

## Center for Regulatory Effectiveness

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Richard Aucoin, Ph.D.  
Executive Director  
Pest Management Regulatory Agency (PMRA)  
Health Canada  
2720 Riverside Drive  
Ottawa, Ontario  
Address Locator: 6604-E2

**Re:** Consultation on Action to Protect Bees from Exposure to Neonicotinoid Pesticides, Notice of Intent, NOI2013-01

Dear Dr. Aucoin:

Writing recently in the *London Free Press*, a former Associate Dean for Research & Innovation of Ontario Agricultural College provided the public with two data points about bee health that define the range of potential consequences stemming from PMRA's pending decision on neonicotinoids:

1. In Ontario, "bee colony numbers are increasing, climbing almost 50% in Ontario since neonic seed treatments were introduced in 2004."
2. "In France, the number of bee colonies dropped by 25% after a neonic ban was imposed in 1999."<sup>1</sup>

Effectively protecting pollinators will require that PMRA abandon any predetermined conclusions about the causes of bee health in favor of an open and thorough review of the scientific record.

The Center for Regulatory Effectiveness (CRE) is pleased to contribute to the Pest Management Regulatory Agency's proceeding on bee protection as we have extensive experience in:

1. Determining the applicability of scientific data to regulatory purposes;
2. Evaluating the scientific record relating neonicotinoid pesticides; and
3. Participating in international regulatory proceedings.

CRE was established in 1996 as an independent, non-partisan *regulatory watchdog* promoting transparency in regulatory action by safeguarding the *good government laws*<sup>2</sup> that *regulate the regulators*. CRE was established by former senior career officials from the White House Office of Management and Budget (OMB).<sup>3</sup> CRE acts in its own name and does not represent any organization. Instead, CRE is funded by

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<sup>1</sup> Terry Daynard, "Proposed insecticide ban buzzes industry," *London Free Press*, Friday, November 22, 2013, available at <http://www.lfpress.com/2013/11/22/proposed-insecticide-ban-buzzes-industry>.

<sup>2</sup> See, "Regulating the Regulatory State," <http://www.thecre.com/oira/?p=1559>.

<sup>3</sup> For more information on CRE's leadership, please see [http://thecre.com/ombpapers/OMB\\_Officials.htm](http://thecre.com/ombpapers/OMB_Officials.htm).

donations from companies, NGOs and trade associations affiliated with a wide range of firms in the industrial and service sectors.<sup>4</sup> For more information about CRE, please see the About section of our OIRA Watch Interactive Public Docket (IPD)<sup>5</sup> focused on the OMB's regulatory office, the Office of Information and Regulatory Affairs (OIRA), [http://www.thecre.com/oira/?page\\_id=8](http://www.thecre.com/oira/?page_id=8).

### **I. Review of Bee Health Decline Interactive Public Docket: A Model for Health Canada/PMRA**

CRE's Review of Bee Health Decline IPD [[http://www.thecre.com/oira\\_pd/](http://www.thecre.com/oira_pd/)] is an interactive forum for the substantive discussion, from all perspectives, of the various pollinator protection scientific and regulatory policy issues. An Interactive Public Docket (IPD) is a series of threaded Wiki-type public generated pages which are seamlessly connected by blog technology, managed by public rules of governance which generates a shadow docket of a federal regulatory proceeding.<sup>6</sup>

What makes CRE's IPDs unique is that, instead of treating complicated issues in a simplistic, binary support/oppose fashion, our IPDs are engineered to support *substantive* in-depth discussions of pollinator protection issues including but not limited to the use of neonicotinoid pesticides. Thus, users are able to post lengthy documents on CRE's IPDs for public review and comment. The IPD accepts files in most popular formats (.pdf, .doc, .xls, .ppt, etc.) to ensure that scientific studies and other supporting data and analyses are available for discussion.

To ensure that all interested persons are able to easily participate in the discussion of bee health issues, there is no registration process and we permit anonymous posts and uploading of materials. CRE reviews the materials before they are posted to prevent spam, obscenity, disrespect of government officials, and other grossly inappropriate materials. Comments which strongly disagree with CRE's views are welcomed and encouraged.

The power and value of IPDs have now been widely recognized by diverse interests including civil society organizations,<sup>7</sup> academia,<sup>8</sup> and National Public Radio (NPR).<sup>9</sup> IPDs are also widely used by the media as a data source for substantive reporting including Thompson Reuters<sup>10</sup> and a distinguished Spanish foreign policy journal.<sup>11</sup>

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<sup>4</sup> See, "Regulatory Advocacy," <http://www.thecre.com/regreview/>.

<sup>5</sup> See, Wikipedia entry for Interactive Public Dockets at [http://en.wikipedia.org/wiki/Interactive\\_Public\\_Docket](http://en.wikipedia.org/wiki/Interactive_Public_Docket).

<sup>6</sup> See, eRulemaking.US here, <http://www.fedfocus.org/science/Rulemaking.html>.

<sup>7</sup> See, James Godwin, "CRE's Proposed Interactive Public Dockets—Tilting the Regulatory Process Further in Industry's Favor," Center for Progressive Reform, October 08, 2010, available at <http://www.progressivereform.org/CPRBlog.cfm?idBlog=8CB82125-FDE7-1BB5-04DAB9B697EFEACB>.

<sup>8</sup> See, "Remarks of Jim Tozzi at the University of Pennsylvania Law School, Seminar on "Obama's Regulatory Agenda: A One-Year Retrospective, January 26, 2010, p. 4, available at <https://www.law.upenn.edu/institutes/regulation/papers/TozziOIRAComments.pdf>.

<sup>9</sup> See, Web Resources at <http://www.npr.org/templates/story/story.php?storyId=4599065>.

<sup>10</sup> See "AGS-20" link from, Katie M. Scholz, "Nanopesticides: weighing the risks and benefits in U.S. policy," Thompson Reuters/Sustainability, 14 December 2012 available at <http://sustainability.thomsonreuters.com/2012/12/14/nanopesticides-weighing-the-risks-and-benefits-in-u-s-policy/>.

<sup>11</sup> See link from "Cyber Guard" in Acerca de Enrique Fojón Chamorro, "La transformación del U.S. Cyber Command," Elcano Blog – Analyses and debates on Spain's foreign affairs, available at <http://www.blog.rielcano.org/la-transformacion-del-us-cyber-command/>.

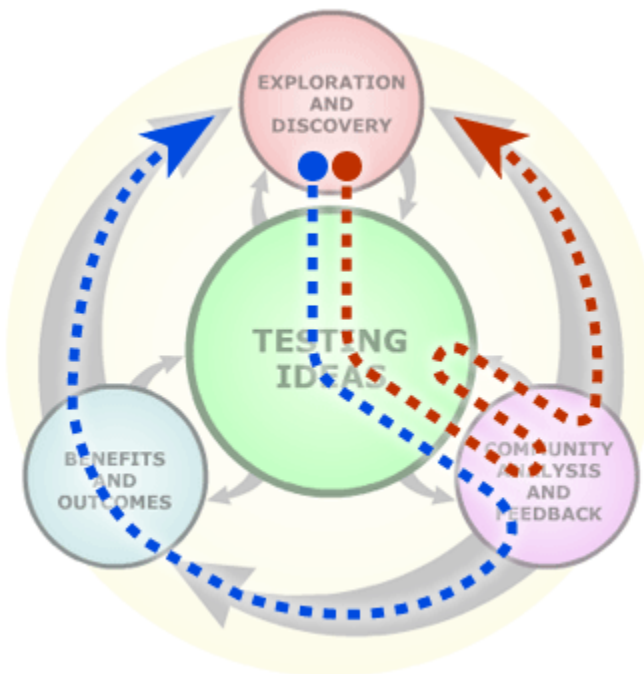
***IPDs: The Real Process of Science***

On their *Understanding Science – how science really works*, website,<sup>12</sup> the University of California at Berkeley<sup>13</sup> explains that “the process of science is not predetermined,” an understanding that is in stark contrast to Health Canada’s Notice of Intent which concludes “that the majority of pollinator mortalities were a result of exposure to neonicotinoid insecticides....”

Of particular note, Health Canada’s Notice gives only the most cursory attention to the non-pesticide causes of bee health “including parasites, disease and climate.” The danger to bees and the humans who depend on them is that Health Canada’s proceeding may be following a scripted process to a predetermined conclusion.

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**The process of science is not predetermined.**



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**SOURCE: UNIVERSITY OF CALIFORNIA/BERKELEY**

To be effective, regulatory processes need to be modeled based on the example of open, interactive scientific inquiry. Canned/predetermined policies which are not open to new ideas can never protect as effectively as regulatory responses which integrate regulatory and scientific processes through informed public discussion. It is for this reason that CRE developed the Interactive Public Docket.<sup>14</sup>

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<sup>12</sup> See, [http://undsci.berkeley.edu/article/0\\_0\\_0/howscienceworks\\_02](http://undsci.berkeley.edu/article/0_0_0/howscienceworks_02).

<sup>13</sup> See, <http://www.berkeley.edu/news/features/nobel/>.

<sup>14</sup> See, Wikipedia entry for Interactive Public Dockets, [http://en.wikipedia.org/wiki/Interactive\\_Public\\_Docket](http://en.wikipedia.org/wiki/Interactive_Public_Docket).

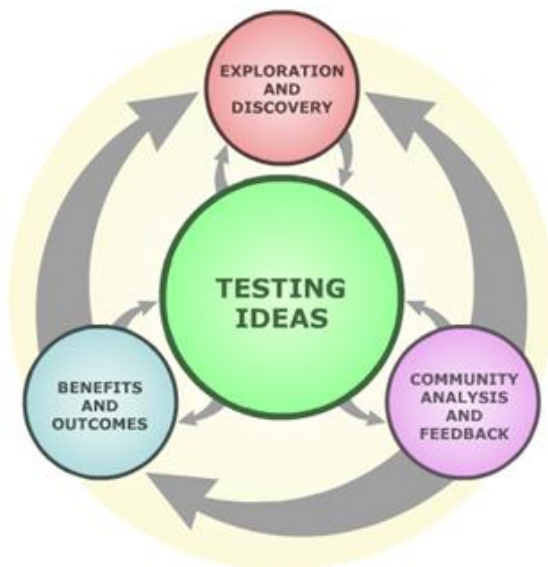
Commonly, regulatory agencies review materials and develop a near-final proposal before seeking substantive input through a brief public review process before shutting itself off from the public and developing the final rule. The result is that the public may have only a two month window of opportunity to participate in a multi-year rulemaking process.<sup>15</sup>

A crucial deficiency inherent in the one-shot approach to public participation is that the public has virtually zero opportunity to comment on the data, analyses and recommendations submitted by other stakeholders. Science, however, is an iterative process, not a linear one. Continuous feedback is a basic part of the scientific process. The core concept illustrated below is that ideas need to be tested and refined through an iterative process.

