

# Center for Regulatory Effectiveness

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September 25, 2012

Marianne Lewis  
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Office Pesticide Programs  
Environmental Protection Agency  
1200 Pennsylvania Ave NW  
Washington DC 20460-0001

**Re: Center for Regulatory Effectiveness Comments on Emergency Petition to Suspend Clothianidin, 77 FR 44233<sup>1</sup> (July 27, 2012)**

Dear Ms. Lewis:

The Center for Regulatory Effectiveness (CRE) is pleased to submit these comments to the United States Environmental Protection Agency (EPA) concerning the “Emergency Citizen Petition” to suspend registrations for clothianidin. The CRE agrees with the EPA’s conclusion to deny the request to suspend clothianidin by finding that the petition does not demonstrate a substantial likelihood of imminent, serious harm that would justify the suspension of this pesticide under FIFRA. Likewise, the EPA should also deny the suspension request for clothianidin and the inaccurate assertions that it is an unlawful registration, that it is a misbranded product, and that its sale violates the Endangered Species Act.

In evaluating the petition, the EPA must ensure that all data and reports to support the petition that the EPA considers and relies on comply with the Data Quality Act (DQA). Moreover, section II of this comment outlines studies used by the petitioners that are clearly not compliant with the DQA and therefore the EPA shall not consider the studies in evaluating the petition. Finally, a substantial number of recent scientific studies conclude that Varroa Mites are

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<sup>1</sup> Available at <http://www.gpo.gov/fdsys/pkg/FR-2012-07-27/pdf/2012-18321.pdf>

a major cause of bee health decline, not clothianidin. Thus, the EPA would not be justified in suspending the registration of clothianidin.

## **I. All Data Submitted By Third Parties in the Petition Must Comply with the Data Quality Act**

### *A. Applicability of the DQA to Agency Reliance on “Third-Party” Studies and Information*

The Petitioners rely on several “third-party” studies that claim clothianidin is toxic to honeybees. These studies suffer several flaws in the research and data, but this will be addressed in the subsequent section. More immediately, however, we want to remind the Agency that such “third-party” studies or information must comply with the quality requirements of the DQA and its guidelines if they are to be relied on or agreed with by the Agency. The DQA government-wide guidelines promulgated by the Office of Management and Budget (OMB) state:

*If an agency, as an institution, disseminates information prepared by an outside party in a manner that reasonably suggests that the agency agrees with the information, this appearance of having the information represent agency views makes agency dissemination of the information subject to these guidelines.*

67 Fed. Reg. 8452, 8454 (Feb. 22, 2002).<sup>2</sup> EPA’s DQA guidelines, issued to conform to the OMB guidelines, are similar, stating:

- EPA initiates a distribution of information if EPA distributes information prepared or submitted by an outside party in a manner that reasonably suggests that EPA endorses or agrees with it; if EPA indicates in its distribution that the information supports or represents EPA’s viewpoint; or if EPA in its distribution proposes to use or uses the information to formulate or support a regulation, guidance, policy, or other Agency decision or position.
- Agency-sponsored distribution includes instances where EPA reviews and comments on information distributed by an outside party in a manner that indicates EPA is endorsing it, directs the outside party to disseminate it on EPA’s behalf, or otherwise adopts or endorses it.<sup>3</sup>

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<sup>2</sup> The OMB government-wide peer review guidance, described below in section IV, reiterates the substance of this statement. 70 Fed. Reg. at 2667 1st col.

<sup>3</sup> EPA Guidelines sec. 5.3, available at [http://www.epa.gov/quality/informationguidelines/documents/EPA\\_InfoQualityGuidelines.pdf](http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf)

*B. DQA Standards*

The basic DQA quality standards are “quality, objectivity, utility, and integrity.” It is recognized that there is overlap among these standards,<sup>4</sup> and the OMB government-wide guidelines state that “quality” encompasses the other standards. In addition, the OMB guidelines contain a standard of “reproducibility” for “influential scientific information.” These standards are summarized below.<sup>5</sup>

