



THE CENTER FOR FOOD SAFETY

May 27, 2014

OPP Docket
Environmental Protection Agency Docket Center
1200 Pennsylvania Ave. NW.
Washington, DC 20460-0001
Submitted online at: www.regulations.gov

Re: Pesticide Product Registration; Applications for New Uses, EPA HQ-OPP-2014-0011; FRL-9907-63

Greetings,

This letter of comment with respect to the above-referenced Notice (79 Fed. Reg. 22963, Apr. 25, 2014) is submitted on behalf of the Center for Food Safety (CFS). With over one-half million members nationwide, CFS is a 501(c)(3) nonprofit organization that addresses the impacts of our current industrial food production system on human health, animal welfare, and the environment.

CFS is commenting here only on the first of the Registration Applications in the Notice, which is Syngenta Crop Protection's proposal to register several new foliar uses for three products: 1) **Thiamethoxam Technical**, reg. no. 100-936; 2) **Endigo ZC**, reg. no. 100-1276; and 3) **Endigo ZCX**, reg. no. 100-1458. The new uses are on: **alfalfa; corn (field, pop, seed, sweet); legumes; rice; small cereal grains (barley, buckwheat, oats, rye, triticale, wheat); and sunflower.**

Please take notice that the first two of the three products already are in jeopardy as far as the legality of their prior registrations as explained in litigation against EPA led by CFS, four beekeepers and several non-profit groups, Ellis v. Bradbury.¹ Thiamethoxam Technical and Endigo ZC are included in Claim Six of the Plaintiffs' Second Amended Complaint filed on May 9, 2014, alleging violation of Section 7 of the Endangered Species Act (ESA). That violation also will extend to use of all three of the products on all of the proposed new uses, unless there has been full and adequate ESA Section 7 analysis and consultation for those new uses in the interim.

The scope of the ESA Section 7 violation is explained more below. **These products should not be approved until that legal jeopardy is adequately resolved and the nation's threatened and endangered species are ensured their required protections.**

¹ U.S District Court for the Northern District of California, San Francisco Division, Case No.: 3:13-cv-01266-MMC

We also note that EPA's publishing these "new use" applications in the Federal Register is commendable because it is a change of course from EPA's prior practice of failing to publish required new use notices as is detailed in Claim Four of the Ellis v. Bradbury Second Amended Complaint. EPA's prior failures include earlier new uses of the two of the same products involved here, Endigo ZC and ZCX, on pecan, pome fruit, stone fruit, tobacco, tree nuts, tuberous and corm vegetables, and perhaps other new uses as well. EPA is urged to ensure it has published required Federal Register notices for all new uses of these and all other thiamethoxam products.

We would also, as a preliminary matter, note that the neonicotinoid clothianidin is a transformation product of thiamethoxam.² In honeybees, thiamethoxam is metabolized into clothianidin. In short, the two are closely related chemically with comparable applications, toxicity and effects. Risk information for clothianidin should be considered also in assessing the risks of thiamethoxam, which indeed has been EPA's practice in some past risk assessments. CFS has submitted extensive information in many prior comments to EPA on the risks of both clothianidin and thiamethoxam and EPA is again urged to consider that information.³

Key Points in EPA's Thiamethoxam Records

EPA's Registration Review process for thiamethoxam recognizes that, now 14 years after it first approved uses of this compound, the agency still lacks vital information about its environmental effects. The "Thiamethoxam Final Work Plan" admits the environmental fate database is "only partially fulfilled and several ecological effects data gaps were also identified."⁴ It then lists at least 25 tests, studies and other data requirements that must be fulfilled, including such basic information as:

- 850.2100 – Avian oral toxicity with a passerine*
- 850.3030 - Honey bee toxicity of residues on foliage study*
- 850.3040 – Field test for pollinators*
- 850.1735 – Whole sediment acute toxicity invertebrates, freshwater*
- Special Study – Larval toxicity study (honey bee)*
- Special Study – Residues, pollen and nectar*
- Special Study – Laboratory (chronic) pollinator feeding study (honey bee)*

