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Filed online at www.regulations.gov

Attn: Docket No. EPA-HQ-OPP-2012-0334 - Comment and Request for Reconsideration

Re: Emergency Petition for Suspension of Registration - Clothianidin dated March 20, 2012

Dear Ms. Lewis,

Thank you for the opportunity to comment on the above-referenced Petition docket and to request reconsideration of the Environmental Protection Agency’s (EPA) prior decision. This comment and reconsideration request is on behalf of the Center for Food Safety, the International Center for Technology Assessment and Beyond Pesticides, the non-governmental organizations who, together with a coalition of 25 beekeepers and other groups, submitted the original Petition to EPA on March 20, 2012. We then submitted extensive first and second supplemental filings in support of the Petition, dated May 3 and June 18, respectively. They consisted of information that came to light after the Petition was filed, including critical new information on how certain uses of clothianidin constitute an “imminent hazard” to honey bees and other beneficial insects.

This filing will not reiterate what we stated in our prior three documents in the docket. We make six new key points here and urge the agency to make a rapid decision on each claim in our Petition.

1. EPA’s partial response to the Petition on the “imminent hazard” question was itself arbitrary and capricious and must be reconsidered.

The evidence we provided in the original Petition and in our first and second supplemental filings clearly describes an “unreasonable adverse effect on the environment” in terms of a vast number of bee kills impacting likely hundreds of U.S. (and Canadian) colonies and tens of millions of valuable honey bees. These acute bee kills that were ongoing during EPA’s decisionmaking period on the Petition are in addition to the chronic impacts of clothianidin that fall under the rubric of Colony Collapse Disorder.
EPA’s July 17 Response letter that partially denied the Petition (“EPA’s Response Letter”) admitted the agency did not consider any of Petitioners’ supplemental filings, the ongoing bee kills associated with Spring corn planting or any other information it received after May 3, in denying an “imminent hazard” existed. Ignoring this information available to the agency, including the ongoing clothianidin-related bee kills during the ten weeks between May 3 and July 17 when it responded, was inadequate to the risks presented and constituted an arbitrary and capricious EPA action. EPA must reconsider its July 17 decision.

2. New information indicates clothianidin poses an imminent hazard.

As we documented in our first supplemental filing, independent researchers, such as 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.1 Sublethal exposure of honey bees to thiamethoxam (clothianidin’s precursor) 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 (EFSA) reviews have since confirmed that 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.2 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.

Out of concern that Bayer’s critique of the Henry et al. paper may influence EPA’s views on the pending matter - as it was sent to agency officials – Petitioners’ second supplement included attachments that rebutted Bayer’s scientists. Appendix A to that supplement was prepared by Christian H. Krupke, Ph.D., Associate Professor of Entomology, Purdue University, dated June 7, and entitled: “A response to a recent review of publications on neonicotinoids and pollinators prepared by Heintzelman, Kelly, Fischer and Maus,” and Appendix B was a comparable rebuttal of Heintzelman et al., dated June 14, by James L. Frazier, Ph.D., Professor of Entomology, Pennsylvania State University. EPA is urged to pay close attention to these statements from respected objective experts and not to rely on the obviously self-interested views of the registrants who seek to minimize the importance of the Henry et al. results.

Further, EPA’s Response Letter based its denial of an “imminent hazard” largely on the low number of reported, documented U.S. bee kills associated with clothianidin. EPA’s Response states: “...if clothianidin were causing serious harm, the EPA would expect to see far more incident reports.

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2 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
indicating more frequent mass deaths of honey bees than it has historically received." But, EPA knows its bee kill information system is not reliable.³

The EPA Response relies on the agency’s Ecological Incident Information System (or “EIIS”). 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 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 corn planting. In a recent response to a Freedom of Information Act request from the Center for Food Safety to EPA, the 2012 U.S. bee kill incidents in the agency’s files likely associated with neonicotinoid seed treatments total at least 18 incidents with more than 2,100 colonies impacted.

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 14 or 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 bee kill reporting systems.

