



CENTER FOR FOOD SAFETY

Docket No. EPA-HQ-OPP-2011-0668

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Comments to EPA on Cyantraniliprole as a New Active Ingredient, Insecticide Formulated as a Technical Product and Fourteen End Use Products

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INTRODUCTION

The E.I. DuPont de Nemours and Company (DuPont) and Syngenta Crop Protection (Syngenta) have applied for the registration of the new insecticide cyantraniliprole for a variety agricultural and non-agricultural uses. In addition to the technical formulation of cyantraniliprole, DuPont has also proposed eight end-use product formulations for registration. Syngenta has proposed five end-use product formulations, three of which are co-formulated with the registered neonicotinoid insecticide thiamethoxam.¹ The United States Environmental Protection Agency (EPA) is proposing to grant unconditional registrations of the new active ingredient cyantraniliprole and its technical product formulation and the fourteen proposed end-use product formulations.²

The undersigned groups, Center for Food Safety and American Bird Conservancy, submit the following comments on the above-referenced docket on the EPA's proposal to unconditionally register the new active ingredient cyantraniliprole, its technical product formulation and fourteen end-use product formulations, under Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).³

¹ Office of Pesticide Programs – Environmental Fate and Effects Division, EPA, Environmental Fate and Ecological Risk Assessment for the Registration of the New Chemical Cyantraniliprole – Amended (Apr. 30, 2013), *available at* <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0668-0008>. [*hereafter* Amended Risk Assessment].

² Office of Pesticide Programs – Registration Division, EPA, Proposed Registration of the New Active Ingredient Cyantraniliprole: An Insecticide for Use on Multiple Commodities, Ornamentals, Turfgrass, and in Commercial or Residential Buildings (June 5, 2013), *available at* <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0668-0008>.

³ 7 U.S.C. § 136a(c)(5).



CENTER FOR
FOOD SAFETY

The Center for Food Safety (CFS) is a Washington, D.C.-based public interest non-profit membership organization that also has offices in San Francisco, CA, and Portland, OR. Since its founding in 1997, CFS has sought to ameliorate the adverse impacts of industrial farming and food production systems on human health, animal welfare, and the environment. CFS has over 300,000 members nationwide.



AMERICAN BIRD
CONSERVANCY

The American Bird Conservancy (ABC) is a 501(c)(3) not-for-profit membership organization whose mission is to conserve native birds and their habitats throughout the Americas. ABC acts by safeguarding the rarest species, conserving and restoring habitats, and reducing threats, while building capacity in the bird conservation movement.

SUMMARY

EPA should not register the new active ingredient cyantraniliprole and the proposed technical product and fourteen end-use product formulations. EPA's ecological risk assessment of cyantraniliprole contains a significant number of data gaps, unreliable assumptions, and uncertainties, all of which preclude registrations of cyantraniliprole and its product formulations at this time.⁴ Moreover, the agency's assessment of existing information demonstrates that cyantraniliprole may have "unreasonable adverse effects on the environment," and thus should not be registered under section 3(c)(5) (unconditional registration) or section 3(c)(7) (conditional registration) of FIFRA.

As made clear below, EPA's ecological risk assessment of cyantraniliprole demonstrates that cyantraniliprole poses acute and/or chronic harms to terrestrial invertebrates, including honey bees; freshwater invertebrates; estuarine/marine invertebrates; and benthic invertebrates. EPA's risk assessment also demonstrates that cyantraniliprole may pose chronic harms to terrestrial plants (monocots), estuarine/marine fish, and mammals.⁵ EPA admits throughout the agency's risk assessment of cyantraniliprole and its various formulations that there are numerous data gaps and points of uncertainty regarding the toxicity and environmental effects of cyantraniliprole and its product formulations. Based on the agency's own risk assessment and information to the contrary, EPA cannot reach the requisite FIFRA determination that the registrations of the new active ingredient of cyantraniliprole and its technical formulation and fourteen end-use products would not result in "unreasonable adverse effects on the environment."⁶

⁴ EPA, Amended Risk Assessment, *supra* note 1.

⁵ *Id.* at 5.

⁶ 7 U.S.C. § 136a(c)(5).

EPA's proposed decision to unconditionally register the new active ingredient cyantraniliprole and its technical and end-use product formulations for a variety of uses also violates EPA's duty under the Endangered Species Act (ESA). As discussed below, Section 7 of the ESA requires that EPA consult with the expert agencies to ensure that its actions will not jeopardize listed species' survival nor adversely modify designated critical habits.⁷ EPA's proposed registrations of the new active ingredient cyantraniliprole as a technical formulation and end-use products fall within Section 7 of the ESA, triggering the duty to consult. Yet, there is no indication that EPA consulted with the expert agencies to ensure the protection of federally threatened and endangered species and their critical habitats.

EPA's proposed decision to register cyantraniliprole and its numerous technical and end-use product formulations is also flawed, because the agency has failed to consider the synergistic and cumulative risks posed by the uses of cyantraniliprole-containing systemic pesticide products in addition to existing uses of systemic neonicotinoid pesticides. As discussed in detail below, cyantraniliprole and its formulations pose similar risks presented by the existing widespread uses of toxic neonicotinoid pesticides. EPA's failure to consider the cumulative impacts of the addition of yet another systemic active ingredient (and its technical formulation and fourteen end-use formulations) for nationwide use, in both non-agricultural and agricultural applications, is arbitrary and capricious, in violation of the Administrative Procedure Act (APA). Similarly, EPA's failure to consult on the cumulative impacts of registering cyantraniliprole and its product formulations on the nation's listed species and their critical habitats is a violation of EPA's duty under the ESA.