EPA admits to many other major data gaps, including some involving health risks to mammals. It is incomprehensible that the agency believes it can continue to propose major new uses every year, as it has done in the above-referenced Notice, in the face of 25 major gaps in the fundamental effects

² CFS, together with a coalition of 25 other beekeepers and other groups, submitted an Emergency Petition to EPA to suspend the registration of clothianidin on March 20, 2012 (Docket No. EPA-HQ-OPP-2012-0334). We followed that Petition with two supplemental filings that provided new information prior to the opening of the public comment docket, and then with three comments to that docket. Virtually all of the documents we have filed with respect to the various risks of clothianidin also apply to the risks of the very similar insecticide, thiamethoxam, which is the active ingredient in the three products at issue here. In honeybees, thiamethoxam is metabolized into clothianidin. Krupke CH, Hunt GJ, Eitzer BD, Andino G, Given K. 2012. Multiple routes of pesticide exposure for honey bees living near agricultural fields, *7 PLoS ONE* 1, e29268. doi:10.1371/journal.one.0029268 .

³ Petition, other supporting materials and related public comments are in Public Docket No. EPA-HQ-OPP-2012-0344 : *Clothianidin*; created pursuant to this Notice: *Emergency Petition to Suspend; Notice of Availability*, 77 Fed. Reg. 44,233 (July 27, 2012); see also CFS et al. letter, "Comment and Notice – Risks of Insecticide Thiamethoxam" sent to Steven Bradbury, EPA, on October 16, 2012.

⁴ EPA, Thiamethoxam Final Work Plan for Registration Review, June 2012, *available at* <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0581-0024>.

information. As with clothianidin, no accepted field study exists showing thiamethoxam's impacts on pollinators, which provide key services to a vast number of agricultural crops and to horticultural and native plants. The minimum level of knowledge to protect honey bees and other beneficial insects from the risks of the proposed new uses is not in place.

In addition to the massive gaps EPA acknowledged in its Registration Review process, numerous risk assessments, internal memoranda and other agency documents obtained via the Freedom of Information Act reveal the risks of thiamethoxam. For example, the *Ecological Risk Assessment for the Proposed New Use of Thiamethoxam as a Seed Treatment for Alfalfa*, (dated Dec. 28, 2010; lead author: Anita Ullagadi; p. 3), states (emphasis added):

EFED assumes risk to non-target beneficial arthropods, including pollinators such as bees, due to exposure to translocated thiamethoxam residues, including its degradate clothianidin, in pollen and nectar as a result of the proposed seed treatment. Pollinator field study data have previously been requested to reduce uncertainties and to better characterize potential effects (including sublethal ones) and the translocation ability of the chemical within tissues of the crop. Two field studies have been received and were reviewed since the previous assessment but do not satisfy data requirements.

Alfalfa is one of the crops Syngenta is proposing new foliar uses for now. The risks to “non-target beneficial arthropods” from seed treatment of alfalfa cited above likely extend to foliar applications as well. Four years after the EFED statement, above, there still is no satisfactory pollinator field study for thiamethoxam and there is still no compliance with this critical “core” condition imposed by EPA on the thiamethoxam conditional registrations back in the early 2000s.

EPA's treatment of the field test condition to determine the risks to honey bees has resembled a theatre of the absurd for thiamethoxam's prior registrations. On June 20, 2012, the agency issued a conditional registration to Syngenta Crop Protection for “CruiserMaxx Vibrance **Cereals**”.⁵ Page 2 of the approval document states:

d. Field Test for Pollinators (test guideline 850 3040) An acceptable study must be submitted or cited no later than the time this study is required to be submitted or cited for current thiamethoxam registrations.

