



NATURAL RESOURCES DEFENSE COUNCIL

January 5, 2016

**Comments from the Natural Resources Defense Council (NRDC) Supporting the NIEHS Office of Health Assessment and Translation (OHAT) Review of Neonicotinoid Pesticides. (80 FR 60692; October 7, 2015)**

*Neonicotinoid pesticides: imidacloprid, thiamethoxam, clothianidin, acetamiprid, thiacloprid, dinotefuran, and nitenpyram. More information [online](#)*

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Dear NIEHS-OHAT Staff,

We strongly support a scientific review of the hazards of the neonicotinoid pesticides by the NIEHS Office of Health Assessment and Translation (OHAT). The OHAT is very well placed to conduct this review, having expertise in many relevant scientific disciplines including carcinogenesis and endocrine disruption.

While there are a number of factors contributing to the dramatic die-off of bees - both honey bees and native bees - there is now a wealth of science that demonstrates that pesticides are a big part of the problem. In particular, the increasing use of a class of highly bee-toxic neonicotinoid pesticides (neonics) are linked to impaired bee health, making it more difficult for the colony to breed, to fight off disease and pathogens, and to survive winter. What makes neonics so harmful to bees is that they are systemic – meaning they poison the whole treated plant, including the nectar and pollen that bees eat – and they are persistent, lasting months or even years in the plant, soil, and waterways. Traditional best management practices for bee protection, such as not spraying during the day or on bloom, doesn't work for neonics. For these reasons, NRDC submitted a petition to EPA in 2014 asking for an urgent review of neonics, supported by signatures of nearly 275 thousand NRDC members (for ecosystem and biodiversity impacts see [van der Sluijs et al 2014](#); [Pisa et al 2014](#)).

Now there are data linking neonics in milkweed to adverse impacts on the iconic Monarch butterfly, whose population has declined precipitously within the past two decades. Monarchs lay all their eggs exclusively on milkweed – it is the only food source for the larvae. When ingested by the newly born larvae, milkweed makes them toxic to predators. Now data shows that neonics such as clothianidin in milkweed plants can be toxic to Monarch larvae. Sublethal effects that impede normal development of monarchs are observed even at low levels that can be found in milkweed growing adjacent to neonic-treated fields ([Pecenka and Lundgren 2015](#)).

And, it's not just the impacts to invertebrates that the public is concerned about. There are potential adverse impacts to mammalian wildlife and people.

There is disturbing evidence that these neonics are making their way into our food and water supply. A study by the [U.S. Geological Survey](#) found that neonics are widespread contaminants of surface and groundwater that could be a source of drinking water. In nine rivers monitored in the Midwest, where neonics are most heavily used, the study found clothianidin in about three-quarters of monitored sites, thiamethoxam in about one-half, and imidacloprid in about one-quarter. [Limited testing](#) by the USDA has found neonics in fruits and vegetables, where the pesticide's systemic nature means it cannot just be washed off the surface of these foods prior to consumption.

The presence of neonics in food and water raises concerns about their potential health effects on people. Results from animal studies are not reassuring. Animal studies report neurobehavioral impairments in rodents that were exposed to imidacloprid prenatally, from a single high-dose injection of the pesticide to the pregnant rat (337 mg/kg at day 9 of pregnancy) ([Abou-Donia et al 2008](#)). In fact, a study by the German [chemical giant Bayer](#), a major neonic maker, reported similar findings in rats born to mothers that received daily doses of imidacloprid in their food throughout pregnancy and lactation (55-58 mg/kg/day). [EPA reviewers](#) concluded that the treatment produced persistent changes in brain structures and poor performance on some behavioral tests.

Even more alarming, a [study by NIH-funded researchers](#) from UNC Chapel Hill and UC Davis reported that frequent exposure (self-reported by parents) to imidacloprid applied as flea and tick treatments for pets (Advantage by Bayer) during pregnancy was associated with Autism spectrum disorder (OR 2.0, 95% CI 1.0-3.9) in prenatally-exposed children ([Keil et al 2014](#)). While the study is limited by the potential for exposure misclassification and by the small number of cases that were exposed, it is consistent with effects reported for other related pesticides, and highlights the need for more study (see [Roberts et al 2007](#) and [Eskenazi et al 2007](#) for health impacts from organophosphate pesticides, which share a similar mechanism of toxicity to the neonics).

Laboratory tests with cell cultures and rodents led the European Food Safety Authority (EFSA) to [categorize two neonics](#) – imidacloprid and acetamiprid – as possibly impairing the developing human nervous system.

For these reasons, NRDC contracted ToxServices to conduct a hazard screen for imidacloprid, thiamethoxam, and clothianidin. We chose these three neonics for the first screens because of their widespread use, high toxicity, and implications for ecological harm. The chemical hazard assessments were conducted following the GreenScreen® for Safer Chemicals (GreenScreen) method. We chose GreenScreen because of its widespread acceptance by governments, industry, and non-governmental organizations alike. GreenScreen integrates aspects of EPA's Design for Environment Alternatives Assessment (DfE) and the Globally Harmonized System (GHS) of Classification and Labelling of Chemicals. GreenScreen is routinely used by governments and industry, including IBM, Hewlett-Packard, and EPA's Design for the Environment (DfE) program. GreenScreen is also increasingly being incorporated into environmental scorecards and standards- for example, the assessments are now acceptable for earning [LEED v4](#) credits and [Cradle-to-Cradle®](#) certification, and used by the State of California to screen chemicals in its [Safer Consumer Products](#) program.