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### The *real* process of science

The process of [science](#), as represented here, is the opposite of "cookbook" (to see the full complexity of the process, roll your mouse over each element). In contrast to the linear steps of the simplified scientific method, this process is non-linear:



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SOURCE: UNIVERSITY OF CALIFORNIA/BERKELEY

*Community Analysis and Feedback* is an essential component of the idea testing process and IPDs are the e-Rulemaking tool for facilitating community involvement in the community analysis and feedback process. As illustrated by below in the University of California at Berkeley’s online discussion of the scientific process, community participation involves several functions including but not limited to:

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<sup>15</sup> For more information on the limited window for public participation in the regulatory process, please see OIRA Watch, “The Social Media and Public Participation in Rulemaking: 1.0,” *available at* <http://www.thecre.com/oira/?p=2175>.

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- Peer review;
- Replication;
- Discussion with knowledgeable persons; and
- Developing new questions and ideas.

In short, IPDs are the open, transparent mechanism regulatory agencies and should use for engaging the public in the Community Analysis and Feedback process. The community feedback is needed because, as UCal Berkeley, as we have noted, “The process of science is not predetermined.”<sup>16</sup> Thus, regulatory proceedings that proceed toward a pre-determined end do *not* represent the culmination of a scientific process but, instead, represent a policy process that has avoided both science and meaningful public participation.

From the Cal Berkeley chart, we can see that:

1. Community analysis and feedback is an integral part of the scientific process; and
2. Community participation needs to be on an ongoing basis.

CRE’s Review of Bee Health Decline IPD is a freely available discussion forum for in-depth analysis of pollinator protection issues on an ongoing basis. PMRA should make use of one or more Interactive Public Dockets in their neonicotinoid consultation process so as to establish an ongoing dialog.

With respect for the need for increased transparency in PMRA’s review of neonicotinoids two distinguished professors from McGill University have just published the results of their research, funded by the Social Science and Humanities Research Council of Canada, on the “the role of science-based knowledge in the Executive decision-making processes of Westminster-based governments.”<sup>17</sup> Two of the key points made by the authors are:

- “Our participants identified a number of factors affecting the value of science-based evidence to strategic public policy processes. They described a lack of access to appropriately contextualized knowledge and a lack of accountability to demonstrate how science was considered in Cabinet decision-making.”<sup>18</sup>
- “Concomitant was the desire for fundamental institutional changes, including greater use of deliberative public participation tools in environmental science and policy and more networked approaches to science.”<sup>19</sup>

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<sup>16</sup> See, [http://undsci.berkeley.edu/article/0\\_0\\_0/howscienceworks\\_02](http://undsci.berkeley.edu/article/0_0_0/howscienceworks_02).

<sup>17</sup> Briony M. Lalor and Gordon M. Hickey, “Environmental science and public policy in Executive government: Insights from Australia and Canada,” *Science and Public Policy*, Advance Access published November 13, 2013, available at <http://spp.oxfordjournals.org/content/early/2013/11/13/scipol.sct022.abstract>.

<sup>18</sup> Lalor and Hickey, Abstract.

<sup>19</sup> Ibid.

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To these ends, CRE is using its Bee Health Interactive Public Docket [http://www.thecre.com/oira\\_pd/](http://www.thecre.com/oira_pd/) to ventilate the major policy and scientific issues in the PMRA neonicotinoid proceeding. We recommend that PMRA:

1. Notify all stakeholders of the existence of the CRE IPD and encourage them to post relevant information thereto , and
2. Subsequent to the close of the public comment period provide to the public timely releases of its interim analyses as well as describing any informational gaps it might encounter.

The PMRA review process would be improved greatly if it became more transparent and interactive using the CRE Interactive Public Docket for Bee Health Decline, [http://www.thecre.com/oira\\_pd/](http://www.thecre.com/oira_pd/).<sup>20</sup>

With respect to improving the use of science in regulatory processes, we also call your attention to a Canadian government report on the topic which was discussed in the just-released Lalor and Hickey paper, *A Framework for Science and Technology Advice: Principles and Guidelines for the Effective Use of Science and Technology Advice in Government Decision Making*.

- “In 2007, the Government of Canada released a report outlining principles and guidelines for improving the use of science in decision-making in government (Industry Canada 2007). This document represented a strategy for federal government departments to improve inclusiveness and accountability to use science in internal decision-making and the briefing of their Ministers. However, the extent to which this policy document has driven improvements in the relationship between science and policy in the decision-making processes of Canada’s current Executive government is not clear.”<sup>21</sup>

The Industry Canada Report included the following Principle:

*“Departments should review key decisions to determine whether recent advances in scientific knowledge affect the science and science advice used to inform the decision.”*

-- Industry Canada (2007) [p. 11]

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<sup>20</sup> Industry Canada. (2007) *A Framework for Science and Technology Advice: Principles and Guidelines for the Effective Use of Technology Advice in Government Decision Making*. Ottawa: Industry Canada, p. 11, available at <http://publications.gc.ca/collections/Collection/C2-500-2000E.pdf>.

<sup>21</sup> Lalor and Hickey, p.8.

## II. Bee Health Decline

Throughout these comments, we will refer to Bee Health Decline rather than use the more popular phrase Colony Collapse Disorder (CCD) because the use of the term CCD implies that honeybee health problems represent a single, specific phenomenon. To the contrary, as the United States Department of Agriculture (USDA) explains, “[c]onsensus is building that a complex set of stressors and pathogens is associated with CCD, and researchers are increasingly using multi-factorial approaches to studying causes of colony losses.”<sup>22</sup>

*“The parasitic mite Varroa destructor remains the single most detrimental pest of honey bees, and is closely associated with overwintering colony declines.”*

-- US Department of Agriculture, Report on the National Stakeholders Conference on Honey Bee Health, p. vi.

Innumerable factors, plausible and implausible, have been *associated* with bee health decline in either the scientific literature or the popular imagination. USDA even has a section on their honeybee health website devoted to Cell Phones and CCD which notes that “[d]espite a great deal of attention having been paid to the idea, neither cell phones nor cell phone towers have been shown to have any connection to CCD or poor honey bee health.”<sup>23</sup>

The University of Florida recently noted that at “this point, almost every conceivable and realistic cause [of CCD] remains a possibility.”<sup>24</sup> Leading candidates to be a cause of CCD include, according to the university publication include “Varroa mites and associated pathogens,” “Traditional bee pests and diseases (including American foulbrood, European foulbrood, chalkbrood, nosema, small hive beetles, and tracheal mites),” and “Nutritional fitness.”<sup>25</sup> It is worth noting that the popular website About.com has their own list of the top ten possible causes of CCD which starts with Malnutrition and culminates with Electromagnetic Radiation and Climate Change.<sup>26</sup>

Given the many uncertainties regarding the causality of bee health decline, we are surprised by the determinative statement made on the first page of its Notice, that the agency has already “concluded that the majority of pollinator mortalities were a result of exposure to neonicotinoid insecticides....”

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<sup>22</sup> US Department of Agriculture, “Report on the National Stakeholders Conference on Honey Bee Health: National Honey Bee Health Stakeholder Conference Steering Committee,” (“Report”) October 15-17, 2012, p. v, *available at* <http://www.usda.gov/documents/ReportHoneyBeeHealth.pdf>.

<sup>23</sup> USDA, Agriculture Research Service, Honey Bees and Colony Collapse Disorder, *available at* <http://www.ars.usda.gov/News/docs.htm?docid=15572#phones>.

<sup>24</sup> Jamie Ellis, “Colony Collapse Disorder (CCD) in Honey Bees,” University of Florida, IFAS Extension, Publication #ENY-150, Publication date May 2007. Revised July 2010 and September 2013. p. 2.

<sup>25</sup> *Ibid.*, pp 2-3.

<sup>26</sup> “10 Possible Causes of Colony Collapse Disorder,” *available at* <http://insects.about.com/od/antsbeeswasps/tp/CausesofCCD.htm>.

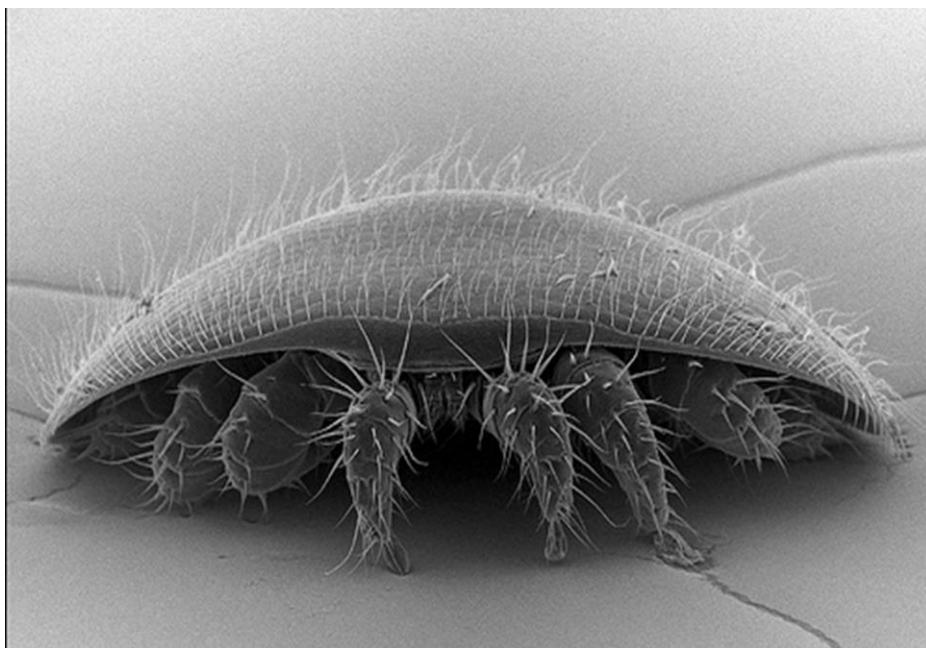
The definitive nature of the agency’s statement was particularly surprising since PMRA admitted that its policies based on its assumption that bee colonies declining because of pesticides *failed* to remedy the problem. Instead of analyzing why its policies didn’t work and keeping an open mind, PMRA has chosen to double-down on its preconception that “current agricultural practices related to the use of neonicotinoid treated corn and soybean seed are not sustainable.”<sup>27</sup>

USDA, which has a more in-depth, science-based approach to bee health, has left no doubt as to the leading cause of bee health decline, the *varroa destructor* mite. It is for this reason that we begin our discussion of bee health problems with a focus on varroa.

**A. *Varroa Destructor: The Predominant Cause of Bee Health Decline***

In addition to the direct damage done to bees by varroa, a USDA-lead state-of-the-science report on bee health found that “Varroa is known to cause amplified levels of viruses.”<sup>28</sup> Because varroa has been identified by federal science authorities as the leading threat to bees, CRE’s conversations with regulators around the world have included extensive discussion of the varroa mite.<sup>29</sup>

In these comments, CRE will leverage the work we have already performed in analyzing the bee health/varroa issue through two mechanisms, (1) the scientific record which is analyzed on our Bee Health IPD and (2) our comments to regulatory agencies in Europe and the US. Through the IPD and our regulatory filings, we provide PMRA officials with an overview of what we have learned about honey bee health.



*Varroa Destructor, Honey Bee Enemy #1.*

<sup>27</sup> Pest Management Regulatory Agency, Notice of Intent NOI2013-01, “Action to Protect Bees from Exposure to Neonicotinoid Pesticides,” 13 September 2013, p. 1.

<sup>28</sup> USDA, Report, p. vi.

