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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CENTER FOR BIOLOGICAL DIVERSITY, CENTER FOR FOOD SAFETY and DEFENDERS OF WILDLIFE, Plaintiffs, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, Defendant.	Case No.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. Pesticides are toxic substances designed and manufactured to kill pest organisms. Because there is rarely, if ever, absolute separation of the targeted pests and other wildlife, pesticide use can have devastating impacts on non-target wildlife; causing death or injury, adversely affecting food supplies and habitat, and impairing growth, immunity to disease, or

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reproduction. Based on the Environmental Protection Agency's ("EPA") own findings, the new pesticide cyantraniliprole ("CTP") may have one or more of these impacts on up to 1,377 federally-protected, threatened and endangered ("listed") species. Despite its findings, EPA did not consult with the expert biologists at the U.S. Fish and Wildlife Service or the National Marine Fisheries Service (collectively, "the Services") as required by the Endangered Species Act ("ESA") before it authorized the widespread use of this novel chemical. Plaintiffs Center for Biological Diversity, Center for Food Safety, and Defenders of Wildlife seek to ensure that use of CTP will not jeopardize the continued existence of listed species, adversely affect their critical habitat, or otherwise cause harm to listed species that could be avoided or reduced with appropriate mitigation. EPA's failure to consult with the Services on its authorization of CTP allows this pesticide to harm listed species and injures the Plaintiffs' aesthetic, recreational, and scientific interests in conserving these species.

2. The Plaintiffs seek a judgment declaring that EPA's failure to consult on its registration of authorization of uses of CTP under it CTP Registration Decision, *see infra* at ¶ 39, violates section 7(a)(2) of the ESA and an order requiring EPA to consult with the Services by a date certain. The Plaintiffs further seek an order vacating, setting aside, and enjoining EPA's authorization of CTP uses that do not include the protections necessary to avoid harm to listed species until such time as consultation is complete and EPA has put in place measures that ensure against likely jeopardy or adverse modification of critical habitat.

PARTIES

3. The Center for Biological Diversity ("Center") is a non-profit, public interest corporation with approximately 775,000 members and online activists, and offices in Washington, D.C.; San Francisco, California and elsewhere in the United States. The Center and its members are dedicated to protecting diverse native species and habitats through science,

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policy, education, and environmental law. Recognizing that pesticides are one of the main threats to the earth's environment, biodiversity, and public health, the Center works to prevent and reduce the use of harmful pesticides and to promote sound conservation strategies. The inadequately mitigated use of CTP harms listed species and impairs the interests of the Center and its members and supporters.

4. The Center for Food Safety ("CFS") is a nonprofit, public interest organization with over 450,000 members and offices in Washington, D.C.; San Francisco, California; and Portland, Oregon. CFS and its members are dedicated to protecting public health and the environment by curbing the use of harmful food production technologies and instead promoting sustainable alternatives. CFS's pesticides campaign is a multi-faceted approach utilizing legal, scientific, and policy mechanisms to protect our environment and food. The inadequately mitigated use of CTP harms listed species and impairs the interests of CFS and its members and supporters.

5. Defenders of Wildlife ("Defenders") is a non-profit corporation headquartered in Washington, D.C. with offices throughout the United States. Defenders has nearly one million total members and supporters throughout the United States. Defenders is dedicated to the protection of native wild animals and plants in their natural communities and advocates for new approaches to wildlife conservation that will help keep species from becoming endangered. Defenders' programs encourage protection of entire ecosystems and species that serve as indicators of ecosystem health. Defenders works to protect imperiled wildlife from all threats to their survival and recovery, including the use of harmful pesticides. The inadequately mitigated use of CTP harms listed species and impairs the interests of Defenders and its members and supporters.

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6. Members of the plaintiff organizations use and enjoy many of the species and habitats that will be affected by the authorized uses of CTP across the country. EPA concluded that CTP may affect the species identified in Appendix I of EPA's "Environmental Fate and Ecological Risk Assessment for the Registration of the New Chemical Cyantraniliprole" (Apr. 30, 2013)[1], as well as their designated critical habitat. Plaintiffs' members engage in wildlife observation, recreation, research, photography, restoration activities, and scientific and educational programs involving listed species and their habitats that may be impacted by CTP. For example, EPA concluded that CTP may affect the Fender's blue butterfly and its critical habitat in Oregon; the San Bruno elfin butterfly and its proposed critical habitat in California; the Pearlymussel (pink mucket) and its habitat in Arkansas, Kentucky, Louisiana, and Missouri; the San Joaquin Kit Fox and its habitat in California; and more than twenty ESA-listed salmon and steelhead species and their critical habitat throughout Washington, Oregon, and California. Members of the plaintiff organizations have cognizable interests in these and other species affected by CTP based on, among other things, their visits to habitats where the species can be found and their observation of, or participation in, activities that depend on the species. For example, Plaintiffs' members derive recreational, scientific, aesthetic, and cultural benefits from the ESA-listed salmon and steelhead species and their habitats that EPA concluded will be directly and indirectly affected by CTP use in the Pacific Northwest and California through fishing, boating, photography, and recreation in and around the rivers, streams, and estuarine/marine habitats of these fish. Plaintiffs' members plan to continue their activities in the

[1] That document is available at: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0668-0008 (last visited May 22, 2014).

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future, but their use and enjoyment of these species and their habitats is harmed by the registration of CTP without necessary protections for ESA-listed species.

7. EPA's failure to consult with the Services over the impacts of CTP results in inadequate mitigation of harm to listed species and their designated critical habitats – including, but not limited to, the examples listed above – that benefit Plaintiffs' members. This harms the members' past, present, and future enjoyment of these species and their habitats. The injuries to the above-described interests of Plaintiffs and their members are actual, concrete injuries that are presently suffered by Plaintiffs and are directly caused by EPA's failure to consult with the Services. Consultation would ensure that EPA's registration of CTP does not affect listed species and Plaintiffs' members' cognizable interests in these species. If the Court orders EPA to engage in consultation as required, the Services would analyze the extent to which CTP affects listed species and their habitats and would develop reasonable and prudent alternatives or other mitigation measures necessary to protect the species and otherwise minimize harm. This would protect Plaintiffs' members' interests in the species and redress Plaintiffs' injuries. Plaintiffs have no other adequate remedy at law.

8. Defendant EPA is the federal agency with authority to register, regulate, and authorize pesticide use under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y. EPA's headquarters, where many of the decisions and omissions giving rise to this case were made, is located in Washington, D.C. Under the ESA, EPA is responsible, in consultation with the Service, for ensuring that its authorization of pesticide uses do not jeopardize the survival and recovery of listed species or adversely affect their critical habitat. *See* 16 U.S.C. § 1536(a)(2).

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JURISDICTION

9. The Court has jurisdiction pursuant to 28 U.S.C. § 1331 and 16 U.S.C. § 1540(g)(1)(A). Venue is proper under 28 U.S.C. § 1391(e) because Plaintiffs reside in the District of Columbia, Defendant resides in this district, and because a substantial part of the events or omissions giving rise to the claims occurred in this district.

10. The Court has jurisdiction to review EPA's failure to consult with the Services under the citizen-suit provision of the ESA, 16 U.S.C. § 1540 (g)(1), which provides that the "district courts shall have jurisdiction…to enforce any such provision or regulation" of the ESA. As required by the ESA, the Plaintiffs provided sixty days' notice of their intent to sue by letter sent to EPA and the Services on March 21, 2014. A copy of that letter is appended as Exhibit 1. EPA has not remedied the violations set out in that sixty-day notice. *See* 16 U.S.C. § 1540(g)(2)(A). In the alternative, jurisdiction is proper under FIFRA, 7 U.S.C. § 136n(a).