Significantly, three of the proposed cyantraniliprole end-use products by Syngenta are co-formulated with thiamethoxam, a widely-used neonicotinoid pesticide with demonstrated adverse effects on honey bees, vital pollinators, insects, mammals, and birds, including many federally listed threatened and endangered species.⁸ As discussed in detail below and in the attached Appendix A, thiamethoxam is highly toxic to invertebrates, and its range of effects also impact mammals, birds, and plants. EPA should not approve the unconditional registrations of cyantraniliprole co-formulations with thiamethoxam.

Finally, the proposed labels of cyantraniliprole product formulations and cyantraniliprole-thiamethoxam product formulations are also inadequate to mitigate the numerous unreasonable adverse effects that the use of these products will have on the environment, in violation of EPA's duty under FIFRA.⁹

Based on EPA's risk assessment of cyantraniliprole and cyantraniliprole-thiamethoxam co-formulations, the existing knowledge regarding the harms associated with these formulations, as well as known data gaps and uncertainties regarding the

⁷ 50 C.F.R. § 402.14.

⁸ See App. A - Letter from Peter T. Jenkins, Ctr for Food Safety, to Dr. Steven P. Bradbury, Director, Office of Pesticide Programs, EPA (Oct. 16, 2012).

⁹ 7 U.S.C. § 136a.

behavior and toxicity of cyantraniliprole and the cyantraniliprole-thiamethoxam co-formulation chemicals, the proposed registrations are not supported by substantial evidence, and are arbitrary and capricious, in violation of EPA's duty under FIFRA and the APA. EPA's failure to consider the cumulative effects of cyantraniliprole use and existing uses of neonicotinoid pesticides is also arbitrary and capricious, in violation of the APA. Furthermore, EPA violated its duty under the ESA by failing to consult on the direct, indirect, and cumulative impacts of the proposed registrations of cyantraniliprole and its product formulations on federal listed species and their critical habitats.

Therefore, EPA should not register cyantraniliprole as a new active ingredient; nor should the agency approve the proposed formulations and uses of cyantraniliprole (including cyantraniliprole-thiamethoxam co-formulations), because the chemical and its product formulations pose unreasonable adverse effects on the environment, and may harm listed species and their designated habitats.

RELEVANT LEGAL STANDARDS

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

FIFRA authorizes EPA to regulate the registration, use, sale, and distribution of pesticides in the United States. Pursuant to FIFRA, EPA oversees both initial registration of an active ingredient as well as any new uses of the registered active ingredient.

Section 3(c) of FIFRA requires a manufacturer must submit an application to register the use of a pesticide.¹⁰ Under Section 3(c)(5) of FIFRA, EPA shall register a pesticide if the agency determines that the pesticide “will perform 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.”¹¹ FIFRA defines “unreasonable adverse effects on the environment” as “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.”¹² Alternatively, where there are data gaps and missing information, EPA can register a pesticide with conditions (conditional registration) under Section 3(c)(7) of FIFRA “for a period reasonably sufficient for the generation and submission of required data,” but only if EPA also determines that the conditional registration of the pesticide during that time period “will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest.”¹³

The culmination of the registration process is EPA's approval of a label for the pesticide, including use directions and appropriate warnings on safety and environmental risks. It is a violation of FIFRA for any person to sell or distribute a “misbranded”

¹⁰ 7 U.S.C. § 136a(c)(1); 40 C.F.R. § 152.42.

¹¹ 7 U.S.C. § 136a(c)(5).

¹² 7 U.S.C. §136(bb).

¹³ 7 U.S.C. §136a(c)(7)(C).

pesticide.¹⁴ A pesticide is misbranded if the “labeling accompanying it does not contain directions for use which...if complied with...are adequate to protect health and the environment.”¹⁵

Pursuant to FIFRA’s judicial review provisions, EPA’s determination “shall be sustained if it is supported by substantial evidence when considered on the record as a whole.”¹⁶

Endangered Species Act (ESA)

Section 7(a)(2) of the ESA requires every federal agency to consult the appropriate federal fish and wildlife agency—Fish and Wildlife Service (FWS), in the case of land and freshwater species and National Marine Fisheries Service (NMFS) in the case of marine species—to “insure” that the agency’s actions are not likely “to jeopardize the continued existence” of any listed species or “result in the destruction or adverse modification” of critical habitat.¹⁷ The ESA’s implementing regulations broadly define agency action to include “all activities or programs of any kind authorized, funded or carried out . . . by federal agencies,” including the granting of permits and “actions directly or indirectly causing modifications to the land, water or air.”¹⁸ A species’ “critical habitat” includes those areas identified as “essential to the conservation of the species” and “which may require special management considerations or protection.”¹⁹

Pending the completion of consultation with the expert agency, an agency is prohibited from making 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.”²⁰

Administrative Procedure Act (APA)

Under the APA, a reviewing court shall “hold unlawful and set aside agency action, findings, and conclusions” that it finds to be “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.”²¹ “Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.”²²

¹⁴ 7 U.S.C. § 136j(a)(1)(E).

¹⁵ 7 U.S.C. § 136(q)(1)(F).

¹⁶ 7 U.S.C. § 136n(b).

¹⁷ 16 U.S.C. § 1536(a)(2); *see also* 50 C.F.R. § 402.01(b).

¹⁸ 50 C.F.R. § 402.02 (emphasis added).

¹⁹ 16 U.S.C. § 1532(5)(A).

²⁰ 16 U.S.C. § 1536(d).

²¹ 5 U.S.C. § 706(2)(A).