The defects in the EIIS system were well described in the July 2012 Pesticide Research Institute (PRI) beekeeper survey on pesticides, prepared for the EPA’s own Pesticide Program Dialog Committee. Specifically, the responses to Question 12 make clear that far more bee kills are happening than the EIIS system records. Over 70% of the 50 responding commercial beekeepers reported they have suffered acute bee kills from pesticide use on non-pollination dependent crops, such as corn. Over 35% of them specifically mentioned “exposure to contaminated dust from seeds treated with pesticides” and the same exposure route was reported by 20% of the 244 noncommercial beekeepers who responded. Large numbers also reported chronic problems as well.

In the PRI beekeeper survey, Question 7(b) asked “If you reported a bee kill to the authorities in your state, what response did you get?” A large percentage of kills are not reported to officials at all. For those that are, the responsiveness of the official investigators in terms of taking samples and investigating incidents verbally with the beekeepers were extremely low – below 10% for both commercial and non-commercial respondents. (Anecdotal information from beekeepers, not from the

³ This fact was publicly admitted by Thomas Steeger, Senior Science Advisor, Environmental Fate and Effects Division, at the FIFRA Science Advisory Panel meeting on September 12, 2012, in response to a question from the panel after the public comment period.
PRI survey, indicated that some state primacy partners did not view bee kills associated with contaminated dust to constitute “pesticide incidents,” so they did not investigate them.) In no cases was any violation issued or any pesticide applicator fined. **Far less than 5% of beekeepers indicated “For most incidents, I reported directly to the US Environmental Protection Agency.”**

In sum, the PRI survey report documents that many beekeepers don’t report because they don’t get adequate investigations and they don’t see results. No one gets penalized for causing their kills and no compensation comes to them, so eventually their efforts spent reporting come to be seen as wasted.

In short, EPA’s reliance on lack of bee kill incident data in its Response Letter is a product of information collection and enforcement failures rather than reality. The logical extrapolation from the admitted 120 documented bee kill incidents in Canada associated with neonicotinoid seed treatments, together with at least 18 incidents that were reported to EPA when fewer than 5% of U.S. beekeepers indicate that they report incidents directly to the agency, in combination with the other available information about extensive additional bee kills in press accounts, is that a vastly greater number of similar incidents actually occurred in the United States in 2012. A realistic estimate is that more than one hundred incidents occurred impacting tens of thousands of bee colonies.

**Given the acknowledged defects in the EIIS, the agency should recognize that a high foreseeability of hundreds of acute bee kill incidents recurring during the corn planting season in 2013 and again in 2014 and beyond, in the United States and Canada, in addition to the chronic hazards, do amount to an “imminent hazard”**.

The agency also should take note of new science indicating the difficulty of obtaining lab results to document the presence of clothianidin inside live or dead impacted bees, especially as the PRI Survey indicates that many bee kill investigations do not occur in a timely way. The report of a very recent study by Tapparo, Giorio et al., states:

> 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 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:

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...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.

When major U.S. bee kills occur during the Spring when clothianidin and/or thiamethoxam-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. The Tapparo, Giori et al. findings reinforce this point.

The contaminated dust/talc exposure route and its impact on honeybees led Germany, Italy, Slovenia and, to some extent, France, to prohibit various neonicotinoid seed treatments. EPA’s Response Letter fails to address the compelling Italian data, instead focusing on the major incidents in Germany (2008) and Slovenia (2011) which led to suspension of these products in those countries (p. 10 of EPA Response). It discounts these incidents, partially due to EPA’s assertion they resulted from “planting of clothianidin-treated corn seed during unusual dry, windy conditions”. It is specious to suggest that dry and windy conditions would be “unusual” in the United States during planting season; indeed, they are exceedingly common during this prolonged drought afflicting the “Corn Belt”. Further, an examination of the very detailed Slovenian report on the “catastrophic” bee kills there indicates that the corn seed planted was examined for its “adhesion properties” and “the seed meets the prescribed requirements for commercial distribution”. EPA’s attempt to blame the repeated and widespread Slovenian poisonings on speculative “issues with regards to sticking agents not being used according to industry practices” is consistent with the agency’s broad, inexcusable pattern of minimizing bee kill incidents and parroting the industry registrants’ perspectives.

