



July 24, 2017

**Comments from Center for Food Safety on the
EPA's Preliminary Aquatic Risk Assessment to Support the
Registration Review of Imidacloprid, dated December 22, 2016**

Imidacloprid Docket ID: EPA-HQ-OPP-2008-0844
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The Center for Food Safety (CFS) is a nonprofit, membership organization with a mission to empower people, support farmers, and protect the earth from the harmful impacts of industrial agriculture. Through groundbreaking legal, scientific, and grassroots action, CFS protects and promotes the public's right to safe food and the environment. CFS has more than 900,000 consumer and farmer supporters across the United States. We are pleased to submit these comments on the Preliminary Aquatic Risk Assessment to Support the Registration Review of Imidacloprid (PARA).

Unacceptable Delays in the Registration Review Process

Imidacloprid's Registration Review process is far behind the schedule to which the agency formally committed. The "Preliminary Work Plan" for this Registration Review, issued in 2008, had a "2014– Jul-Sep" completion date.¹ It also had this statement (emphasis added): "After reviewing and responding to comments and data received in the docket during this initial comment period, the Agency will develop and **commit** to a final work plan and schedule for the registration review of imidacloprid." The current "Final Work Plan" was issued in 2010.² It has this statement in the schedule: "Final Decision and Begin Post-Decision Follow-up - 2016– Jan-Mar." The agency has failed to comply with its own commitment, with a likely completion date now at least two years later than scheduled. EPA must expedite completion of this process.

Noncompliance with the Endangered Species Act

EPA acknowledges the lack of Endangered Species Act (ESA) analysis or compliance stating (p. 119):

"Given that the agencies are continuing to develop and work toward implementation of the Interim Approaches to assess the potential risks of pesticides to listed species and their designated critical habitat, this ecological problem formulation supporting the Preliminary Work Plan for imidacloprid does not describe the specific ESA analysis, including effects determinations for specific listed species or designated critical habitat, to be conducted during registration review."

¹ <https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0844-0003>.

² July 23, 2010. Imidacloprid Amended Final Work Plan; <https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0844-0121>.

However, EPA's PARA, taken together with an extensive amount of independent science, underscores that the ongoing contamination of aquatic ecosystems with imidacloprid run-off is adversely affecting a large variety of aquatic species – which includes ESA-listed aquatic species. Illustrative examples of ESA-listed aquatic species known to be vulnerable to these harmful effects include, but are not limited to (indeed there are scores of others): Hines emerald dragonfly (*Somatochlora hineana*); Nashville crayfish (*Orconectes shoupi*); Salt Creek tiger beetle (*Cicindela nevadica lincolniiana*); and San Diego fairy shrimp (*Branchinecta sandiegonensis*).

It is essential that EPA act contemporaneously in this Registration Review risk analysis process to also include thorough analyses of foreseeable effects to ESA-listed aquatic species now. Under the ESA implementing regulation, 50 C.F.R. § 402.14(a), agencies must review their actions at the “earliest possible time.” EPA must not delay this ESA-mandated review or else it will be in violation of the law.³ Referencing alleged changes in the Interim Approaches document is not an excuse for non-compliance or for the extensive delays that have already occurred.

Harm to Aquatic Ecosystems and the Broader Environment

A growing number of studies show that North American waters are in jeopardy from continued contamination by neonicotinoid insecticides used widely for agricultural and outdoor uses. A 2016 U.S. Geological Survey (USGS) review of pesticide detections in streams across the Midwest found high concentrations of imidacloprid in 98% of the sites sampled.ⁱ Of all the insecticides tested, imidacloprid was detected at the highest concentrations, with numerous detections exceeding levels known to cause harm to aquatic invertebrates.ⁱⁱ This USGS review is part of a growing body of research that highlights the alarming levels of contamination exposed in national and regional monitoring data,ⁱⁱⁱ and builds on other reported detection frequencies such as: the 76% detection rate of one or more neonicotinoids in streams across the Midwest in 2013,^{iv} the 70% detection frequency of downstream samples in the southern Appalachians in 2012 and 2013,^v and an overall 63% detection rate in streams sampled across the United States.^{vi} EPA recognizes this research in the PARA and yet did not conclude that such vast contamination warranted immediate action to restrict uses. This clear failure to take immediate action is particularly concerning given that numerous analyses of peer-reviewed research have shown severe risk to aquatic ecosystems—most notably Sanchez-Bayo et al. 2016, which alarmingly concluded, “Negative impacts of neonicotinoids in aquatic environments are a reality” and continues, “Solutions must be found soon if we are to save the biodiversity not only of aquatic ecosystems, but all other ecosystems linked by the food web.”^{vii}