²² *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

COMMENTS

Overview of Cyantraniliprole: Chemical Class & Behavior

Cyantraniliprole is a systemic insecticide belonging to the diamide class of pesticides. Because of its systemic nature, cyantraniliprole poses many similar dangers to the widely-used neonicotinoid pesticides. As a systemic pesticide, translocation of cyantraniliprole through the xylem and phloem results in expression of the chemical throughout the plants that it is applied to, resulting in multiple routes of exposure for various non-target organisms. Cyantraniliprole is proposed for a wide variety of uses, including both agricultural and non-agricultural applications. It is also proposed for a number of application methods, including foliar spray, micro sprinkler chemigation, bark spray, drip chemigation, soil drench, soil treatment, seed treatment, seed piece treatment, or bait; many of the application methods have significant non-target effects.

Cyantraniliprole works by binding with insect ryanodine receptors, which leads to unregulated activation of ryanodine receptor.²³ Insects exposed to cyantraniliprole “first exhibit lethargy, followed by muscle paralysis, and then death.”²⁴ The diamide class of insecticides is harmful to non-target insects and is also toxic to mammals, fish, and plants along with its targeted invertebrates. Systemic pesticides have been shown to pose particular dangers to non-target organisms because of their ability to travel throughout the plants where they are applied. Thus, the proposed registration of yet another systemic product should be analyzed thoroughly, especially in light of the negative impacts posed by other major classes of systemic pesticides, including neonicotinoids.

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. Degradation times in soils and sediments reached 89 and 25 days, respectively, showing an extended period of activity after application.²⁵ When the total toxic residues were calculated (including degradates), a range from 88 to 1327 days was identified.²⁶ Cyantraniliprole is also characterized as moderately mobile, suggesting that it can move off-site from an application and affect adjacent terrestrial and aquatic ecosystems.²⁷ 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.²⁸

²³ EPA, Amended Risk Assessment, *supra* note 1, at 9.

²⁴ *Id.* at 9.

²⁵ *Id.* at 22.

²⁶ *Id.* at 25.

²⁷ *Id.* at 22-25.

²⁸ *Id.* at 22-25.

I. EPA's Risk Assessment Does Not Support the Required Finding that Cyantraniliprole and Its Formulated Products Would Not Have "Unreasonable Adverse Effect on the Environment" Warranting Registration Under FIFRA.

EPA's amended ecological risk assessment fails to adequately evaluate the unreasonable adverse effects stemming from the proposed registration of cyantraniliprole in its technical formulation and fourteen end-use products. EPA admits that "it is anticipated that use [of cyantraniliprole and its products] will be widespread,"²⁹ and the agency's current proposal would allow cyantraniliprole and its formulated products (including products co-formulated with thiamethoxam) to be used on a wide variety of agricultural crops, ornamental plants and turfgrass, as well as in and around various agricultural, commercial, and residential structures.³⁰ Yet, the risk assessment is replete with examples of uncertainties and data gaps.

Significantly, the risk assessment uses the seasonal maximum usage amount listed for cyantraniliprole use on agricultural products to be the yearly maximum, despite the fact that many of the crops for which the use of cyantraniliprole is proposed have more than one season per year.³¹ Similarly, despite acknowledging that "application rates [of cyantraniliprole products] vary, but most seasonal maximums are 0.4 to 0.42 lb ai/A (two uses have maximums of 0.5 and 0.69 lb ai/A)," EPA relies on application rates significantly below the listed seasonal maximums in determining acute and chronic risks from cyantraniliprole. We believe that there is a lack of reliable studies or data to support a determination that the proposed uses of cyantraniliprole would not have unreasonable adverse effect to the environment. To the contrary, numerous studies cited by EPA in the agency's amended risk assessment suggest that cyantraniliprole poses significant risks to our waters and environment, and threatens the existence of vital pollinators, terrestrial invertebrates, and aquatic invertebrates, including federally-listed species.

Similarly, EPA's assessment of cyantraniliprole's biodegradation process and the toxicity of cyantraniliprole and its degradates, are insufficient to support unconditional registration under FIFRA. As stated previously, 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 be able to accumulate over time.³² The assumption used by EPA that the degradates were equally toxic to the parent should not substitute for full assessments of the degradates, especially given that EPA asserts later that "two of the degradates (IN-HGW87 and IN-J9Z38) may be more toxic on an acute oral basis than the parent, but given that the endpoints were non-definitive, there is uncertainty."³³ This concern is especially crucial for the degradates that showed more persistence and mobility.

²⁹ *Id.* at 9.

³⁰ Office of Pesticide Programs, EPA, Proposed Registration of the New Active Ingredient Cyantraniliprole (June 5, 2013).

³¹ EPA, Amended Risk Assessment, *supra* note 1, at 9.

³² *Id.* at 22-25.

³³ *Id.* at 73.

Moreover, EPA lacks sufficient data to determine potential water contamination stemming from the uses of cyantraniliprole and its product formulations. Because cyantraniliprole is a new chemical, no existing monitoring data for aquatic exposure exists.³⁴ Given the relative mobility and persistence of cyantraniliprole and its degradates, the potential for water quality effects is real. EPA acknowledges that given the mobility and persistence of cyantraniliprole and its degradates, the chemicals may contaminate surface water as a result of run-off after application.³⁵ The agency also admits that some of cyantraniliprole's degradates may contaminate groundwater through leaching.³⁶ EPA's risk assessment identifies toxicity to a range of aquatic species, which could signal problems for aquatic habitats with the widespread use of cyantraniliprole. Benthic invertebrates were particularly sensitive to cyantraniliprole toxicity, with 46% of the proposed uses presenting a risk of chronic toxicity.³⁷ With these risks to various aquatic species, surface water contamination is a serious potential problem from the use of cyantraniliprole. EPA should further analyze the potential water contamination by cyantraniliprole and its degradates and the impact of such contamination on aquatic species to ensure that registering products containing cyantraniliprole would not result in unreasonable adverse effects on the environment.