The benefits of a precautionary perspective by EPA would be experienced by U.S. bees and beekeepers nationally, promptly and across the board, as was clearly the case in Italy after its suspension of neonicotinoid seed treatments. On June 26 of this year, Italy’s Ministry of Health announced it would continue the suspension it originally imposed in 2009 in response to bee kills that clearly resulted from using clothianidin and thiamethoxam on corn seeds. On June 27, the EFSA issued a report noting that Italy’s suspensions had been extremely effective in reducing bee kill incidents. Just as importantly, the Italian researchers found no evidence that the suspensions are causing economic problems for farmers. Italian corn farmers have not seen serious pest attacks on untreated seed and have maintained yields. EPA’s own “Technical Support Document for the Response to the Emergency Citizen Petition,” dated July, 17, 2012, (p. 8) concurs that:

Additional mass acute bee poisonings on the scale of these incidents have not been reported in Germany since it suspended clothianidin maize seed treatment.
Yet, on the very same page that Technical Support Document repeats the unsupported suggestion that the more than 100 U.S. and Canadian documented bee kills of 2012 all should be discounted due to unusual dry and windy conditions. Again, superficial attempts to downplay this route, especially during an extended drought across North America and in a gradually warming and drying climate, are ill-advised.

EPA should take careful notice of the expert opinion submitted to the FIFRA Scientific Advisory Panel (SAP) by Dr. Christian Krupke of Purdue University, dated Sept. 6, 2012, which reinforces this point (attached hereto as Appendix A). Dr. Krupke’s stated (emphasis added):

\[ The \textit{highlights of our work and that of others (Tapparo et al. 2012) reflect that pesticide-contaminated dust produced during planting moves out of the planted field, contaminating nearby flowers and the bees themselves, sometimes at rates causing mortality. In the past year, I have presented this information to thousands of corn growers through face-to-face extension meetings, and many others have contacted me after viewing webinars that Dr. Hunt and I produced. Although corn and soybean producers are planting treated seeds strictly according to label directions, bee kills continued this past spring. Treated seeds will continue to be planted across hundreds of millions of acres in 2013, and to date there has been no guidance from registrants or EPA on how to minimize non-target effects, how and where to clean out planters, or what steps to take to avoid effects to nearby honeybees or insect-pollinated plants. } \]

In short, this imminent hazard will be re-initiated in about six months’ time when corn planting begins again. As Dr. Krupke points out, vague suggestions by EPA that it can mandate and enforce mechanical fixes across the (likely) tens of thousands of U.S. corn planting machines in the next six months is completely unfounded. EPA also could wait and hope that no “dry, windy” conditions re-occur, but that also would be unreasonable.

3. EPA’ Response Letter improperly ignored the imminent hazard to beneficial native bees.

Clothianidin has also been observed to be highly toxic to wild bee species, including beneficial pollinators, like the common eastern bumble bees (Bombus impatiens (Cresson)), alfalfa leafcutting bees (Megachile rotundata (F.)) and the blue orchard bee (Osmia lignaria Cresson). EPA’s Response Letter completely ignores these risks.

Ignoring the risks of clothianidin to the ~4,000 species of native North American bees is a major failure given the extremely high stakes. Several of these species face severe declines. These bees lack the carefully-bred adaptability and resilient social structure of Apis mellifera and typically have entirely different life cycles and vulnerabilities. More solitary bees with small colonies cannot withstand the stresses as well as colonies of Apis bees. For example, Osmia lignaria eats more pollen than Apis bees and is exposed to insecticides in its soil habitat; this additional contact toxicity is critical. Honey bees are generalists, while solitary bees have a narrower host range. The contaminated dust/talc and other acute

exposure routes are just as dangerous to them but have not been assessed in detail; neither have the chronic exposure routes.

Key findings of a recent study of a neonicotinoid closely related to clothianidin, by Laycock et al., document the threats to non-Apis bees: “Effects of imidacloprid, a neonicotinoid pesticide, on reproduction in worker bumble bees (Bombus terrestris)” (emphasis added):\(^9\)