This is an unlawfully vague condition because it neither sets nor refers to any real time limit. EPA's lax approach is compounded by the fact that it has allowed “*the time this study is required to be submitted or cited for current thiamethoxam registrations*” to drag out for five years or more with no definite date for completion, as it has with the identical clothianidin pollinator field test “condition”. **As cereal grains are included in Syngenta's new proposed uses, clearly there must be a full “acceptable study” prior to approving any new uses for these crops, as was the case for the CruiserMaxx Vibrance Cereals registration.**

⁵ EPA, Notice of Pesticide Registration, June 20, 2012, available at http://www.epa.gov/pesticides/chem_search/ppls/000100-01383-20120620.pdf

Thiamethoxam's risks are not limited to honey bees. The following remarkable admissions are from EPA's *Ecological Risk Assessment for the Section 3 New Use Registration of Thiamethoxam on Citrus Fruits and Tree Nuts* (dated Sep. 11, 2008; lead author: Sujatha Sankula; p. 47):

3.1 Direct and Indirect Effects

The current assessment suggests that the proposed use of thiamethoxam on citrus fruits and tree nuts poses potential for direct adverse effects on freshwater invertebrates, birds, and mammals. The concerns for adverse impacts of thiamethoxam on the above species were supported by thiamethoxam's mode of action, available laboratory toxicology data, and risk quotient calculations. Table 29 presents the number of listed species in various states of the United States on which direct and indirect effects are expected to occur from the proposed new thiamethoxam uses.

In view of the sensitivity of aquatic invertebrates, birds, and mammals to thiamethoxam, direct impact of its use would be loss of the above species due to impacts on reproduction and mortality. The loss of these species will result in structural and functional changes of both the aquatic and terrestrial ecosystems. Importantly, changes will be manifested in the form of disruption of food chain and reduced biodiversity.

Aquatic invertebrate communities play a critical role as an important food source for aquatic vertebrates such as fish and other fauna. Prolonged exposure to thiamethoxam and associated disruption of aquatic communities may have the potential to impact growth, reproduction, and abundance of both freshwater and estuarine/marine fish. However, this risk assessment cannot quantify the extent to which invertebrate community effects would impact aquatic vertebrates through food source impairment.

Biodiversity or species diversity ensures that ecosystems survive through the flows of energy. A change in the life of one species, especially through extinction, could ripple throughout an ecosystem, changing the life for many other species. Through these ripple effects, the loss of above species is likely to cause indirect effects such as loss of productivity and stability leading to multiple complex imbalances in ecosystems they thrive in. For example, if invertebrates are lost in a particular ecosystem, insect larvae and fish that feed on invertebrates will be affected first. Negative impacts on fish and insect larvae trigger indirect food web-related effects on higher-level organisms such as big fish, birds, and amphibians.

The "Table 29" in that document indicates there are 100s of Federally-listed threatened and endangered species occurrences in States with the proposed uses of thiamethoxam in which direct or indirect effects are foreseeable. The same concerns exist with foliar applications to the many proposed crops involved here. Yet, there is no indication EPA undertook the required Section 7 consultation with the U.S. Fish and Wildlife Service (FWS) under the ESA for the uses proposed here (see ESA section of comment below).

New Science Specific to Thiamethoxam

In 2012, Henry et al. published essential new information that EPA has failed to obtain earlier from the neonicotinoid product registrants themselves.⁶ Feeding of honey bees with thiamethoxam at field-realistic dosing was shown to cause high mortality due to homing failure at levels that could put a colony at risk of collapse. Despite severe questioning by Bayer CropScience and others, both independent and European Food Safety Agency reviews have since confirmed the thiamethoxam doses in the Henry et al. study were field-relevant.

Extensive new published science specific to thiamethoxam's risks has arisen in the last two years, beyond the information CFS and others have submitted previously in formal comments. EPA must review this new risk information, including, but not limited to, these expert overviews, which include information on thiamethoxam:

- a) Goulson, D. 2013. An overview of the environmental risks posed by neonicotinoid insecticides. *Journal of Applied Ecology*, 50:977-987.
- b) van der Sluijs, JP, N Simon-Delso, D Goulson, L Maxim, J-M Bonmatin, and LP Belzunces. 2013. Neonicotinoids, bee disorders and the sustainability of pollinator services. *Current Opinion in Environmental Sustainability*, 5(3-4): 293-305.
- c) Hopwood, J, SH Black, M Vaughn, and E Lee-Mader. 2013. *Beyond the Birds and the Bees: Effects of Neonicotinoid Insecticides on Agriculturally Important Beneficial Invertebrates*. Report by the Xerces Society, Portland, OR.⁷