Finally, EPA entirely neglected to consider the synergistic and cumulative impacts of approving cyantraniliprole and its related products in light of the existing stressors placed upon honey bees, vital pollinators, birds, other sensitive species, and the environment. EPA's oversight is significant, in light of similar effects of cyantraniliprole and other neonicotinoid pesticides, as well as proposed co-formulations of cyantraniliprole and thiamethoxam. EPA's oversight is arbitrary and capricious, in direct violation of the APA.³⁸

Adverse Effects and Data Gaps for Effects on Non-Target Species

The uncertainties with regard to chronic exposure for various species, including federally listed species, make it unacceptable for EPA to register cyantraniliprole and the related proposed products. According to EPA's risk assessment, direct effects from applications of cyantraniliprole have been identified for:

- terrestrial invertebrates (acute)
- mammals (chronic)

³⁴ *Id.* at 43.

³⁵ Office of Chemical Safety and Pollution Prevention, EPA, Tier I Drinking Water Exposure Assessment for Cyantraniliprole in Support of New Chemical Registration on Various Crops 6-7 (November 21, 2012), available at <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0668-0007>.

³⁶ *Id.* at 8.

³⁷ EPA, Amended Risk Assessment, *supra* note 1, at 107.

³⁸ *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) ("Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.").

- freshwater invertebrates (acute)
- terrestrial plants (monocots)
- estuarine/marine invertebrates (acute)
- estuarine/marine fish (chronic)
- benthic invertebrates (acute and chronic).³⁹

The range of direct effects from the use of cyantraniliprole is extensive. Within each of these broad categories, there are a number of concerning findings that suggest that cyantraniliprole should not be registered for use. Some categories were also only comprised of supplemental studies that had various deficiencies, which should preclude EPA from adequately assessing harms (e.g., estuarine/marine fish).⁴⁰ There was also no data available for chronic effects on estuarine/marine invertebrates.⁴¹ Evaluations of effects on monocots were inconclusive, suggesting that cyantraniliprole may also be toxic to plants.⁴² Field and semi-field studies for pollinators had a wide range of deficiencies as well, which will be discussed further below.⁴³

As EPA itself acknowledges, “[i]n the absence of data needed to make the required findings under FIFRA, EPA cannot register...a pesticide.”⁴⁴ Before approving cyantraniliprole’s registration as a new active ingredient used in a technical product and end-use products, EPA must resolve the extensive data gaps and uncertainties in order to ensure that the registration of cyantraniliprole and its end-use products would not have unreasonable adverse effects on the environment.

Impacts to Terrestrial Invertebrates, Including Pollinators

We are alarmed by the negative impacts and incomplete data surrounding the effects determination for pollinators, especially honey bees (*Apis mellifera*). There are a number of problems with the pollinator assessment, mostly acknowledged by EPA, which should preclude registration of cyantraniliprole. Studies performed to assess impacts on pollinators and other terrestrial invertebrates were all conducted well below the proposed label rate.

EPA’s ecological risk assessment demonstrates that, in acute toxicity testing, cyantraniliprole was classified as highly toxic for both oral and contact exposure to terrestrial invertebrates including honeybees. Risk quotient analyses showed direct risks to individual honeybees. Larval toxicity was not assessed because experiments were only performed to evaluate adult honeybees. Moreover, the harm to pollinators including *Apis mellifera* is especially grave because three of the proposed end-use products containing cyantraniliprole are also co-formulated with thiamethoxam. EPA’s risk assessment found

³⁹ *Id.* at 5-6.

⁴⁰ *Id.* at 57.

⁴¹ *Id.* at 62.

⁴² *Id.* at 7, 86.

⁴³ *Id.* at 69.

⁴⁴ Office of Pesticide Programs, EPA, Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency 33 (January 2004). *available at* <http://www.epa.gov/espp/consultation/ecorisk-overview.pdf>.

that a study with the formulated product that also includes thiamethoxam showed greater toxicity to honeybees than technical cyantraniliprole.⁴⁵ The additional toxicity of products that include thiamethoxam should be considered when reviewing proposed products.⁴⁶ Sublethal effects were also seen with contact toxicity tests from foliar applications, suggesting that bees may suffer sublethal impacts just from contact with treated crops.⁴⁷ Moreover, the spray applications (foliar and bark) all exceeded 0.4 LOC that signifies concerns for bee health.⁴⁸ EPA concluded that, “[o]verall, the results indicate that the typical end-use products for registration are of concern to bees for most of the proposed uses.”⁴⁹ As populations are already in decline, this alone should preclude EPA from registering the cyantraniliprole products.