<sup>29</sup> CRE’s Latin American sister organization, CRE Brazil, has discussed the dangers of varroa here, <http://cre.org.br/index.php?action=see-news&wneCode=631&language=por>.



## 1. Varroa Destructor Review

The Review of Bee Health Decline often analyzes the science behind media reports on major regulatory policy controversies. Two examples of the forum's analyses of major media reports on varroa-related bee health decline may be found starting on page 9. The first of these media report analyses is about a segment on the Canadian news program 16x9 discussing bee health. The second media analysis discusses the *Guardian's* account of the UK government's decision to reject EU's moratorium on some neonicotinoids. This second media analysis also covers the Parliamentary debate on bee health following the government's pollinator protection decision.

All of the forum's discussions, including those referenced in these comments, are available for public review and comment on an ongoing basis at [http://www.thecre.com/oira\\_pd/](http://www.thecre.com/oira_pd/). For instructions on how the Review of Bee Health Decline's readers are easily able to comment on articles and post their own materials, please see below.

### *Open Posting of Comments and Supporting Materials on the Review of Bee Health Decline*

To comment on a specific article, readers use the **Leave a Comment** function highlighted below.

The screenshot shows the 'Review of Bee Health Decline' forum interface. At the top, there is a navigation bar with links for 'HOME', 'ABOUT FORUM', and 'CONTACT THE FORUM', along with a search box. The main content area features a post titled 'Syngenta "This study shows that risk to bees is much lower in the field, than under artificial conditions used in laboratory studies – some of which exaggerated the doses."' with an 'Editor's Note' and a quote from the author. Below the quote, there is a 'Read the full post' link and a 'Leave a Comment' button, which is highlighted with a green arrow. To the right of the main content, there is a sidebar with sections for 'Links' (CRE, OIRA Watch), 'Submit a Post' (with a 'Content' section for 'Post Title' and 'Post Text (Required)'), and 'Upload Files' (with an 'Upload' section for 'Browse...' and 'Upload Now!').

To submit new posts, readers use the **Submit a Post** function, as illustrated below, including the **Post Title**, **Post Text** and have the option of the **Upload** function to make their supporting documents publicly available.



**a. 16x9 = Misreporting on Bee Health Decline**

The Canadian news program 16x9 televised a segment, *Flight of the Bees*, which attributes the decline of bee health to neonicotinoids. CRE decided to analyze the science behind 16x9's bee story. CRE posted our analysis on our bee health IPD.<sup>30</sup>

CRE found several problems with 16x9's reporting. First, a news program which attempts to explore the problem of bee health decline didn't discuss the role of varroa destructor despite its widespread recognition as the leading threat to bee health. Beyond the obvious, CRE also found that the criticism of the study at the center of the program – a study vetted by Canadian and US regulatory authorities, was unfounded.

<sup>30</sup> See, [http://www.thecre.com/oira\\_pd/?p=11094](http://www.thecre.com/oira_pd/?p=11094).

*“The U.S. Environmental Protection Agency (EPA) and Canadian Pest Management Regulatory Agency (PMRA) oversaw and approved the field study protocols and an independent quality assurance team supervised data collection and analysis. As stated by Dr. Scott-Dupree the shortcomings of lab studies are much greater than field studies, “The importance of these field studies is substantial because a lot of the critical data indicating that neonics are killing the bees is based on laboratory studies,” she said. Dr. Scott-Dupree continued, “The doses the bees are exposed to (in lab studies) are far above what a realistic field dose exposure would be.” Importantly there have not been field studies conducted that demonstrate neonicotinoids are harming bees. [Emphasis added]*

*Notably, the Scott-Dupree study found that for the bees exposed to neonicotinoids there was no reduction in honey yield, which is an indication of overall colony health. Similarly, the study found impacts on bee death or weight gain for the bees exposed to neonicotinoids.”*

-- Review of Bee Health Decline responding to 16x9  
[http://www.thecre.com/oira\\_pd/?p=11094](http://www.thecre.com/oira_pd/?p=11094)

### **b. UK Rejects EU Moratorium on Neonicotinoids**

Because, “Stories about the declining bee population and its effects on the environment trickle through the news cycle nearly every day” the UK-based *Guardian* newspaper began highlighting and analyzing major bee stories to “make sense of the issues...”<sup>31</sup> The Review of Bee Health Decline evaluated the news story and found that it may several crucial points.<sup>32</sup> The news account discussed both the government’s decision to support use of neonicotinoids and concerns from some Members of Parliament. The paper also, however, discussed the role of varroa in endangering British bees and that bees were not being treated appropriately for mite infestations. As the *Guardian* explained it:

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<sup>31</sup> [Alison Benjamin](#), [Amanda Holpuch](#) and [Ruth Spencer](#), “Parliament questions pesticide ban, mites hit hives, and almond-CCD theory,” *The Guardian*, 11 September 2013 available at <http://www.theguardian.com/environment/2013/sep/11/bees-buzzfeeds-parliament-hives-almonds>.

<sup>32</sup> See, [http://www.thecre.com/oira\\_pd/?p=10422](http://www.thecre.com/oira_pd/?p=10422).

**“What happened:**

*Experts in the UK say honey bee populations are being allowed to collapse because current treatments like oxalic acid are often applied in quantities too low to be effective, or so high that it harms the [bees](#) as well as parasites.*

**Key quote:**

*Now researchers have found that when applied as a vapour rather than a solution, and at a particular dosage, [oxalic acid] can remove virtually all traces of varroa from hives without any harmful outcomes for bees. Because the treatment is simple and cheap, costing about 10p and taking 10 minutes to apply, it could present an effective and affordable solution to the crisis affecting Britain’s bees, it was claimed.*

**Why it matters:**

*The varroa mite is a big problem for our Western honey bee. It jumped species from the eastern honey bee, with which it coexists, but our honey bee has not had millions of years of evolution to adapt accordingly. The mite feeds on our bees, weakening their immune system and spreading potentially lethal viruses which can deform the bees wings and reduce their life span. Beekeepers use a variety of methods to try and reduce the number of varroa in the hive, but the mite is endemic. Sussex University’s research suggests there is a better way to administer oxalic acid, than the method beekeepers currently use, meaning we may have a better way to reduce our high bee mortality.” [Emphasis added]*

-- From *The Guardian* as quoted on Review of Bee Health Decline

## **2. Varroa Destructor: CRE Comments to American and European Regulatory Authorities**

We noted on p.7 that the Review of Bee Health contains various types of materials including analyses of media reports on bee health issues and discussion of CRE’s comments to regulatory agencies in the US and other industrial countries. Summarized below are three CRE filings which discuss the role of the varroa mite in bee health decline. The CRE filings discussed below are to the US Environmental Protection Agency (EPA), the European Food Safety Authority (EFSA) and to the Welsh government.

### **a. CRE Comments to EPA re: Clothianidin**

CRE’s comments to the US EPA were in response to an administrative petition filed with the agency by a coalition of environmental organizations in 2012. Under the administrative process initiated by the civil society organizations, there is no scientific threshold requirement for demonstrating the merit of the

underlying argument prior to the regulatory agency soliciting public comment. EPA denied the petitioners request for an emergency suspension of clothianidin even before taking public comments.<sup>33</sup>

CRE's [comments](#) to the US EPA agreed with the EPA's conclusion that it "does not believe there is a substantial likelihood of imminent serious harm from the use of clothianidin"<sup>34</sup> in denying the petitioners' request to suspend use of clothianidin.

Likewise, the CRE argued that 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. Nevertheless, one of the core arguments as to why it would be inappropriate for the EPA to suspend clothianidin was the Petition's failure to address any research on the Varroa mite.

Specifically, the Petition failed to address a recent study led by Dr. Stephen Martin from the University of Sheffield and published in the journal, *Science*. The Dr. Martin study concluded that the Varroa Mite "has resulted in the death of millions of honey bee (*Apis Mellifera*) colonies."<sup>35</sup> The study found that "there is general consensus that 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>36</sup> One particular disease, deformed wing virus, can be directly linked to Varroa Mites' infestation of honey bee colonies.<sup>37</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. It should be noted that 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>38</sup> In contrast, "the island of Kauai and Maui remained mite-free, and no unusual colony losses or disease problems were reported there."<sup>39</sup> Specifically, "In Varroa-free areas, [deformed

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<sup>33</sup> EPA, "Pesticide News Story: The EPA Denies Petition Seeking Emergency Suspension of Clothianidin and Releases Petition for Public Review," July 19, 2012 *available at* [http://www.epa.gov/oppfead1/cb/csb\\_page/updates/2012/clothianidin.html](http://www.epa.gov/oppfead1/cb/csb_page/updates/2012/clothianidin.html).

<sup>34</sup> EPA, Pesticide News Story.

<sup>35</sup> Stephen J. Martin, et al., *Global Honey Bee Viral Landscape Altered by a Parasitic Mite*, 336 *Science* 1304, (June 8, 2012).

<sup>36</sup> *Id.* at 1304.

<sup>37</sup> *Id.*

<sup>38</sup> *Id.*

<sup>39</sup> *Id.*

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>40</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>41</sup> Furthermore, Dr. Martin’s study mirrors similar findings by Yves Conte’s report in 2010.<sup>42</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 CRE argued that the EPA must very closely consider the implications of suspending the registration of clothianidin, and the unintended consequences that may result.

At the conclusion of the comment period, the EPA rejected the petition to suspend clothianidin.

### ***b. CRE Comments to European Food and Safety Authority***

CRE drafted a communication to the European Food and Safety Authority’s (EFSA) in response to their report on neonicotinoids. CRE’s letter outlined the serious deficiencies of the EFSA report and demonstrates why the EFSA report. More specifically, CRE explained that the EFSA report failed to maximize the objectivity of the data by failing to reconcile numerous studies whose conclusions contradicted the findings of the EFSA report.

In particular, the EFSA report failed to address the following studies: (1) the varroa mite studies; (2) Dr. James Creswell’s Report “Comment on a ‘Common Pesticide Decreased Foraging Success and Survival in Honey Bees’”; and (3) the UK’s Department for Environment, Food and Rural Affairs recent studies and findings on neonicotinoids. Moreover, the EFSA report violated the DQA, because there are huge gaps in the data that EFSA relied upon (which is even acknowledged by FSA).

Nonetheless, above all these data quality deficiencies was EFSA’s failure to include the substantial research performed on Varroa’s impact on bees. As was true with the NGO Citizen Petition to Suspend Clothianidin to the EPA, a fatal defect of the EFSA research was its failure address the primary concern of Varroa.

The EFSA report did not consider the impact that Varroa Mites are having on bee health. Rather than presenting a comprehensive report on bee health decline, the EFSA report was biased and lacked objectivity. Thus, the European Commission, and its member states, acted prematurely in banning the use of neonicotinoids, particularly in light of the convincing evidence that neonicotinoids are not the cause of bee health decline. In sum, the European Commission banned of neonicotinoids without fully considering all available scientific data on the decline of bee health.

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<sup>40</sup> *Id.* at 1305.

<sup>41</sup> Victoria Gill, *Honeybee Virus: Varroa Mite Spreads Lethal Disease*, BBC Nature, (June 7, 2012).

<sup>42</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.