**“Objectivity”**: Under the guidelines, “objectivity” requires that information be presented in an “accurate, clear, complete, and unbiased manner” with “error sources affecting data quality ... disclosed to users.”<sup>6</sup> The agency must also ensure that the information is “accurate, reliable, and unbiased,” and that the “original and supporting data shall be generated, and the analytic results shall be developed, using sound statistical and research methods.” If data and analytic results have been subjected to formal independent peer review, there is a rebuttable presumption that the information is “objective.” However, as the OMB peer review guidelines (discussed below) make clear, journal peer review is given less weight than other more rigorous and transparent forms of external, independent peer review and cannot substitute for peer review conducted in accordance with the DQA peer review guidance.<sup>7</sup> As discussed below in the section on the DQA peer review guidance, the objectivity standard is regarded as particularly important for peer review.

**“Utility”**: Utility means simply that the information must be useful to intended users. Although not stated explicitly in the guidelines, utility in a scientific context appears to be equivalent to relevance. The guidelines also state that the agency must address transparency of the information if it would affect its utility.<sup>8</sup> Transparency, in turn, is the basis for the standard of “reproducibility,” explained below.

**“Reproducibility”**: This standard applies to “influential” scientific information, which is defined as information that the agency can reasonably determine will have or does have a clear and substantial impact on important public policies or important private sector decisions. Reproducibility means that the information disseminated is sufficiently transparent with regard to data and methods that a qualified member of the public could conduct an independent reanalysis in an attempt to generate similar results, subject to an acceptable degree of

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<sup>4</sup> For example, information that does not meet the standard for objectivity could be regarded as lacking utility, and transparency of data and methods is an aspect of both utility and reproducibility.

<sup>5</sup> With the exception of the Clean Water Act risk assessment standards required to be “adopted or adapted” by each agency (explained below), the EPA guideline definitions for objectivity, utility, and reproducibility mirror almost exactly the OMB guideline definitions. The standard of “integrity” relates to security of information and is not relevant for purposes of these comments.

<sup>6</sup> 67 Fed. Reg. at 8459.

<sup>7</sup> *Id.* at 8459.

<sup>8</sup> *Id.*

imprecision or error. This standard applies to both individual studies and analyses that combine information from multiple studies.<sup>9</sup>

*C. Applicability of the DQA Peer Review Guidance*

If the EPA provides the relief the Petitioners are seeking by suspending clothianidin, the EPA would need to conduct a new rulemaking that complies with notice and comment requirements under the Administrative Procedures Act. Moreover, a change in the registration status of clothianidin would be required to undergo independent, external peer review subject to the DQA peer review guidance.<sup>10</sup> Under that guidance, any new findings by the EPA regarding clothianidin would undoubtedly be classified as a “highly influential scientific assessment,”<sup>11</sup> and therefore would be subject to certain more stringent peer review measures that supplement the original DQA guidance described above.

“Peer review is one of the important procedures used to ensure that the quality of published information meets the standards of the scientific and technical community.” The peer review guidance is especially important from an agency perspective because it requires that any agency regulatory action that relies on scientific information subject to the guidance “shall include in the administrative record for that action a certification explaining how the agency has complied with the requirements of this [peer review] Bulletin and the applicable data quality guidelines.”<sup>12</sup>

For purposes of responding to the Petition, the peer review guidance is especially pertinent in that it reinforces the need for peer reviewers to take into consideration the quality requirements of the DQA and its guidance, and particularly the requirements for “objectivity” and “reproducibility.” The “substantive” portion of the guidance states that “[p]eer reviewers shall be charged with reviewing scientific and technical matters, leaving policy determinations for the agency. Reviewers shall be informed of applicable access, objectivity, reproducibility and other quality standards under the Federal laws governing information and quality.”<sup>13</sup> The preamble, or supplemental explanation portion of the guidance, elaborates on this requirement, stating:

*[W]here appropriate, reviewers should be asked to provide advice on the reasonableness of judgments made from the scientific evidence. However, the charge should make clear that the reviewers are not to provide advice on the policy (e.g., the amount of uncertainty that is acceptable or the amount of*

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<sup>9</sup> *Id.* at 8460.

<sup>10</sup> 70 Fed. Reg. 2664 (Jan. 14, 2005).