All of the semi-field and field studies conducted with *Apis mellifera* were classified as supplemental because of inconsistencies, demonstrating that EPA lacks sufficient data to determine that cyantraniliprole and its uses would not have unreasonable adverse effects on the environment.⁵⁰ All of the studies were also conducted at levels well below the proposed application rates, suggesting that higher rates could increase the exposure of pollinators.⁵¹ This is a serious deficiency in the risk assessment because the proposed real-world application rates are entirely untested. Studies with the lower application rates did suggest negative effects on pollinators that could affect pollination, finding that “the combination of mortality, sublethal effects, and repellence (decreased foraging) in cyantraniliprole-treated plants may affect pollinator services.”⁵² Brood studies intended to assess the effects on the colonies were also inadequate. While residue testing showed concentrations in pollen and nectar food sources that were below the acute toxicity values for honeybees, these studies were also conducted well below the maximum application rates. Risk quotients from this data also suggest potential risks from dietary exposure at the rates tested, up to 0.134 lb ai/A, still below the maximum proposed rate of 0.68 lb ai/A. Based on the negative impacts identified at lower rates, and the ongoing pressures on pollinators, cyantraniliprole, both in technical formulation and end-use product formulations, should not be approved without further study. In residue studies, higher concentrations of cyantraniliprole were consistently found in pollen, suggesting that bees may be exposed to high concentrations.⁵³ Without adequate examination, EPA cannot rule out unreasonable adverse effects on these pollinators.

Even at the lower application rates, the concentrations of cyantraniliprole in guttation fluid were concerning. Studies have demonstrated that honeybees drink

⁴⁵ EPA, Amended Risk Assessment, *supra* note 1, at 69.

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.* at 119.

⁴⁹ *Id.*

⁵⁰ *Id.* at 69.

⁵¹ *Id.* at 69-73.

⁵² *Id.* at 139.

⁵³ *Id.* at 136.

guttation fluid and it can be a pathway for exposure to systemic pesticides.⁵⁴ The studies cited in EPA's risk assessment found levels of cyantraniliprole in guttation fluid were also conducted with a 15-day application interval, while some labeled uses would allow for a 7-day interval. This could also contribute to higher levels of cyantraniliprole in guttation fluid in the field. Given that this effect was noticed at a lower rate than proposed, and with less-frequent applications, more studies should be conducted to evaluate this exposure pathway.

One of the pollinator studies showed that colonies had increased susceptibility to *Varroa* mite infestations, which could be mediated by the active ingredient. In this study, it appeared that the hives not exposed to cyantraniliprole were better able to resist infestation than those that were exposed.⁵⁵ It has been suggested that neonicotinoids may be interfering with the bees' immune systems and decreasing their ability to fight other similar pathogenic infestations, such as *Nosema*.⁵⁶ A similar effect may be occurring with cyantraniliprole, but the increase in *Varroa* prevalence was not further investigated. Before registering cyantraniliprole and its technical and end-use products, EPA must critically assess the indirect effect that exposure to cyantraniliprole may have on bees' ability to resist *Varroa* infestations, since *Varroa* mites have been identified as one of the major contributing factors in bee declines by the recent EPA/USDA Stakeholder Report.⁵⁷ Pollinator exposure to dust from cyantraniliprole-treated seeds was also not assessed. This has been a major exposure route for honeybees with neonicotinoid-treated seeds as dust containing the active ingredients contacts the bees or settles on flowering plants nearby.⁵⁸ This route of exposure should be assessed before cyantraniliprole is approved.

Avian Impacts

EPA lacks sufficient information to determine that cyantraniliprole and cyantraniliprole-thiamethoxam co-formulations would not have unreasonable adverse effects on avian species. Cyantraniliprole was classified as non-toxic to moderately toxic on an acute oral basis.⁵⁹ However, without access to the specific study protocols, it is difficult to evaluate the extent to which cyantraniliprole will become a threat to birds.

⁵⁴ Girolami, V. et al. 2009. Translocation of Neonicotinoid Insecticides from Coated Seeds to Seedling Guttation Drops: A Novel Way of Intoxication for Bees. *J Econ Entomol* 102(5): 1808-1815.; Hoffman, E & Castle, S. 2012. Imidacloprid in Melon Guttation Fluid: A Potential Mode of Exposure for Pest and Beneficial Organisms. *J Econ Entomol* 105(1): 67-71.; Reetz, J. et al. 2011. Neonicotinoid insecticides translocated in guttated droplets of seed-treated maize and wheat: a threat to honeybees? *Apidologie* 42: 596-606.

⁵⁵ EPA, Amended Risk Assessment, *supra* note 1, at 73.

⁵⁶ Pettis, J. et al. 2012. Pesticide exposure in honey bees results in increased levels of the gut pathogen *Nosema*. *Naturwissenschaften* 99: 153-158; Alaux et al. 2009. Interactions between *Nosema* microspores and a neonicotinoid weaken honeybees (*Apis mellifera*). *Environmental Microbiology* 12(3): 774-782.

⁵⁷ United States Department of Agriculture, *Report on the National Stakeholders Conference on Honey Bee Health* (October 15-17, 2012). available at <http://www.usda.gov/documents/ReportHoneyBeeHealth.pdf>.

⁵⁸ Krupke, C. 2012. Multiple Routes of Exposure for Honey Bees Living Near Agricultural Fields. *PLoS ONE* 7(1): e29268.

⁵⁹ EPA, Amended Risk Assessment, *supra* note 1, at 66.

As previously stated, the pesticide is proposed for use as a foliar spray, bark spray, micro sprinkler chemigation, drip chemigation, soil drench, soil treatment, seed treatment, seed piece treatment, or bait. It is unfortunate to see seed treatment on the list of proposed uses. EPA includes potatoes, mustard, and sunflower seeds among the seeds to be treated. This is in contrast to the registration documents we have seen from the European Food Safety Authority, which specifically exclude pesticide use as a seed treatment. From mercury-based coatings to aldrin and dieldrin to the neonicotinoids, seed treatments have been associated with heavy exposure to and harmful impacts on birds. Unlimited quantities of treated seeds will be available to birds foraging on fields.