BACKGROUND

I. STATUTORY FRAMEWORK

A. The Federal Insecticide, Fungicide, and Rodenticide Act

11. FIFRA prohibits the use of a pesticide in the United States unless EPA has registered that particular use. 7 U.S.C. § 136a(a). EPA may only register a pesticide if it determines that "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." *Id.* § 136a(c)(5); *see also id.* § 136a-1(a)(2). FIFRA defines "unreasonable adverse effects on the environment" to mean "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 . . . ." *Id.* § 136(bb).

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12. After determining that a pesticide-active ingredient is eligible for registration, EPA registers the individual end-use products that contain those pesticide-active ingredients. *See* 40 C.F.R. § 152 (product registration requirements); *id.* § 156 (labeling requirements). In the product registration process, EPA collects and evaluates additional information regarding the effects of individual pesticide products and may register that product only after finding, among other things, that it complies with the FFDCA and FIFRA, including the requirement that the product does not cause "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5). As with registration of pesticide active ingredients, EPA has the authority to subsequently "cancel, deny, or reclassify registration of a pesticide product because uses of that product may cause unreasonable adverse effects on the environment . . . .." 40 C.F.R. § 154.1(a).

B. The Endangered Species Act

13. When a species is listed as threatened or endangered under the ESA, section 7(a)(2) of the Act requires that all federal agencies "insure" that their actions "are not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of" their critical habitat. 16 U.S.C. § 1536(a)(2). The "institutionalized caution" embodied in the ESA requires federal agencies to give the benefit of the doubt to listed species and places the burden of risk and uncertainty on the proposed action. *See Sierra Club v. Marsh*, 816 F.2d 1376, 1386 (9th Cir. 1987); *Tennessee Valley Auth. v. Hill*, 437 U.S. 153, 180 (1978).

14. The Act establishes an interagency consultation process to assist federal agencies in complying with their substantive section 7(a)(2) duty to guard against jeopardy to listed species or destruction or adverse modification of critical habitat. Under section 7(a)(2), federal agencies must consult with the appropriate expert fish and wildlife agency to determine whether their actions will jeopardize any listed species' survival or adversely modify designated critical

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habitat and, if so, to identify ways to modify the action to avoid that result. *See* 50 C.F.R. § 402.14. The National Marine Fisheries Service ("NMFS") is the expert fish and wildlife agency with respect to anadromous and marine species and the U.S. Fish and Wildlife Service ("FWS") is the expert agency with respect to terrestrial and freshwater species.

15. The Services have adopted joint regulations governing the section 7(a)(2) consultation process. Under the joint regulations, a federal agency must initiate a section 7(a)(2) consultation with NMFS or FWS whenever it undertakes an "action" that "may affect" a listed species or critical habitat. 50 C.F.R. § 402.14(a). The threshold for a "may affect" determination and the required ESA section 7(a)(2) consultation is low. *See* 51 Fed. Reg. 19926, 19949 (June 3, 1986) ("Any possible effect, whether beneficial, benign, adverse or of an undetermined character, triggers the formal consultation requirement."). *See also* Endangered Species Act section 7 Consultation Handbook at 3-13, 4-26. An agency is relieved of the obligation to consult only if the action will have "no effect" on listed species or designated critical habitat.

16. The joint regulations broadly define the scope of agency actions subject to ESA section 7(a)(2) mandates to encompass "all activities or programs of any kind authorized, funded, or carried out, in whole or in part, by [f]ederal agencies," including the promulgation of regulations and the granting of licenses. *See* 50 C.F.R. § 402.02 (definition of "action").

17. If an agency determines that its action "may affect" but is "not likely to adversely affect" a listed species or its critical habitat, ESA regulations permit "informal consultation," in which there is no requirement for a biological opinion so long as NMFS or FWS concurs in writing with the "not likely to adversely affect" determination. 50 C.F.R. § 402.13. If the Service(s) do not concur in the "not likely to adversely affect" determination or if the action

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agency determines that the action is "likely to adversely affect" the listed species, the agencies must engage in "formal consultation." 50 C.F.R. §§ 402.02, 402.14(a).

18. Formal consultation "is a process between the Service and the [f]ederal agency that commences with the [f]ederal agency's written request for consultation under section 7(a)(2) of the Act and concludes with the Service's issuance of the biological opinion under section 7(b)(3) of the Act." 50 C.F.R. § 402.02.

19. In a biological opinion, the Service must determine whether the federal action subject to the consultation will jeopardize the survival and recovery of listed species or will destroy or adversely modify critical habitat. 16 U.S.C. § 1536(b)(4). If the Service determines that the action will jeopardize the species or destroy or adversely modify its critical habitat, the biological opinion must specify any reasonable and prudent alternative ("RPA") the action agency could take to avoid jeopardy or specify that there is no RPA. 16 U.S.C. § 1536(b)(4)(A); 50 C.F.R. § 402.14(h)(3). The Service and the action agencies must use the best available science in consultations, biological opinions, and jeopardy and adverse modification determinations. 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.14(g)(8).

20. Compliance with the procedural provisions of the ESA—identifying the likely effects of the action through the consultation process—is integral to compliance with the substantive requirements of the Act. Under the statutory framework, federal actions that "may affect" a listed species or critical habitat may not proceed unless and until the federal agency ensures, through completion of the consultation process, that the action is not likely to cause jeopardy or adverse modification of critical habitat. 16 U.S.C. § 1536(a); 50 C.F.R. §§ 402.14, 402.13; *see also* 16 U.S.C. § 1536(d).

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21. Even after the procedural requirements of a consultation are complete, the ultimate duty to ensure that an action will not likely jeopardize a listed species or adversely modify its critical habitat lies with the action agency. If the Services find that a proposed action avoids jeopardy and adverse modification of critical habitat, this substantive duty is fulfilled by implementing that action in accordance with any conditions or requirements established during the consultation process, including any measures necessary to minimize take. If the Services develop an RPA necessary to avoid jeopardy and/or adverse modification of critical habitat, the action agency can most easily fulfill its substantive duty by implementing the RPA and any other measures developed during the consultation process. However, an action agency is technically free to choose another alternative course of action if it can independently ensure that the alternative will avoid jeopardy and adverse modification.

C. The National Academy of Sciences Report and the Agencies' Interim Approaches Guidance.

22. EPA and the Services have historically used different information and methods to assess the impacts of pesticides on listed species. To resolve their longstanding differences, the agencies formally requested help from the National Academy of Sciences. A committee of the National Research Council of the National Academy of Sciences conducted a multi-year study, and on April 30, 2013 issued a final report recommending the best available scientific approaches and data to be used in ESA consultations on pesticide uses. *See Assessing Risks to Endangered and Threatened Species from Pesticides* ("NAS Report") *available at* http://www.nap.edu/openbook.php?record_id=18344&page=1 (last visited May 22, 2014).

23. EPA's pesticide registration process is typically a narrower assessment of a pesticide's risks to species than the contextual inquiry and precautionary approach required by the ESA. To assess a pesticide's effects, EPA generally conducts an ecological risk assessment

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that focuses on the toxicology of the active ingredient at issue and the registration of that chemical alone. EPA's single-chemical risk assessment process is driven by laboratory tests and models of exposure. This general analysis typically is not species or place-specific and therefore does not encompass consideration of a listed species' current status or cumulative effects of other stressors affecting the species in their habitat. Nor does it thoroughly consider a variety of indirect or sublethal impacts to endpoints such as growth, reproduction, migration, impacts to prey species, or susceptibility to disease.