<sup>11</sup> A “highly influential scientific assessment” is defined as one that could have potential impacts of more than \$500 million in any year, or is novel, controversial, is precedent-setting, or has significant interagency interest. 70 Fed Reg. at 2675.

<sup>12</sup> 70 Fed. Reg. at 2677.

<sup>13</sup> *Id.* at 2675 1st and 2d cols. and 2671 3d col.

*precaution that should be embedded in an analysis). Such considerations are the purview of the government.*<sup>14</sup>

In other words, policy-driven assumptions or defaults cannot be used to fill gaps in scientific knowledge; any such gaps must be treated objectively as gaps or uncertainties.

## II. Studies Used by the Petitioners that do not Comply with the Data Quality Act

The Petitioners rely on several studies in making their argument that clothianidin adversely affects honeybees. However, these studies have flaws in their administration thus tainting the findings. Accordingly, these studies do not comply with the DQA. Thus, the EPA cannot rely on these studies when responding to the Petition. Though it is not an exhaustive list, three studies that suffer from such deficiencies include Cédric Alaux’s report *Interactions Between Nosema Microspores and a Neonicotinoid Weaken Honeybees*, Cyril Vidau’s report *Exposure to Sublethal Doses of Fipronil and Thiacloprid Highly Increases Mortality of Honeybees Previously Infected by Nosema Ceranae*, and Judy Wu’s report *Sub-Lethal Effects of Pesticide Residues in Brood Comb on Worker Honey Bee*. The flaws in these reports are outlined below.

### A. Cédric Alaux’s report “*Interactions Between Nosema Microspores and a Neonicotinoid Weaken Honeybees*”

The petition cites the Alaux study, *Interactions Between Nosema Microspores and a Neonicotinoid Weaken Honeybees (Apis Mellifera)*, along with the Vidau study, discussed below, to support the existence of a “synergistic effect between *Nosema* and other neonicotinoid pesticides wherein bee mortality is dramatically increased.”<sup>15</sup>

#### i. Background of the Study

The Alaux study aimed to test the current hypotheses which describe honeybee losses as a multifactorial syndrome.<sup>16</sup> The researchers did this by investigating integrative effects of “an infectious organism and an insecticide on honeybee health.”<sup>17</sup> Specifically, the study looked at interactive effects between chemical and biological stressors on pollinators through an analysis of the interaction between *Nosema* and imidacloprid that was found in honeybees.<sup>18</sup> The authors believed that because honey bees were social organisms, that it was best to test integrative effects

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<sup>14</sup> 70 Fed. Reg. at 2669 1st col. [footnote omitted]

<sup>15</sup> Center for Food and Safety and International Center for Technology Assessment, Emergency Citizen Petition Regarding Clothianidin, March 20, 2012, at 16 [hereinafter *Petition*]

<sup>16</sup> Alaux et. al., *Interactions between Nosema microspores and a neonicotinoid weaken honeybees (Apis mellifera)*, 12 *Envtl. Microbiology* 774 (2010)

<sup>17</sup> *Id.*

<sup>18</sup> *Id.* at 775

on honeybee health on two levels: individual and colony. The study observed the possible effect on:

1. individual mortality and energetic demands;
2. individual immunity; and
3. social immunity.<sup>19</sup>

Specifically, Alaux focused on glucose oxidase (GOX) enzymatic activity to analyze as a parameter of social immunity.<sup>20</sup> Alaux noted that GOX catalyzes hydrogen peroxide, which has antiseptic properties and these antiseptic properties are then secreted into larval food and honey where then “contributes to colony-food sterilization and therefore to diseases prevention.”<sup>21</sup>

ii. Experimental Setup

To test the interactions between *Nosema* and imidacloprid on both mortality and immunity, Alaux created four experimental groups:

1. the control,
2. infected with *Nosema*,
3. chronically exposed to imidacloprid, and
4. both infected with *Nosema* and chronically exposed to imidacloprid.<sup>22</sup>

