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Submitted to: www.regulations.gov

U.S. Environmental Protection Agency
Office of Pesticide Programs
1200 Pennsylvania Ave., NW
Washington, DC 20460

Re: Comments for FIFRA Scientific Advisory Panel Public Meeting on the Pollinator Risk Assessment Framework, Sept. 11-14, 2012; Docket ID: EPA-HQ-OPP-2012-0543

Dear OPP Staff and SAP Members:

EPA has an excellent record in complying with the Data Quality Act (DQA), the first part of the document is aimed at educating the SAP of DQA requirements.

Because the Risk Assessment Framework under discussion is intended to lay the foundation for, or be the first step in, what is almost certain to be a highly influential risk assessment that will eventually be peer reviewed by the SAP, CRE believes that the framework should incorporate, affirm, and apply the requirements of the DQA and its guidelines that apply to scientific assessments which will be disseminated by the Agency and that might eventually be used in regulatory proceedings. Furthermore, since EPA declared that no imminent hazard exists, CRE will not be commenting on this matter.

I. Applicability of the DQA to Agency Reliance on "Third-Party" Studies and Information

During these proceedings, and in any eventual risk assessment, there will almost certainly be discussion of scientific information that has been developed by researchers from outside the agency. We want to remind the SAP and the Agency that such "third-party" studies or information must comply with the quality requirements of the DQA and its guidelines if they are to be relied on or agreed with by the Agency. The DQA government-wide guidelines promulgated by the Office of Management and Budget (OMB) state:

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

67 Fed. Reg. 8452, 8454 (Feb. 22, 2002).[1] EPA's DQA guidelines, issued to conform to the OMB guidelines, are similar, stating:

- EPA initiates a distribution of information if EPA distributes information prepared or submitted by an outside party in a manner that reasonably suggests that EPA endorses or agrees with it; if EPA indicates in its distribution that the information supports or represents EPA's viewpoint; or if EPA in its distribution proposes to use or uses the information to formulate or support a regulation, guidance, policy, or other Agency decision or position.

- Agency-sponsored distribution includes instances where EPA reviews and comments on information distributed by an outside party in a manner that indicates EPA is endorsing it, directs the outside party to disseminate it on EPA's behalf, or otherwise adopts or endorses it.

EPA Guidelines sec. 5.3.[2]

II. DQA Standards

The basic DQA quality standards are "quality, objectivity, utility, and integrity." It is recognized that there is overlap among these standards,[3] and the OMB government-wide guidelines state that "quality" encompasses" the other standards. In addition, the OMB guidelines contain a standard of "reproducibility" for "influential scientific information." These standards are summarized below.[4]

"***Objectivity***": Under the guidelines, "objectivity" requires that information be presented in an "accurate, clear, complete, and unbiased manner" with "error sources affecting data quality ... disclosed to users."[5] The agency must also ensure that the information is "accurate, reliable, and unbiased," and that the "original and supporting data shall be generated, and the analytic results shall be developed, using sound statistical and research methods." If data and analytic results have been subjected to formal independent peer review, there is a rebuttable presumption that the information is "objective." However, as the OMB peer review guidelines (discussed

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

[2] http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf.

[3] For example, information that does not meet the standard for objectivity could be regarded as lacking utility, and transparency of data and methods is an aspect of both utility and reproducibility.

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

[5] 67 Fed. Reg. at 8459.

below) make clear, journal peer review is given less weight than other more rigorous and transparent forms of external, independent peer review and cannot substitute for peer review conducted in accordance with the DQA peer review guidance.[6] As discussed below in the section on the DQA peer review guidance, the objectivity standard is regarded as particularly important for peer review.

"***Utility***": Utility means simply that the information must be useful to intended users. Although not stated explicitly in the guidelines, utility in a scientific context appears to be equivalent to relevance. The guidelines also state that the agency must address transparency of the information if it would affect its utility.[7] Transparency, in turn, is the basis for the standard of "reproducibility," explained below.

"***Reproducibility***": This standard applies to "influential" scientific information, which is defined as information that the agency can reasonably determine will have or does have a clear and substantial impact on important public policies or important private sector decisions. Reproducibility means that the information disseminated is sufficiently transparent with regard to data and methods that a qualified member of the public could conduct an independent reanalysis in an attempt to generate similar results, subject to an acceptable degree of imprecision or error. This standard applies to both individual studies and analyses that combine information from multiple studies.[8]

Objectivity in risk assessments: The OMB guidelines required agencies to "adopt or adapt" in their own DQA guidelines the risk assessment standards contained in the Safe Drinking Water Act amendments. The EPA guidelines contain an adaptation of those standards, making some minor qualifications to them.