24. By contrast, the section 7 consultation process under the ESA requires a much more comprehensive look at the status of each potentially impacted species and the baseline conditions of their habitat, and requires the Services to ask whether a pesticide's effects, when added to existing and likely future impacts to the species in their real-world habitat, are likely to jeopardize species "in the wild" or adversely modify their critical habitat. 50 C.F.R. §§ 402.02; 402.14. This necessarily entails consideration of a much broader array of effects and exposures that occur in the ecosystems where these species are found rather than the single-chemical, dose-response approach used by EPA. For example, while single-chemical tests may provide information on the toxicity of that chemical, diverse land use and cropping patterns often means that more than one pesticide will affect a single watershed or landscape. The Services' ESA analyses must therefore consider the additive or synergistic effects of a species' exposure to multiple pesticides. These types of landscape or watershed-level effects are not considered in EPA's ecological risk assessment process.

25. Because EPA's risk assessment process typically considers a narrower range of impacts than the Services' consultation process under the ESA, in many instances EPA's risk assessments fail to capture the full range and magnitude of effects a pesticide may have on listed

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species. *See Wash. Toxics Coal. v. Dep't of Interior*, 457 F. Supp. 2d, 1158, 1184 (W.D. Wash. 2006) ("EPA's risk assessment process is not only less protective than Service determinations, there is overwhelming evidence on the record that ... EPA risk assessments … would actually result in harm to listed species.").

26. The NAS Report addressed many of these differences, and largely validates the general approaches, data, modeling, and underlying science so far relied on by NMFS in preparing biological opinions as well as the general principles that FWS has articulated for completing consultations. The NAS Report confirms that the general underlying methodologies and data the Services rely on are relevant, appropriate, and valid, and that the Services' more comprehensive approach to assessing the effects of a pesticide within an ecosystem is necessary. For example, the NAS Report stresses that factors such as sublethal effects, cumulative and indirect effects, and the effects of mixtures all should be included in pesticide consultations. *See* NAS Report at 49-50, 59, 71-73, 81-82, 96. The NAS Report also stresses that EPA's approach of relying on risk quotients to quantify risks to species from a particular pesticide is inappropriate and that risk quotients should not be used in pesticide consultations. *See id.* at 108. EPA's risk assessment process is not an adequate substitute for consultation.

27. On November 13, 2013, EPA, the Services, and the Department of Agriculture published their "Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report," *available at* http://www.epa.gov/espp/2013/interagency.pdf (hereinafter "Interim Approaches"). This guidance document outlined the agencies' evolving development of "shared scientific approaches that reflect the advice provided by NAS," as well their "joint interim

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scientific approaches for assessing the risks of pesticides to [listed] species based on the NAS recommendations." *Id.*

28. In the Interim Approaches, the agencies agreed to adopt the NAS recommendations regarding Step 1 of the ESA consultation process for pesticides. The NAS Report and the Interim Approaches define "Step 1" of the ESA consultation process as a "no effect/may effect determination." A "no effect" determination means no consultation is necessary, whereas a "may effect" determination requires further consultation (either formal or informal) with the Services. *See supra* at ¶ 15. Under the framework of the NAS Report and the Interim Approaches, "any species or critical habitat that overlaps with the action area will be considered a '[m]ay [a]ffect.'" Interim Approaches at 4. The action area is determined by examining "potential [pesticide] use sites combined with the range of off-site transport to identify the area of potential effects in and around the use sites." Interim Approaches at 4-5. In other words, the agencies agreed that if there is overlap between a species or its critical habitat and the places a pesticide might be used or might otherwise reach (through mechanisms such as drift or water transport), then consultation is required. *See id.*

II. EPA'S AUTHORIZATION OF CYANTRANILIPROLE

29. Cyantraniliprole is a novel broad-spectrum systemic insecticide, with a unique chemistry among the diamide pesticide class to which it belongs. Environmental Fate and Ecological Risk Assessment for the Registration of the New Chemical Cyantraniliprole – Amended (Apr. 30, 2013) ("EPA Risk Assessment") at 4.[2] Once applied, it is absorbed and systemically distributed throughout plants where organisms directly contact or ingest it. *Id*. at 9.

[2] The EPA Risk Assessment is available at: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0668-0008 (last visited May 22, 2014).

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It kills by causing unregulated activation of ryanodine receptors, which results in unregulated muscle contraction, paralysis, and death. *Id*. at 2. *See also id*. at 9 (insects "exposed to cyantraniliprole first exhibit lethargy, followed by muscle paralysis, and then death").

30. CTP degrades in soil and water at different rates, depending on pH (faster degradation at higher alkalinity), water (degrades faster with higher moisture), exposure to light (more light results in faster degradation), and aerobic condition (less oxygen results in faster degradation). *Id.* at 22. EPA estimated the half-life of CTP in various soil types to range from 4 to 1,638 days. *Id*. at 23 (Table 7). Moreover, CTP degrades into at least ten residues of concern. *Id.* at 25. EPA calculated the combined half-lives of CTP and its residues of concern to use in its exposure models. Those half-life values range from 88 to 1327 days. *Id.*

31. While CTP is a new pesticide, EPA expects that "use will be widespread" because it is approved for use on a wide variety of agricultural crops as well for non-agricultural use on golf courses, lawns, ornamental plants, fly bait, and public health pests. *Id*. at 9. It can be applied through a variety of methods including aerial and ground spray, drip chemigation, soil drench, seed treatment, and in bait. *Id*. at 4; *see also* "Registration of the New Active Ingredient Cyantraniliprole" (Jan. 24, 2014) ("Registration Decision") at 2.[3]

32. On February 29, 2012, EPA announced that it had received applications from the E.I. DuPont de Nemours and Company and Syngenta Crop Protection to register several products containing the new active ingredient CTP. 77 Fed. Reg. 12295-98 (Feb. 29, 2012). On June 6, 2013, EPA posted a proposed decision document and asked for public comment within thirty days on its proposal "to register the new active ingredient, cyantraniliprole, an insecticide

[3] The Registration Decision is available at: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0668-0057 (last visited May 22, 2014).

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formulated as a technical product and fourteen end use products."[4] EPA later extended the comment period through July 14, 2013.

33. EPA completed its ecological risk assessment for CTP on April 30, 2013. The purpose of the risk assessment is to evaluate the risks posed by the new chemical to determine whether it will cause unreasonable adverse effects on the environment, including impacts to listed species. EPA's assessment included information on both acute (immediate) and chronic (long-term) impacts of CTP to whole taxa rather than to particular species within each taxon. *See EPA Risk Assessment* at 143 ("screening-level" process employed in the risk assessment "uses the generic taxonomic group-based process to make inferences on direct effect concerns for listed species.").

34. Based on data showing the concentrations or amounts of CTP that cause direct effects, EPA classified the chemical as "slightly to moderately toxic to freshwater fish; slightly toxic to estuarine/marine fish; slightly to very highly toxic to freshwater invertebrates; moderately to highly toxic to estuarine/marine invertebrates, highly toxic to benthic invertebrates; highly to very highly toxic to terrestrial insects" from acute exposures. EPA Risk Assessment at 5. Data on chronic effects showed impacts to the size of freshwater invertebrates and estuarine/marine fish. *Id.* EPA found that CTP was not acutely toxic to birds and mammals, but that mammals and their offspring showed some impacts to weight and effects to thyroid and liver from chronic exposures. *Id.* EPA noted a lack of data on chronic toxicity to estuarine/marine invertebrates. *Id*. Although the risk assessment did not consider these effects

[4] The proposed decision notice is available at: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0668-0028 (last visited May 22, 2014). EPA's request for comment is available at: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0668-0006 (last visited May 22, 2014)

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in detail, *see supra* ¶¶ 22-26 (explaining limitations in EPA's risk assessment process), EPA found potential indirect effects to all species that rely on aquatic and terrestrial invertebrates, estuarine/marine fish, mammals, or terrestrial monocots (a group of plants including grasses and grains), for prey or habitat. *See, e.g.*, EPA Risk Assessment at 124-125, 131.

