been properly tested for toxicity. EPA should be more specific in requiring a separate registration for each new formulation. *See* 40 C.F.R. § 152.43.

[113] 7 U.S.C. § 136(u); *see also* 7 USC § 136(n) ("The term 'ingredient statement' means a statement which contains … the name and percentage of each active ingredient, and the total percentage of all inert ingredients, in the pesticide…").

"active." FIFRA defines "active ingredient" as "an ingredient which will prevent, destroy, repel, or mitigate any pest."[114] This is the main *ingredient* in a pesticide that the registrant intends to have the pest control effect, but it is only one ingredient. FIFRA also defines "inert" ingredients, but only as those ingredients that are "not active," which just mean they are not the intended pet control ingredients.[115] Accordingly, a "pesticide" is a mixture of the "active ingredients" as well as "inert ingredients" other than the active ingredient, and thus when FIFRA requires the testing and registration of a "pesticide" it means the whole formula. Indeed, FIFRA explicitly requires as part of registration the "complete formula of the pesticide."[116]

EPA's regulatory definition of "formulation" bears out this interpretation:

> Formulation means:
>
> (1) The process of mixing, blending, or dilution of one or more active ingredients with one or more other active or inert ingredients, without an intended chemical reaction, to obtain a manufacturing-use product or an end-use product, or
>
> (2) The repackaging of any registered product.[117]

EPA requires that information on the composition of a pesticide must be furnished for "each product," including active ingredients and inert ingredients.[118] Further, EPA's regulations refer to the "statement of formula" throughout, including all ingredients, not just active ingredients.[119] Finally, the definition of "pesticide" in the Federal Food, Drug, and Cosmetic Act (FFDCA),[120] which applies to pesticide regulation under EPA's own regulations,[121] "includes all active and inert ingredients."[122]

Thus, both statutory and regulatory definitions support the idea that "pesticide" is more than just active ingredients and therefore the whole pesticide formula is subject to FIFRA's requirements. EPA's treatment of pesticide safety review to generally exclude inert ingredients starkly contrasts with this straightforward definition of "pesticide."

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[114] 7 U.S.C. § 136(a)(1).
[115] *Id.* § 136(m).
[116] *Id.* § 136a(c)(1)(D).
[117] 40 C.F.R. § 158.300.
[118] *Id.* § 158.320.
[119] *Accord* 40 C.F.R. § 158.130(b)(1); 40 C.F.R. § 155.53(b)(2); *see also* Pesticide Registration Manual, Ch. 2, *supra* note 20 (defining confidential statement of formula as including active and inert ingredients).
[120] 21 U.S.C. § 301 *et seq.*
[121] 40 C.F.R. § 158.3 ("Applicable terms from the Federal Food, Drug, and Cosmetic Act also apply to this part.")
[122] 21 U.S.C. § 321(q)(1)(A).

B. FIFRA's Safety Standard Requires Testing of Whole Formulas and Tank Mixtures.

FIFRA's safety standard allows EPA to register a pesticide (again, the whole pesticide product) only when it will not have unreasonable adverse effects on the environment.[123] This standard specifically couches "effect on the environment" in the context of a pesticide's actual use, i.e. the whole pesticide formulation or tank mixture.[124] FIFRA requires EPA to consider both the "intended effect" of the pesticide and its "widespread and commonly recognized" use when determining whether a given pesticide meets the safety standard.[125] Further, in its regulations, EPA is required to take into account different environmental risk and appropriate data for evaluating this risk between agricultural, non-agricultural, and public health pesticides.[126] The appropriate data for evaluating agricultural and non-agricultural outdoor use pesticides in accordance with their widespread and common use necessarily must include testing on the whole formula that is actually used in the field, as well as any tank mixtures.

EPA's existing regulations setting registration approval standards also provide for EPA examining the whole formula rather just the active ingredient: "EPA will approve an application [] only if . . . [t]he Agency has determined that the *product* will perform its intended function without unreasonable adverse effects on the environment, and that, when used in accordance with widespread and commonly recognized practice, the *product* will not generally cause unreasonable adverse effects on the environment."[127] The regulations also define "pesticide product" as "a pesticide in the particular form (including composition, packaging, and labeling) in which the pesticide is intended to be, distributed or sold."[128]

FIFRA commands EPA to determine whether pesticides pose any unreasonable adverse effects on the environment, and both Congress and EPA unwaveringly identify pesticides as the whole formulations. Congress plainly intended that EPA evaluate the entire pesticide mixture as used in the field against FIFRA's safety standard.