It is important to note that European regulatory authorities have incorrectly blamed neonicotinoids for bee mortality in the past according to the USDA. In 2008 Germany revoked the registration of clothianidin. Investigation into the actual incident revealed that the die-off was not caused by clothianidin, but rather “a combination of factors.”<sup>43</sup> Specifically, the die-off was caused by multiple factors, including “the failure to use a polymer seed coating known as a ‘sticker’” and, when combined with weather and other factors, resulted in “a higher application rate than had been authorized was used to treat for a severe root worm infestation.”<sup>44</sup>

*“We know that neonicotinoids affect honeybees, but there is no evidence that they could cause colony collapse. When we repeated the previous calculation with a realistic birth rate, the risk of colony collapse under pesticide exposure disappeared.*

*I am definitely not saying that pesticides are harmless to honeybees, but I think everyone wants to make decisions based on sound evidence – and our research shows that the effects of thiamethoxam are not as severe as first thought.*

*We do not yet have definitive evidence of the impact of these insecticides on honeybees and we should not be making any decisions on changes to policy on their use. It is vital that more research is conducted so that we can understand the real impact of neonicotinoids on honeybees, so governments can put together a proper plan to protect them from any dangers that the chemicals pose.”*

James Cresswell, *Pesticides Not Yet Proven Guilty of Causing Honey Bee Declines*, University of Exeter Press Release, 20 Sept 2012, available at [http://www.eurekalert.org/pub\\_releases/2012-09/uoc-pny091812.php](http://www.eurekalert.org/pub_releases/2012-09/uoc-pny091812.php).

### ***c. CRE Comments to the Welsh Government***

CRE submitted comments to the Welsh Government in response to their request for comment on their draft pollinator protection Action Plan.<sup>45</sup> CRE explained the need for the Welsh Government to address the Varroa Mite.

USDA: The parasitic mite Varroa destructor remains the single most detrimental pest of honey bees, and is closely associated with overwintering colony declines.

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<sup>43</sup> U.S. Department of Agriculture, *Honey Bees and Colony Collapse Disorder*, <http://www.ars.usda.gov/News/docs.htm?docid=15572#research>

<sup>44</sup> U.S. Department of Agriculture, *Honey Bees and Colony Collapse Disorder*, <http://www.ars.usda.gov/News/docs.htm?docid=15572#research>

<sup>45</sup> See, [http://www.thecre.com/oira\\_pd/?p=11134](http://www.thecre.com/oira_pd/?p=11134).

USDA: The parasitic Varroa mite is recognized as the major factor underlying colony loss in the U.S. and other countries. There is widespread resistance to the chemicals beekeepers use to control mites within the hive. New virus species have been found in bees in the U.S. and several of these have been associated with CCD. The Varroa mite is the primary factor known to increase levels of some bee viruses.

University of Illinois: First of all the varroa mite, a parasite of honey bees, has been the real game changer. It is not the cause of Colony Collapse Disorder but it is a huge factor. It has weakened bees by the pathogens that it harbors that it passes along to the bees and perhaps also by damage that it does directly to the bees.

DEFRA - Conclusion: While this assessment cannot exclude rare effects of neonicotinoids on bees in the field, it suggests that effects on bees do not occur under normal circumstances. This assessment also suggests that laboratory based studies demonstrating sub-lethal effects on bees from neonicotinoids did not replicate realistic conditions, but extreme scenarios. Consequently, it supports the view that the risk to bee populations from neonicotinoids, as they are currently used, is low.

At the conclusion of the consultation period, the Welsh government concluded that “**Neonicotinoids are not the primary cause for the reduction of pollinator numbers.**” Similarly, the Welsh Government concluded that the “spread of *Varroa* from 1994 in Wales caused much greater losses. As beekeepers have learnt to control *Varroa*, there are fewer winter losses attributable to *Varroa*, however winter losses since 2011 suggest slightly higher than expected figures of 14% – 22% in 2011 and 15% – 19% in 2012.”<sup>46</sup>

## **B. A Multifactor Approach to Understanding Bee Health Decline**

CRE noted at the beginning of our discussion of bee health decline (p. 6) that we do not use the popular term “colony collapse disorder” because it implies that the ill-defined categories symptoms has a single root cause. To the contrary, as the USDA explained the emerging scientific consensus is that is called “CCD” is actually a complex set of health problems.

Thus, the Review of Bee Health Decline analyzes numerous potential causes of bee health problems ranging from genetics to nutrition. Given, however, the intense media focus on neonicotinoids, the question arises, however, as to whether there is even the need to look at bee health hazards beyond pesticides. The study discussed below, published in PLOS One, makes clear, the answer is yes, neonicotinoids cannot explain many bee health problems because colonies which were systemically exposed to a widely-used neonicotinoid, thiamethoxam, remained as strong as unexposed control colonies year after year.

*“Consensus is building that a complex set of stressors and pathogens is associated with CCD, and researchers are increasingly using multi-factorial approaches to studying causes of colony losses.”*

-- US Department of Agriculture, Report on the National Stakeholders Conference on Honey Bee Health, p.v.

<sup>46</sup> Available at, <http://wales.gov.uk/docs/desh/consultation/130409pollinators-action-plan-en.pdf>.



### *1. The PLOS One/Syngenta Study*

The Review of Bee Health Decline recently published an analysis of a four-year long study examining the impact on honey bees of use of thiamethoxam, a neonicotinoid, as a seed treatment on oilseed rape and maize.<sup>47</sup> The study received financial support from Syngenta, a company which produces thiamethoxam. Of note, the article's Editor is a distinguished bee researcher affiliated with the University of Maryland.<sup>48</sup>

The study of the effect of neonicotinoids measured the residues of thiamethoxam and of the metabolite clothianidin in pollen collected from honey bees after foraging on flowering seed treated with the neonicotinoid and residues in the hive. Moreover, the study also examined the “long-term risk to honey bee colonies in the field was also investigated, including the sensitive overwintering stage, from four years consecutive single treatment crop exposures to flowering maize and oilseed rape grown from thiamethoxam treated seeds at rates recommended for insect control.”<sup>49</sup> The illustration below, from the PLOS One study, describes the detailed exposure and monitoring design for the four year multiple exposure field trial.

With respect to the study design, the authors explained that “Three long-term overwintering trials were established in maize in the Lorraine, Alsace and Aveyron regions of France in 2006, and two trials in oilseed rape in the Picardie and Alsace regions in 2005. As illustrated on the next page, each trial site was isolated from other bee attractive crops or other maize and oilseed rape fields to avoid diluting exposure to potential residues of thiamethoxam.”<sup>50</sup>

*[This space left intentionally blank]*

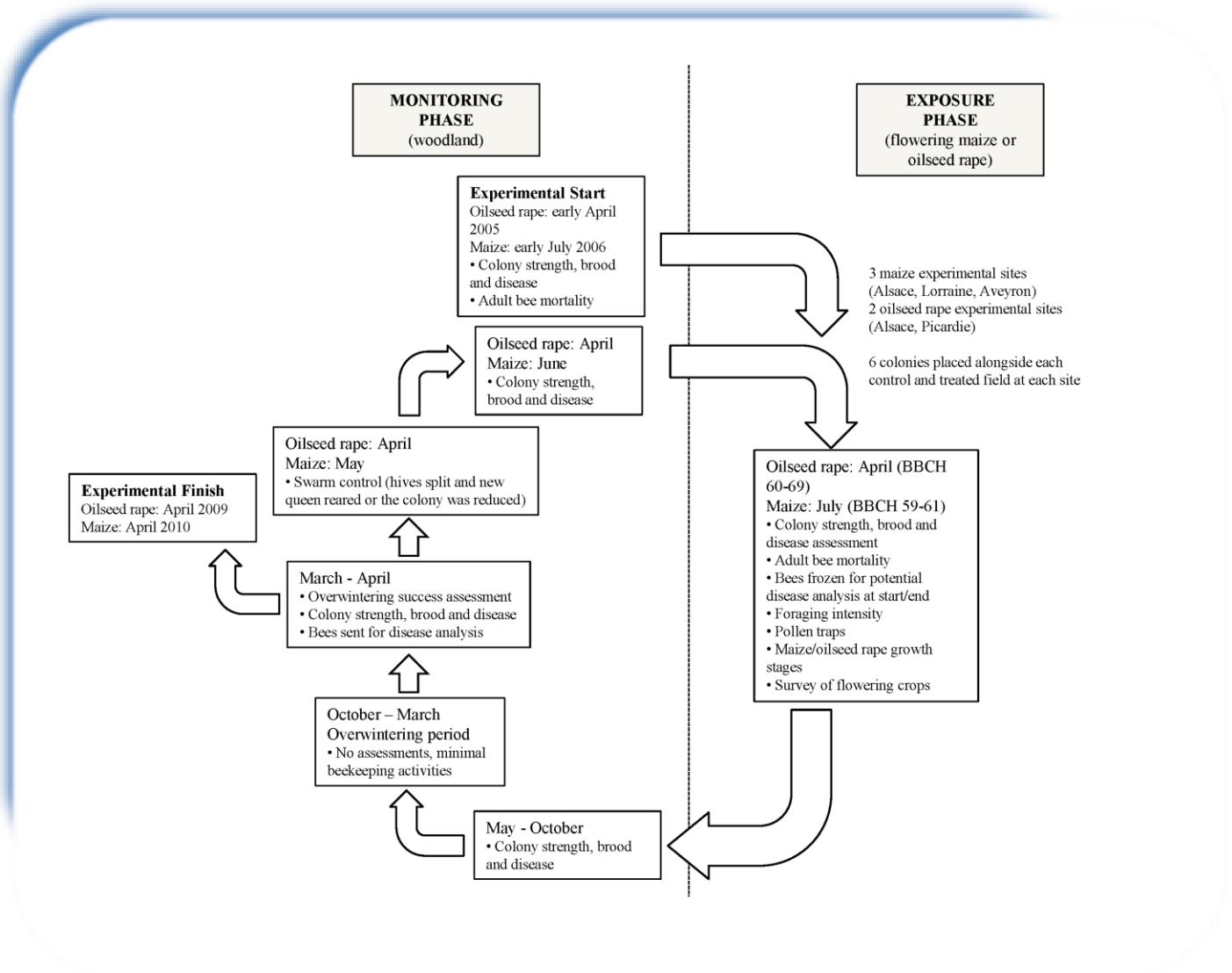
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<sup>47</sup> See, [http://www.thecre.com/oira\\_pd/?p=11191](http://www.thecre.com/oira_pd/?p=11191).

<sup>48</sup> See, [http://www.ted.com/speakers/dennis\\_vanengelsdorp.html](http://www.ted.com/speakers/dennis_vanengelsdorp.html).

<sup>49</sup> Edward Piling, Peter Campbell, Mike Coulson, Natalie Ruddle, Ingo Tornier, “A Four-Year Field Program Investigating Long-Term Effects of Repeated Exposure of Honey Bee Colonies to Flowering Crops Treated with Thiamethoxam,” October 2013, Volume 8, Issue 10, e77193, Published October 23, 2013 available at [http://www.thecre.com/oira\\_pd/wp-content/uploads/2013/11/PLOS-One-Syngenta.pdf](http://www.thecre.com/oira_pd/wp-content/uploads/2013/11/PLOS-One-Syngenta.pdf).