Three cages of 30 bees each and two cages of 120 bees each were used in each experimental group. For the *Nosema* infection, each bee was fed individually with 2 µl of 50% sucrose solution which had 200,000 spores of *Nosema*. The control bees were fed with a sucrose solution. For the imidacloprid bees, a stock solution of imidacloprid was diluted with dimethyl sulfoxide, water and sucrose. Three levels of imidacloprid were tested: 0.7, 7 and 70 µg kg<sup>-1</sup>.

iii. Issues with the results

*Imidacloprid levels too high*

The study tested bees with an imidacloprid concentration of 70 µg kg<sup>-1</sup>, which is considerably higher for both imidacloprid and clothianidin than would be expected to be found in pollen and/or nectar. The authors noted that

“[W]hen the food was treated with imidacloprid, the boost in food intake caused by parasitism was associated with an increase in imidacloprid exposure. Although imidacloprid contamination in the hive is usually found at sub-lethal doses,

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<sup>19</sup> *Id.*  
<sup>20</sup> *Id.*  
<sup>21</sup> *Id.*  
<sup>22</sup> *Id.* at 779

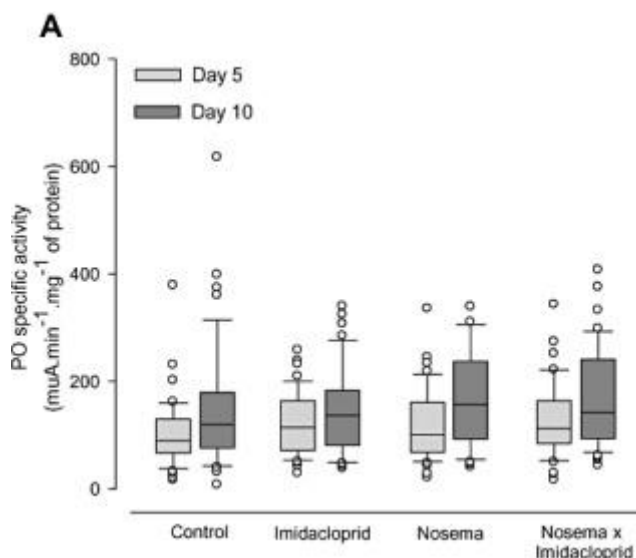
microsporidia infection could have the capacity to expose bees to lethal doses by increasing the intake of contaminated food.<sup>23</sup>

It appears the authors are justifying their use of a high imidacloprid level by stating that because a concentration of imidacloprid this high is possible, that it is scientifically sound for them to use that level. However, that is not the case, for testing bees with 70 µg kg<sup>-1</sup> imidacloprid concentrations provides no real value in the field.

*Individual and Social Immunity have no value*

One aspect of the study was the examination of the effect of *Nosema* infection and/or exposure to imidacloprid on individual immunity. Whereas social immunity is a cooperation between the individual group members to prevent disease contamination<sup>24</sup>, individual immunity is where an individual bee promotes their own survival. Phenoloxidase enzymatic activity and total haemocyte count (THC) are two such measures of individual immunity that were used by the study's authors.

In the Alaux study, the phenoloxidase specific activity was not affected by the *Nosema* infection and/or exposures to imidacloprid, as clearly seen in figure 3A of the report, and reproduced below.<sup>25</sup>



In regards to social immunity, one sound measure of the phenomenon, according to the study, is the GOX-specific activity, mentioned above. The *Nosema* infected group that was also exposed to imidacloprid supposed had a decrease in GOX-specific activity but the authors

<sup>23</sup> Id. at 778  
<sup>24</sup> Id.  
<sup>25</sup> Id. at 776

neglected to mention the amount of imidacloprid used in this group and once again, the study provides little value in the field.<sup>26</sup>

### *Utility Standard*

In order to meet the utility standard set forth by the OMB, the information provided should be useful to intended users, including the public.<sup>27</sup> By failing to distinguish results between the Imidacloprid levels in a meaningful way, the study may not provide usefulness from the public's perspective. The utility standard also points out that, "when transparency of information is relevant for assessing the information's usefulness from the public's perspective, agencies must take care to ensure that transparency has been addressed in their review of the information."<sup>28</sup> Though the Alaux study mentions that different amounts of imidacloprid were administered, it did not properly explain why they chose to use such a high concentration of the insecticide that is not commonly found in field. Additionally, they did not discuss the level of imidacloprid used in the GOX-specific activity. This lack of transparency diminishes the utility of the article.