Following is a non-exhaustive list of other new studies describing thiamethoxam's risks published since the above overviews. EPA must review these also and undertake additional research on the risks to ensure it has considered all current information prior to deciding on the proposed new uses in the Notice:

- 1) Fauser-Misslin, A, BM Sadd, P Neumann, and C Sandrock. 2014. Influence of combined pesticide and parasite exposure on bumblebee colony traits in the laboratory. *Journal of Applied Ecology*, 51:450–459. doi: 10.1111/1365-2664.12188.
- 2) Sanchez-Bayo F, and K Goka. 2014. Pesticide Residues and Bees—A Risk Assessment, *PLoS ONE* 9(4): e94482. doi: 10.1371/journal.pone.0094482.
- 3) Sandrock, C, LG Tanadini, JS Pettis, JC Biesmeijer, SG Potts, and P Neumann. 2014. Sublethal neonicotinoid insecticide exposure reduces solitary bee reproductive success, *Agricultural and Forest Entomology*, 16:119-128. doi: 10:1111/afe.12041.

⁶ Henry M, Beguin M, Requier F, Rollin O, Odoux J-F, Aupinel P, Aptel J, Tchamitchian S, Decourtye A. 2012. A common pesticide [thiamethoxam] decreases foraging success and survival in honey bees. *Scienceexpress* 1215039.

⁷ Online at: http://www.xerces.org/wp-content/uploads/2013/09/XercesSociety_CBCneonics_sep2013.pdf .

Failure to Comply with the Endangered Species Act

As indicated, it appears EPA has failed to comply with the ESA Section 7 in issuing the proposed new use approvals for all three products as issue. The basic problems are:

1) It appears that EPA has violated Section 7 of the ESA by failing to: a) ensure, in consultation with the U.S. Fish and Wildlife Service (FWS) and National Marine Fisheries Service (NMFS), that the proposed uses of thiamethoxam would not be likely to jeopardize the continued existence of any threatened or endangered species or result in the destruction or adverse modification of the critical habitat of such species; b) request from FWS and NMFS information on whether any threatened or endangered species, or designated critical habitat, may be present within or near the areas of the proposed uses; c) prepare, at the earliest possible time, a biological assessment to determine whether any threatened and endangered species may be affected by the proposed uses or the agency's changes from the conditional classification for those uses; d) engage in consultation with FWS and NMFS regarding the potential adverse effects of thiamethoxam on threatened and endangered species and critical habitat; and e) ensure that the agency, registrants, and users of thiamethoxam products would not make any irreversible or irretrievable commitment of resources with respect to the sale and use of these compounds prior to EPA initiating and completing consultation with FWS. EPA's Section 7 failures appear to be occurring despite clear evidence in the agency's own risk assessment documents that EPA's actions would adversely affect particular listed species and posed a risk to broad suites of listed species. It appears that approving the proposed products would constitute a violation of the ESA within the meaning of 16 U.S.C. § 1540(g).

2) More than fifteen threatened or endangered insects, including, but not limited to, plant pollinators, ranging from beetles to butterflies to grasshoppers and other taxa, would be potentially directly affected by the nationwide approval and use of the proposed thiamethoxam products. By way of illustration, these species include, but are not limited to (followed by their listing dates):

