



THE CENTER FOR FOOD SAFETY

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Rick P. Keigwin, Jr.
Deputy Office Director for Programs
U.S. Environmental Protection Agency
Ariel Rios Building, MC 1101A
1200 Pennsylvania Ave. NW
Washington, D.C. 20004
Via 1st Class Mail and email: keigwin.richard@epa.gov

Re: Whole Colony Studies – Clothianidin and Thiamethoxam – Registration Reviews

Dear Mr. Keigwin,

The **Center for Food Safety**, together with **Beyond Toxics, Central Maryland Beekeepers, Environment America, Kansas Rural Center, Maryland Pesticide Education Network, Pesticide Action Network, Pesticide Research Institute, Pollinate Minnesota** and the **Pollinator Stewardship Council**, offer these comments with respect to the ongoing risk assessment process for the Registration Reviews for two of the neonicotinoid insecticides, Clothianidin and Thiamethoxam (respectively, Reg. Review No. 7620, Docket No. EPA-HQ-OPP-2011-0865; and Reg. Review No. 7614, EPA-HQ-OPP-2011-0581).

In particular, we critique the two whole colony feeding studies submitted by the registrants, Bayer CropScience and Syngenta Crop Protection, respectively. We obtained copies of the study reports through a Freedom of Information Act request. **EPA should reject these studies as inadequate and order that they be re-done.** Until re-done, they could not serve as the basis for the Registration Reviews or other EPA decisions with respect to the safety of these compounds for honey bees.

I. The Bayer whole colony study for Clothianidin was inadequate and should be re-done.¹

- a) The Bayer clothianidin study is not robust and should be re-done as the findings are based on just one North Carolina test area over a winter with very high mortality in almost all hives (treated and control). The very high mortality indicates the experiment followed substandard beekeeping practices that should not be accepted by EPA for this critical study. The goal of robust findings regarding possible overwintering chronic effects was defeated by the abnormally high mortality in the control hives that masked possible comparative effects in the treated hives that may appear under more typical overwintering mortality.

¹ *Colony feeding study evaluating the chronic effects of clothianidin-fortified sugar diet on honey bee (Apis mellifera) colony health under free foraging conditions - Final Report* - by Jessica Louque, for Bayer CropScience, Study ID No. 13798.4143. EPA date stamped 2-11-16.

- b) The exposure model excluded any consideration of effects from exposure to pollen and contaminated dust, air, guttation fluid or marginal vegetation to which honey bees are normally exposed. Thus, the exposure model was unrealistic.
- c) There is no accounting for any other synergistic effects to which honey bees are normally exposed. Single active ingredients were used, whereas in field exposures synergized mixes are the rule. See a recent seminal review paper on this, Sanchez-Bayo et al. 2016. “Are bee diseases linked to pesticides? – A brief review”.² A major new report by the Center for Biological Diversity also addresses aspects of the synergy concern, *Toxic Concoctions: How the EPA Ignores the Dangers of Pesticide Cocktails*.³ The revelations of synergistic effects related to several specific clothianidin products therein should be addressed in the whole colony study for clothianidin.
- d) The experiment length was inadequate. It was too short to detect chronic effects that weaken bee colonies. Honey bee experts generally agree that a study for less than one year is inadequate to detect chronic effects.
- e) The feeding regime only lasted 6 weeks (from June to August), which is not long enough to assess bees' normal foraging activities in North Carolina, where bees likely could forage from March to October.
- f) The researchers did not describe post-mortem observations for the dead hives in detail. When a dead hive was observed, were dead bees found at the bottom of the hive - or simply disappeared? It is critical to differentiate hives that died from exposure from hives that may have died from other causes, such as Varroa mite. The report did not adequately mention Varroa mite baseline data to be able to assess whether the mites contributed to hive mortalities.
- g) On p. 29, the author lists several “deviations,” but with inadequate explanations to indicate whether they constituted serious errors. The explanation suggests there were effects on the study, which are not fully explained.
- h) On pp. 35-36, figs. 6 through 8, there are colony strength reductions noted at 10 and 20 ppb, but they are statistically discounted. The explanation in the report is too sparse to conclude that those colony strength reductions did not lead to long-term effects, particularly given the short length of the study.

² Sanchez-Bayo, F., Goulson, D. Pennacchio, F., Na Koichi Goka, F., Desneux, N., 2016. Are bee diseases linked to pesticides?—A brief review. *Environment International*. 89-90:7-11

³ Donley, N. 2016. *Toxic Concoctions - How the EPA Ignores the Dangers of Pesticide Cocktails*. Unpublished report, Center for Biological Diversity, Tucson, AZ. Online at: http://www.biologicaldiversity.org/campaigns/pesticides_reduction/pdfs/Toxic_concoctions.pdf.