### *B. Cyril Vidau's report "Exposure to Sublethal Doses of Fipronil and Thiacloprid Highly Increases Mortality of Honeybees Previously Infected by Nosema Ceranae"*

As mentioned with regards to the Alaux study above, the petition employs Vidau's study, *Exposure to Sublethal Doses of Fipronil and Thiacloprid Highly Increases Mortality of Honeybees Previously Infected by Nosema ceranae*, to support a finding of a relationship between *Nosema* and neonicotinoid pesticides that leads to bee mortality.<sup>29</sup>

#### i. Background of Study

Vidau's study hypothesized that the detoxification system of honeybees could be modified by *Nosema*, given that the detoxification mainly occurs in the gut and that is also the site of the *Nosema* proliferation.<sup>30</sup> The study aimed to assess the impact of *Nosema* on detoxification activity of honeybees, along with their sensitivity to fipronil and thiacloprid, two pesticides they claim to be found in high levels in hives.<sup>31</sup>

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<sup>26</sup> *Id.* at 777

<sup>27</sup> Information Quality Guidelines of the U.S. Department of Agriculture: Report to the Office of Management and Budget, page 5, Revision. of October 7, 2002, [http://thecre.com/pdf/20021014\\_usda-final.pdf](http://thecre.com/pdf/20021014_usda-final.pdf) [hereinafter *OMB Report*]

<sup>28</sup> *Id.*

<sup>29</sup> Petition, *supra* note 155, at 16

<sup>30</sup> Vidau et. al., *Exposure to Sublethal Doses of Fipronil and Thiacloprid Highly Increases Mortality of Honeybees Previously Infected by Nosema ceranae*. 6 PLoS ONE e21550 at 2

<sup>31</sup> *Id.*



ii. Study Set Up

Vidau's study used approximately 2000 bees, which were confirmed to be free of *Nosema*, found in three colonies. The bees were confined to laboratory cages in groups of 50 and were fed with candy and water and were also supplied with pollen. After five days of feeding, there were six experimental groups created:

1. uninfected controls,
2. infected with *Nosema*,
3. uninfected and chronically exposed to fipronil,
4. uninfected and chronically exposed to thiacloprid,
5. infected with *Nosema* and chronically exposed 10 days post-infection (p.i.) to fipronil, and
6. infected with *Nosema* and chronically exposed 10 days p.i. to thiacloprid.<sup>32</sup>

Thereafter, the relevant honeybees were individually infected with *Nosema* and ten days after that infection, they were exposed to fipronil or thiacloprid through ingestion of insecticide-containing sugar syrup. Those bees not exposed to the insecticides were fed with a dimethyl sulfoxide-containing sugar syrup.<sup>33</sup>

After 20 days, there was an increase in mortality observed in groups (v) and (vi), which consisted of honeybees that were infected with *Nosema* and were chronically exposed to fipronil and thiacloprid.<sup>34</sup>

iii. Issues with the Study

As mentioned above, an increase in mortality was observed in the bees that were both infected with the *Nosema* spores as well as exposed to the neonicotinoids. However, what was not observed was an increase in mortality for the bees that were just exposed to fipronil and thiacloprid, groups (iii) and (iv). As seen in table 3A, reproduced below, the mortality rate of these groups appeared to be remarkably similar to the control groups' mortality rate.<sup>35</sup>