35. While EPA lacked information for specific species within each taxa, it nevertheless performed a "risk quotient" analysis based on the proposed uses to evaluate the likelihood that one or more permitted CTP uses would overlap with listed species within each taxa and could expose species to concentrations that cause adverse impacts. EPA Risk Assessment at 87-151. Despite the shortcomings of EPA's analytical approach, the agency still concluded that "the proposed uses for cyantraniliprole have the potential for direct adverse effects to federally listed threatened/endangered . . . and non-listed mammals from chronic exposure, listed freshwater invertebrates from acute exposures, listed estuarine/marine invertebrates from acute exposures, listed terrestrial invertebrates from acute exposures, listed benthic invertebrates from acute exposures, and listed and non-listed benthic invertebrates from chronic exposures." *Id*. at 5-6. EPA concluded that "[d]irect effects to terrestrial monocots and estuarine/marine fish (chronic) cannot be excluded because of an absence of data." *Id. See also id*. at 143. EPA also concluded that the direct effects to these taxa would result in indirect effects to other listed species that depend on any of the directly affected species, primarily through effects on food or other elements of critical habitat. *Id.* at 147, 149 (Table 54), 150. Based on these indirect effects, EPA also found potential impacts to critical habitat for many of these taxa, though it lacked the ability to "make a definitive identification of species that are potentially affected indirectly or designated critical habitats that are potentially affected directly by the proposed uses of cyantraniliprole." *Id.* at 150.

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36. Several of the products proposed for registration contain CTP mixed with the insecticide thiamethoxam. Thiamethoxam is a neonicotinoid insecticide that acts on target pests by interfering with nicotinic acetylcholine receptors. EPA registered this chemical for use on a variety of crops in 2000. *See* "Preliminary Problem Formulation for the Environmental Fate, Ecological Risk, Endangered Species, and Drinking Water Exposure Assessments for Thiamethoxam" (Dec. 13, 2011) at 3-4.[5] Although EPA had initially identified potential risks to "aquatic invertebrates, birds, mammals, terrestrial invertebrates, and terrestrial plants (in the absence of data)" from thiamethoxam, it has never completed a consultation on the impacts of this chemical on listed species. *Id.* While EPA did not adequately evaluate the full combined harmful impacts of these two chemicals in the CTP risk assessment, it still found that end-use products containing both of these chemicals posed a far greater risk to many species than use of CTP alone. *See* EPA Risk Assessment at 147. EPA did not, however, conduct any additional species-specific analysis for this mixture, nor did EPA include additional restrictions on uses of this mixture to address these greater risks.

37. Based on the available evidence showing direct and/or indirect effects to listed species in nearly all taxa, EPA found that spray buffers would be necessary to reduce exposure below its identified Levels of Concern for many taxa.[6] For terrestrial insects, EPA found that buffers of 797 to 1,000 feet would be required for products that contained only CTP. *Id.* at 147. For products where CTP is mixed with thiamethoxam, buffers "in excess of 1000 ft. for all uses"

[5] This document is available at: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0581-0003.

[6] EPA's Level of Concern ("LOC") criteria are levels used to indicate when an authorized pesticide use may cause adverse effects to non-target organisms. The Services have in the past expressed concern "that the relatively generic LOCs employed in many cases were inaccurate and could result in" underestimating the impacts to listed species. *Wash. Toxics Coal. v. Dep't. of Interior,* 457 F.Supp.2d 1158, 1186 (W.D. Wash. 2006).

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were necessary. *Id.* Freshwater invertebrates would require buffers of 0 to 197 feet for products that contain only CTP and from 0 to over 1,000 feet for products where CTP is mixed with thiamethoxam. *Id.*

38. While EPA admitted that it lacked the ability to make determinations about the specific species and habitats affected by CTP, it "identified a total of 1377 listed species that overlap at the county-level with areas where cyantraniliprole is proposed to be used …. This preliminary analysis indicates that there is a potential for cyantraniliprole use to overlap with listed species and that a more refined assessment is warranted." *Id.* at 151. *See also id.* at 150 (noting that "the next step for EPA and the Services is to identify which listed species and their designated critical habitat(s), if applicable, are potentially implicated.").Based on these risks, several entities, including some of the Plaintiffs here, urged EPA to consult with the Services before authorizing uses of cyantraniliprole. *See, e.g.*, Comments from Center for Food Safety (July 13, 2013); Comments of Center for Biological Diversity (July 14, 2013).[7]

39. On January 24, 2014, EPA registered cyantraniliprole (EPA Registration #352-856) and fourteen end use products, including product mixtures containing thiamethoxam, and associated labels in a single Registration Decision.[8] A list of the specific product labels EPA approved and the uses authorized by these labels is included as Attachment 1 to EPA's

[7] Those comments are available at: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0668-0047 and http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0668-0041.

[8] The 14 end-use product registrations (by registration number and product name) include: #352-857, DuPont Benevia Insect Control; #352-858, DuPont Lumiderm Insecticide Seed Treatment; #352-859, DuPont Exirel Insect Control; #352-860, DuPont Verimark Insect Control; #352-862 HGW86 Fly Control Bait; #352-863, HGW86 GH & N Insect Control; #352-865, HGW86 T & O Insect Control; #352-868, HGW86 SC Insect Control; #100-1418, Fortenza Red Insecticide [seed treatment]; #100-1420, Fortenza Insecticide [seed treatment]; #100-1421, Minecto Duo Insecticide; #100-1422 A16901B Ornamental Insecticide; #100-1423 A16901B, Residential Insecticide; #100-1424, Spinner Insecticide.

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Registration Decision. EPA's registration of the active ingredient CTP, its registration of fourteen end use products including product mixtures containing thiamethoxam, and its approval of the associated labels are each distinct final agency actions, but because EPA combined them in a single decision, they are hereinafter collectively referred to as the "CTP Registration" or "CTP Registration Decision."

40. Despite specific comments urging EPA to consult and EPA's conclusions in the Risk Assessment that additional analyses and cooperation with the Services were necessary, EPA finalized its CTP Registration Decision without consulting with NMFS or FWS as required by Section 7 of the ESA. EPA did not follow the Interim Approaches agreed to by the agencies following the NAS study, *see supra* ¶¶ 27-28, nor has EPA consulted by any other process.

41. The CTP Registration Decision did not include any additional analysis of the risk posed to listed species, nor the buffers identified in the risk assessment or other label restrictions requested by several water quality management agencies. *See, e.g.*, Comments of the California Stormwater Quality Association (July 6, 2013); Comments of the San Francisco Bay Regional Water Quality Control Board (July 8, 2013) (explaining that buffers alone are not effective in preventing aquatic exposures through runoff in urban or developed areas).[9] Instead, EPA's label restrictions require only twenty-five-foot buffers for ground applications and fifty-foot buffers for aerial applications for all products, including those where CTP is mixed with thiamethoxam.