The EPA guidelines state that the agency will ensure objectivity in influential scientific risk assessment information for ecological hazards by using, to the extent practicable and consistent with statutory and regulatory requirements, [9] "the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including, when available, peer reviewed science and supporting studies; and … data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies the use of the data)." The guidelines also require the identification of each significant uncertainty and disclosure of peer-reviewed studies known to the agency that support, are directly relevant to, or fail to support any estimate of risk, and the methodology used to reconcile inconsistencies in the scientific data. Sec. 6.4

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[6] *Id*. at 8459.

[7] *Id*.

[8] *Id*. at 8460.

[9] The EPA guidelines note that this phrase was deemed necessary to allow it to use incident data and non-peer-reviewed company submissions under FIFRA.

III. Applicability of the DQA Peer Review Guidance

The presumption of the framework discussion is that EPA will eventually develop and disseminate a pollinator risk assessment. A draft of such an assessment would be required to undergo independent, external peer review subject to the DQA peer review guidance.[10] Under that guidance, such an assessment would undoubtedly be classified as a "highly influential scientific assessment,"[11] and therefore would be subject to certain more stringent peer review measures that supplement the original DQA guidance described above. Although the peer review guidance arguably does not directly apply to the "framework" discussions, because it will apply to a draft agency risk assessment document, as will the DQA quality standards discussed above, the peer review requirements should be taken into consideration in developing the framework.

The peer review guidance is especially important from an agency perspective because it requires that any agency regulatory action that relies on scientific information subject to the guidance "shall include in the administrative record for that action a certification explaining how the agency has complied with the requirements of this [peer review] Bulletin and the applicable data quality guidelines."[12]

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

> *[W]here appropriate, reviewers should be asked to provide advice on the reasonableness of judgments made from the scientific evidence. However, the charge should make clear that the reviewers are not to provide advice on the policy (e.g., the amount of uncertainty that is acceptable or the amount of precaution that should be embedded in an analysis). Such considerations are the purview of the government.* [Footnote omitted.]

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[10] 70 Fed. Reg. 2664 (Jan. 14, 2005). It is clear from the guidance itself that it applies to FACA advisory committees and supplements the requirements of FACA.

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

[12] 70 Fed. Reg. at 2677.

[13] Id. at 2675 1st and 2d cols. and 2671 3d col.

70 Fed. Reg. at 2669 1st col.

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

IV. The Lu *et al*. 2012[14] Study as an Example of a Third-Party Study That Is Clearly Non-Compliant with the DQA and That Therefore Could Not Be Used.

This study report claims that it provides "convincing evidence that exposure to sub-lethal levels of imidacloprid [administered in high-fructose corn syrup within hives for 13 weeks] causes honey bees to exhibit symptoms consistent to [sic] CCD [colony collapse disorder] months after imidacloprid exposure."[15] It also claims that the study results "show a profound and devastating effect of low levels of imidacoprid in HFCS [high fructose corn syrup fed to bees] on honey bee colonies."[16] These claims in the study have received widespread publicity in Harvard press releases and articles, the media, and blogs, with imidacloprid being described often as a the "likely culprit" in bee health decline.

The most basic flaw in the study – and there are many – is that it fails to satisfy the standard of "utility"/relevance. The stated purpose of the study was to examine whether feeding high-fructose corn syrup ("HFCS") to bee colonies -- a practice often[17] used by beekeepers to supplement the diets of their honey bee colonies during winter -- and which was assumed to contain imidacloprid residues from imadicloprid-treated corn, would result in bee health decline in a number of observed colony clusters and control hives. The control hives were fed with HFCS that was not artificially spiked with various levels of imadicloprid, while four colony clusters were fed with HFCS spiked with various levels of imadicloprid. The authors concluded that the control hives were unaffected with bee health decline, while the hives fed spiked HFCS exhibited bee health decline. The study therefore appears, contrary to what it states, to support the conclusion that ordinary HFCS used by beekeepers does not have an effect, and thus the study has no utility for showing that imadicloprid causes bee health decline. The reproducibility flaw described below also negates the utility of the study.