American burying beetle (<i>Nicrophorus americanus</i>)	07/13/1989
Behren's fritillary (<i>Speyeria zerene behrensii</i>)	12/05/1997
Callippe silverspot (<i>Speyeria callippe callippe</i>)	12/05/1997
Delhi Sands flower-loving fly (<i>Rhaphiomidas terminatus abdominalis</i>)	09/23/1993
Fender's blue (<i>Icaricia icarioides fenderi</i>)	01/25/2000
Hine's emerald dragonfly (<i>Somatochlora hineana</i>)	01/26/1995
Karner blue (<i>Plebejus melissa samuelis</i>)	12/14/1992
Kern primrose sphinx moth (<i>Euproserpinus euterpe</i>)	04/08/1980
Lange's metalmark (<i>Apodemia mormo langei</i>)	06/01/1976
Mitchell's satyr butterfly (<i>Neonympha mitchellii mitchellii</i>)	05/20/1992
Myrtle's silverspot (<i>Speyeria zerene myrtleae</i>)	06/22/1992
Northeastern beach tiger beetle (<i>Cicindela dorsalis dorsalis</i>)	08/07/1990
Ohlone tiger beetle (<i>Cicindela ohlone</i>)	10/03/2001
Quino checkerspot butterfly (<i>Euphydryas editha</i>)	01/16/1997

<i>quino</i>) Salt Creek tiger beetle (<i>Cicindela nevadica lincolniana</i>)	10/06/2005
San Bruno elfin (<i>Callophrys mossii bayensis</i>)	06/01/1976
Schaus swallowtail (<i>Papilio aristodemus ponceanus</i>)	listed as threatened 4/22/1975; as endangered 8/31/1984
Zayante band-winged grasshopper (<i>Trimerotropis infantilis</i>)	01/24/1997

More insect species are regularly listed and numerous “Candidate” species, including native bees, await further action.

3) Scientific information on the impacts of thiamethoxam on invertebrates, birds, and ecosystems compels ESA § 7 effects determinations and consultation with the FWS and NMFS. Such information includes, but is by no means limited to, the March 2013 report by the American Bird Conservancy, which shows high direct and indirect mortality risks to a broad suite of birds from thiamethoxam products.⁸ The report was researched and coauthored by Pierre Mineau, PhD, a renowned Canadian avian toxicologist.

Four of the proposed new foliar uses are on **corn** (field, pop, seed, sweet). The evidence before EPA is clear on the risks of corn use to birds listed under the ESA. Direct and indirect effects on at least these ESA-protected species are foreseeable: **whooping crane** (*Grus Americana*); **Mississippi sandhill crane** (*Grus canadensis pulla*); **Attwater’s prairie chicken** (*Tympanuchus cupido attwateri*) and the **southwestern willow flycatcher** (*Empidonax traillii extimus*). (This list is illustrative and not exhaustive.) These effects relate primarily to ingestion of treated corn and other crops but also, especially in the case of the flycatcher, to other indirect effects from reduction of insect and invertebrate populations those species rely on.

a) The **Mississippi sandhill crane** is a non-migratory listed subspecies of the sandhill crane that once was found along much of the central Gulf Coast but now only nests on a USFWS refuge, established in 1975 in Jackson County, SE Mississippi. The refuge consists of open pine savannah habitat interspersed with bay heads and marshes. Grain crops, e.g. winter **wheat** (one of the crop uses proposed here) are planted specifically for the use of the birds. Sandhill cranes (the species at large) are known to be highly attracted to agricultural fields generally and corn seedlings specifically. Indeed, they have entered into conflict with corn growers in areas where they are more abundant. Individuals of the Mississippi subspecies are known to leave the refuge and forage in farmland areas north of the refuge. Their exact whereabouts outside of the protected area are not known but might include privately held cornfields although the number of these appears to have been declining. Based on 1985-1989 NASS data, there were between 800 to 1200 acres planted to corn in Jackson County.⁹ Lack of more recent data suggests that corn is not as important as other crops in that county.

⁸ Mineau P and C Palmer, Am. Bird Conservancy, *The Impact of the Nation’s Most Widely Used Insecticides on Birds* (Mar. 2013), available at http://www.abcbirds.org/abcprograms/policy/toxins/Neonic_FINAL.pdf.

⁹ NASS Quick Stats Ad-Hoc Query Tool, accessed 16 July 2013.

http://quickstats.nass.usda.gov/?long_desc_LIKE=corn+jackson+county+mississippi&x=44&y=9#A3C5500E-6A91-3133-ACB5-9137906C2158 .