Potential Impacts to Human Health

Furthermore, new research is emerging about the potential public health risks that imidacloprid and other persistent neonicotinoid pesticides pose. A 2017 study from USGS and the University of Iowa, *Occurrence of Neonicotinoid Insecticides in Finished Drink Water and Fate During Drinking Water Treatment*, found imidacloprid, clothianidin, and thiamethoxam in 100% of samples taken from University of Iowa tap water.^{viii} The concentrations detected range from 0.00024 ppb to 0.0573 ppb. The report is the first peer reviewed study to examine neonicotinoid concentrations in finished drinking water. Although the study is limited to a small sampling area, the authors of the report conclude, “because of their pervasiveness in source waters, and persistence through treatment systems, neonicotinoids are likely present in other drinking water systems across the United States.” While this study is preliminary and did not expose any concentrations known to have direct impact on humans, a 2015 publication by National

³ The scope of agency actions triggering Section 7 duties is broad, including all activities or programs of any kind authorized, licensed, funded, or carried out by federal agencies, including activities directly or indirectly causing modifications to land, water, or air. 50 C.F.R. § 402.02 (definition of “action”). The potential “effects” of an action that an agency must consider are similarly broad, and include both “direct” and “indirect” effects of the action and all activities “interrelated or interdependent” with that action. Id.

Institute of Health called for further research on the chronic human health impacts of neonicotinoids.^{ix} Since there are currently no standards for neonicotinoids in drinking water in the United States, CFS encourages EPA to consider this route of exposure as a potential threat to human health and immediately conduct a full array of safety testing. Then, appropriate health-based restrictions on them may be needed.

Proposed Action to Phase-Out Uses of Imidacloprid in Canada

In deciding the fate of the continued use of imidacloprid and other neonicotinoid insecticides, EPA should also consider the actions proposed by Health Canada's Pest Management Regulatory Agency (PMRA). PMRA's 2016 re-evaluation of imidacloprid includes a wealth of data from both government and peer-reviewed research and concludes (emphasis added):

*“The environmental assessment showed that, in aquatic environments in Canada, **imidacloprid is being measured at levels that are harmful to aquatic insects.** These insects are an important part of the ecosystem, including as a food source for fish, birds and other animals. Based on currently available information, **the continued high volume use of imidacloprid in agricultural areas is not sustainable.**”^x*

Based on the documented exceedance of water quality thresholds and aquatic life benchmarks in monitoring data, PMRA proposed action necessary to protect aquatic ecosystems from imidacloprid and called for similar evaluations for other neonicotinoid insecticides. Specifically, PMRA proposed to “phase-out all the agricultural and a majority of other outdoor uses of imidacloprid over three to five years.”^{xi} EPA relied on data from the PMRA analysis in its PARA, yet no similar proposals were made to phase-out or even restrict uses of imidacloprid in the U.S. Given that EPA, PMRA, and California Department of Pesticide Regulation have been working together on the neonicotinoid registration reviews, CFS strongly urges EPA to propose similar actions to prevent continued damages to vulnerable ecosystems.

The following points address additional shortcomings in EPA's PARA. CFS encourages EPA to consider these shortcomings in its final review of imidacloprid:

1. Gross Underestimation of Seed Treatment Contamination and Risk

EPA's PARA analysis proposes the unrealistic assumption that neonicotinoid chemicals applied as coatings on seeds planted below two centimeters do not move into surface waters and therefore are low risk.^{xii} It is unacceptable that EPA's models do not account for lateral movement of these chemicals in soil and run-off. It is well documented that these chemicals move down into ground water—to assume they don't move laterally through surface soil (especially surface soil broken up by tillage) with precipitation is indefensible in view of numerous published reports showing that they do so.^{xiii}

Roughly 1,116,000 pounds of imidacloprid were used on crops in the United States between 2004 and 2013. Fifty-six percent of this usage was as seed coatings—and more specifically 36% was as a coating on soybeans.^{xiv} Ninety-four percent of agricultural use scenarios modeled (29 of 31) in the PARA identified acute risks to freshwater species. A majority of use scenarios were seed-coating applications—pointing to the considerable risk from this route of exposure.