<sup>50</sup> Piling, et al, p. 8.



Assessments of colony condition were based on:

- “Strength of the colony (estimation of adult worker bee numbers based on the Liebefeld method
- Presence of a healthy egg-laying queen and freshly laid (one day old) eggs
- Estimate of the pollen storage area and area with nectar (in % of the comb area)
- Estimate of the area containing eggs, larvae and capped cells (in % of the comb area)
- Weight of the colony”<sup>51</sup>

<sup>51</sup> Ibid., p. 9.

The study makes detailed findings about the exposure of bees to neonicotinoids through pollen and nectar and found the exposure to be low. Regulators need to understand the real-world exposure of bees to pesticides in order to be able to set effective pollinator protection policies.

*“The detailed residue data reported in this paper provide yet further confirmation that residues of thiamethoxam and its primary metabolite CGA322704 in pollen and nectar collected from bees exclusively foraging in flowering thiamethoxam seed treated maize and oilseed rape are typically low, with median values between, 1 and 7 mg/kg for pollen) and ,0.5 and 4 mg/kg for nectar.” [p. 12]*

Regulators should also take note that the four-year study directly contradicts the Health Canada Notice of Inquiry which incorrectly states that “the majority of pollinator mortalities were a result of exposure to neonicotinoid insecticides.” To the contrary,

*“The results reported here from the large scale field studies also show no evidence of detrimental effects on colonies that were repeatedly exposed over a four-year period to thiamethoxam residues in pollen and nectar, following seed treatment of oilseed rape and maize.” [p. 12]*

*“The authors concluded that dietary exposure to neonicotinoids present in trace levels in pollen and nectar cannot be implicated in honey bee declines, but that gaps remain in our current knowledge. In this study, at realistic field exposures to pollen and nectar from the recommended use of thiamethoxam as a seed treatment on maize and oil seed rape, no detrimental effects on colony survival and overwintering success were reported. These results are consistent with the findings of Cresswell et al.. and contribute towards improving our understanding of exposure*

*“We’re taking a novel approach to studying the colony collapse phenomenon,” Toth said. “A lot of scientists are looking at viruses or nutrition or pesticides; our approach is the interaction among many factors and evaluating how they all work together.”*

[http://www.thecre.com/oira\\_pd/?p=848](http://www.thecre.com/oira_pd/?p=848)

There is a broad consensus that researchers and regulators need to take a multi-factor approach to examining bee health decline. Even civil society organizations that have taken strong positions against the use of neonicotinoids recognize the need for a multi-factor understanding of bee health. For example, the Pesticide Action Network North America (PANNA) stated that “Most scientists agree that there is no single cause of CCD. Rather, recent population declines are caused by a combination of actors acting in concert to weaken bee colonies to the point of collapse.”<sup>52</sup> Similarly, the NGO Operation Bee defines CCD as the “rapid disappearance of bees as a multi-factor syndrome.”<sup>53</sup>

### ***Health Canada Falls Short in Recognizing the Need for a Multi-Factor Approach to Understanding Bee Health Decline.***

The scope of Health Canada’s *Notice of Intent-Action to Protect Bees From Exposure to Neonicotinoid Pesticides* fails to acknowledge the widespread multi-factor cause of bee health decline. Instead, as was noted earlier, the Notice of Inquiry barely even acknowledges the role of mites and other factors influencing bee health.

It is essential for any credible inquiry to consider issues identified in the literature as bee health hazards as part of its review on neonicotinoids. Based on the scientific literature and discussed on the Review of Bee Health Decline, below are set forth some of the multitude of factors which are influencing bee health.

- **Multi-Factor: Genetics, Behavior and Nutrition.** Researchers at Iowa State University, with the assistance of USDA funding, are explicitly taking a multi-factor approach to understanding bee health decline.
- **Pathogens.** University researchers in Montana are focusing on pathogens as a culprit behind bee health decline.

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<sup>52</sup> Pesticide Action Network North America, “Pesticides and Honey Bees: State of the Science,” p. 2, available at <http://utahpests.usu.edu/bees/files/uploads/Bees&Pesticides.pdf>.

<sup>53</sup> Operation Bee, Crisis 101, available at <http://www.operationbee.com/crisis101.php>.

*“The researchers found that the four main forms of Se in plants — selenate, selenite, methylselenocysteine and selenocystine — cause mortality and delays in development in the honey bee.”*

[http://www.thecre.com/oira\\_pd/?p=11126](http://www.thecre.com/oira_pd/?p=11126)

- **Immune System.** Researchers at Lund University in Sweden are examining how bacteria in the gut of bees affects their immune system.

*“We still think it’s a pathogen – a concurring infection of at least two different organisms that cause colony collapse, and they all happen to infect the intestines of the bees,” said Colin Henderson, a project research manager at Bee Alert Technology and a professor at Missoula College.*

*“We’ve done whole-colony experiments on this, and it works every time.”*

[http://www.thecre.com/oira\\_pd/?p=8752](http://www.thecre.com/oira_pd/?p=8752)

- **Metal Pollution: Selenium.** According to researchers at the University of California at Riverside,

*“A Lund University research team has made an astounding discovery – bees have a battery of healthy bacteria in their honey stomach that protects them. Giving these lactic acid bacteria back to bees boosts their natural immune system, helping them fight off disease.*

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*The Lund University-developed product, SymBeeotic, is a natural supplement containing lactic acid bacteria, and is given to bees as nutrition, ideally before and after their winter hibernation. “This is the only existing product that boosts bees’ natural immune system so they can fight multifactorial diseases”, says Dr Tobias Olofsson, who developed the product together with Dr Alejandra Vasquez.”*

[http://www.thecre.com/oira\\_pd/?p=11010](http://www.thecre.com/oira_pd/?p=11010)

***Australia: Lots of Neonicotinoids, No CCD***

Regulators who attempt to place primary responsible for bee health decline on neonicotinoids have a paradox to resolve, neonicotinoids are widely used in agricultural areas that have healthy bee populations. If neonicotinoids are a leading cause of CCD, why are colonies not collapsing in Australia and other places that enjoy the benefits of both healthy pollinator populations and neonicotinoids?

A member of the Victoria Apiarist Association, writing in the Australia Bee Journal put it thusly,

*“As food for thought, I’ll leave you with the following:*

- *Neonicotinoids are widely used in Australia and our bees are not (yet) in decline.*
- *The 1999 and 2005 neonicotinoid bans in France did not lead to improved colony survival. Anecdotal reports of short-term improvements post-2005 are now attributed to a mild winter and losses have risen again.*
- *Canadian bee losses remain fairly steady despite the bulk of the honey crop coming from neonicotinoid treated canola.”* [Emphasis added]

Chris Strudwick  
VAA member

Australian Bee Journal (October 2012)  
<http://www.vicbeekeepers.com.au/what-is-wrong-with-our-bees-.html>

It’s not only in Australia that we see neonicotinoids and honey bees peacefully co-existing. Bees and neonicotinoids are also working together in Illinois

**C. Seed Treatment Protects the Environment, Minimizing Use Agricultural Chemicals**

“Seed treatment” is defined by the US Federal Seed Act to mean seeds which have been “given an application of a substance or subjected to a process designated to reduce, control, or repel disease organisms or other pest, which attack seeds or seedlings growing there from.”<sup>54</sup>

The advantage of treated seeds for farmers and the environment is that, compared with conventional techniques for applying agricultural chemicals is that, “Seed treatments can be an environmentally more friendly way of using pesticides as the amounts used can be very small.”<sup>55</sup> There is concern, however, that

<sup>54</sup> See, <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRD3317429>.

<sup>55</sup> See, Wikipedia definition of Seed Treatment, [http://en.wikipedia.org/wiki/Seed\\_treatment](http://en.wikipedia.org/wiki/Seed_treatment).

that seed treatment is contributing to bee health decline as pollinators are exposed to pesticide residues including in pollen and nectar.

The Syngenta/PLOS One study that we discussed (starting on p. 16) used a detailed methodology to measure actual honey bee exposure to a neonicotinoid during its routine commercial use over several years and found that real-world bee exposures the pesticide were and that “there is a low risk to honey bees from systemic residues in nectar and pollen following the use of thiamethoxam as a seed treatment on oilseed rape and maize.”<sup>56</sup>

The focus for Health Canada should be to minimize the impacts of neonicotinoid through the development of best practices management during planting in order to minimize unnecessary dust. As research has shown, significant incidents of bee deaths from neonicotinoids can be directly related to the improper planting methods. For example, as USDA explained, a 2008 bee die-off that authorities had attributed to a neonicotinoid was actually caused by factors “including the failure to use a polymer seed coating....”<sup>57</sup>

### ***Seed Treatment Technologies which Enhance Bee Safety are Advancing***

As is true of smart phones, seed coatings are high technology products which are achieving new levels of environmental performance through research and development. Of particular note, the agricultural press recently reported that “Canadian corn growers will have access next spring to a new product from Bayer CropScience that reduces dust emissions by 90 per cent.”<sup>58</sup>

*“Here, corn and soybean agriculture use one of the most controversial classes of insecticides, the neonicotinoids. But there are no problems in this area with Colony Collapse Disorder. We’re ground zero for neonicotinoid use but we have no documented cases of Colony Collapse Disorder.”*

-- Gene Robinson, Director University of Illinois’ Institute for Genomic Biology [http://www.thecre.com/oira\\_pd/?p=6799](http://www.thecre.com/oira_pd/?p=6799)

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<sup>56</sup> Syngenta/PLOS One, Abstract.

<sup>57</sup> U.S. Department of Agriculture, *Honey Bees and Colony Collapse Disorder*, <http://www.ars.usda.gov/News/docs.htm?docid=15572#research>

<sup>58</sup> Allan Dawson, “Bayer’s new product cuts potentially toxic corn dust 90 per cent,” AgCanada, October 1, 2013, available at <http://www.agcanada.com/albertafarmer/2013/10/01/bayers-new-product-cuts-potentially-toxic-corn-dust-90-per-cent/>.

Health Canada has already taken the appropriate steps by developing the *Pollinator Protection: Reducing Risk from Treated Seed*.<sup>59</sup> As noted by the best management practices identified by PMRA, most, if not all, neonicotinoid exposure comes from the dust during planting.<sup>60</sup> Using an alternative seed lubricant, other than talc, substantially reduces the dust during the planting. At this time, however, the scientific data demonstrates that seeds treated with neonicotinoids, and properly planted to minimize unnecessary dust exposure, do not expose bees to unsafe levels of neonicotinoids.

**1. Data Shows That Neonicotinoids Are Not the Cause of Bee Decline in Canada**

PMRA has called for the review on neonicotinoids, because of a high number of reported bee mortalities throughout Quebec and Ontario in 2012. The data, however, show that the deaths were not caused by neonicotinoids.<sup>61</sup>

*It's common for corn growers to add talc, graphite or both to the seed bins on their corn planters to aid seed flow and increase planting accuracy, Zamecnik said.*

*Dust comes from the planter when the vacuum used to place the seed is released. Bayer's new fluency agent is made of a polyethylene wax substrate. It reduces dust because less of it is required, it adheres well to the seed, and it's not as abrasive, he said.*

*"And more importantly there's a very significant reduction in the amount of insecticide in the dust, which is really the issue," Zamecnik said.*

*Bayer tested the new product on 40,000 acres throughout North America this spring, including 25,000 acres in Ontario and Quebec. Farmers said it worked just as well as their traditional lubricants, he said.*

<http://www.agcanada.com/albertafarmer/2013/10/01/bayers-new-product-cuts-potentially-toxic-corn-dust-90-per-cent/>

<sup>59</sup> Pest Management Regulatory Agency, *Pollinator Protection: Reducing Risk from Treated Seed*, April 8, 2013, available at <http://www.hc-sc.gc.ca/cps-spc/pubs/pest/fact-fiche/pollinator-protection-pollinisateurs/index-eng.php>

<sup>60</sup> Id.