42. In its response to public comments, EPA did not dispute that consultation on CTP is required, but asserted that it did not consult on its CTP Registration because "the Agency is focusing most of its resources for assessing impacts to listed species on the Agency's registration

[9] Those comments are available at: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0668-0035 and http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0668-0034.

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review program for currently registered pesticides." *See* "Response to Public Comments on EPA's Proposed Registration of the New Active Ingredient Cyantraniliprole" at 40-41.[10]

43. EPA's CTP Registration Decision is agency action that "may affect" listed species. EPA's failure to consult with the Services before it finalized its CTP Registration Decision violates EPA's mandatory duty under section 7(a)(2) of the ESA, 16 U.S.C. § 1536(a)(2).

CLAIM FOR RELIEF

EPA HAS FAILED TO CONSULT REGARDING ITS AUTHORIZATION OF CYANTRANILIPROLE; AN ACTION THAT "MAY AFFECT" LISTED SPECIES AND ADVERSELY MODIFY CRITICAL HABITAT

44. Paragraphs 1 through 43 are hereby realleged as though set out in full.

45. Section 7(a)(2) of the ESA prohibits agency actions that jeopardize the survival of listed species or that destroy or adversely modify their critical habitat. 16 U.S.C. § 1536(a)(2). To assist in complying with this duty, federal agencies, like EPA, must consult with NMFS and FWS whenever they take an action that "may affect" a listed species or the species' critical habitat. 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.14(a).

46. The ESA and its implementing regulations broadly define agency action. 50 C.F.R. §§ 402.02, 402.03. FIFRA prohibits use of a pesticide in the United States unless EPA has registered that specific use after determining that it "will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5). EPA's CTP Registration Decision under FIFRA constitutes "agency action" under ESA section 7(a)(2). 50 C.F.R. §§ 402.02, 402.03.

[10] EPA's Response to Comments is available at: *available at* http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0668-0058.

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47. Under the ESA, agency actions that "may affect" a listed species or critical habitat may not proceed unless and until the federal agency first ensures, through completion of the consultation process, that the action is not likely to cause jeopardy or adverse modification of critical habitat. 16 U.S.C. § 1536(a), (d); 50 C.F.R. §§ 402.14, 402.13.

48. Uses of CTP in accordance with EPA's CTP Registration Decision "may affect" listed species and their critical habitat by, inter alia, causing lethal, sublethal, and indirect harm to listed species and their prey, and by harming and altering their habitat. EPA itself determined that CTP poses risks to a broad range of fish, invertebrates, and mammals from acute and chronic exposures. These findings satisfy the low threshold that the ESA, its implementing regulations, and the agencies' joint Interim Approaches set for a "may affect" determination.

49. EPA has violated the ESA by finalizing its CTP Registration Decision without first completing consultation with NMFS and FWS regarding this pesticide that "may affect" listed species and/or their critical habitat. EPA's failure to consult with the Services for an action that "may affect" listed species violates the ESA, 16 U.S.C. § 1536(a)(2), its implementing regulations, and the Administrative Procedure Act, 5 U.S.C. §§ 701-706.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiffs pray that the Court:

A. Declare that EPA is in violation of section 7(a)(2) of the ESA, 16 U.S.C. § 1536(a)(2), by failing to complete consultation necessary to ensure that its CTP Registration Decision is not likely to jeopardize the continued existence of listed species or destroy or adversely modify their critical habitat;

B. Enjoin, vacate, and set aside EPA's authorization of any use of CTP that does not include protections necessary to avoid harm to listed species, until such time as EPA has put in

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place adequate permanent measures that ensure against jeopardy to listed species or adverse modification of their critical habitat;

C. Award Plaintiffs their attorneys' fees and costs in this action pursuant to 16 U.S.C. § 1540(g)(4) and 28 U.S.C. § 2412; and

D. Grant such other and further relief as Plaintiffs may request and as the Court deems just and proper.

Respectfully submitted this 3rd day of June, 2014.

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EXHIBIT 1

CENTER for BIOLOGICAL DIVERSITY

March 21, 2014

Sent via Email and Certified Mail Return Receipt Requested

Gina McCarthy, Administrator
United States Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue NW
Mail Code: 1101A
Washington, DC 20460
Mccarthy.gina@epa.gov

Re: Notice of Violations of the Endangered Species Act Regarding Registration of Cyantraniliprole

On behalf of the Center for Biological Diversity, Center for Food Safety and Defenders of Wildlife, we hereby provide notice, pursuant to section 11(g) of the Endangered Species Act ("ESA"), 16 U.S.C. §1540(g)(2)(A)(i), that the United States Environmental Protection Agency ("EPA") is in violation of the ESA.

The Center for Biological Diversity ("Center") is a non-profit, public interest corporation with approximately 50,000 members and offices in Washingtin, D.C. and elsewhere in the United States. The Center and its members are dedicated to protecting diverse native species and habitats through science, policy, education, and environmental law. Recognizing that pesticides are one of the foremost threats to the earth's environment, biodiversity, and public health, the Center works to prevent and reduce the use of harmful pesticides and to promote sound conservation strategies.

The Center for Food Safety ("CFS") is a nonprofit, public interest organization with over 450,000 members and offices in Washington, DC, San Francisco, California, and Portland, Oregon. CFS and its members are dedicated to protecting public health and the environment by curbing the use of harmful food production technologies and instead promoting sustainable alternatives. CFS's pesticides campaign is a multi-faceted approach utilizing legal, scientific, and policy mechanisms to protect our environment and food.

Defenders of Wildlife is a nonprofit environmental organization with nearly one million total members and supporters. Defenders is dedicated to the protection of native wild animals and plants in their natural communities and advocates for new approaches to wildlife conservation that will help keep species from becoming endangered. Defenders' programs encourage protection of entire ecosystems and species that serve as indicators of ecosystem health. Defenders works to protect imperiled wildlife from all threats to their survival and recovery, including the use of harmful pesticides.

EPA has violated the ESA's Section 7 consultation requirement regarding its discretionary decision to register the new active ingredient cyantraniliprole, as well as approve 14 end-use product/labels containing cyantraniliprole and even more-toxic cyantraniliprole-thiamethoxam product mixtures. EPA's failure to consult with the U.S. Fish and Wildlife Service ("FWS") and National Marine Fisheries Service ("NMFS") (collectively "the Services") is particularly egregious given that EPA's own risk assessment identified 1,377 listed species that may overlap with the potential use areas of cyantraniliprole,[1] and because EPA found cyantraniliprole is toxic to several taxonomic groups.[2]

In addition to its failure to consult, EPA's registration of cyantraniliprole, and its approval of labels for products containing cyantraniliprole, jeopardizes listed species and adversely modifies critical habitat. The EPA's ecological risk assessment for cyantraniliprole indicates that substantial habitat buffers may be required to protect listed species and their critical habitat from adverse effects. Yet EPA unilaterally approved labels that contain inadequate buffers and otherwise lack restrictions needed to prevent harm to listed species, which will lead to adverse effects on listed species and their critical habitat thereby violating the agency's ESA duty to prevent jeopardy and adverse modification of critical habitat.

Finally, EPA is in violation of Section 9 of the ESA for the "take" of listed species which is resultant from cyantraniliprole as well as the 14 end-use products containing cyantraniliprole and even more-toxic cyantraniliprole-thiamethoxam product mixtures.