IV. The FQPA Requires Whole Formulation and Tank Mixture Testing.

The FQPA amended both FIFRA and FFDCA to establish a health-based safety standard for pesticide residues on food products. [129] FQPA requires EPA to establish tolerance levels of pesticide residues to ensure a "reasonable certainty that no harm will result" from dietary or other aggregate exposures for which there is reliable information.[130] "In establishing a tolerance for a pesticide chemical residue, the EPA is required to consider all 'available information concerning the cumulative effects of such residues and other substances that have a common

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[123] 7 U.S.C. § 136a(c)(5).
[124] *Id.*
[125] *Id.*
[126] *Id.* § 136w(a)(1).
[127] 40 C.F.R. § 152.112(e) (emphasis added).
[128] *Id.* § 152.3.
[129] Pub. L. No. 104-170, 110 Stat. 1489 (1996).
[130] *Id.* §§ 103, 405.

mechanism of toxicity,' and 'available information concerning the aggregate exposure levels of consumers (and other major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances.'"[131] Under FIFRA, if a pesticide exceeds its allowable tolerance established under FQPA, there is an unreasonable adverse effect on the environment.[132] By failing to require or conduct testing of whole formulations and tank mixtures, EPA cannot effectively establish tolerance levels per FQPA because it fails to consider information on all potentially toxic substances and the actual residues on food.

V. EPA Has the Authority to Issue Regulations to Require Testing of Whole Pesticide Formulations and Tank Mixtures.

FIFRA commands that EPA "shall" publish guidelines for registration support information and shall revise them from time to time.[133] EPA can also require additional data to maintain existing registrations.[134] While FIFRA does not explicitly mandate specific ingredient testing or testing of whole formulations and tank mixtures, it does so implicitly (*see supra* section III.A-B, pp. 18-20), and it grants EPA broad discretion in determining data requirements for pesticide registration.[135] In line with FIFRA's safety standard, EPA has the authority to promulgate regulations to collect data on all pesticide ingredients, whole pesticide formulations, and tank mixtures as well as evaluate their impact on the environment.

Currently, EPA focuses its attention on active ingredients alone and collects safety data on active ingredients almost exclusively, ignoring other ingredients and potential synergistic effects. However, as explained above, EPA has acknowledged the potential toxicity of so-called inert ingredients. The more researchers look into the toxicity of inerts and the synergism between these inerts and active ingredients and between multiple active ingredients, the clearer it becomes that the current data requirements are not fully capturing the potential adverse impacts to the environment. EPA has the power and duty to remedy this problem, by requiring data for registration (and registration reviews) that examines the actual pesticide formulation and not merely the active ingredient or different formulations of the same active ingredient.

Notably, FIFRA does not protect inert ingredients, whole pesticide formulations, or tank mixtures from regulation or testing.[136] Even while the publication of all ingredients in whole formulations may, in some instances, be protected as trade secrets,[137] FIFRA authorizes EPA to

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[131] Michael W. Graf, *Regulating Pesticide Pollution in California Under the 1986 Safe Drinking Water and Toxic Exposure Act (Proposition 65)*, 28 Ecology L.Q. 663, 754 (2001) (citing 21 U.S.C. § 346a(b)(2)(D)(v-vi)).
[132] 7 U.S.C. § 136(bb); *see* 21 U.S.C. § 346a (FFDCA tolerance and exemption for pesticide chemical residues), 40 C.F.R. § 158.1410 (Residue chemical data requirement table), 40 C.F.R. § 158.1300 (Environmental fate data requirement table), 40 C.F.R. § 158.630 (Terrestrial and aquatic nontarget organisms data requirements table).
[133] 7 U.S.C. § 136a(c)(2)(A).
[134] *Id.* § 136a(c)(2)(B).
[135] *See id.* § 136a(c)(2).
[136] *See id.* § 136 et. al.
[137] *See* Cal. Gov. Code, § 6254.2; 7 U.S.C. § 136h(b).

reveal "information relating to formulas of products[,]" however, "when necessary to carry out the provisions of [FIFRA]."[138] Furthermore, even if EPA deems pesticide formulation identities protected from publication, it still has the authority to require testing with these whole formulations and tank mixtures for a full safety review in compliance with FIFRA's safety standard of no unreasonable adverse effects to the environment.

EPA can and must revise its regulations to require data and testing on whole formula and tank mixtures to support both future and existing registrations under FIFRA.