<sup>61</sup> See also OPERA, *Bee Health in Europe – Facts and Figures 2013*. OPERA Research Centre, Univesita Cattolica del Sacro Cuore, Italy. P 64 (2013) (“the reasons [for overwinter colony losses in the US] that were more frequently mentioned by the beekeepers were: starvation, weak colonies in the fall; poor wintering conditions; poor queens and Varroa mites. Responders who suspected as responsible for their losses poor wintering conditions, Varroa mites, small hive beetles and/or CCD were proved to have higher average losses than those who suspected other factors.”).



A report released in August 2013 titled *Honey Bees, Neonicotinoids, and Bee Incident Reports: the Canadian Situation* analyzes the instances of bee mortalities reported to PMRA in detail.<sup>62</sup> This reported by Christopher Cutler, Cynthia Scott-Dupree, David Drexler reviewed all 110 incidents of bee mortalities reported to PMRA since 2007. The Cutler research initially notes that clothianidin was detected in seventy percent (70%) of bee samples from Ontario. Suggesting that clothianidin was the cause of the majority of bee mortalities, this figure has been a leading cause of a large number of media report, both nationally in Canada and internationally, and ultimately led to the calls by some groups to ban neonicotinoids in Canada. The value of the Cutler study, however, is that it parses through the actual data gathered by PMRA.

The findings of the Cutler study were that that of 110 incidents, 91% of those involving neonicotinoids were classified as minor (e.g. no lethal or sublethal effects). More importantly, there were, however, five (5) times as many major incidents due to non-neonicotinoid products. For instance, in Saskatchewan, over half of the incidents that were moderate or major were due to exposure to dimethoate or chlorpyrifos during foliar spray. Moreover, a large number of major incidents were attributed to formic acid used by beekeepers to treat for Varroa. In short, while traces of neonicotinoids were found in seventy percent (70%) of the dead bee samples, these levels were ultimately not lethal levels. In other words, the neonicotinoids were not found to be the cause of the bee deaths. One of the key messages of the Cutler study is that, “it is important that scientists, regulators, farmers, and beekeepers, and the public remember that bees are exposed to pesticides other than neonicotinoids,” such as formic acid used to control varroa mites.<sup>63</sup>

Moreover, there are large parts of Canada that have been planted with neonicotinoid treated seeds that did not experience bee die-offs. For instance, “millions of hectares of clothianidin seed-treated canola have been grown in the Canadian provinces of Alberta, Saskatchewan, and Manitoba for over a decade, and honey bees in those provinces survive as well or better than those in other Canadian provinces...there has never been a single documented incident involving bees and neonicotinoids in Alberta, Saskatchewan, and Manitoba.”<sup>64</sup> In contrast, in Vancouver Island, where annual colony losses have ranged between 60-76%, neonicotinoid use is relatively small.<sup>65</sup> These huge losses have been attributed to varroa mites rather than neonicotinoids.

Similarly, neonicotinoids are widely used in Australia. Specifically, there are 37 registered neonicotinoid insecticides that are registered and in use since the 1990s.<sup>66</sup> Despite the widespread use of neonicotinoids in Australia, Australian honey bees have remained healthy. The likely explanation for Australia’s thriving bee population is that the varroa mite has not yet spread to Australia. In fact, the Australian government

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<sup>62</sup> G. Christopher Cutler, Cynthia D. Scott-Dupree, David M. Drexler, *Honey bees, Neonicotinoids and Bee Incident Reports: the Canadian Situation*, Society of Chemical Industry, August 19, 2013.

<sup>63</sup> *Id.*

<sup>64</sup> *Id.* (citing CAPA, CAPA Statement on Honey Bee Wintering Losses in Canada (2012), Canadian Association of Professional Apiculturists).

<sup>65</sup> *Id.*

<sup>66</sup> The Australian Beekeeper, *Neonicotinoids in Australia*, available at <http://www.theabk.com.au/article/neonicotinoids-australia>

views Varroa as such a major threat that the government recently released the report, “A Honey Bee Industry and Pollination Continuity Strategy Should Varroa Become Established in Australia.”<sup>67</sup>

In addition, “multi-year monitoring studies in several European countries, including France, Germany, Austria, Spain, and Belgium, found no links between health of honey bee colonies and exposure to neonicotinoid treated crops.”<sup>68</sup> Similarly, “The bee protection organization COLOSS (Prevention of honey bee Colony LOSSes) compared surveys of honey bee losses in 2009 and 2010 in Europe with the rates of neonicotinoid application in the same geographical areas (in a separate survey). They found no correlation.”<sup>69</sup>

The Cutler study also qualifies much of the recent laboratory research on neonicotinoids. Cutler states, “when it comes to the pollinator-neonicotinoid issue, evidence of potential harm seems to be readily accepted, whereas evidence of safety or low risk most often is subject to heavy scrutiny or is ignored.” Cutler continues, “Although considerable attention has been given to a number of recent laboratory-based studies that suggest neonicotinoid seed treatments pose an unacceptable risk to pollinators, many studies under field and semi-field conditions have demonstrated that normal/typical neonicotinoid exposure is safe to pollinators.” Accordingly, the subsequent section will address the actual negligible levels of neonicotinoids that are used as part of the seed treatment application as demonstrated by recently conducted field studies that accurately reflect typical exposure to neonicotinoids.

PMRA has called for the review on neonicotinoids, because of a high number of reported bee mortalities throughout Quebec and Ontario in 2012. The data, however, show that the deaths were not caused by neonicotinoids.

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<sup>67</sup> Australian Government – Department of Agriculture, Fisheries, and Forestry, *A Honey Bee Industry and Pollination Continuity Strategy Should Varroa Become Established in Australia* (May 2011) available at [http://www.daff.gov.au/data/assets/pdf\\_file/0004/1910029/honeybee-report.pdf](http://www.daff.gov.au/data/assets/pdf_file/0004/1910029/honeybee-report.pdf)

<sup>68</sup> G. Christopher Cutler, Cynthia D. Scott-Dupree, David M. Drexler, *Honey bees, Neonicotinoids and Bee Incident Reports: the Canadian Situation*, Society of Chemical Industry, August 19, 2013.

<sup>69</sup> Henry Miller, *Bee-ing Smart: Regulators Must Distinguish Activists’ Bad Dreams From Good Evidence*, Forbes, March 13, 2013, available at <http://www.forbes.com/sites/henrymiller/2013/03/13/bee-ing-smart-regulators-must-distinguish-activists-bad-dreams-from-actual-evidence/>

<sup>70</sup> G. Christopher Cutler, Cynthia D. Scott-Dupree, David M. Drexler, “Honey bees, Neonicotinoids and Bee Incident Reports: the Canadian Situation,” Society of Chemical Industry, August 19, 2013.

half of the incidents that were moderate or major were due to exposure to dimethoate or chlorpyrifos during foliar spray. Moreover, a large number of major incidents were attributed to formic acid used by beekeepers to treat for Varroa. In short, while traces of neonicotinoids were found in seventy percent (70%) of the dead bee samples, these levels were ultimately not lethal levels. In other words, the neonicotinoids were not found to be the cause of the bee deaths. One of the key messages of the Cutler study is that, “it is important that scientists, regulators, farmers, and beekeepers, and the public remember that bees are exposed to pesticides other than neonicotinoids,” such as formic acid used to control varroa mites.<sup>71</sup>

The Cutler study also qualifies much of the recent laboratory research on neonicotinoids. Cutler states, “when it comes to the pollinator-neonicotinoid issue, evidence of potential harm seems to be readily accepted, whereas evidence of safety or low risk most often is subject to heavy scrutiny or is ignored.” Cutler continues, “Although considerable attention has been given to a number of recent laboratory-based studies that suggest neonicotinoid seed treatments pose an unacceptable risk to pollinators, many studies under field and semi-field conditions have demonstrated that normal/typical neonicotinoid exposure is safe to pollinators.” Accordingly, the subsequent section will address the actual negligible levels of neonicotinoids that are used as part of the seed treatment application as demonstrated by recently conducted field studies that accurately reflect typical exposure to neonicotinoids.

## 2. PMRA Should Consider Field Studies Rather than Laboratory Studies

It is essential that PMRA only consider field studies when considering the effects of neonicotinoids. Recent laboratory studies relied upon by in advocating for a ban on neonicotinoid exposure bees to unrealistic doses of neonicotinoids that are not found in real world conditions. The government of the United Kingdom recently acknowledged the problems with relying upon laboratory studies alone in its criticism of the Henry study:<sup>72</sup>

“The Henry et al study provides information regarding the potential adverse effects of thiamethoxam on the foraging behaviour and resulting survival of honey bees. Due to the artificiality of the test design and dosing regime, there are uncertainties regarding the risk in a more realistic field exposure situation. As part of the regulatory assessment, an extensive dataset on the potential effects of thiamethoxam on honey bees when used as a seed treatment on oilseed rape was considered. This included multi-year / multi-site field trials which indicated an acceptable risk.”<sup>73</sup>

The UK government has widely criticized the laboratory studies for exposing bees to unrealistic doses of neonicotinoids that are not found in real world conditions.<sup>74</sup> There has been recent field studies conducted in Europe which:

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<sup>71</sup> *Id.*

<sup>72</sup> The Henry study is the primary research relied upon by EFSA in advocating for the EU ban on neonicotinoids.

