



THE CENTER FOR FOOD SAFETY

October 16, 2012

Steven P. Bradbury, PhD.
Director, Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave. NW.,
Washington, DC 20460-0001

FEDERAL EXPRESS

Re: comment and notice - risks of insecticide thiamethoxam

Dear Dr. Bradbury,

This letter of comment and notice is **on behalf of the Center for Food Safety, the International Center for Technology Assessment, Beyond Pesticides** and **Steve Ellis**, a Minnesota and California beekeeper who owns and operates the Old Mill Honey Company. Together with a coalition of 25 other beekeepers and other groups, we 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 very similar insecticide, thiamethoxam. The former is a transformation product of the latter. In honeybees, thiamethoxam is metabolized into clothianidin.¹ In short, the two are closely related chemically with comparable applications, toxicity and effects.

According to EPA records, there are 77 active, approved uses of thiamethoxam and 12 pending uses (these totals may need updating with more current internal information). Thiamethoxam is the other major neonicotinoid insecticide in use as a crop seed treatment besides clothianidin.

Key Points in EPA's Thiamethoxam Records

EPA's Registration Review process for thiamethoxam recognizes that, 12 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." It then lists at least 25 tests, studies and other data requirements that must be fulfilled, including such basic information as:

¹ 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.

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 allow the 77 active uses and approve several new uses every year, as it has done, in the face of 25 major gaps in its fundamental effects 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 is not in place.

EPA must suspend the pesticide's registrations until these gaps are no longer so extensive. It cannot reasonably wait until the Registration Review process is complete in 2018 (per EPA's current schedule) before making a decision on the appropriateness of thiamethoxam's registration.

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 (FOIA) reveal the risks of thiamethoxam and that EPA views them as closely tied to the risk assessment process for clothianidin. For example, the *Ecological Risk Assessment for the Proposed Rate Increase of Thiamethoxam as a Seed Treatment and Foliar Spray for Cotton* (dated May 2, 2011; lead author: Anita Ullagadi) includes several sections assessing the risks of clothianidin as a degradate of thiamethoxam, with impacts generally predicted in relation to the amount of the degradate that results after application, noting the two compounds have "similar toxicity" (p. 16). The document recognizes the risks of contaminated dust associated with treated seeds in terms of honey bee kills are basically equivalent (p. 3).

Similarly, 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:

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.

Two years after that EFED statement there still are no satisfactory field studies for either clothianidin or thiamethoxam and still no compliance with this critical “core” condition imposed by EPA on their registrations long ago.

EPA’s treatment of this field test condition for clothianidin and thiamethoxam’s registrations has lately resembled a theatre of the absurd. On June 20, 2012, the agency issued a conditional registration to Syngenta Crop Protection for “CruiserMaxx Vibrance Cereals”. 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”.

Thiamethoxam’s risks are not limited to honeybees. 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. Yet, there is no indication EPA undertook the required Section 7 consultation with the U.S. Fish and Wildlife Service under the Endangered Species Act. That is unlawful.

New Science Specific to Thiamethoxam

Just in 2012, critical new science specific to thiamethoxam has arisen, beyond the information we and others have submitted in support of the Petition to suspend clothianidin’s registration. Henry et al. published essential new reports on the type of in-depth, controlled pollinator field tests that EPA has failed to obtain earlier from the neonicotinoid product registrants themselves.² 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. That study, as well as other new science developments and bee kill incidents, led the Agriculture Ministry in France to suspend its prior approval of thiamethoxam products as seed treatments on oilseed crops, on June 24 of this year.³ The Ministry did so notwithstanding detailed submissions by Syngenta arguing against the suspension. A subsequent court challenge by Syngenta to this Ministry decision also failed.

EPA also should note new science indicating the difficulty of obtaining lab results confirming the presence of thiamethoxam inside live or dead contaminated bees, especially as it is clearly true that many U.S. bee kill investigations do not occur in a timely way (if they occur at all; they are the exception rather than the rule). The report of a very recent study by Tapparo, Giorio et al. 2012, states:⁴

A[] current study in which our analytical method has been successfully applied deals with degradation mechanisms of neonicotinoids after uptake by bees. In this respect, it is worth noting that spring mortality was often hard to associate with neonicotinoid contamination, mainly because bees found dead in the field or close to the hive exhibited

² Henry M, Beguin M, Requier F, Rollin O, Odoux J-F, Aupinel P, Aptel J, Tchamitchian S, Decourtye A. 2012. A common pesticide decreases foraging success and survival in honey bees. *Scienceexpress* 1215039.