LEGAL BACKGROUND

A. The Endangered Species Act

The ESA was enacted, in part, to provide a "means whereby the ecosystems upon which endangered species and threatened species depend may be conserved…[and] a program for the conservation of such endangered species and threatened species…."[3]

The ESA vests primary responsibility for administering and enforcing the statute with the Secretaries of Commerce and Interior. The Secretaries of Commerce and Interior have delegated this responsibility to the NMFS and the FWS respectively.[4]

Section 2(c) of the ESA establishes that it is "the policy of Congress that all Federal departments and agencies shall seek to conserve endangered species and threatened species and shall utilize their authorities in furtherance of the purposes of this Act."[5] The ESA defines "conservation" to mean "the use of all methods and procedures which are necessary to bring any endangered

1 EPA. 2013. ENVIRONMENTAL FATE AND ECOLOGICAL RISK ASSESSMENT FOR THE REGISTRATION OF THE NEW CHEMICAL CYANTRANILIPROLE – AMENDED at 151 (hereafter "CYANTRANILIPROLE RISK ASSESSMENT"). Office of Pesticide Programs Environmental Fate and Effects Division. Docket #: EPA-HQ-OPP-2011-0668-0008.
2 CYANTRANILIPROLE RISK ASSESSMENT at 5.
3 16 U.S.C. §§ 1531-1544; 16 U.S.C. § 1531(b)
4 50 C.F.R. § 402.01(b)
5 16 U.S.C. § 1531(c)(1)

species or threatened species to the point at which the measures provided pursuant to this Act are no longer necessary."[6] Similarly, Section 7(a)(1) of the ESA directs that the Secretary review "…other programs administered by him and utilize such programs in furtherance of the purposes of the Act."[7]

In order to fulfill the substantive purposes of the ESA, federal agencies are required to engage in consultation with FWS (and/or NMFS) to "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 adverse modification of habitat of such species . . . determined . . . to be critical . . . ."[8]

Section 7 consultation is required for "any action [that] may affect listed species or critical habitat."[9] Agency "action" is broadly defined in the ESA's implementing regulations to include "(b) the promulgation of regulations; (c) the granting of licenses, contracts, leases, easements, rights-of-way, permits, or grants-in-aid; or (d) actions directly or indirectly causing modifications to the land, water, or air."[10]

At the completion of consultation, FWS or NMFS issues a biological opinion that determines if the agency action is likely to jeopardize the species. If so, the opinion may specify reasonable and prudent alternatives that will avoid jeopardy and allow the agency to proceed with the action.[11] FWS and NMFS may also "suggest modifications" to the action (called reasonable and prudent measures) during the course of consultation to "avoid the likelihood of adverse effects" to the listed species even when not necessary to avoid jeopardy.[12]

Section 7(d) of the ESA, provides that once a federal agency initiates consultation on an action under the ESA, the agency, as well as any applicant for a federal permit, "shall not make any irreversible or irretrievable commitment of resources with respect to the agency action which has the effect of foreclosing the formulation or implementation of any reasonable and prudent alternative measures which would not violate subsection (a)(2) of this section."[13] The purpose of Section 7(d) is to maintain the environmental status quo pending the completion of consultation. Section 7(d) prohibitions remain in effect throughout the consultation period and until the federal agency has satisfied its obligations under Section 7(a)(2) that the action will not result in jeopardy to the species or adverse modification of its critical habitat.

Section 9 of the ESA prohibits any person, including federal agencies, from taking any endangered or threatened species.[14] The term "take" is defined broadly to include "harass, harm, pursue, hunt, shoot, wound, trap, kill, capture, or collect, or to attempt to engage in any such

6 16 U.S.C. § 1532(3)
7 16 U.S.C. § 1536(a)(1)
8 16 U.S.C. § 1536(a)(2) ("Section 7 consultation")
9 50 C.F.R. § 402.14
10 50 C.F.R. § 402.02
11 16 U.S.C. § 1536(b)
12 50 C.F.R. § 402.13
13 16 U.S.C. § 1536(d)
14 16 U.S.C. § 1538(a)(1)(B); 50 C.F.R. § 17.21(c)

conduct."[15] "Harm" is further defined as "an act which actually kills or injures wildlife. Such act may include significant habitat modification or degradation where it actually kills or injures wildlife by significantly impairing essential behavioral patterns, including breeding, feeding or sheltering."[16] Thus, an action which indirectly (e.g. habitat modification) or directly causes a decline in the population of an endangered species harms that species. Additionally, any action that precludes the recovery of an endangered species also falls within the meaning of harm.

Federal agencies may be limitedly exempt from the take prohibition through the issuance of an Incidental Take Statement ("ITS") as part of a Biological Opinion.[17] The ITS must identify the expected impacts of the authorized take, the reasonable and prudent measures necessary to minimize those impacts, and the terms and conditions that the agency must comply with to adequately implement those measures.[18]

B. The Federal Insecticide, Fungicide, and Rodenticide Act

Congress enacted the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") to regulate the use of pesticides in the United States.[19] FIFRA charges EPA with registering, reviewing, amending, and reregistering chemicals and chemical formulations for use as insecticides, fungicides, and pesticides in the United States.[20] Under FIFRA, a pesticide generally may not be sold or used in the United States unless it has an EPA registration for that particular use.[21]

EPA may register a pesticide if it makes the following determinations: (1) the labeling complies with FIFRA's requirements; (2) the composition claims are warranted; (3) the pesticide will perform its intended function; and (4) the pesticide will not cause unreasonable adverse effects on the environment.[22] The culmination of the registration process is EPA's approval of a label for the particular pesticide. FIFRA makes it unlawful to use a pesticide in a manner inconsistent with the label,[23] or to make any claims that differ substantially from the label.[24] The ESA's Section 7 requirements apply to EPA's discretionary registration of pesticides under FIFRA, and its actions in exercising its continuing authority over pesticide regulation.[25]

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15 16 U.S.C. § 1532(19); 50 C.F.R § 17.3
16 50 C.F.R. § 17.3
17 16 U.S.C. § 1536(o)(2); 50 C.F.R. § 402.14(i)(5)
18 16 U.S.C. § 1536(b)(4); 50 C.F.R. § 402.14(i)(1)(i)-(v)
19 *See* 7 U.S.C. §§ 136-136y
20 *Id*.
21 7 U.S.C. § 136a(a)
22 7 U.S.C. § 136a(c)(5)
23 *Id*. at § 136j(2)(G)
24 *Id*. at § 136j(1)(B)
25 *Wash. Toxics Coalition v. EPA*, 413 F.3d 1024, 1032 (9th Cir. 2005) ("We agree with the Eighth Circuit that even though EPA registers pesticides under FIFRA, it must also comply with the ESA when threatened or endangered species are affected."); *Defenders of Wildlife v. Administration*, 882 F.2d 1294 (8th Cir. 1989) (affirming section 7's application to EPA's registration of pesticides).