<sup>73</sup> U.K. Department for Environment, Food, and Rural Affairs, *Neonicotinoid Insecticides and Bees: The State of the Science and Regulatory Response*, page 3, September 13, 2012 available at <http://webarchive.nationalarchives.gov.uk/20130123162956/http://www.defra.gov.uk/publications/files/pb13818-neonicotinoid-bees-20120918.pdf>

<sup>74</sup> See the CRE’s IPD addressing this issue. [http://www.thecre.com/oira\\_pd/?p=11191](http://www.thecre.com/oira_pd/?p=11191)

“shows that exposure and hence risk to bees from thiamethoxam is much lower in the field, than under forced artificial conditions used in many published laboratory studies – some of which exaggerated the doses. “The exposure and risk is lower in field studies because residues of thiamethoxam in nectar and pollen from seed-treated crops are generally very low. Also under real field conditions bees have a choice where they forage and hence will forage on a range of food sources, not just a treated crop.”<sup>75</sup>

In fact, field studies have shown that normal neonicotinoid exposure is safe to pollinators. One such study, is the research currently being completed by Dr. Cynthia Scott-Dupree. Dr. Scott-Dupree’s study consisted of placing 40 bee colonies in 10 canola fields.<sup>76</sup> Five canola fields had seeds treated with clothianidin, while five fields were left untreated. The fields were 10 kilometers apart and five acres in size. All of the colonies used in the Scott-Dupree study were screened for the presence of agricultural pesticides and all of the colonies used in the study had no detectable residues of any neonicotinoids. The 40 colonies were placed in the fields at 25 percent canola bloom, where the bees foraged canola for two weeks.<sup>77</sup> Following the exposure, the 40 colonies were moved to an isolated military site to ensure the bees wouldn’t forage on crops treated with neonicotinoids for the remainder of the summer. Eighty-eight percent (88%) of the pollen identified by the foraging bees was canola from the fields the bees were placed in (no other canola available within 10km).<sup>78</sup>

EPA and PMRA oversaw and approved the field study protocols and an independent quality assurance team supervised data collection and analysis. As stated by Dr. Scott-Dupree the shortcomings of lab studies are much greater than field studies, “The importance of these field studies is substantial because a lot of the critical data indicating that neonics are killing the bees is based on laboratory studies,” she said.<sup>79</sup> Dr. Scott-Dupree continued, “The doses the bees are exposed to (in lab studies) are far above what a realistic field dose exposure would be.”<sup>80</sup> Notably, there have not been field studies conducted that demonstrate neonicotinoids are harming bees.

Importantly, the Scott-Dupree study found that for the bees exposed to neonicotinoids there was no reduction in honey yield, which is an indication of overall colony health. Specifically, hives that foraged on clothianidin treated seeds produced 52.8 kilograms of honey, while the control group produced 51 kg of honey.<sup>81</sup> Average Ontario honey yield in 2012 was 37 kg. Similarly, the study found no impacts on bee death or weight gain for the bees exposed to neonicotinoid treated seeds. Most importantly, there were “no effects or ‘poor performance’ in treatment colonies.”<sup>82</sup>

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<sup>75</sup> *Id.*

<sup>76</sup> Cynthia Scott-Dupree, *Field Study Reliability: A Honey Bee Neonicotinoids Perspective*, page 9 available at [http://sesss08.setac.eu/embed/sesss08/Cynthia\\_Scott-Dupree\\_Field\\_study\\_Reliability\\_-\\_A\\_Honey\\_bee\\_Neonicotinoid\\_PERSPECTIVE.pdf](http://sesss08.setac.eu/embed/sesss08/Cynthia_Scott-Dupree_Field_study_Reliability_-_A_Honey_bee_Neonicotinoid_PERSPECTIVE.pdf)

<sup>77</sup> *Id.*

<sup>78</sup> *Id.* at 12.

<sup>79</sup> Robert Arnason, *Ontario field study finds no link between seed treatments, bee deaths*, The Western Producer, February 21, 2013, available at <http://www.producer.com/daily/ontario-field-study-finds-no-link-between-seed-treatments-bee-deaths/>.

<sup>80</sup> *Id.*

<sup>81</sup> Cynthia Scott-Dupree, *Field Study Reliability: A Honey Bee Neonicotinoids Perspective*, page 9 available at [http://sesss08.setac.eu/embed/sesss08/Cynthia\\_Scott-Dupree\\_Field\\_study\\_Reliability\\_-\\_A\\_Honey\\_bee\\_Neonicotinoid\\_PERSPECTIVE.pdf](http://sesss08.setac.eu/embed/sesss08/Cynthia_Scott-Dupree_Field_study_Reliability_-_A_Honey_bee_Neonicotinoid_PERSPECTIVE.pdf).

<sup>82</sup> *Id.* at 28.

The findings by Dr. Scott-Dupree are also consistent with the research by Christian Krupke.<sup>83</sup> Krupke is one of the leading advocates for banning neonicotinoids, and his research is often cited for the premise that that neonicotinoids are absorbed into the plants through uptake by the root systems.<sup>84</sup> Accordingly, the pollen of the treated plant contains neonicotinoids. Pollen collected from the treated plants containing neonicotinoids has been found in the actual hives. The Krupke research shows, however, that the levels of neonicotinoids absorbed by the plant are negligible are for short of levels that are toxic to bees. This conclusion is consistent with the Dupree-Scott study and the Cutler study. Moreover, “recent research data (Pistorious *et al.*, 2012; Keppler *et al.*, 2010) have demonstrated that the issue of guttation is of comparably low importance compared to intoxications by spray applications and indicate that in certain circumstances only small numbers of bees of a hive may become intoxicated, even if colonies are placed directly next to crops.”<sup>85</sup>

Moreover, Krupke also argues that the greatest threat of neonicotinoid exposure to bees occurs during the planting period when there is potential for exposure to high concentrations of neonicotinoids in waste talc.<sup>86</sup> Accordingly, the neonicotinoid contaminated dust settles on the foliage and flowers of untreated plants, creating exposure to bees. The CRE agrees that the waste talc dust is greatest concern that should be addressed by PMRA.

### 3. PMRA should be Focusing on Dust Reduction

As noted by the Krupke study, the only risk of neonicotinoid exposure comes during the planting phase an unnecessary neonicotinoid contaminated dust. Specifically, Krupke notes that “Our results suggest that of the factors we quantified in this study, used talc exhausted during and after planting (the latter would occur during routine cleaning of planting equipment) stands out as potential routes for exposure that should be prioritized for further quantification and remediation.”<sup>87</sup> PMRA’s Notice of Intent also attributes dust during planting as a problem that needs to be addressed. *See PMRA, Action to Protect Bees from Exposure to Neonicotinoid Pesticides*, September 13, 2013 (levels of mortalities were caused “likely through exposure to contaminated dust generated during the planting of treated corn seed”).

Talc is used as a lubricant in pneumatic planters to reduce seed-to-seed friction and improve uniformity of planting. The use of talc (or graphite) is recommended by planter manufactures and has become standard practice. The role of talc, however, has contributed to the amount of dust exhausted by pneumatic seed planters. Moreover, the extra dry product picks up residues from the neonicotinoid treated seeds which creates dust containing neonicotinoids. The role of dust created by talc has been raised as a possible contributor to exposure of treatment.

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<sup>83</sup> Christian Krupke, Greg Hunt, Brian D. Eitzer, Gladys Andino, and Krispn Given, *Multiple Routes of Pesticide Exposure for Honey Bees Living Near Agricultural Fields*. Plos ONE7(1):e29268 (2012) (citing OPERA, Bee Health in Europe – Facts and Figures 2013. OPERA Research Centre, Univesita Cattolica del Sacro Cuore, Italy. P 64 (2013).

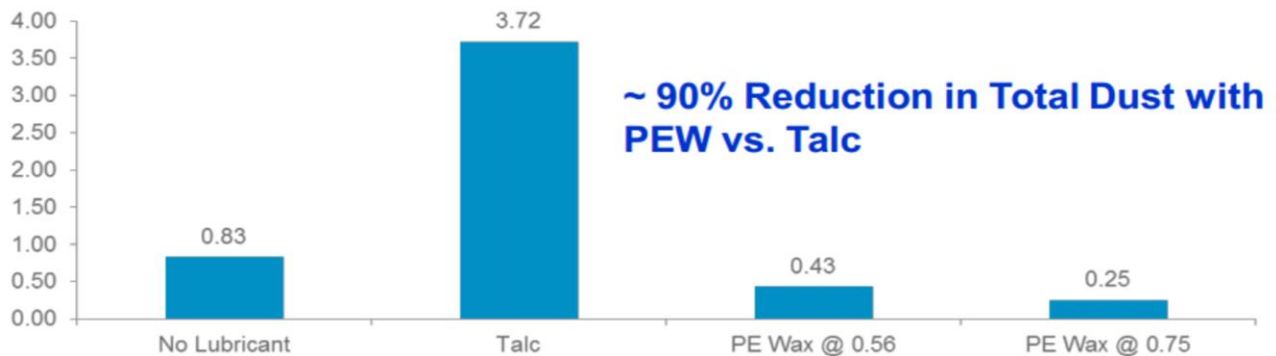
<sup>84</sup> *Id.*

<sup>85</sup> OPERA, Bee Health in Europe – Facts and Figures 2013. OPERA Research Centre, Univesita Cattolica del Sacro Cuore, Italy. P 38 (2013).

<sup>86</sup> *Id.*

<sup>87</sup> *Id.*

Talc versus Polyethylene Wax Lubricant – Gms Total Dust / 100K Seed



Source: Bill Hairston, *Talc Replacement Update*, EPA/USDA Pollinator Summit, March 5, 2013.

Krupke further comments measure taken in the EU “may reduce the dust generated during planting by 99%.”<sup>88</sup> However, “in North America, different planting equipment is used and there are currently no guidelines for disposal of waste talc, nor are there devices filtering exhaust material from the vacuum planting systems.” Krupke argues that the waste talc is “worthy of further investigation and possibly corrective action.”

Heeding the call of Krupke, since the publication of his study, there has been substantial advancement in the research to address the problems posed by the waste talc during planting.

Specifically, Bayer has been working to develop a talc replacement. The fluency agent is made out of polyethylene wax. The talc replacement has been shown to significantly decrease dust and emissions during planting. Laboratory tests have shown ninety percent (90%) reductions in total dust using the polyethylene wax agent compared to talc.<sup>89</sup> Similarly, the tests have shown a sixty percent (60%) reduction in dust compared to graphite. Moreover, these laboratory tests have shown that the talc replacement is equally effective regarding planting uniformity of the seeds, while using significantly less of the product.<sup>90</sup> The graph below shows the decreased amount of dust created using the polyethylene wax. Bayer recently completed field studies of the polyethylene wax and on the levels of dust created.<sup>91</sup> The results of the field studies mirror the laboratory studies, show a ninety percent (90%) reduction in dust.<sup>92</sup>

<sup>88</sup> *Id.*

<sup>89</sup> Bill Hairston, *Talc Replacement Update*, EPA/USDA Pollinator Summit, March 5, 2013.