The following graphic from the EPA PARA depicts the surface water contamination across the United States in relation to thresholds established for specific freshwater invertebrate species.^{xv} As shown, concentration levels of imidacloprid detected in various water bodies are routinely exceeding benchmarks known to cause harm to critical aquatic species (with some

storm event models showing nearly 100% exceedance). **EPA in the final ecological assessment should more accurately portray the harms caused by imidacloprid seed-coatings.**⁴

2. New Endpoints but No Mandates to Ensure High Water Quality

After analyzing aquatic toxicity research, international benchmarks, and available monitoring data, and conducting acute lab testing, EPA's PARA proposed new acute and chronic endpoints for imidacloprid for freshwater invertebrates. Prior to the Assessment, EPA's endpoints were exponentially higher than other regulatory and non-regulatory benchmarks from around the world.^{xvi} The new proposed endpoints of 0.39 ppb (acute) and 0.01 ppb (chronic) are not only more in line with the conclusions of PMRA, but they also are more consistent with the thresholds proposed by Morrissey et al., and discussed in CFS's 2015 *Water Hazard Report*. Yet, these endpoints have not been updated on EPA's Aquatic Life Benchmarks for Pesticide Registration website.⁵ Moreover, there is no mandate by which toxicity benchmarks are enforced. According to its website, EPA's Office of Water may use the "aquatic toxicity data to develop ambient water quality criteria that can be adopted by states and tribes to establish water quality standards under the Clean Water Act,"^{xvii} however there are no mandates to establish such standards. Given that current monitoring data shows exceedances of the proposed thresholds across the United States in various surface water bodies, **EPA should formally update proposed water quality standards.**

3. No Mention of Pesticide Synergies

EPA's PARA contains almost no mention of pesticide synergies and the particular threat of chemical combinations to aquatic ecosystems unable to escape continued exposure to multiple pesticide stressors. According to Morrissey et al. 2015, "neonicotinoids are known to be additively or synergistically toxic when they occur together or when combined with certain fungicides..."^{xviii} These combined "tank mixes" of pesticide formulations are patented and even encouraged by agrichemical companies for their increased toxicity. In fact, a 2016 Center for Biological Diversity analysis of recently approved products from major pesticide companies found that 69% of patent applications claimed or demonstrated synergistic action.^{xix} Additionally, when neonicotinoids were tested together for impacts on *Daphnia magna* species, a species known to be highly *tolerant* to neonicotinoid toxicity, the effects included notable impacts on reproduction, growth, and survival, in correlation to chemical synergism.^{xx} Due to the tendency for aquatic ecosystems to be contaminated by several neonicotinoid chemicals from a range of application sites as well as other chemicals present in surface water bodies, **EPA's final risk assessment should include the threat from combined exposure and synergistic effects of multiple pesticides.**

4. Limited Field Realistic Conditions and Lack of Evaluation of Sub-lethal Impacts to Ecosystem Functioning and Food Chains

The PARA addresses the lack of higher-tier data stating that the final risk assessment will include "*an independent review of mesocosm data,*" however this delay in analysis poses a significant risk to aquatic ecosystems. EPA, in its assessment of impacts to fish and aquatic phase amphibians notes:

⁴ Imidacloprid, Clothianidin, Thiamethoxam, Dinotefuran, Acetamiprid

⁵ Not updated as of July 11, 2017 <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/aquatic-life-benchmarks-pesticide-registration>

“While the risk of direct effects of imidacloprid to fish and amphibians is considered low, the potential exists for indirect risks to fish and aquatic-phase amphibians through reduction in their invertebrate prey base.”