FACTUAL BACKGROUND

A. Cyantraniliprole Overview

Cyantraniliprole is a systemic insecticide belonging to the diamide class of pesticides. Cyantraniliprole works by binding with insect ryanodine receptors, which leads to unregulated activation of ryanodine receptor. Insects exposed to cyantraniliprole "first exhibit lethargy, followed by muscle paralysis, and then death."[26]

Cyantraniliprole has a wide variety of uses, including both agricultural and non-agricultural applications, and can be applied from a variety of applicator methods: foliar spray, micro sprinkler chemigation, bark spray, drip chemigation, soil drench, soil treatment, seed treatment, seed piece treatment, and bait.[27]

As a systemic insecticide, translocation of cyantraniliprole through the xylem and phloem results in expression of the chemical throughout exposed plants, resulting in multiple routes of exposure for various non-target organisms, including mammals, fish, invertebrates and plants.[28]

Cyantraniliprole biodegradation proceeds more slowly in aerobic conditions than anaerobic conditions, suggesting that it could be fairly persistent in the agricultural environment and adjacent ecosystems.[29] Degradation times in soils and sediments reached 89 and 25 days, respectively, showing an extended period of activity after application.[30] When the total toxic residues were calculated (including degradates), a range from 88 to 1327 days was identified.[31] Cyantraniliprole is also characterized as moderately mobile, meaning that it can move off-site and affect nearby terrestrial and aquatic ecosystems.[32] Some of the degradates of cyantraniliprole are more persistent and mobile than the parent compound, a concern for ecological effects as some may be more toxic than the parent and may accumulate over time.[33]

B. EPA's Approval of Cyantraniliprole

On February 29, 2012, EPA published a notice in the Federal Register that it had received applications for new pesticide ingredients pursuant to Section 3(c)(4) of FIFRA and announced the opening of 11 new dockets including a docket for Cyantraniliprole (Docket #: EPA-HQ-OPP-2011-0668).[34] On May 23, 2012, EPA published a notice in the Federal Register that it had received applications for residues of pesticide chemicals ("tolerances") for 11 new pesticide

26 CYANTRANILIPROLE RISK ASSESSMENT at 9.
27 CYANTRANILIPROLE RISK ASSESSMENT at 4.
28 CYANTRANILIPROLE RISK ASSESSMENT at 4, 147.
29 CYANTRANILIPROLE RISK ASSESSMENT at 4.
30 CYANTRANILIPROLE RISK ASSESSMENT at 21-22.
31 CYANTRANILIPROLE RISK ASSESSMENT at 25.
32 CYANTRANILIPROLE RISK ASSESSMENT at 4.
33 *Id*.
34 *Pesticide Products; Registration Applications*, 77 Fed. Reg. 12295 (Feb. 29, 2012).

tolerances and 7 amended tolerances for existing pesticide formulations, including cyantraniliprole.[35]

Rather than providing public notice and comment through the Federal Register, all subsequent decisions and announcements regarding registration of cyantraniliprole were posted to the docket on Regulations.gov. On June 6, 2013, EPA posted an announcement to Regulations.gov stating its intention to register cyantraniliprole nationwide and provided the public with 30 days to submit comments on the registration (see Appendix A). EPA extended the public comment period by an additional 8 days, which was also announced on the cyantraniliprole docket. EPA received comments from 18 parties: 6 supporting registration and 12 opposing registration.

On January 24th, 2014, Stephen Bradbury, Director of the Office of Pesticides Program, approved the registration of cyantraniliprole as a new active ingredient (see Appendix B). As of March 20, 2014, the following products and their labels have been approved and posted to EPA's Pesticide Product Label System.[36]

Product Name	Product Number	Date Approved	Active Ingredient %
Cyazypyr	358-856	1/24/2014	Cyantraniliprole - 96.7%
Exirel	352-859	1/24/2014	Cyantraniliprole - 10.2%
Verimark	352-860	1/28/2014	Cyantraniliprole - 18.6%
Benevia	352-857	1/30/2014	Cyantraniliprole - 10.2%
HGW86 Fly Control Bait	352-862	1/30/2014	Cyantraniliprole - 18.6%
Lumiderm Insecticide	352-858	1/30/2014	Cyantraniliprole – 50%
Fortenza Red Insecticide	100-1418	1/30/2014	Cyantraniliprole – 48.8%
Fortenza Insecticide	100-1420	1/30/2014	Cyantraniliprole – 48.8%
Minecto Duo Insecticide	100-1421	2/6/2014	Cyantraniliprole - 20%; Thiamethoxam - 20%
A16901B Ornamental	100-1422	2/7/2014	Cyantraniliprole - 20%; Thiamethoxam - 20%
A16901B Residential	100-1423	2/7/2014	Cyantraniliprole - 20%; Thiamethoxam - 20%
Spinner Insecticide	100-1424	2/7/2014	Cyantraniliprole - 20%; Thiamethoxam - 20%
HGW86 T&O Insect Control	352-865	2/18/2014	Cyantraniliprole - 18.6%
HGW86 G&H Insect Control	352-863	2/20/2014	Cyantraniliprole - 0.5%

C. Cyantraniliprole's Risks to Listed Species

EPA's own ecological risk assessment demonstrates that cyantraniliprole will cause both acute and chronic adverse effects on a wide variety of listed species:

> The results of this screening-level risk assessment indicate that the proposed cyantraniliprole uses have the potential for direct adverse effects to listed and

35 *Receipt of Several Pesticide Petitions Filed for Residues of Pesticide Chemicals in or on Various Commodities*, 77 Fed. Reg. 30481 (May 23, 2012). On February 5, 2014, EPA announced a final rule on tolerances for cyantraniliprole. 79 Fed. Reg. 6826 (Feb. 5, 2014).

36 label for HGW86 SC Insect Control, #352-868 is not available yet on EPA's PPLS website.

> non-listed mammals (chronic), freshwater invertebrates (acute), terrestrial invertebrates, estuarine/marine invertebrates (acute) and benthic invertebrates (acute and chronic).[37]
>
> Direct effects to listed terrestrial monocots also cannot be precluded because of an absence of data. This indicates a potential risk for direct adverse effects to federally listed aquatic invertebrates, terrestrial invertebrates, terrestrial monocots, and mammals and indirect adverse effects to any listed species that rely on these taxa as resources critical to their life cycle.[38]

While is clear that fish, terrestrial invertebrates, and aquatic invertebrates are at most direct risk from cyantraniliprole, the EPA risk assessment concludes that acute and chronic harm (which includes potential harm to designated critical habitat) will occur for nearly all taxonomic groups that are represented on the list of threatened and endangered species:[39]

Listed Taxon	Direct Effects	Indirect Effects
Terrestrial and semi-aquatic plants – monocots	Yes	Yes
Terrestrial and semi-aquatic plants – dicots	No	Yes
Terrestrial invertebrates	Yes (acute)	Yes
Birds	No	Yes
Terrestrial-phase amphibians	No	Yes
Reptiles	No	Yes
Mammals	Yes (chronic)	Yes
Aquatic plants	No	Yes
Freshwater fish	No	Yes
Aquatic-phase amphibians	No	Yes
Freshwater invertebrates	Yes (acute)	Yes
Benthic invertebrates	Yes (acute and chronic)	Yes
Marine/estuarine fish	Yes (chronic)	Yes
Marine/estuarine invertebrates	Yes (acute)	Yes

Because cyantraniliprole has been approved for industrial, residential, and agricultural uses across the nation, the list of species that will be adversely affected is large. In fact, EPA's database, LOCATES, completed an initial screening of listed species that would overlap with cyantraniliprole use areas and concluded as follows:

> LOCATES identified a total of 1377 listed species that overlap at the county-level with areas where cyantraniliprole is proposed to be used (see Appendix I for a complete species list). This preliminary analysis indicates that there is a potential for cyantraniliprole use to overlap with listed species and that a more

37 CYANTRANILIPROLE RISK ASSESSMENT at 5.
38 CYANTRANILIPROLE RISK ASSESSMENT at 143.
39 CYANTRANILIPROLE RISK ASSESSMENT at 149.

> refined assessment is warranted. The more refined assessment should involve clear delineation of the action area associated with proposed uses of cyantraniliprole and best available information on the temporal and spatial co-location of listed species with respect to the action area.[40]

Despite the clear need for this refined assessment, EPA merely stated "This analysis has not been conducted for this assessment."[41] Appendix C contains the results from the LOCATES analysis.