It remains unclear precisely how the studies were carried out to conclude that cyantraniliprole is harmless to birds on an acute or chronic basis. The use of Mallard ducks and Bobwhite quail as the test species led the agency to significantly underestimate risk to birds from the neonicotinoids, and similar variation in species sensitivity may be in play for cyantraniliprole.

The combined effects of the cyantraniliprole-thiamethoxam co-formulations are also cause for concern. The ABC report, *The Impact of the Nation's Most Widely Used Insecticides on Birds*, concluded that it would take only six corn seeds coated with thiamethoxam to achieve a 50 percent chance of lethality (LD50) given sensitivity at the 5% tail of bird distribution, assuming an avian body weight of 50 g – somewhere between a large sparrow and a blue jay. Likewise only 0.3 (roughly a third) of a treated seed would be enough to impair reproduction. The possible synergism in treating seeds with a combination of thiamethoxam and cyantraniliprole remains to be seen.

Cyantraniliprole's systemic and persistent nature and its high toxicity to aquatic and terrestrial invertebrates raise red flags as well. Significant effects are likely at the lower rungs of the food chain, as has resulted from the neonicotinoids. These will likely cause harm to birds and other wildlife populations.

The degradates of cyantraniliprole are described as both mobile and persistent. EPA states that “given the uncertainty of the behavior and toxicity of these degradates, their toxicity is assumed to be equivalent to the parent compound, cyantraniliprole.”⁶⁰ Yet, the exposure characterization stated: “Based on degradate aerobic soil metabolism and mobility studies, six of the eight major degradates had longer dissipation half-life (DT50) values (more persistent) and three of the eight degradates were more mobile than the parent cyantraniliprole.”⁶¹ Thus, the assumption that the toxicity of the degradates is equivalent to that of the parent seems a leap of faith.

Mammals

Several potential risks to mammals were identified during the risk assessment. Many of the proposed uses have the potential to present chronic risks to mammalian species. Chronic risk quotients exceeded the chronic risk to mammals LOC of 1 for most

⁶⁰ *Id.* at 4.

⁶¹ *Id.* at 4.

proposed uses of cyantraniliprole.⁶² Species that rely on grasses, broadleaf plants, and insects for their diet are at a greater risk than those that primarily consume seeds, fruits, or pods. Some of the chronic effects identified included thyroid weight increase and other thyroid abnormalities. Offspring were affected by chronic exposure with declines in organ weight and overall pup body weight. These findings suggest that cyantraniliprole may affect a number of mammalian species adversely.

Aquatic Species

EPA's risk assessment does not preclude unreasonable adverse effect to many aquatic species from exposure to cyantraniliprole. Many of the studies relied upon by EPA to determine acute and chronic toxicity to aquatic species were deemed "supplemental" by the agency due to uncertainties, problematic study designs, and inconclusive findings.⁶³

To the contrary, the data strongly suggest that cyantraniliprole poses acute and chronic effects to a wide variety of aquatic species. As EPA points out in the risk assessment, "cyantraniliprole is ... moderately to highly toxic to estuarine/marine invertebrates, highly toxic to benthic invertebrates ... on an acute exposure basis."⁶⁴ EPA also found that "[c]hronic exposure resulted in effects on growth in freshwater invertebrates and estuarine/marine fish." EPA needs to review further data before the agency can determine that cyantraniliprole and its product formulations would not have unreasonable adverse effect on these species. As the agency acknowledges, there were no acceptable toxicity data to assess the risks to estuarine/marine invertebrates from chronic exposure to cyantraniliprole.⁶⁵ Similarly, EPA's risk assessment fails to adequately evaluate the acute effects of cyantraniliprole on aquatic invertebrates.⁶⁶

Aquatic invertebrates (freshwater, marine/estuarine, and benthic) may be subject to acute toxicity from cyantraniliprole applications. Cyantraniliprole-thiamethoxam formulated products were also more toxic than cyantraniliprole alone to freshwater aquatic invertebrates. An acute risk to benthic invertebrates was identified for one use, but about half of the proposed uses could present chronic risks. There was uncertainty in the risk assessment for marine/estuarine fish based on non-definitive data. This should be further assessed. Cyantraniliprole's proposed uses may cause adverse effects to a wide range of aquatic species, potentially including listed species.

Adverse Impacts of Cyantraniliprole Products Co-Formulated with Thiamethoxam

EPA's risk assessment also fails to adequately consider the harm stemming from thiamethoxam in the proposed products containing both cyantraniliprole and thiamethoxam. EPA acknowledges several times in its risk assessment that the

⁶² *Id.* at 130.

⁶³ *See, e.g., id.* at 58, 60-61.

⁶⁴ *Id.* at 57.

⁶⁵ EPA, Amended Risk Assessment, *supra* note 1, at 7.

⁶⁶ *Id.*

cyantraniliprole-thiamethoxam product present higher risk to honeybees, and are more acutely toxic to freshwater invertebrates and terrestrial invertebrates.⁶⁷ EPA also acknowledges that the agency lacked the appropriate field study to verify the risks to honey bees posed by cyantraniliprole-thiamethoxam co-formulations. As made clear in the attached Appendix A, EPA's ongoing registration review of thiamethoxam as well as significant new information on thiamethoxam and its toxicity clearly establish that the use of thiamethoxam has detrimental effect on honey bee mortality, is extremely harmful to invertebrates, birds and numerous sensitive species, and has resulted in significant economic losses in U.S. agriculture.⁶⁸ EPA must separately assess the risks stemming from the use of cyantraniliprole-thiamethoxam co-formulations before approving those product registrations.