The second most obvious flaw with the study is that it fails to identify the HFCS that was used, its source, whether it was tested for the presence of imadicloprid, and how it was stored. These omissions make it impossible to attempt to substantially replicate the study, and violate the "reproducibility" standard. One would ordinarily expect the HFCS to be clearly identified by

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[14] Lu C *et al*. 2012. *In situ* replication of honey bee colony collapse disorder. *Bull Insectology* 65(1):99-106. The study was conducted by Dr. Lu of Harvard's School of Public Health and two beekeepers. The journal is published by the University of Bologna, Italy.

[15] *Id*. at 103-04.

[16] *Id*. at 105.

[17] The publication does not provide data on how often beekeepers employ this practice, as opposed, for example, to using sucrose.

source, brand, and lot number, not only for purposes of reproducibility, but to ensure that the HFCS is the same as, or at least similar to, that actually used by beekeepers in that region. Use of an insufficiently identified control substance also violates the DQA requirements for use of "reliable" data, the use of "sound and objective scientific practices," and collection of data "by accepted methods or best available methods."

The Lu *et al*. study also violates numerous other DQA standards, particularly with regard to "transparency,"[18] but the above deficiencies are sufficiently serious to render the study unsuitable for use in an agency bee health decline risk assessment.

V. DQA Analysis: Pettis et al. "Pesticide exposure in honey bees results in increased levels of the gut pathogen *Nosema*"

A. Background of Study

Dr. Jeffrey S. Pettis et al. recently published an article titled "Pesticide exposure in honey bees results in increased levels of the gut pathogen *Nosema*'[19] The article discussed the interactions between honeybee colonies that were exposed to imidacloprid in a chronic and sublethal manner and the infection of those individual honey bees with the fungal gut parasite *Nosema*.[20] The imidacloprid dosages used were claimed to be below the levels that Pettis stated were demonstrated to cause effects on longevity or foraging in adult honey bees.[21]

B. Study setup

Pettis set up three treatment groups for the study, with ten bee colonies in each group. The first group was fed a diet consisting of 20 ppb imidacloprid, the second group was fed 5 ppb imidacloprid and the third group was the untreated control group that was not fed any imidacloprid.[22] Two colonies of each of the treatment groups were placed in five different apiaries, about half a kilometer apart. Five weeks into the treatment, the brood combs were removed and the bees were exposed to *Nosema* spores. There were two trials of the experiment, one in July and the other in August.[23] The *Nosema* growth was tested for each of the groups in each of the trials.

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[18] For example, the authors do not explain why they greatly increased the spiking doses after four weeks, what data supported their use of the ten-fold concentration factor (p. 104), and why feeding of HFCS during the summer months was appropriate.

[19] Pettis JS *et al*. 2012. Pesticide exposure in honey bees results in increased levels of the gut pathogen *Nosema*, Naturwissenschaften, 99:153-158 ,

[20] *Id.* at 153, abstract

[21] *Id.*

[22] *Id*. at 154

[23] *Id.*

C. Guidelines to be Followed

Dr. Pettis, as an employee of the Department of Agriculture, must follow OMB's binding DQA Guidelines. As discussed below, the Pettis study is simply not in compliance with the procedures.

D. Issues with the Results

1. Dose-response relationship missing

Even though the two of three groups that were treated with imidacloprid were treated with considerably different amounts (5 ppb versus 20 ppb) the discussion of results in the article presented in the study did not discuss the difference between these two groups and merely lumped them together as the treatment group.[24] After the trials had concluded, eight of the thirty colonies were found to be infested with *Nosema* but no correlation was drawn between the amount of imidacloprid exposure and the rate of *Nosema* infestation. The authors then simply concluded that there is an interaction between exposure to imidacloprid and *Nosema* spore production in bees.

The Pettis study did not show a dose-response effect and the effects that were shown appear to be limited to individual bees, not to entire colonies. As the EPA noted in regard to pesticides:

> *"These effects that were typically seen in concentrations above those that would be expected in the environment or would be likely to be observed in pollen and nectar from the most widespread use patterns for . . . neonicotinoids."*[25]

Without demonstrating a dose-response effect, the Pettis study could at most, if there were no additional study problems, show a mere increased sensitivity to pathogens and nothing further. As will be seen, there are additional critical problems with the study design negating even a sensitivity finding.