\[...The\ \textit{key result emerging from our work is that ingestion of imidacloprid at environmentally realistic levels substantively reduced the fecundity of worker bumble bees. This finding is consistent with those of previous studies, which have shown that exposure of B. terrestris workers to dietary imidacloprid at 10 ppb in feeder syrup reduced larval production by 43\% (Tasei et al. 2000) and drone production by between 41 and 62\% (Tasei et al. 2000; Mommaerts et al. 2010). However, wild bees are probably exposed to imidacloprid residues lower than 10 ppb when they consume the nectar and pollen of treated crops (Bonmatin et al. 2003, 2005; Chauzat et al. 2006). We have now demonstrated that dietary trace residues of imidacloprid in the range of 1 ppb can reduce worker fecundity by at least one third.....\]

\[Our\ \textit{findings raise further concern about the impact of systemic neonicotinoids on wild bumble bee populations. A recent review summarising 15 years of research on the hazards of neonicotinoids to bees highlighted the sub-lethal effects of exposure in the laboratory to neonicotinoids > or = 6 ppb on reproduction and behaviour in bumble bees (Blacquière et al. 2012). We have now shown that dietary neonicotinoids in the range < 6 ppb can cause substantive sub-lethal effects on bumble bee reproduction.\]

Even before the Laycock et al. findings were published, the risks to non-Apis bees were catalogued in the Xerces Society report, \textit{Are Neonicotinoids Killing Bees? A Review of Research into the Effects of Neonicotinoid Insecticides on Bees, with Recommendations for Action} (cited in full in our first supplemental filing), which concludes by making the same points we make here (p. 26):

\[Applications\ \textit{of neonicotinoids should be limited until we have data on how neonicotinoid use on a specific plant may be managed to provide pest protection without exposing beneficial insects to sublethal or lethal levels in nectar and pollen. Without clear evidence that they are not causing long-term harm to non-target species such as pollinators, the use of neonicotinoids should be restricted to applications that will not affect these vital insects.}\]

Many native bees have rapidly shrinking localized ranges. They lack any margin for agency error in ensuring their survival. The September, 2012, FIFRA Science Advisory Panel specifically commented during its meeting that EPA’s work to date in assessing the risks to non-Apis bees was not adequate. The EPA-enabled acute and chronic hazards posed to them from clothianidin’s continued use across nearly 100 million acres in this country are imminent by any reasonable definition.

4. EPA has relied on misleading statements regarding adequate prior studies.

EPA has repeatedly publicly asserted it uses “weight-of-evidence risk characterization” based on a total of “34 studies” to support the proposition that clothianidin does not pose unreasonable adverse effects to pollinators. EPA’s public assurances are misleading. We reviewed the information EPA relies on, as posted on the agency webpage listing available “field studies” and other documents regarding clothianidin. Except for the later-discredited “Cutler and Scott-Dupree 2007” study, only ten field filed studies are listed. None of them were classified as “Acceptable”; seven were classified as “Supplemental” and three were “Invalid”. Almost all of these studies relied on for the proposition that clothianidin does not pose unreasonable adverse effects to pollinators in the field are more than ten years old, were of short duration, and were performed in Germany by Bayer or in Canada by Dr. Scott-Dupree of the University of Guelph.

At the same time, an official EPA notice delivered in 2011 to Bayer CropScience regarding a proposed label amendment for clothianidin, to allow an increased seed treatment use rate, includes this admission (emphasis added):

Field Test for Pollinators. There are uncertainties regarding the potential effects of clothianidin on insect pollinators and specifically the honey bee (Apis mellifera). These uncertainties have not been adequately addressed by the current studies.

It is incomprehensible that EPA can state this to Bayer CropScience while at the same time the agency publicly claims it has adequate field testing in hand to determine there are no unreasonable adverse effects on pollinators. Agency actions based on self-contradictory assertions are inherently arbitrary and capricious.

Repeated annual patterns going back several years leaves little doubt that Spring bee kills will recur in 2013 and 2014, that is, during the period it is likely to take EPA to resolve our Petition if the agency does not suspend clothianidin’s registration in the interim. The chronic exposures are 100% foreseeable to continue in the interim as well. Continuing financial damage and occupational and emotional stress to beekeepers, as well as ecosystem damage, are foreseeable in view of the agency’s admission that it lacks adequate studies on the effects of these exposures.