³ Official Gazette No 0172 of 26 July 2012, p. 12 246, Order of 24 July 2012 on the prohibition of use and placing on the market for use in the national territory of seeds of oilseed crucifers treated with plant protection products containing thiamethoxam NOR: AGRG1230159A . Online at: www.legifrance.gouv.fr/affichTexte.do;jsessionid=B6BA3FD207F4511CFC5DE479AD94C239.tpdjo08v_2?cidTexte=JORFTEXT000026223233&dateTexte=20120814

⁴ Tapparo A, Giorio C, Soldà L, et al. 2012. UHPLC-DAD method for the determination of neonicotinoid insecticides in single bees and its relevance in honeybee colony loss investigations. *Anal Bioanal Chem* DOI 10.1007/s00216-012-6338-3.

very low concentrations of these insecticides (see, e.g., the bee deaths that occurred in Italy in spring 2008). As is commonly the case, the sampling analysis procedure was done some days after the bees had died. Our hypothesis was that a metabolic degradation of the insecticide could significantly affect its real concentration. The first laboratory tests (250–500 ng of thiamethoxam, in alcoholic solutions or adsorbed in talc particles was deposited on the bee tegument) showed a real degradation, which was more rapid when the bees were alive but was also significant after they had died.

The authors conclude that their study shows:

... new evidence on the rapid metabolic pathway which occurs in bees after acute exposure to these insecticides could explain the remarkable lack of insecticides often detected in bees collected in the field some days after their death.

The point is that when bee kills occur during the Spring when thiamethoxam and clothianidin-treated seeds are being planted across the nation, in areas where no other pesticides typically are being used, and the kill patterns fit classic pesticide bee poisoning, it would be arbitrary and capricious to ignore such kills due to a lack of definitive lab results, as often can be the case.

Recent U.S. and Canadian Bee Kills Caused by Thiamethoxam

Each time over the last seven months that we have written a petition or comment to EPA touching on the topic of U.S. and Canadian bee kills in 2012, we must increase the totals because new incidents come to light. EPA generally relies on the agency's Ecological Incident Information System (EIIS), which contains only a small number of thiamethoxam-associated bee kills. However, it is well accepted across numerous stakeholders that the EIIS does a very poor job of collecting comprehensive national bee kill incident data. In contrast, Canada's PRMA reporting system is well-regarded. Here's an illustration: EPA's Response Letter (July 17, 2012) to the Emergency Petition to suspend the registration of clothianidin states with respect to the EIIS (p. 9; emphasis added):

We are, however, aware of 14 additional incidents occurring in the U.S. in 2012 that are not yet present in the database and approximately 120 additional incidents reported in Canada.

Extensive media and non-EIIS reports make clear that both Canadian and U.S. beekeepers suffered vast numbers of Spring 2012 bee kills due to the contaminated dust/talc exposure route associated with thiamethoxam and clothianidin-treated corn planting. A recent EPA response to a FOIA request from the Center for Food Safety established that the 2012 U.S. bee kill incidents in the agency's files likely associated with neonicotinoid seed treatments totaled about 18 incidents with more than 2,100 colonies impacted. However, it is not plausible that 120 documented bee kill incidents associated with neonicotinoid seed treatments, involving several thousand bee colonies, occurred in Canada's relatively small corn planting area - mostly in southwestern Ontario and some in Quebec - but according to EPA's records only 18 additional bee kill incidents occurred in the entire United States across its orders-of-magnitude larger corn areas. The seed treatment products, machinery used and environmental conditions

do not change dramatically at the U.S./Canadian border. What changes is the reliability of the kill reporting systems.

Now new information has come to light showing that there were more than 200 bee kills in Ontario alone (Paul Kozak, Ontario Provincial Apiarist, pers. comm.), as well as another 100-plus from Quebec (Valérie Fournier, Ph.D., Université Laval, pers. comm.). These total over **300 reports** – almost triple the number that EPA admitted in its July 17 letter, above. They do not all have test lab confirmation, but that likely is due to the slow pace of testing and the rapid degradation of these compounds in dead bees.