A more thorough analysis of available peer-reviewed research will show that the indirect risks to fish and aquatic-phase amphibians are a reality and that the continued use of imidacloprid and other persistent neonicotinoid chemicals weakens the base of the food-web and is detrimental to entire watershed ecosystems—including birds. **If EPA continues to disregard the indirect but significant impacts, then the repercussions will extend far beyond the aquatic invertebrate prey base.**

5. Ignores Risks to Non-aquatic Species

Initially intended to be a complete ecological risk assessment of imidacloprid, EPA justified its decision to only include aquatic risks, stating:

“... a substantial body of aquatic monitoring and toxicity data have been generated for imidacloprid since the Agency’s last comprehensive risk assessment was conducted. In contrast, very little new data have been generated on the toxicity of imidacloprid to birds and mammals since the Agency’s most recent ecological risk assessments.”

This is an underestimation of the research that has emerged showing risks to non-aquatic species—particularly birds, which are impacted by the use of neonicotinoid chemicals as shown in the findings of the comprehensive Palmer and Mineau report, *The Impact of the Nation’s Most Widely Used Insecticides on Birds*, as well as substantial other journal-published bird research. It also is a setback in finalizing the registration review and initiating regulatory action on these environmental contaminants.^{xxi} **Rather than wait on the full ecological risk assessment, EPA should recognize the risks to aquatic species as well as the interconnection of aquatic and terrestrial environments and immediately restrict uses of imidacloprid to prevent these harms.**

6. Strong Evidence of Risk, Yet No Regulatory Action

EPA concluded in its PARA (emphasis added):

*“It is evident, however that **concentrations of imidacloprid** detected in streams, rivers, lakes and drainage canals **routinely exceed acute and chronic toxicity endpoints** derived for freshwater invertebrates.”*

Again, based on the substantial impacts to aquatic invertebrates, including ESA-protected species, happening on a wide-scale by registered uses, it is clear that EPA needs to take immediate action to restrict uses of imidacloprid and other neonicotinoid insecticides to prevent further damage to ecosystem services.

Furthermore, EPA identifies that:

“...the risk findings summarized in this assessment are in general agreement with recent findings published by Canada’s Pest Management Regulatory Agency and the European Food Safety Authority.”

EPA should follow PMRA's example in proposing a prompt full phase-out of imidacloprid for agricultural and outdoor uses. PMRA recognizes that due to imidacloprid's persistence and water solubility, regional restrictions will not be sufficient in mitigating risks. **EPA needs to enforce strong action now to prevent continued, potentially irreparable, damages to vulnerable species and ecosystems.**

Due to the reasons above, as well as those outlined in detail in the attached two reports, which are incorporated into this comment by reference, *Water Hazard 2.0: Continued Aquatic Contamination by Neonicotinoid Insecticides in the United States (2017)* and *Water Hazard: Aquatic Contamination by Neonicotinoid Insecticides in the United States (2015)*, CFS urges EPA to take action to immediately restrict uses of imidacloprid to prevent further adverse impacts to aquatic ecosystems, pollinators, other vulnerable species, and the broader environment.

Recommendations to EPA

The agency should:

- 1. Expedite completion of the final risk assessment and the overall Registration Review for Imidacloprid, which is now at least two and likely three years behind the schedule to which EPA had committed.**
- 2. Conduct full ESA Sec. 7 compliance now, contemporaneous with the risk assessments in the Registration Review process, rather than afterwards, which would violate the ESA.**
- 3. In the final risk assessment, more accurately portray the risk posed by seed-coatings and include a thorough field-realistic analysis of imidacloprid seed-coatings to aquatic systems.**
- 4. Update its water quality benchmarks for imidacloprid using the newly proposed thresholds referenced in this comment.**
- 5. In the final risk assessment, include a comprehensive examination of the threats from additive and synergistic effects of combined exposure of imidacloprid and multiple other pesticides, fungicides, inerts and other compounds.**
- 6. Include higher-tier and mesocosm analyses to fully determine the risk to fish, amphibian, and bird species.**
- 7. Immediately enforce strong action to restrict uses of imidacloprid and other neonicotinoid insecticides to prevent continued, potentially irreparable, damages to vulnerable aquatic ecosystems.**

CC: California Department of Pesticide Regulation

Attachments –*Water Hazard 2.0: Continued Aquatic Contamination by Neonicotinoid Insecticides in the United States (2017)*; *Water Hazard: Aquatic Contamination by Neonicotinoid Insecticides in the United States (2015)*

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