II. EPA Failed to Consult with Expert Agencies Regarding the Potential Impacts on Federally Listed Species and Their Critical Habitats.

EPA cannot approve the proposed registrations of cyantraniliprole as a new active ingredient and cyantraniliprole-containing product formulations without first consulting with the expert fish and wildlife agencies as required under the ESA. Section 7 of the ESA requires that EPA consult with the expert agencies FWS and/or NMFS to “insure” that actions taken by the agency will not jeopardize the survival of federally listed species or destroy or adversely modify their designated critical habitats.⁶⁹ EPA's assessment of impacts to federally listed species concluded that all listed taxa may be indirectly affected and a number may be directly affected by cyantraniliprole application. As noted *supra*, the proposed product registrations of cyantraniliprole, if approved, will allow for cyantraniliprole products and cyantraniliprole-thiamethoxam products to be applied nationwide across a wide variety of crops, ornamental plants, turf-grass, and in and around various residential, commercial, and agricultural structures. Thus, the widespread application of cyantraniliprole poses substantial risks to threatened and endangered species and their critical habitats around the nation.

Yet, EPA makes no reference to any consultation with FWS and/or NMFS, which should be completed before approving cyantraniliprole, given its wide-ranging proposed applications. EPA's failure to consult is egregious given that direct impacts to threatened and endangered species were identified throughout the agency's risk assessment. As discussed *supra*, EPA's risk assessment found that cyantraniliprole is “slightly to moderately toxic to freshwater fish; slightly toxic to estuarine/marine fish; slightly to very highly toxic to freshwater invertebrates; highly to very highly toxic to terrestrial insects.”⁷⁰ EPA's risk assessment also found that buffers from applications could be necessary to adequately protect sensitive species (in this case terrestrial and freshwater invertebrates) from cyantraniliprole formulations and cyantraniliprole-thiamethoxam co-formulations.⁷¹

⁶⁷ *Id.* at 69, 76, 77, 82, 119, 141, 144, 147.

⁶⁸ *See* App. A.

⁶⁹ *See* 16 U.S.C. § 1536(a)(2); *see also* 50 C.F.R. § 402.01(b).

⁷⁰ EPA, Amended Risk Assessment, *supra* note 1, at 7.

⁷¹ *Id.* at 147.

EPA failed to consider or consult on the effects of the degradates of cyantraniliprole on listed species and their critical habitats. As stated previously, 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 they may be able to accumulate over time.⁷²

Nor did the agency consider or consult on the potential impacts to listed species and their designated habitats from the other ingredients in the proposed cyantraniliprole-containing end-use products, particularly harm to species and habitats from the co-formulations containing cyantraniliprole and thiamethoxam. Indeed, the proposed product labels do not even disclose what “other ingredients” are, only listing the percentages of cyantraniliprole (for products containing cyantraniliprole) or cyantraniliprole and thiamethoxam (for products containing both ingredients). Other ingredients in the proposed end-use product formulations may have adverse effects on listed species or their critical habitats. EPA’s failure to consider or consult on their impacts violates EPA’s duty under the ESA.⁷³

Finally, as previously noted, EPA entirely neglected to consider the cumulative and synergistic impacts of approving cyantraniliprole and its related products in light of the existing stress to protected species and critical habitats caused by already-approved uses of neonicotinoid pesticides. EPA’s failure to consider or consult on the cumulative impacts of these toxic chemicals violates EPA’s duty under the ESA.

EPA cannot approve the proposed registrations of the new active ingredient cyantraniliprole and its technical formulation and end-use products without first consulting the expert agencies on the potential impacts to listed species and designated habitat. EPA must consider potential impacts stemming from cyantraniliprole and its degradates, as well as the other ingredients in the proposed product formulations, including thiamethoxam and other unnamed ingredients, in order to effectuate congressional intent to protect threatened and endangered species and their critical habitats in enacting the ESA.

III. EPA Failed to Consider Adverse Effects on U.S. Agriculture.

EPA’s risk assessment and the studies and data examined therein strongly suggest that the use of cyantraniliprole would have adverse effects on honey bees and other terrestrial invertebrates, including native bees and other vital pollinator species whose existence is the backbone of the U.S. agricultural economy. As EPA is aware, honey bees are the most economically valuable pollinators of agricultural crops worldwide. Other important pollinating bee species include: common eastern bumble bee (*Bombus impatiens*), alkali bee (*Nomia melanderi*), blue orchard mason bee (*Osmia lignaria*), hornfaced bee (*O. cornifrons*), and alfalfa (or Lucerne) leafcutter bee (*Megachile*

⁷² *Id.* at 22-25.

⁷³ See *Washington Toxics Coalition v. U.S. Dept. of Interior*, 457 F. Supp. 2d 1158 (W.D. Wash 2006).

rotundata). Many other unmanaged native insects are also effective pollinators of crops and other plants.

In the U.S., pollination contributes to crop production worth \$20-30 billion in agricultural production annually. Indeed, about 90% of flowering plants require pollinators.⁷⁴ Bee pollination of agricultural crops accounts for about one-third of the U.S. diet, including a wide range of high-value fruits, vegetables, tree nuts, forage crops, field crops, and other specialty crops.⁷⁵ Meat, milk, and cheese production are also reliant on the pollinated crops that livestock eat, such as alfalfa.⁷⁶ Overall, pollinator-dependent crops make up almost one-third of total U.S. agricultural production.⁷⁷ Pollinators are also crucial pillars of non-crop plant health and survival generally, whether in horticulture or in nature.⁷⁸ Thus, it is clear healthy pollinators are essential to healthy food systems, healthy gardens, and healthy ecosystems.