In short, EPA's lack of thiamethoxam-caused bee kill incident data in the EIIS is a product of information collection failures, not reality. The reasonable extrapolation from the 300-plus incidents in just two Canadian provinces associated with neonicotinoid seed treatments, in combination with the other available information about extensive additional U.S. bee kills in press accounts and other reports, is that a vastly greater number of similar incidents – likely also in the 100s - actually occurred in the United States in 2012. In short, strong evidence exists that thiamethoxam is responsible for major beekeeper losses and economic and personal harm to them.

Steve Ellis's Recent Bee Kill

Steve Ellis of Old Mill Honey Company, a beekeeper signed onto this letter, suffered a major kill in May in Minnesota impacting 1,346 hives. The result was severe economic harm and a draining personal commitment on his part to address and resolve the damage it caused.

According to EPA's own records of the incident, obtained through FOIA, "*It is probable that clothianidin and thiamethoxam alone or in combination resulted in the beekill*". (EIIS Report I023967-001; pp. 2-3). This is typical of many such incidents associated with Spring planting of treated corn seed. Clear indication exists that those two seed treatment compounds were the cause, but retrospective analysis cannot resolve which one was the lead factor. The corn seed involved was labeled as "Pioneer variety P9630AM1," but it remains unclear why both thiamethoxam and clothianidin were in the treatment product, suggesting irregularities in its labeling and use.

This is consistent with findings in the major study of neonicotinoid dust, Krupke et al. 2012, which found "*both clothianidin and thiamethoxam were present on dead bees and in pollen collected from a single hive.*"⁵ In terms of real world risks to beekeepers, thiamethoxam and clothianidin are basically inseparable especially when used simultaneously. This is particularly aggravated by their rapid degradation in dead bees, such as those of Mr. Ellis, resulting in their escape from detection in many laboratory tests (see discussion of Tapparo, Giorio et al., 2012, above).

Labeling Defects Associated with Thiamethoxam Products

Our Emergency Petition on clothianidin spelled out the defects in its labeling; the exact same arguments apply to thiamethoxam, whose various use product labels correspond to clothianidin's. In addition, an examination of several recent thiamethoxam product labels indicates the warnings about bee hazards generally, and on minimizing harm from the contaminated dust/talc exposure route, are inconsistent

⁵ Krupke et al., supra, fn 1.

across various seed treatment products. It is arbitrary and capricious for EPA to rely on inconsistent labels that don't adequately warn of thiamethoxam's risks.

To summarize, EPA has not acted to date as an objective and competent "referee" of the risks of thiamethoxam. The agency has created an almost out-of-control situation where beekeepers are repeatedly and predictably harmed. Reliance on label enforcement would not afford them adequate protection even if such enforcement occurred in any systematic way, which it does not. EPA no longer has statutory authorization to maintain the registration of thiamethoxam because of the outstanding data. By its own terms FIFRA does not allow conditional registrations to go on indefinitely. A conditional registration may only last for a period "reasonably sufficient" to generate the outstanding data necessary for unconditional registration. That period has long passed, 12 years after thiamethoxam was registered. Further, EPA has by its own frequent admissions not determined and, given the state of independent peer-reviewed scientific research, it could not reasonably determine, that thiamethoxam will not have unreasonable adverse effects if the estimated 77 active registrations are allowed to continue.

Both thiamethoxam and clothianidin already were included in the Endangered Species Act Sixty Day Notice Letter indicating our intent to sue your agency over violations of that Act, which we sent to Administrator Jackson on Sept. 6, 2012. You are additionally on notice that failure by EPA to take action promptly to suspend the registration of thiamethoxam products, as per the clothianidin Petition, until the agency complies with FIFRA, as far as ensuring the conditional registration and labeling requirements are met, may result in administrative litigation. However, we remain hopeful that the agency will take precautionary action on its own without litigation.

Please contact Peter T. Jenkins at 202.547.9359; email: pjenkins@icta.org, if you have any questions or would like to meet personally to discuss these points.

Sincerely,

/s/

Peter T. Jenkins, Attorney/Consultant
Center for Food Safety and International Center for Technology Assessment

ALSO ON BEHALF OF:

Jay Feldman, Executive Director, Beyond Pesticides
Steve Ellis, Owner, Old Mill Honey Co.

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