5. EPA’s Response Letter improperly weighed the benefits of clothianidin.

10 S. Bradbury, Director, OPP, EPA, response letter to PANNA, Beyond Pesticides et al. re Requested Stop Sale Use or Removal Order for Clothianidin, dated Feb. 18, 2011.
11 EPA Index of Cleared Science Reviews for Clothianidin, online at: www.epa.gov/pesticides/chemical/foia/cleared-reviews/reviews/044309/044309.htm
12 Even the studies not determined “Invalid” by EPA are questionable. For example, this entry contains disturbing comments by the “Reviewer”: March 20, 2003. Review. 28 Page(s). Valerie Hodge. Environmental Risk Branch. Honey Bee - Field Testing For Pollinators, 141-5 or 850.3040. DP Barcode: D278110 MRID No: 45422435.

“While the study authors detected no significant treatment-related reductions in any parameters, the reviewer noted that several parameters (e.g., mortality, pollen foraging activity, mean # of foragers observed, and mean honey yield) appeared to be negatively impacted by treatment with either TI-435 [clothianidin] or GAUCH00 (imidacloprid). The reviewer could not statistically verify these findings because replicate data were not provided.”
Part of the agency’s reasoning in denying an “imminent hazard” existed was EPA’s argument that the Petitioners failed to account for the “benefits” of clothianidin. As in the case of the herbicide Imprelis discussed in the original Petition, FIFRA authorizes EPA to take immediate action, regardless of the benefits, when a pesticide is being distributed or sold with inadequate labeling to prevent unreasonable adverse effects, as is also the case with clothianidin. Allegations of extensive benefits do not in any way ameliorate an imminent hazard, per the statutory definition:

The term “imminent hazard” means a situation which exists when the continued use of a pesticide during the time required for cancellation proceeding would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered or threatened by the Secretary pursuant to the Endangered Species Act.

This definition leaves no room for the agency to “weigh” the adverse effects and the hazard to threatened and endangered species against the loss of clothianidin’s benefits if its registration was temporarily suspended pending a Special Review proceeding per the Petition. If the Federal government did the sort of offsetting that EPA’s Response Letter has suggested, then Imprelis, DDT, and other harmful pesticides would still be on the market in the United States. The burden of proof to determine that clothianidin’s registration is valid under FIFRA in the first instance rests not on Petitioners, rather it rests on the proponents of its registration and neither the registrants nor EPA have met that burden.


Petitioners have seen statements from the registrants of clothianidin products suggesting that a six year statute of limitations applies to entirely bar EPA from granting the claim in the Petition related to failure to comply with Section 7 of the Endangered Species Act (ESA) due to the initial registration of clothianidin in 2003, or nine years ago. This is mistaken. Statutes of limitation apply to litigation; not to citizen petitions. There is no statute of limitation that prevents the agency from exercising its discretion (indeed, its duty) under FIFRA and the ESA to recognize and correct past compliance failures. Furthermore, even if the matter were in litigation, the claimed six year statute of limitations might (for the sake of argument) bar claims based on ESA compliance failures prior to 2007. But, the record is very clear that EPA has approved dozens of new clothianidin-based product uses since 2007. Each of those approvals has also suffered from failure to comply with Section 7 of the ESA and would be legally challengeable even assuming a six year statute of limitations applied.

Conclusion

If EPA fails to suspend the registration for clothianidin by a prompt order, the hazard posed to honey bees and pollinators in the interim will be unacceptable. Failure to suspend would allow repeated acute Spring bee kills to recur, likely through 2014 at least. It will allow continued build-up of long-persisting

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14 7 U.S.C. § 136k(a).
15 7 U.S.C. § 136l
16 40 CFR § 154.5 on Special Review petitions.
clothianidin in dusts, soils and vegetation, and will contribute to the chronic aspects of Colony Collapse Disorder, which is steadily putting beekeepers into “the red” and in many cases out of business altogether. It also will allow additional years of unanalyzed effects and potentially unmitigated jeopardy to Federally-protected threatened and endangered species, which would be blatantly unlawful under the ESA.

The agency is urged to reconsider its prior partial denial and make a final determination to grant the Petition in full. In view of the emergency nature of this matter, an emergency acknowledged in EPA’s Response Letter of July 17, failure by the agency to take action promptly may result in administrative litigation against the agency. Please contact me if you have any questions.

Sincerely,

/s/
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Attachment: Appendix A – Comment letter by Prof. Christian Krupke