Yet, over the past decade, honeybee colonies nationwide have suffered record annual losses of typically about 30% to upwards of 90% in worst case situations. Pesticides have recently been identified as a primary contributing factor in these alarming population losses. Introducing yet another systemic pesticide that is highly toxic to bee populations will only exacerbate these problems, contribute to the loss of beekeeper livelihoods, damage the agricultural economy, and threaten our nation's food security. Synergistic effects of cyantraniliprole and other stressors (additional pesticides, parasites, etc.) have also not been addressed. It is crucial to examine the realistic uses of cyantraniliprole and assess its impacts in light of the environmental stressors already faced by pollinator populations. Given the uncertainties and initial results that point to significant acute hazards, cyantraniliprole presents unreasonable adverse effects to bee species.

⁷⁴ See Janet N. Abramovitz, Putting a Value on Nature's "Free" Services, Worldwatch Institute (1998), available at www.worldwatch.org/system/files/EP111B.pdf.

⁷⁵ See May R. Berenbaum, Univ. of Ill., Statement Before the Subcomm. on Horticulture and Organic Agriculture, U.S. House of Reps., March 29, 2007, available at <http://agriculture.house.gov/testimony/110/h70329/Berenbaum.pdf>.

For example, a number of agricultural crops are almost totally (90%-100%) dependent on honey bee pollination, including almonds, apples, avocados, blueberries, cranberries, cherries, kiwi fruit, macadamia nuts, asparagus, broccoli, carrots, cauliflower, celery, cucumbers, onions, legume seeds, pumpkins, squash, and sunflowers. Other specialty crops also rely on honey bee pollination, but to a lesser degree. These crops include apricot, citrus (oranges, lemons, limes, grapefruit, tangerines, etc.), peaches, pears, nectarines, plums, grapes, brambleberries, strawberries, olives, melon (cantaloupe, watermelon, and honeydew), peanuts, cotton, soybeans, and sugar beets.

⁷⁶ See James R. Hagler et al., *Foraging Range of Honey Bees, Apis Mellifera, in Alfalfa Seed Production Fields*, 11 J. INSECT SCIENCE 1 (2011); Honey Industry Facts, Nat'l Honey Bd. (2011), available at www.honey.com/nhb/media/press-kit.

⁷⁷ Renée Johnson, Honey Bee Colony Collapse Disorder, Cong. Research Serv. Report for Congress, 7-5700, RL33938.

⁷⁸ See, e.g., J.C. Biesmeijer et al., *Parallel Declines in Pollinators and Insect-Pollinated Plants in Britain and the Netherlands*. 313 SCIENCE 351 (2006).

IV. The Proposed Labels Are Inadequate.

The proposed product labels for cyantraniliprole products are insufficient to ensure protection to human health and the environment.⁷⁹ Many of the studies relied upon by EPA in its risk assessment found adverse effects on honey bees beyond exposure to cyantraniliprole from direct application. For example, one study found “increased mortality [of bees] for two days after treatment and reduced foraging activity for one day after the application [of cyantraniliprole product.]”⁸⁰ Another study found that hive populations decreased dramatically after cyantraniliprole application.⁸¹ Yet, the proposed label change for end-use products containing cyantraniliprole only contains the directive “Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area,” without any directive to mitigate long-term effects of cyantraniliprole applications on honey bees, other terrestrial invertebrates, or other pollinators. The draft labels also do not contain adequate warning regarding the adverse effects to aquatic invertebrates or directions of use that would mitigate the risks posed by cyantraniliprole on terrestrial invertebrates, aquatic invertebrates, birds, and/or mammals, including federally listed species. In short, the current proposed labels fall short of the FIFRA requirement that a pesticide’s labeling “contain directions for use which . . . if complied with . . . are adequate to protect health and the environment.”⁸²

CONCLUSION

EPA’s proposed decision to unconditionally register cyantraniliprole as a new active ingredient in both a technical formulation and end-use product formulations for a wide range of uses violates EPA’s duties under FIFRA, the ESA, and the APA. EPA’s risk assessment of the proposed registration of cyantraniliprole as a new active ingredient and the proposed registrations of cyantraniliprole product formulations and cyantraniliprole-thiamethoxam co-formulations contains numerous uncertainties, data gaps, and flawed assumptions that fall short of fulfilling EPA’s duty to determine that the proposed registrations would not result in “unreasonable adverse effects on the environment” under FIFRA. To the contrary, EPA’s risk assessment is replete with findings that show that the approval of cyantraniliprole and its associated product formulations for a variety of uses nationwide will cause substantial harm to species and the environment. EPA also failed to consult the relevant expert agencies to ensure protection for the nation’s listed species and their critical habitats, in violation of the ESA. Finally, EPA completely neglected to consider the synergistic and cumulative impacts of registering yet another systemic pesticide ingredient, in violation of the APA.

EPA’s proposed registration decision is arbitrary and capricious, and is not supported by substantial evidence when considered on the record as a whole. EPA should go back to the drawing board, demand additional studies and further analysis, and

⁷⁹ 7 U.S.C. § 136(q)(1)(F).

⁸⁰ EPA, Amended Risk Assessment, *supra* note 1, at 70.

⁸¹ *Id.* at 71.

⁸² 7 U.S.C. § 136(q)(1)(F).

engage in the required Section 7 consultation process before the agency considers whether cyantraniliprole and its related product formulations can be registered.

Respectfully Submitted,

Center for Food Safety

American Bird Conservancy