- i) On p. 40, regarding the data about Nosema and the Varroa mite, the report appears to signify there was no correlation between the presence of those pathogens/parasites and hive mortality regardless of treatment regimen. However, that issue is not adequately analyzed so as to be meaningful. More analysis is needed.
- j) The study lacked analysis of chronic effects on queens. As the only fertile female in the hive, effects on her are critical to understanding viability and productivity of the colony. Queens should have been marked and egg production should have been measured, as well as long-term brood viability. Superseding of the queen by neonicotinoid stressors and other related effects are now well-documented in several studies published in 2016.⁴ However, those effects were not addressed in this study.
- k) Finally, the whole colony feeding study suggests a NOAEL of 20 ppb. EPA should review other studies and incident reports that have indicated some clothianidin crop applications result in exposures that exceed that NOAEL. If the Bayer Clothianidin study were to be accepted as valid notwithstanding all of the defects outlined above, its findings would indicate that this active ingredient poses unacceptable risks to honey bees in those crop applications. Product registrations allowing those applications should be suspended.

II. The Syngenta whole colony study for Thiamethoxam was inadequate and should be re-done.⁵

- l) The Syngenta thiamethoxam study is not robust and should be re-done as the findings are based on just one North Carolina test area over a winter with extreme mortality in almost all hives (treated and control). The authors admitted this (p. 16; emphasis added): “**The low and uneven distributed number of surviving colonies does not allow any scientifically based conclusion about treatment-related overwintering success.**” The extreme mortality in almost all hives indicates the experiment followed substandard beekeeping practices that should not be accepted by EPA for this critical study.

⁴ Dussaubat, C, A Maisonnasse, D Crauser, S Tchamitchian, M Bonnet, M Cousin, A Kretzschmar, JL Brunet, and Y Le Conte. 2016. Combined neonicotinoid pesticide and parasite stress alter honeybee queens’ physiology and survival. *Scientific Reports*, 6: 31430; DOI: 10.1038/srep31430; Straub, L, L Villamar-Bouza, S Bruckner, P Chantawannakul, L Gauthier, K Khongphinitbunjong, G Retschnig, A Troxler, B Vidondo, P Neumann, and GR Williams. 2016. Neonicotinoid insecticides can serve as inadvertent insect contraceptives. *Proceedings of the Royal Society B*, 283(1835): 20160506; Wu-Smart, J and M Spivak. 2016. Sub-lethal effects of dietary neonicotinoid insecticide exposure on honey bee queen fecundity and colony development. *Scientific Reports*, 6: 32108; DOI: 10.1038/srep32108.

⁵ *Thiamethoxam Technical - Honey Bee Brood and Colony Level Effects Following Thiamethoxam Intake via Treated Sucrose Solution in a Field Study in North Carolina - Final Report* - by Sigrun Bokscho for Syngenta Crop Protection. Report No. S14-02633. EPA date stamped 11-03-15.

- m) The exposure model excluded any consideration of effects from exposure to pollen and contaminated dust, air, guttation fluid or marginal vegetation to which honey bees are normally exposed. Thus, the exposure model was unrealistic.
- n) As with the Bayer clothianidin study, there is no accounting for any synergistic effects to which honey bees are normally exposed. The comment on synergy information that EPA should consider in our comment (c), above, also applies to the Syngenta thiamethoxam study.
- o) The experiment length was inadequate. It was too short to detect chronic effects that weaken bee colonies. Honey bee experts generally agree that a study for less than one year is inadequate to detect chronic effects.
- p) The feeding regime only lasted 6 weeks (from June through July), which is not long enough to cover bees' normal foraging activities in North Carolina, where bees likely could forage from March to October.
- q) The researchers did not describe post-mortem observations for the dead hives in detail. When a dead hive was observed, were dead bees found at the bottom of the hive - or simply disappeared? It is critical to differentiate hives that died from exposure from hives that may have died from other causes, such as Varroa mite. The report did not adequately mention Varroa mite baseline data to be able to assess whether the mites contributed to colony mortalities.
- r) On p. 44, regarding the data about Nosema and Varroa, it appears to signify that there was no correlation between the presence of those pathogens/parasites and hive mortality regardless of treatment regimen. However, that issue is not adequately analyzed to be meaningful. More analysis is needed.
- s) As with paragraph j), above, for clothianidin, the thiamethoxam study also lacked analysis of chronic effects on queens. Those effects should be addressed.
- t) The report contains unclear conclusions when it suggests a NOAEL of 37.5 ppb of thiamethoxam for pupae (p. 16) but then it also suggests the NOAEL is 50 ppb (p. 19). EPA should review the published studies and other reports indicating thiamethoxam crop uses resulting in exposures that exceed either the 37.5 and 50 ppb NOAELs. If the Syngenta thiamethoxam study is accepted as valid, its findings would indicate that this active ingredient poses unacceptable risks to honey bees in those crop applications. Product registrations allowing those applications should be suspended

Thank you for considering this comment. Please contact me at 202.547.9359; email: pjenkins@centerforfoodsafety.org, if you have any questions.

Sincerely,

Peter T. Jenkins

For:

Center for Food Safety

Beyond Toxics

Central Maryland Beekeepers

Environment America

Kansas Rural Center

Maryland Pesticide Education Network

Pesticide Action Network

Pollinate Minnesota

Pesticide Research Institute

Pollinator Stewardship Council

CC: (via email) EPA officials: Kevin Costello, Carissa Cyran, Marietta Echeverria, Yu-Ting Guilaran, Jack Housenger, Anita Pease, Rusty Wasem