<sup>90</sup> *Id.*

<sup>91</sup> *Fluency Agent Update*, Bayer Cropscience, November 2013, available at <http://cdnseed.org/wp-content/uploads/2013/11/SATC-Fluency-Agent-Update.pdf>

<sup>92</sup> Vicky Boyd, *Bayer Tests New Seed Treatments to Protect Honeybees*, The Grower, November 19, 2013 available at <http://www.thegrower.com/news/Bayer-tests-new-seed-treatments-to-protect-honeybees-232509671.html>

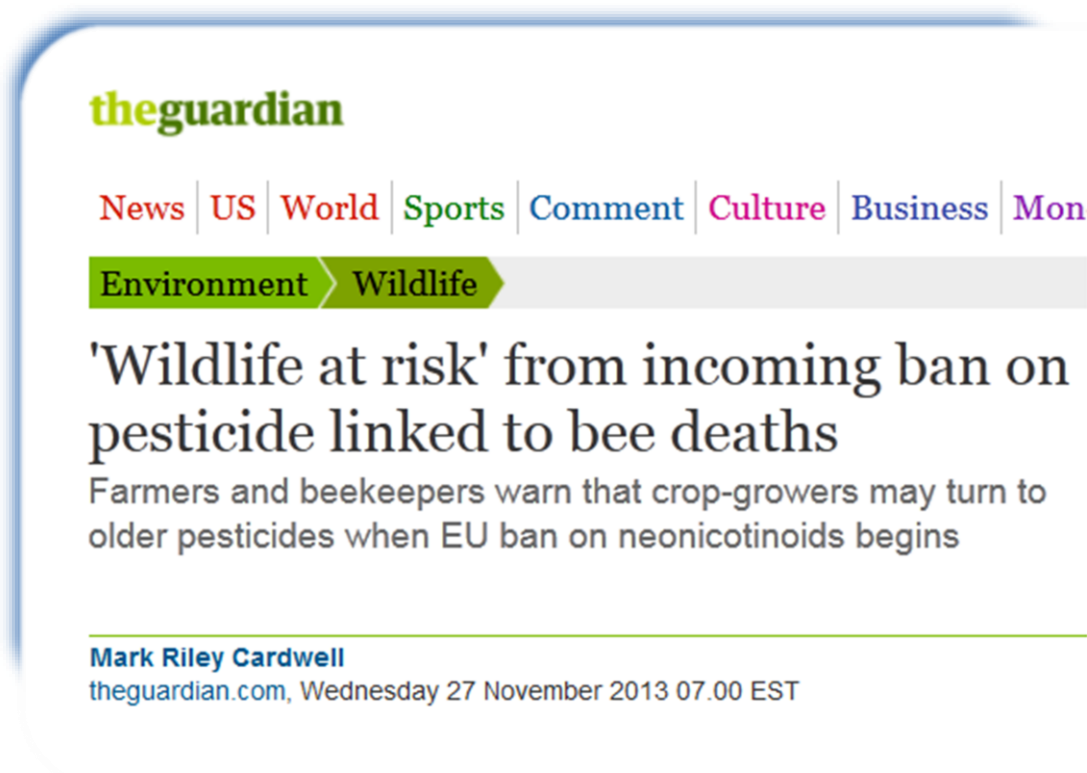
Bayer is also working with the pneumatic planter manufacturers to develop modifications to the equipment to further reduce the dust.

PMRA has also acknowledged that any high level of neonicotinoid exposure can be attributed to high levels of dust during the planting of treated corn seeds.<sup>93</sup> Accordingly, PMRA's should focus its attention on establishing best practices that minimize dust exposure, which includes the adoption of talc replacement as a lubricant for the pneumatic seed planters.

While risks from insecticide contaminated dust during planting with pneumatic seeders needs to be minimized, the evidence indicates that beekeepers can maintain healthy hives while being surrounded by neonicotinoid seed-treated corn.

### *Neonic Bans Create an Environmental Threat*

Although hazards associated with neonicotinoids receive tremendous publicity, regulatory officials also need to give consideration to the broad environmental hazards that would be posed by the planned restrictions on neonicotinoids described in Canada's Notice of Intent. In the UK there is growing recognition that a ban on neonicotinoids does not mean taking a threat to bees off the table, it means replacing neonics with pesticides that may pose broader threats to the environment.



A recent story in the Guardian began by stating that “Wildlife could be at risk from an imminent ban on pesticides linked to bee deaths, farmers and beekeepers have warned.”<sup>94</sup>

<sup>93</sup> PMRA, *Action to Protect Bees from Exposure to Neonicotinoid Pesticides*, September 13, 2013 (neonicotinoid exposure, “likely [caused] through exposure to contaminated dust generated during the planting of treated corn seed”).

<sup>94</sup> [Mark Riley Cardwell](http://www.theguardian.com/environment/2013/nov/27/wildlife-risk-ban-pesticide-bee-death-neonicotinoids), “Wildlife at risk' from incoming ban on pesticide linked to bee deaths,” *The Guardian*, 27 November 2013, available at <http://www.theguardian.com/environment/2013/nov/27/wildlife-risk-ban-pesticide-bee-death-neonicotinoids>.

The Guardian further explained that “On Sunday, a European Union-wide ban on three neonicotinoids will come into force, but the National Farmers Union (NFU) and British Beekeepers Association (BBKA) have said the restriction could fuel a rise in spray-based pesticides. They say such alternatives could harm bees, soil-dwelling insects and spiders, and lead to higher genetic resistance to pesticides among crop-eating insects.”

Of particular relevance to Canadian regulatory officials is the statement, discussed in the news article, from the National Farmers Union (NFU) who explained that “there has not been a full assessment of the environmental effects of the ban....”

*“It is alarming that we are about to see these restrictions come into force and there still hasn’t been an impact assessment done to determine whether or not there will be net environmental benefits, or what the scale of impacts on food and ornamentals production will actually be.”*

*“Decision makers should conduct an impact assessment urgently and rethink the decision to restrict the use of what is an absolutely critical product for many farmers.”*

NFU Deputy President Meurig Raymond  
<http://www.nfuonline.com/news/latest-news/neonicotinoid->

CRE explained, on page 3 of these comments “the process of science is not predetermined,” a perspective which directly contradicts the certainty expressed in Health Canada’s Notice of Intent “that the majority of pollinator mortalities were a result of exposure to neonicotinoid insecticides....” The Guardian article makes clear, however, that certainty about the wisdom of new neonicotinoid restrictions comes at the expense of environmental protection.

Prior to making any neonicotinoid decisions, Health Canada/PMRA should analyze, for public review and comment, the environmental impact assessment of its planned pesticides policy. As the Supreme Court of Canada opined, “Environmental impact assessment is, in its simplest form, a planning tool that is now generally regarded as an integral component of sound decision-making.”<sup>95</sup>

Based on the totality of the issue, we can see that the downside of additional restrictions on neonics is not *over* protection of bees but an uncalculated increase in risk to the environment.

### **III. Precautionary is Not Protective: The Emerging Consensus on the Need for Regulatory Science Quality Standards**

The British government has initiated the process to strengthen the powers of the Forensic Science Regulatory so as to increase the rigor of science used in criminal justice proceedings. The Forensic Science Regulator’s duties include setting “the quality standards for the provision on forensic science services to the police and the wider criminal justice system and by monitoring compliance with these

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<sup>95</sup> Friends of the Oldman River Society v. Canada (Minister of Transportation), (SCC 1992), available at <http://scc-csc.lexum.com/decisia-scc-csc/scc-csc/scc-csc/en/item/829/index.do>.



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standards.” Currently, however, the “Regulator does not have statutory powers or the ability to enforce compliance with his standards.”<sup>96</sup>

To overcome the limitations on the Regulator’s authority to ensure that all participants, defense and prosecution, government officials and private sector contractors, are required to adhere to the standards.

We raise the issue of Britain’s development of mandatory data quality standards for two reasons. First, CRE’s comments to US regulators often discuss regulatory science with respect to the enforceable quality requirements set by the American Data Quality Act (DQA).<sup>97</sup>

*“Quality standards will prevent systematic poor quality analysis and errors resulting from poor processes. Whilst quality standards will not always prevent human error, where such an error does occur it will be identified more quickly and will be easier to isolate, meaning the review of other affected cases will be smaller and could be completed more quickly.”*

From: “Impact Assessment-- Maintaining Quality Forensic Evidence,” p. 11. [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/255867/131106\\_IA\\_on\\_Forensic\\_Regulator.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/255867/131106_IA_on_Forensic_Regulator.pdf)

We are calling attention to Britain’s development of enforceable regulatory science quality standards to demonstrate that data quality is not simply an American concern but instead reflects a growing international consensus on the need for regulatory officials to base their decisions on the best available science.

*“From September 11 to 14, 2012, the EPA participated in a Federal Insecticide, Fungicide and Rodenticide Act Scientific Advisory Panel (SAP) meeting on a proposed framework for determining the potential risks of pesticides to honey bees.*

*The EPA, in collaboration with Health Canada's Pest Management Regulatory Agency and the California Department of Pesticide Regulation, developed a [White Paper](#) describing the new risk assessment process and the exposure and toxicity data needed to inform that process.”*

US EPA <http://www.epa.gov/opp00001/ecosystem/pollinator/science.html>

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<sup>96</sup> Norman Baker MP, Minister of State for Crime Prevention, Home Office, “Consultation on new statutory powers for the Forensic Science Regulator,” November 2013, p.4.

<sup>97</sup> For a discussion of the applicability of the DQA in international regulatory proceedings, please see <http://www.foreffectivegov.org/node/925>.

*“Maintaining the quality of work in forensics and biometrics is an essential part of protecting the public, protecting their freedom and privacy, and in maintaining public confidence in the administration of justice. The Forensic Science Regulator plays a key part in this by setting the quality standards for the provision on forensic science services to the police and the wider criminal justice system and by monitoring compliance with these standards.”*

-- Norman Baker MP  
Minister of State for Crime Prevention

Development of an international consensus on the need for quality controls on data and analyses used in regulatory processes is part of a larger and welcome move toward international cooperation in regulatory development activities. PMRA deserves substantial praise for its important ongoing work on pollinator protraction with EPA and with the State of California’s California Department of Pesticide Regulation.

The second reason why CRE is highlighting the UK’s data quality legislation is because of the clarity it brings to an issue on which American and European regulators often clash, the precautionary principle which “implies that there is a social responsibility to protect the public from exposure to harm, when scientific investigation has found a plausible risk. These protections can be relaxed only if further scientific findings emerge that provide sound evidence that no harm will result.”<sup>98</sup>

When seen in light of the UK’s forensic regulatory quality standards, the precautionary principle actually represents a threat to public safety. Who would protected by low forensic science quality standards? The defense? The prosecution? Society in general?

When the issue of science quality is taken out of the Hollywood-style good guy/bad guy scenario and placed in a real world context, it becomes apparent that the precautionary principle is simply a form of bias, albeit one that is unmeasured and of unknown impact.

When the precautionary principle is seen without its public protection guise and with its unstated operating principles of bias and limited scientific quality exposed, it becomes clear the term is a synonym for shoddy work.

A regulatory regime that has low standards for what constitutes acceptable scientific quality protects neither defendants nor society. Instead, low science quality merely allows for an increased frequency in the instances of justice being miscarried.

Similarly, lack of scientific rigor in evaluating neonicotinoids would protect neither honey bees nor the farmers who depend on them. Instead of protecting anyone, biases in evaluating the neonicotinoid scientific record would simply allow threats to bees to go unaddressed.

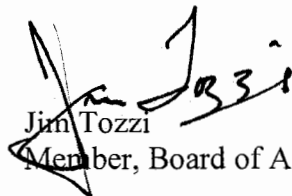
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<sup>98</sup> See, Wikipedia entry, [http://en.wikipedia.org/wiki/Precautionary\\_principle](http://en.wikipedia.org/wiki/Precautionary_principle).

**IV. Conclusions**

1. Bee Health decline is a result of a many factors, the most dominant of which being *varroa destructor*.
2. Advancements in seed treatment technology continue to reduce the exposure of bees to neonicotinoids.
3. If PMRA has established metrics it will use in assessing the quality of data in this pollinator protection proceeding, they should advise stakeholders of their existence.
4. The Precautionary Principle should not be a decision criterion, it does not protect bees or farmers.
5. PMRA is to be complimented for its commitment to make the comments it receives available to the public; CRE will publish selected significant comments submitted to PMRA on the CRE Review of Bee Health Decline IPD for public comment.

Respectfully,



Jim Tozzi  
Member, Board of Advisors