Following the GreenScreen method, ToxServices staff provided reports for each of the three neonic pesticides. Each report is attached, and a summary is provided below. The hazard benchmark acronyms, in alphabetical order, are:

(AA) Acute Aquatic Toxicity	(IrS) Skin Irritation/Corrosivity
(AT) Acute Mammalian Toxicity	(M) Mutagenicity and Genotoxicity
(B) Bioaccumulation	(N) Neurotoxicity
(C) Carcinogenicity	(P) Persistence
(CA) Chronic Aquatic Toxicity	(R) Reproductive Toxicity
(D) Developmental Toxicity	(Rx) Reactivity
(E) Endocrine Activity	(SnS) Sensitization- Skin
(F) Flammability	(SnR) Sensitization- Respiratory
(IrE) Eye Irritation/Corrosivity	(ST) Systemic/Organ Toxicity

Note: Hazard levels (Very High (vH), High (H), Moderate (M), Low (L), Very Low (vL)) in italics reflect estimated (modeled) values, authoritative B lists, screening lists, weak analogues, and lower confidence. Hazard levels in BOLD font are used with good quality data, authoritative A lists, or strong analogues. Group II Human Health endpoints differ from Group II\* Human Health endpoints in that they have four hazard scores (i.e., vH, H, M, and L) instead of three (i.e., H, M, and L), and are based on single exposures instead of repeated exposures.

### GreenScreen<sup>®</sup> Hazard Ratings for Imidacloprid

Group I Human						Group II and II* Human								Ecotox				Fate		Physical	
C	M	R	D	E	AT	ST		N		SnS*	SnR*	IrS	IrE	AA	CA	ATV	AFI	P	B	Rx	F
						single	repeated*	single	repeated*												
<i>M</i>	<i>L</i>	<i>M</i>	<i>M</i>	<i>M</i>	<i>H</i>	<b>vH</b>	<b>M</b>	<b>vH</b>	<b>H</b>	<b>L</b>	<b>DG</b>	<b>L</b>	<b>L</b>	<b>vH</b>	<b>vH</b>	<b>H</b>	<b>H</b>	<b>vH</b>	<b>vL</b>	<b>L</b>	<b>L</b>

### GreenScreen<sup>®</sup> Hazard Ratings for Thiamethoxam

Group I Human						Group II and II* Human								Ecotox				Fate		Physical	
C	M	R	D	E	AT	ST		N		SnS*	SnR*	IrS	IrE	AA	CA	ATV	AFI	P	B	Rx	F
						single	repeated*	single	repeated*												
<b>L</b>	<b>L</b>	<i>M</i>	<i>M</i>	<b>DG</b>	<b>M</b>	<b>L</b>	<b>M</b>	<b>H</b>	<b>L</b>	<b>L</b>	<b>DG</b>	<b>L</b>	<b>L</b>	<b>vH</b>	<i>L</i>	<b>L</b>	<b>H</b>	<b>vH</b>	<b>vL</b>	<b>L</b>	<b>L</b>

### GreenScreen<sup>®</sup> Hazard Ratings for Clothianidin

Group I Human						Group II and II* Human								Ecotox				Fate		Physical	
C	M	R	D	E	AT	ST		N		SnS*	SnR*	IrS	IrE	AA	CA	ATV	AFI	P	B	Rx	F
						single	repeated*	single	repeated*												
<b>M</b>	<b>L</b>	<i>M</i>	<i>M</i>	<i>M</i>	<b>M</b>	<b>H</b>	<b>M</b>	<b>vH</b>	<b>H</b>	<b>L</b>	<b>DG</b>	<b>L</b>	<b>L</b>	<b>vH</b>	<b>vH</b>	<b>M</b>	<b>H</b>	<b>vH</b>	<b>vL</b>	<b>L</b>	<b>L</b>

In contrast to EPA's hazard assessment, which relied exclusively on industry-sponsored data for its hazard determinations, the GreenScreen reports include both industry data and also scientific studies from the published literature. Of relevance to OHAT, the results of the GreenScreen hazard review identified potential hazards for the following human health endpoints: cancer (C), reproductive harm (R), developmental harm (D), and potential endocrine disruption (E). These human health hazards lead to the ranking of all three neonics as a Benchmark 1 chemical, which is a GreenScreen Chemical of High Concern to be avoided.

For thiamethoxam, EPA dismissed evidence of cancer based on an industry-supplied study of a proposed mechanism that was purportedly not relevant to humans, resulting in EPA changing its original classification for thiamethoxam from "likely" to "not likely" carcinogenic in humans (EPA 2000; EPA 2012). Dr. Melnick, retired career NIEHS scientist, warned that serious public health consequences may follow if chemicals are misclassified as less toxic or non-toxic based on untested mechanistic hypotheses, poorly validated tests, or incomplete data sets "Declaring a chemical as not hazardous, or reducing a level of health protection, should require validation, not speculation" (Melnick et al 2003).

Also, please note that the GreenScreens identified neurotoxicity as an adverse outcome of neonic exposure, which is relevant to developmental toxicity since neurotoxic agents can have much more severe and long-lasting adverse impacts when exposures take place during early life developmental stages.

The full GreenScreen reports are included as attachments to this letter. We hope that OHAT will conduct the much-needed hazard assessments of the neonicotinoid pesticides. The public deserves a higher level of transparency and scientific accountability than the EPA pesticide office can provide. We look forward to OHAT's assessment.

Sincerely,

A handwritten signature in black ink that reads "Jennifer Sass". The signature is written in a cursive style with a large initial "J" and a long, sweeping underline.

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