Utility Standard

In order to meet the utility standard set forth by the OMB, the information provided should be useful to intended users, including the public.[26] By failing to distinguish results between the Imidacloprid levels in a meaningful way, the study may not provide usefulness from the public's perspective. The utility standard also points out that, "when transparency of information is relevant for assessing the information's usefulness from the public's perspective,

[24] Pettis, *supra* note 19, at 158

[25] United States Environmental Protection Agency, Response to Clothianidin Emergency Citizen Petition Dated March 20, 2009, at 9 [hereinafter *EPA Report*].

[26] OMB Report, *supra* note 24, at 5

agencies must take care to ensure that transparency has been addressed in their review of the information."[27] Though the Pettis study mentions that different amounts of imidacloprid were administered, it did not distinguish the results between the two doses and did not discuss why they chose not to distinguish between the two doses, leaving the reader to assume that all levels of imidacloprid are dangerous, which may not at all be the case. This lack of transparency sharply diminishes the potential utility of the article.

2. Artificial Conditions

Even though the imidacloprid exposures were performed under field conditions with entire bee colonies, when the bees were infested with *Nosema,* it was done under artificial laboratory conditions.[28] After five and eight weeks of imidacloprid exposure in the field, wax combs with emerging brood were then taken into a laboratory.[29] In the laboratory, the bees were removed and then used to either figure out fresh weight or then caged and fed a suspension containing *Nosema* spores over the first two days of adult life.[30] The bees were then sacrificed and the *Nosema* infection in the individual bees was determined.[31] Thus, the individual worker bees were not in the context of their colony when they were exposed to *Nosema* spores.

It is possible that depriving the individual workers of the multifaceted and intricate communications and interactions of their colony could have an immeasurable effect on the way the individual workers bees were infected with *Nosema*. It is not unlikely that a stressor that brings certain effects in a laboratory would have no effects in the field and vice versa, that an effect in the laboratory that did not raise any questions would be highly relevant in the field. Because of this, the finding by Pettis that exposing bees to imidacloprid makes them more susceptible to *Nosema* is, at most, merely a potential effect and not at all definite. Field conditions differ from laboratory conditions in a fundamental way and simply cannot be ignored.

Transparency Standard

In order to meet the OMB analytical results standard, agencies should "ensure sufficient transparency about data and methods that an independent reanalysis could be undertaken by a qualified member of the public."[32] Because Pettis *et al*. uses an odd combination of both field and laboratory testing, not only is it difficult to follow, but it would also be nearly impossible to replicate, thus violating the analytic results guidelines set forth by the OMB. Additionally,

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[27] *Id.*

[28] Pettis, *supra* note 19, at 153 (abstract)

[29] EPA Report, *supra* note 24, at 9

[30] Pettis, *supra* note 19, at 154

[31] *Id.*

[32] OMB Report, *supra* note 24, at 5

although the Pettis study mentioned that portions of the experiment were being conducted in the laboratory, there was no discussion as to how the experimental results could have differed if conducted in the field.

3. Lack of Testing/Reporting Standards

The Pettis study demonstrates variability in results that are difficult to reconcile, in part because of the lack of standards in place to measure occurrences such as *Nosema* infestation -- which can be influenced by a variety of factors. One clear example of result variability occurs in the August trial, when after eight weeks of treatment, the emerged bees were fed 10 mL of sugar solution which contained either 0 spores, for the control group, 100,000 spores for the 5 ppb group, or 1 million spores for the 20 ppb group, of *Nosema* per milliliter in order to explore the "potential effects of inoculum dose of pathogen growth."[33] The resulting spore counts of *Nosema* in these bees were 0 in the control group, approximately 2.2 million in the 5 ppb group and 2 million in the 20 ppb group.[34] These numbers indicate no real correlation at all, much less a positive one. The lack of dose-response relationship outlined here demonstrates how variable the results truly are, especially when no standards are in place to properly measure whether these findings are correlated or a random occurrence.

Utility Standard

As discussed above, the OMB clearly states that in order for their government-wide utility standard to be met, "information must be useful to its intended users, including the public."[35] Without any standards with which to describe the above data regarding spore counts, the information provided is actually not useful at all, as one cannot tell the difference between a correlation and an irregular finding.