Nevertheless, exposure of cranes to thiamethoxam-treated corn, wheat and other crops could expose them to a direct risk. The cranes also frequent aquatic habitats where they feed on aquatic life such as amphibians. These wetland areas could potentially receive runoff from agricultural areas. Runoff containing thiamethoxam could reduce aquatic resources used by the cranes.

- b) The **whooping crane** is another listed species that could be affected. Historically, there would have been broad overlap between the breeding area of whooping cranes and agriculturally-intensive areas. Currently, the only naturally occurring breeding population is in Wood Buffalo National Park in Canada but several re-introduction projects are underway and the breeding range of the species is expanding. The birds winter on the Gulf Coast, notably in the Aransas National Wildlife Refuge (ANWR) in Texas. The birds depart from their wintering grounds between 25 March and 15 April with last birds leaving by May 1. Most of the birds are on breeding grounds by late April. Spring migration lasts 2-4 weeks. Although exposure to freshly planted corn fields is possible if the birds land on agricultural fields on migration, spring migration is rapid and does not involve lengthy staging in agricultural areas as it does in the fall. Fall migration begins mid-September with most birds arriving on wintering grounds late October to mid-November with some straggling in until late December. The largest time on fall migration is spent on harvested grain fields – especially in Saskatchewan, Canada. According to the 2006 recovery plan for the species, “Known staging areas and potential breeding wetlands on the prairies could be negatively impacted by drought, drainage, cattle grazing, contaminated runoff, or other disturbances associated with agricultural activities.”¹⁰ The persistence of thiamethoxam would ensure that birds foraging in treated fields could still receive some exposure.
- c) Only three small breeding areas of **Attwater’s prairie chicken** (APC) still exist given that only 1% of their habitat, the coastal prairie grasslands of Texas and Louisiana remains. Historically, they ranged over much of the Gulf Coast from SW Louisiana to Brownsville, Texas. The critical habitat that is left is surrounded by agricultural lands. An example is the current Austin-Colorado county priority management zone straddling the San Bernard River, a mosaic of grasslands and cropland.¹¹ The birds prefer moderately grazed or burned grasslands but they do obtain some food and cover from surrounding cultivated lands. It is reasonable to conclude that APC would be attracted to corn. NASS has recent survey data (2012) for two of the three counties where naturally occurring populations of APCs persist: Colorado and Goliad counties. In 2012, there were 11,500 and 4,000 acres planted in corn in these two counties respectively.¹² Given the pervasive nature of systemic insecticides such as thiamethoxam, it is likely that terrestrial invertebrate resources will be in decline in and around corn and other crop fields treated with these compounds. To the extent that crop fields contribute to the invertebrate biomass needed by developing APC chicks, it is plausible to infer possible injury from thiamethoxam treatments through this mechanism also.

¹⁰ Canadian Wildlife Service and U.S. Fish and Wildlife Service. 2007. International recovery plan for the whooping crane. Ottawa: Recovery of Nationally Endangered Wildlife (RENEW), and U.S. Fish and Wildlife Service, Albuquerque, New Mexico. 162 pp.

¹¹ U.S. Fish and Wildlife Service. 2010. Attwater’s Prairie-Chicken Recovery Plan, Second Revision. Albuquerque, New Mexico.

¹² NASS Quick Stats Ad-Hoc Query Tool, accessed 16 July 2013.

- d) The **Southwestern willow flycatcher** (SWF) is a listed sub-species of the willow flycatcher broadly distributed throughout the SW United States including southern California, Nevada and Utah, Arizona, New Mexico, Western Texas and SW Colorado. It is a riverine specialist which targets seasonal hatchings of aquatic invertebrates. As such, it foreseeably could be affected by reduction in aquatic emergent insects that are known to be impacted by neonicotinoid insecticides in runoff.¹³ The proximity of SWF habitat and agricultural crop areas in the Southwest is very clear.

Again, these four birds are illustrative and not intended as an exhaustive affected species list. The FWS must be consulted under the ESA to determine the appropriate full list and regarding effects to all of them.