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<sup>32</sup>

*Id.*

<sup>33</sup>

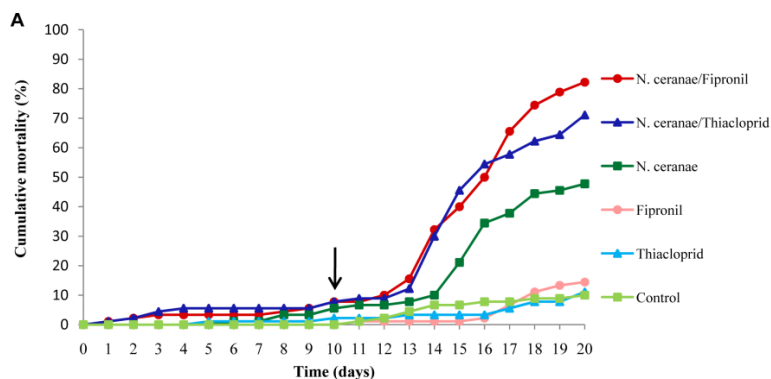
*Id.*

<sup>34</sup>

*Id.*

<sup>35</sup>

*Id.* at 5



The study concluded by making the blanket statement that they “confirm[ed] that interactions between *N. ceranae* and insecticides constitute a significant risk for honeybee health.”<sup>36</sup> However, it has been noted by the EPA’s Environmental Fate and Effects Division that fipronil and thiacloprid are two very different neonicotinoids. Notably, one is a cyano-substituted neonicotinoid and the other is a pyrazole, and most importantly, neither is similar to clothianidin in either their chemical structure nor in their level of toxicity to honeybees.<sup>37</sup> Simply because neonicotinoids were used in this study does not make it relevant to discussing the effects of clothianidin on honeybees, as the petitioners claimed that it does.

Transparency Standard

This study was also conducted entirely in a laboratory, and not in field conditions. In order to meet the OMB transparency results standard, agencies should “ensure sufficient transparency about data and methods that an independent reanalysis could be undertaken by a qualified member of the public.”<sup>38</sup> Vidau uses laboratory cages and incubators to perform this experiment, thus making it almost impossible to replicate. Even though there was the attempt to “mimic the hive environment as much as possible”<sup>39</sup> it was still performed in a laboratory and not in the field. This would therefore violate the transparency results guidelines set forth by the OMB. Moreover, there was no discussion as to how the experiment results could have differed if conducted in the field.

*C. Judy Wu’s report “Sub-Lethal Effects of Pesticide Residues in Brood Comb on Worker Honey Bee”*

The Petition cites the study by Judy Wu, stating that “honey bees are social insects that rely heavily on a certain level of memory, cognition and communication to coordinate activities essential for their survival,” and also when noting that “neonicotinoid pesticides . . . have several

<sup>36</sup> *Id.* at 7

<sup>37</sup> EPA Technical Support Document for the Response to the Emergency Citizen Petition Seeking Suspension of Registration for Clothianidin Based Claims of Imminent Hazard to the Environment, page 13, July 17, 2012, [hereinafter *EPA Technical Support Document*].

<sup>38</sup> OMB Report, *supra* note 27, at 5

<sup>39</sup> Vidau, *supra* note 30, at 2

. . . indirect effects on honey bees, such as premature shifts in hive roles.”<sup>40</sup> The purpose of this study, as seen by the petitioners, is to prove the point that there are studies available that link neonicotinoids to the declining honey bee population and health which justifies their goal of immediately suspending clothianidin.

i. Background of Study

Wu’s study aimed to examine the sub-lethal effects of developmental exposure on pesticide residues in worker honeybees. The bees for the experimental group originated from a brood comb which contained high levels of pesticide residues and the bees for the control came from a brood comb that was relatively free of pesticide residues.<sup>41</sup>

ii. Study Set Up

The study placed control comb blocks (with low pesticide residue) next to treatment comb blocks (with high pesticide residue levels). The control and treatment combs were placed within the same colony during the larval development phase in order to equalize “possible effects of colony activity and quality of resources fed to the brood.”<sup>42</sup> Eggs were laid by the bees and those bees reared in treatment blocks were placed in the same cage as those bees that were reared in the control blocks. The bees were fed water, a sucrose syrup and a pollen supplement. In order to assess the sub-lethal effects of exposure to pesticide residues, successful egg hatching was measured, as was larval mortality and development time from egg to pupa.<sup>43</sup>

iii. Issues with the Study

As described above, the low pesticide and high pesticide residue comb blocks were placed next to each other. This, along with the “repeated use of experimental frames over several replicates” led to the “migration of pesticide residues from treatment to control blocks, reducing the difference in residue levels between treatment and control combs and treatment effect differences.”<sup>44</sup> This contamination issue led to very similar results in mortality as seen in the Figure reproduced below:

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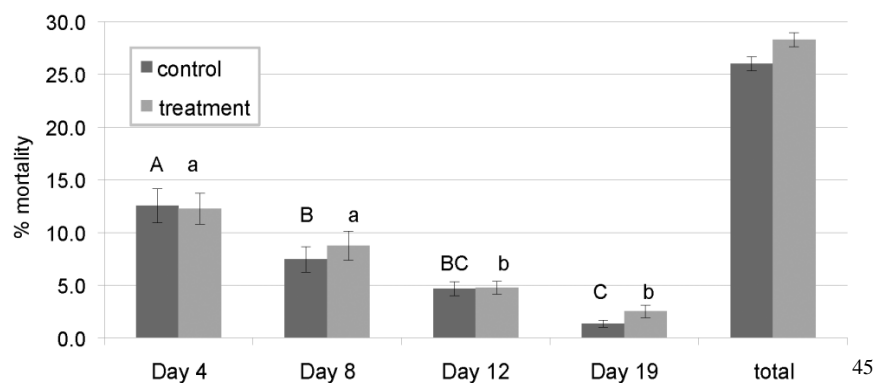
<sup>40</sup> Petition, *supra* note 155, at 33

<sup>41</sup> Wu et al., *Sub-Lethal Effects of Pesticide Residues in Brood Comb on Worker Honey Bee (Apis mellifera) Development and Longevity*, 6 PLoS ONE e14720 (2011) at 2.

<sup>42</sup> *Id.*

<sup>43</sup> *Id.*

<sup>44</sup> *Id.* at 4



Because of these contamination issues, the study provides little in terms of scientific value as there were no accurate control groups to compare results against.

The two chemicals being focused on in the study, fluvalinate and coumaphos are miticides.<sup>46</sup> They are not related to clothianidin, which is a neonicotinoid, a type of insecticide, and do not serve the same purpose. Furthermore, the fluvalinate and coumaphos in this study were applied directly to the brood comb, whereas clothianidin would never be applied directly.<sup>47</sup> Therefore, the value that this study provides to the petitioners is little, as the conditions under which the experiment was being conducted have no relation to clothianidin.

#### *Objectivity Standard*

“To meet the OMB objectivity standard, information disseminated by Federal agencies must be substantively accurate, reliable, and unbiased and be presented in an accurate, clear, complete, and unbiased manner. Data must be generated and analytic results must be developed using sound statistical and research methods.” In the Wu study, because the control was contaminated, the results obtained from the study cannot be relied upon as there was no control group for the scientists to compare their results to. Fluvalinate and coumaphos are not neonicotinoids and using the findings in this study and applying them to neonicotinoids is inaccurate and of low scientific value

### **III. Varroa Mites and Bee Health Decline**

A recent study led by Dr. Stephen Martin from the University of Sheffield and published in the journal, *Science*, has concluded that the Varroa Mite “has resulted in the death of millions of honey bee (*Apis Mellifera*) colonies.”<sup>48</sup> The study found that “there is general consensus that

<sup>45</sup>

*Id.*

<sup>46</sup>

*Id.* at 3

<sup>47</sup>

EPA Technical Support Document, *supra* note 37, at 14

<sup>48</sup>

Stephen J. Martin, et al., *Global Honey Bee Viral Landscape Altered by a Parasitic Mite*, 336 *Science* 1304, (June 8, 2012).

the mites' association with a range of honey bee RNA viruses is a contributing factor in the global collapse of honey bee colonies, because the spread of mites has facilitated the spread of viruses by acting as a viral reservoir and incubator.” The feeding behavior of the mites allows the virus to be transmitted directly into the bee's hemolymph, rather than the traditional means of transmission through oral or sexual contact.<sup>49</sup> One particular disease, deformed wing virus, can be directly linked to Varroa Mites' infestation of honey bee colonies.<sup>50</sup>

The study focused exclusively on the Hawaiian Islands to study the correlation of Varroa Mites and bee health decline. The reason the researchers focused on Hawaii is because while honey bees were first introduced to Hawaii in 1857, Varroa Mites did not arrive in Hawaii until August 2007. And importantly, some of the Hawaiian islands remain Varroa free. This created a unique laboratory environment where the researchers could analyze the impact of the introduction of Varroa Mites on honeybee populations, and also contrast it with the islands that were Varroa Mite free.