4. No Clear Lethal Effect to Bees

In the 'Materials and Methods' section of the article, it is mentioned that mortality was monitored daily and that no cage exceeded 20%.[36] No other mention of mortality was made throughout the entire article as it pertained to the Pettis study. Therefore, without a demonstrated increase in mortality, regardless of the amount of imidacloprid administered in the study, there were no ultimate demonstrated negative effects.

In their response to an emergency citizens petition, filed to compel stopping the use of the chemical clothianidin, the EPA agreed with the petition when it was pointed out that clothianidin

[33] Pettis, *supra* note 19, at 154

[34] *Id* at 155, table 2

[35] OMB Report, *supra* note 24, at 5

[36] Pettis, *supra* note 19, at 154

is acutely toxic to bees.[37] However, they noted that the critical question was whether clothianidin is "generally available in the environment at levels that can cause serious, imminent harm to bee populations."[38]

The same question should be posed here. Just as the EPA noted with clothianidin, it is highly possible that the levels of imidacloprid in pollen and nectar that are typically seen in the field "are, however, generally below the levels at which sublethal effects reportedly happen, and lethal effects occur." Therefore, the data presented by Pettis does not lead to the suggestion that bees are being regularly exposed to such levels of imidacloprid in pollen and nectar that could lead to an imminent population level impact that would be necessary to support an imminent hazard finding.

5. Bee Health Decline

The Pettis study has been cited in numerous articles regarding bee health decline, the recent phenomenon where during the winter of 2006 some beekeepers began to report unusually high losses of 30-90 percent of their hives.[39] It has been noted that as many as 50 percent of all colonies that were affected displayed symptoms that were inconsistent with any other known cause of honeybee death: sudden loss of a colony's worker bee population with few dead bees surrounding the colony.[40] The queen and young bees were still around and the colonies had a relatively abundant amount of honey and pollen reserves. However, a hive cannot sustain itself without worker bees and will eventually die.[41]

The Pettis study asserts that in a laboratory setting, imidacloprid can have sub-lethal effects on honey bees, namely the growth of the gut pathogen *Nosema*. However, there is no discussion as to the ultimate effect on mortality or bee health decline that the study is shown to have. All that is mentioned is that "past studies have found that chronic sub-lethal exposure to pesticides can have an adverse effect on colonies"[42] but no reference is made to imidacloprid's effect on bee health decline specifically is made. Additionally, Pettis has not provided any evidence that the results obtained in the laboratory reflect what would happen in the field and to what degree it would affect populations of honey bees.

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[37] EPA Report, *supra* note 26, at 8

[38] *Id.*

[39] U.S. Environmental Protection Agency, *Pesticide issues in the works: Honeybee colony collapse disorder*, http://www.epa.gov/opp00001/about/intheworks/honeybee.htm

[40] *Id.*

[41] *Id.*

[42] Pettis, *supra* note 19, at 157

6. Multiple Stressors

Pettis states:[43]

> *"We clearly demonstrate an interaction between sub-lethal exposure to imidacloprid at the colony level and the spore production in individual bees of honey bee gut parasite Nosema."*

This argument ignores completely the existence of other studies and offers no views on the reason for the differences. This is a clear violation of the "complete" component of "objectivity under the DQA.

Pettis admits:

> *"Individual bees in our study showed a marked increase in Nosema spore production in the laboratory but the parent colonies failed to show increased Nosema levels over time."*

7. A Reasoned Explanation for the Discrepancy in the Pettis Finding: Varroa Mites

CRE has just initiated a single-forum Interactive Public Docket[44] (IPD) dedicated to bee health decline located here.[45] Discussions are underway to expand the single discussion forum to a five-forum IPD.

All CRE interventions in a regulatory proceeding are very transparent because in virtually all instances the said intervention is posted on an IPD that allows the public, NGOs and the regulated community to offer their comments. The IPDs are highly interactive and accept comments anonymously and without reader registration.

A reasoned explanation for the discrepancy in the Pettis finding is explained in a recent edition of *Science*. In a post[46] on the CRE IPD for bee health decline, the Editor states:

> "***Allvoices.com****, a citizens journal platform, reports on an article in Science, one of the nation's premier scientific journals, on the reason for the decrease in the bee population:*
>
> *"…a small parasitic mite that is known to attack honey bees has been identified as the main carrier of the disease that is responsible for the dwindling of bee populations across the world."*

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[43]" *Pesticide exposure in honey bees results in increased levels of the gut pathogen Nosema*" Naturwissenschaften (20 12) 99: 153- 158 DOl 10.1007/s00 114-0II-0881-1 at 24.