We note also that EPA already has indicated its intent to fully assess the effects of past-approved neonicotinoid insecticides, such as thiamethoxam, under ESA Section 7. That was directly stated in the agency's Response to Public Comments with respect to the Proposed Registration of the New Active Ingredient Cyantraniliprole, date Jan. 24, 2014, in which EPA stated (emphasis added):¹⁴

*It is important to note that the Agency is focusing most of its resources for assessing impacts to listed species on the Agency's registration review program for currently registered pesticides. EPA believes that, as a general matter, currently registered pesticides present a greater degree of risk to listed species than most new chemistries coming to market, including cyantraniliprole, and that it is therefore environmentally preferable in most circumstances for EPA to assess the impacts of existing pesticides sooner in the process than newer pesticides that are designed to compete with more risky alternatives. EPA believes that is especially true for cyantraniliprole, where the alternatives include, organophosphates, carbonates, **neonicotinoids**, and pyrethroids.*

That statement is an inadequate (indeed, unlawful) justification for not conducting the required ESA Sec. 7 analysis for cyantraniliprole. However, it is a commendable recognition that EPA still must fully assess the risks and effects of the neonicotinoid thiamethoxam under the ESA, as the agency admits it has not accomplished, at least as of the date of that Response to Public Comments document.

- 4) Additionally, recently published water quality studies have indicated that neonicotinoid insecticide pollution occurring in surface waters has a strong negative effect on aquatic invertebrate life, with potentially far-reaching consequences for the food chain and ecosystem

¹³ Van Dijk T.C., Van Staaldouin M.A., Van der Sluijs J.P. 2013. Macro-Invertebrate Decline in Surface Water Polluted with Imidacloprid. PLoS ONE 8(5): e62374. doi:10.1371/journal.pone.0062374

¹⁴ 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 p. 40. Docket #: EPA-HQ-OPP-2011-0668-0058.

functions, including, but not limited to, ESA-listed species.¹⁵ EPA’s review of the proposed thiamethoxam products must also consider these threats.

Labeling Defects Associated with Thiamethoxam Products

An examination of several current thiamethoxam product labels indicates that the new warnings about “Pollinator Protection” for these foliar products generally are inadequate. The Aug. 15, 2013, letter from Steven Bradbury to all registrants of foliar use nitroguanidine neonicotinoid products imposed the requirements, but it clear now that the agency’s label revisions have not met the threshold of providing adequate warnings and use directions to protect honey bees and other pollinators.

The inadequacies of the new foliar use *Pollinator Protection Box*, warnings and use directions include at least the following with respect to the agricultural crops involved in the above Notice:

- 1) This new label language was developed to replace undefined, ambiguous and therefore unenforceable, old label language. Not one term in the new *Pollinator Protection Box* is defined, which leaves key language ambiguous and still unenforceable.
- 2) Lack of adequate warnings with respect to the systemic nature of thiamethoxam applications compounds that are expressed in the nectar and pollen of treated plants. Therefore, it is not safe to use on plants which express either pollen or nectar (most plants). Not one of the five conditions for allowable use even when bees are foraging and/or flowers are in bloom takes into account the insecticide’s systemic mode of action.
- 3) Lack of adequate warnings regarding thiamethoxam’s persistence in soil, dust, water and surrounding vegetation through successive plantings, which then can harm pollinators and other beneficial species. The Box language fails to mention bioaccumulation in woody tissue plants, brush, trees, and perennial plants, allowing for re-expression for several years.
- 4) Inconsistent use of the *Pollinator Protection Box* on current foliar product labels and conflicts between the language in the Box and other label contents. There are clear indications that enforcement officials in the State-FIFRA Issues Research and Evaluation Group are confused on how to resolve the conflicts and they believe that the new foliar labels actually provide less protection to pollinators than do other pre-existing label warnings and use directions.¹⁶ This is completely unacceptable and contrary to EPA’s widely-touted claims that the new labels are more protective than the old labels.
- 5) Inadequate protections from the time-of-day (“*after sunset*”) and temperature (“*below 55° F*”) guidelines in view of known activity of bees during those conditions when EPA incorrectly suggests bees are never active. It is known that bees will forage at temperatures as low as 45° F.