Remarkably, during 2007 and 2008, independent researchers recorded the collapse of 274 of 419 colonies in the Varroa infected areas.<sup>51</sup> In contrast, “the island of Kauai and Maui remained mite-free, and no unusual colony losses or disease problems were reported there.”<sup>52</sup> Specifically, “In Varroa-free areas, [deformed wing virus] was detected in 6 to 15% of colonies, but it increased to 75 to 100% where Varroa had been established,” which was also accompanied by a millionfold viral load.<sup>53</sup>

The study concluded, “the spread of Varroa in Hawaii has caused [deformed wing virus], originally an insect virus of low prevalence, to emerge. This association may be responsible for the death of millions of colonies worldwide wherever Varroa and [deformed wing virus] co-occur. The findings in this study is backed by the British Beekeepers Association (BBKA). BBKA chairman, Dr. David Aston stated that the research “increased our understanding of the relationships between Varroa and [this] significant bee virus... These findings underline the need for further research into Varroa... There remains a clear and urgent need for an effective, approved treatment.”<sup>54</sup> Furthermore, Dr. Martin's study mirrors similar findings by Yves Conte's report in 2010.<sup>55</sup>

Importantly, “The only way to control the [deformed wing virus] is to control the levels of the mite,” said Dr. Stephen Martin, and Varroa populations are largely controlled by the use of pesticides. Thus, the EPA must very closely consider the implications of suspending the registration of clothianidin, and the unintended consequences that may result.

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<sup>49</sup> *Id.* at 1304.

<sup>50</sup> *Id.*

<sup>51</sup> *Id.*

<sup>52</sup> *Id.*

<sup>53</sup> *Id.* at 1305.

<sup>54</sup> Victoria Gill, *Honeybee Virus: Varroa Mite Spreads Lethal Disease*, BBC Nature, (June 7, 2012).


<sup>55</sup> Yves Le Conte, et al., *Varroa Mites and Honey Bee Health: Can Varroa Explain Part of the Colony Losses?* 41 *Apidologie* 353 May-June 2010.

#### IV. Conclusion

As the EPA concluded in February 2011, there is substantial scientific evidence that the continued registration of clothianidin does not pose unreasonable risk to bees.<sup>56</sup> As the EPA found in 2011, clothianidin was originally evaluated for registration as an alternative to the organophosphate insecticides that are “generally very highly acutely toxic to bees and unlike clothianidin, also very highly acutely toxic to humans and wildlife”<sup>57</sup> During the initial registration, the EPA reviewed “hundreds of studies,” and continued to stay involved in on-going research as “science advances.”<sup>58</sup> Despite the extensive scientific evidence that the EPA relied on to issue the conditional registration, the Petition cites to flawed studies to assert that clothianidin has led to honeybee decline. The science, however, does not support this conclusion as CRE has demonstrated in Section II above.

Importantly, the Data Quality Act and its guidelines apply to all studies and data authored or collected by “third-party” entities, such as those relied on by the Petitioners. Accordingly, the EPA can only use studies or data that comply with the DQA standards of objectivity, utility, and reproducibility. As demonstrated above, the studies (including but not limited to) of Alaux, Vidau, and Wu do not meet the DQA requirements and thus cannot be considered by the EPA in evaluating the Petition. Furthermore, there are new scientific studies that conclude bee health decline is actually caused by the Varroa Mite. Thus, the EPA should deny the suspension request for clothianidin and devote its attention to Varroa mites as discussed in Section III above.

Respectfully submitted,



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Member, Board of Advisors

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<sup>56</sup> U.S. Environmental Protection Agency, *EPA Response to the Request to Ban Clothianidin*, February 18, 2011.

<sup>57</sup> *Id.* at 2.

<sup>58</sup> *Id.*