VI. EPA's Failure to Implement Regulations to Mandate Testing of Whole Formulations and Tank Mixtures Violates the Law.

Because FIFRA requires that whole pesticides and tank mixtures be assessed to determine whether they meet safety standards for registration, EPA is violating several laws by failing to require adequate testing and data and instead concentrating necessary studies on active ingredients alone.

A. EPA's Failure to Require Sufficient Data to Assess FIFRA Safety Standard is Arbitrary and Capricious in Violation of the APA.

EPA's actions and inactions, as a matter of law, are arbitrary and capricious under the Administrative Procedure Act.[139] EPA has severely harmed the Petitioners' interests in protecting the public and the environment. Requiring testing of whole formulations and tank mixtures is the required remedy.

Agency action may not be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law" and must meet statutory, procedural, and constitutional requirements.[140] By not requiring data on whole pesticide formulations, and tank mixtures to properly assess adverse effects on the environment, EPA acts arbitrarily and capriciously. By prioritizing active ingredients and often dismissing inert ingredients and synergistic effects of whole pesticide formulations and tank mixtures in its registration data regulations, EPA fails to consider an important aspect of pesticide safety review: pesticides are mixtures of active and inert ingredients. Especially considering EPA acknowledges the possible harms posed by inert ingredients,[141] the agency's failure to comprehensively require and collect safety data on whole pesticide formulations and tank mixtures is arbitrary and capricious. EPA cannot reasonably determine that a pesticide has no unreasonable adverse effects on the environment if it does not conduct testing on whole formulations and tank mixtures.

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[138] 7 U.S.C. § 136h(b).; *see also Northwest Coalition for Alternatives to Pesticides et al v. Browner*, 941 F. Supp. 197, 201 (D.D.C. 1996) (finding that plain language of FIFRA did not *per se* exempt inert ingredients from disclosure under FOIA).

[139] 5 U.S.C. § 706; *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971); *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

[140] 5 U.S.C. § 706(A-D).

[141] EPA, Office of Pesticide Programs, *supra* note 72 ; *Public Availability of Identities of Inert Ingredients in Pesticides*, *supra* note 8.

B. EPA's Failure to Require Testing of Whole Formulations and Tank Mixtures Violates the ESA.

EPA must comply with the ESA[142] when acting under FIFRA. "FIFRA does not exempt EPA from complying with ESA requirements when EPA registers pesticides. Indeed, a pesticide registration that runs against the clear mandates of the ESA will most likely cause an unreasonable adverse effect on the environment under FIFRA."[143]

EPA is violating the ESA by registering pesticides that may harm endangered species. Pursuant to the ESA, EPA has a duty to consult with the expert federal wildlife agencies to ensure that pesticide uses authorized by EPA will not likely jeopardize any threatened or endangered species and their critical habitats.[144] EPA regulations specify that upon determining that its actions "may affect" any listed species or any designated critical habitat, it must consult the designated expert wildlife agencies before acting.[145] Effects determinations include the "direct and indirect effects of an action on the species or critical habitat, together with the effects of other activities that are interrelated or interdependent with that action."[146] By not fully testing whole pesticide formulations and tank mixtures, EPA cannot properly determine whether a pesticide as used "may affect" endangered species or critical habitat or whether it should consult with expert federal agencies on a pesticide's impact on endangered species' survival.[147]

CONCLUSION

EPA's regulatory decisions and actions with respect to pesticide registration requirements are flawed because it has disregarded whole pesticide formulations and tank mixtures in most of its safety determinations. For the aforementioned reasons, Petitioners respectfully request that EPA revise its regulations setting data requirements for pesticide registration and review to comprehensively test whole pesticide formulations and tank mixtures for unreasonable adverse effects on the environment and to require ESA consultation on the effects of whole pesticide formulations and tank mixtures on threatened and endangered species.

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[142] 16 U.S.C. § 1531 *et seq.*
[143] *Defenders of Wildlife v. EPA*, 882 F.2d 1294, 1299 (8th Cir. 1989).
[144] 16 U.S.C. § 1536(a)(2) ("Each Federal agency shall, in consultation with and the assistance of the Secretary, insure that any action authorized, funded, or carried out by such agency . . . is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of habitat of such species which is determined . . . to be critical . . . .").
[145] 50 C.F.R. § 402.14(a).
[146] *Id.* § 402.02.
[147] *See generally* NRC, *supra*, note 30, at 13-14, 65-70, 112-116, 118-128.

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