The EPA ecological risk assessment for cyantraniliprole also indicates that substantial habitat buffers may be required to protect critical habitat and listed species from adverse effects. Specifically, the ecological risk assessment concludes that "[f]or freshwater invertebrate exposures, acute listed species buffers range from 0 to 197 ft (TGAI) and 0 to >1000 ft (TEP)."[42] The analysis also determined that the cyantraniliprole-thiamethoxam mixture will require larger buffers (over 1000 ft) than cyantraniliprole-only products.[43] Yet, EPA's label restrictions require only a 25 foot buffer for ground applications and a 50 foot buffer for aerial applications.[44] These buffers are far lower than what EPA's risk assessment concludes is needed to keep exposure below Levels of Concern ("LOCs"), which "are used to indicate when a pesticide use as directed on the label has the potential to cause adverse effects on non-target organisms."[45]

D. Increased Risk from Cyantraniliprole-Thiamethoxam Mixtures

Thiamethoxam is a neonicotinoid insecticide that acts on target pests by interfering with the nicotinic acetylcholine receptor.[46] Thiamethoxam was first registered in the United States in 1999 as under Section 18 of FIFRA as an emergency exemption use on canola seed in North Dakota and again in Missouri as an emergency exemption in early 2000.[47] Thiamethoxam received full registration in 2000 for use on cucurbit vegetables, pome fruit, tomatoes, eggplant, peppers, tobacco, celery, lettuce, spinach, cole crops, sorghum, wheat, and ornamental turf. Initial EPA risk assessments identified potential risks to "aquatic invertebrates, birds, mammals, terrestrial invertebrates, and terrestrial plants (in the absence of data)."[48]

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40 CYANTRANILIPROLE RISK ASSESSMENT at 151
41 *Id*.
42 *Id*. at 147; TGAI = technical grade active ingredient. TEP = Typical End Use Product.
43 *Id*.
44 EPA, 2014. RESPONSE TO PUBLIC COMMENTS ON EPA'S "PROPOSED REGISTRATION OF THE NEW ACTIVE INGREDIENT CYANTRANILIPROLE: AN INSECTICIDE FOR USE ON MULTIPLE COMMODITIES, ORNAMENTALS, TURFGRASS, AND IN COMMERCIAL OR RESIDENTIAL BUILDINGS at 44. Docket #: EPA-HQ-OPP-2011-0668-0058
45 U.S. Environmental Protection Agency Office of Pesticides Program. 2004. OVERVIEW OF THE ECOLOGICAL RISK ASSESSMENT PROCESS: ENDANGERED AND THREATENED SPECIES EFFECTS DETERMINATIONS (hereafter "ECOLOGICAL RISK ASSESSMENT PROCESS") (emphasis added). Available at: http://www.epa.gov/espp/consultation/ecorisk-overview.pdf
46 EPA, 2011. PROBLEM FORMULATION FOR THE ENVIRONMENTAL FATE, ECOLOGICAL RISK, ENDANGERED SPECIES, AND DRINKING WATER EXPOSURE ASSESSMENTS IN SUPPORT OF THE REGISTRATION REVIEW OF THIAMETHOXAM at 3. Docket #: EPA-HQ-OPP-2011-0581-0003.
47 *Id*. at 3.
48 *Id*. at 4.

Thiamethoxam has the potential to cause both acute and/or chronic impacts to a variety of endangered species. Despite these risks, EPA "has not conducted a risk assessment that supports a complete endangered species determination for thiamethoxam."[49]

DuPont, the registrant of cyantraniliprole, proposed several product labels with a mixture of cyantraniliprole, thiamethoxam, and other ingredients at a mixture ratio of 20.0% cyantraniliprole, 20.0% thiamethoxam and Other Ingredients 60.0%.[50] EPA conducted a specific risk assessment of this mixture and concluded that "the typical end-use products with thiamethoxam are also modeled because they presented more sensitive toxicity values than their technical-grade counterparts."[51] In other words, this mixture of these two pesticides is more dangerous than the pure, technical grade active ingredient in isolation. EPA's own initial analysis determined that "cyantraniliprole-thiamethoxam mixture would require buffer in excess of 1000 ft *for all uses*."[52] Despite the clearly higher-toxicity of this mixture, EPA did not conduct any additional species-specific analysis for listed species and imposed no labels-specific restrictions with respect to this mixture.

ESA VIOLATIONS

Consultation under Section 7 of the ESA is required whenever a discretionary agency action "may affect" any listed species or its critical habitat.[53] EPA's risk assessment makes clear that the "may affect" threshold is met for over 1000 species that could be harmed by cyantraniliprole and its end-use products, including those co-formulated with thiamethoxam. Accordingly, EPA is required to initiate consultation to ensure that the registration of cyantraniliprole and its approved products will not jeopardize any listed species or adversely modify critical habitat. EPA's refusal to initiate consultation prior to approving this new pesticide and its associated products violates EPA's Section 7 duty to consult under the ESA.

Moreover, after concluding that the nationwide registration of cyantraniliprole could affect listed species nationwide, after concluding that this pesticide is toxic to several taxonomic groups, and after failing to consult with the Services on this registration, EPA has proposed inadequate buffers, inadequate use restrictions, and virtually no meaningful conservation measures to protect listed species. As such, EPA's registration of cyantraniliprole and its associated end-use products/labels violates EPA's Section 7 duty to avoid jeopardizing the continued existence of any endangered species or threatened species, and to avoid the destruction or adverse modification of critical habitat of listed species.

Simply put, EPA's own risk assessment establishes that use of cyantraniliprole may affect hundreds of listed species or adversely modify critical habitat. EPA must satisfy its duty to avoid

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49 EPA, 2011. Thiamethoxam Summary Document Registration Review: Initial Docket December 2011, Docket #: EPA-HQ-OPP-2011-0581-0002.

50 See, e.g. A16901B CP Product Label, Docket #: EPA-HQ-OPP-2011-0668-0016

51 CYANTRANILIPROLE RISK ASSESSMENT at 150.

52 CYANTRANILIPROLE RISK ASSESSMENT at 150 (emphasis added).

53 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.14(a) ("Each Federal agency shall review its actions at the earliest possible time to determine whether any action may affect listed species or critical habitat. If such a determination is made, formal consultation is required…"); *see Wash. Toxics Coalition v. EPA*, 413 F.3d 1024, 1032 (9th Cir. 2005); *Defenders of Wildlife v. Administration*, 882 F.2d 1294 (8th Cir. 1989).

jeopardizing listed species, or adversely modifying their critical habitat, by initiating the consultation process for its actions in registering cyantraniliprole and its end-use products.

Section 9 of the ESA prohibits any person, including federal agencies, from taking any endangered or threatened species. Federal agencies may be limitedly exempt from the take prohibition through the issuance of an Incidental Take Statement as part of an ESA section 7 Biological Opinion. As discussed above, registration of cyantraniliprole and its products is a federal action that can cause the take of listed species due to the chemical's ability to harm and/or kill listed species. Consequently, in order to achieve safe harbor from ESA take liability in regard to cyantraniliprole, EPA must have written authorization from FWS and/or NMFS in the form of an ITS. Because EPA has thus far failed to even initiate consultation as to cyantraniliprole, it does not possess an ITS from the wildlife agencies and is therefore in violation of not only section 7 of the ESA, but also section 9 of the ESA.

CONCLUSION

If EPA does not act within 60 days to correct the violations described in this letter, we will pursue litigation against EPA. If you have any questions, or would like to discuss, please contact us.

Sincerely,

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