¹⁵ Huseth AS, Groves RL. 2014. Environmental fate of soil applied neonicotinoid insecticides [thiamethoxam] in an irrigated potato agroecosystem. *PLoS ONE* 9(5): e97081. doi:10.1371/journal.pone.0097081, see other contamination papers cited therein.

¹⁶Ambrosio, P. 2014. Regulators see potential label conflicts with instructions on neonicotinoid use. *BNA Daily Environment Report* May 13 under Pesticides header.

- 6) Excessive vagueness and inadequate protections for honey bees and the environment from allowance for thiamethoxam spraying despite the presence of bees and/or blooming plants “*when an application is made due to an imminent threat of significant crop loss.*” Determining that “threat” is entirely left to farmers who plainly will view that as a broad exception.
- 7) Beekeepers can be compelled to move or cover their bees from spraying on 48 hours’ notice, which is completely impractical in many contexts. Bees range many miles and full notice to owners of all potentially impacted colonies is undefined and likely to be evaded by many farmers. It is essential to have clear standards for what constitutes adequate notice or else that term will cause repeated farmer/beekeeper conflicts. Insufficient registry programs exist in a large number of States to implement this requirement effectively.
- 8) Requiring beekeepers to move their colonies to protect them violates the beekeepers’ rights to protection from toxic spray drift and may not be possible for many colonies.
- 9) In the *Pollinator Protection Box*, the requirement merely to “minimize” exposure of the product to bees and minimize off-site implies that some exposure to bees or drift is allowable. “Minimize” is too weak and should be replaced with a stronger mandate to “**Avoid**” such exposures and off-site drift.
- 10) The Box says not to apply the product “*until all petals have fallen off*”. That is not meaningful for many crops, including the **sunflower** use proposed in the Notice here, as the petals of such crops do not fall completely off.
- 11) Flowering, bee-attracting, weeds may be interspersed with the crops, even if the latter are not flowering. The Box language is inadequate in that it does not restrict spraying when such weeds are flowering in the crop fields or margins when bees are present.
- 12) There is no protection whatsoever for non-honey bee pollinators and other beneficial species, including potentially ESA-protected species, through the allowance of spraying after giving 48 hours’ notice to beekeepers or other through any other measures in the Box.
- 13) Failure to advise or adequately warn against surface and groundwater contamination risks, including, but not limited to, the newly discovered exposure pathway of continual recycling of thiamethoxam-contaminated water in sprayed irrigation water.¹⁷
- 14) The suggested Best Management Practices in the form of referring applicators to so-called “pesticide stewardship” websites are voluntary and in meaningless in effect. Further, those stewardship websites are heavily influenced by the views of the pesticide industry. EPA should not be relying on them and steering farmers to websites of the regulated companies.

This is not an exhaustive analysis of all the “new label” defects as EPA has not indicated precisely what language would be applied to the proposed uses in the Notice. **In any event EPA cannot reasonably approve the proposed new foliar products with the expectation that the risks can be mitigated by the “Pollinator Protection” label language** approved in Dr. Bradbury’s Aug. 15, 2013, letter.

¹⁷ Huseth and Groves. 2014. footnote 15, *supra*.

To summarize, EPA must objectively and fully assess the risks of these proposed new uses of thiamethoxam. Reliance on label language enforcement would not afford adequate “risk management” even if such enforcement occurred in any systematic way, which it does not. Further, we cannot overstate the fact that CFS’ position is that EPA no longer has statutory authorization under Federal law to maintain the conditional or unconditional registrations of any thiamethoxam products because of the outstanding data requirements, including, but not limited to, a pollinator field test, and the failure to comply with the ESA.

Further, given the state of independent, peer-reviewed, scientific research on risks to honey bees and the broader environment, EPA could not reasonably determine that proposed new uses for thiamethoxam will not have unreasonable adverse effects.

Please contact me at 202.547.9359; email: pjenkins@icta.org, if you have any questions regarding this comment.

Sincerely,

/s/

Peter T. Jenkins, Attorney/Consultant
Center for Food Safety

CC: Mark Dyner, EPA Office of General Counsel (via email)