[44] http://en.wikipedia.org/wiki/Interactive_Public_Docket

[45] http://www.thecre.com/oira_pd/

[46] http://www.thecre.com/oira_pd/?p=73

The BBC investigated the parasite issue in-depth and concluded[47] that:

"*The new study has pinned down exactly which virus is the honeybee killer.*"

The BBC investigative reporter, Ms. Victoria Gill, also conducted an in-depth interview with Dr. Stephen Martin from the University of Sheffield, the author of the study. Dr. Martin noted the following to BBC Nature:

- Most viruses were not normally harmful to the bees, but the mite "selected" one lethal strain of one specific virus.
- "In an infected bee there can be more viral particles than there are people on the planet."
- "The only way to control the virus is to control the levels of the mite."

The BBC[48] article goes on to state:

- Prof Ian Jones, a virologist from the University of Reading said the findings mirrored "other known mechanisms of virus spread."
- He added: "[This] reinforces the need for beekeepers to control Varroa infestation."
- The British Beekeepers Association (BBKA) praised the research.

Dr. Martin[49] and his co-authors conclude:

"*Therefore, the global spread of Varroa has selected DWV (deformed wing virus) variants that have emerged to allow it to become one of the most widely distributed and contagious insect viruses on the planet.*"

"*During the past 50 years, the global spread of the ectoparasitic mite Varroa destructor has resulted in the death of millions of honey bee (Apis mellifera) colonies.*"

There are other studies[50] which relate the spread of Varroa mites track the destruction of honey bees.

[47] http://www.thecre.com/oira_pd/?p=106

[48] Prof Ian Jones, a virologist from the University of Reading said the findings mirrored "other known mechanisms of virus spread."

[49] http://www.thecre.com/oira_pd/?p=101

[50] http://www.ca.uky.edu/entomology/entfacts/ef608.asp

> *"Mites develop on the bee brood. A female mite will enter the brood cell about one day before capping and be sealed in with the larva. Eggs are laid and mite feed and develop on the maturing bee larva. By the time the adult bee emerges from the cell, several of the mites will have reached adulthood, mated, and are ready to begin searching for other bees or larvae to parasitize. There is a preference for drone brood. Inspection of the drone brood in their capped cells will often indicate whether or not a colony is infested. The dark mites are easily seen on the white pupae when the comb is broken or the pupae are pulled from their cells."*

A key question to be examined is evidence available which supports the statement that deformed wing virus (DWV) is responsible for colony collapse disorder around the world. The answer to this question is of particular regulatory significance. If Varroa mites are indeed the cause of the problem, that observation leads to one type of regulatory approach. If, however, there is another causal factor, such observation may lead to a completely different regulatory strategy.

Pettis claims that bee health decline is a multifactor occurrence and suggests that a wide range of regulatory actions need to be taken. The fallacy in this approach is that if there is one overwhelming cause of bee health decline, blaming its existence on a multitude of factors will only prolong the problem because critical resources will be diverted to address non-existent problems.

More specifically, there may be multiple stressors but Pettit fails to demonstrate that each and every one of the stressors exceeds the threshold of causality and fails to consider Varroa mites as a potential cause of bee health decline.

There is a wide body of literature that demonstrates that Varroa mites are at a minimum one of the culprits and most probably the leading culprit. Consider for example the work of Conte[51] et al:

> *"The hypothesis that CCD is due to the invasive Varroa mite and its capability to suppress immune responses cannot be excluded, and in fact is supported by the study of van Engelsdorp et al. (2009)."*

The essence of these findings is that the USDA, in conjunction with EPA, should foster the development of an enhanced miticides research program.

Conte also states at page 5:

> *"The lack of effective miticides to control Varroa lets the mite populations grow to injurious levels triggering colony collapse directly by the number of mites per bee or indirectly by decreasing bee immunity and favoring virus multiplication."*

[51] http://entomology.unl.edu/faculty/ellispubs/Varroa.pdf

It can be expected that research studies on an emerging issue will often differ. However, even when research cannot identify any casual agent, be it mites, viruses or pesticides, the pathogenic response, viruses in mites, dominates the environmental background.

van Engelsdorp[52] states:

"Of 61 quantified variables (including adult bee physiology, pathogen loads, and pesticide levels), no single measure emerged as a most-likely cause of CCD. Bees in CCD colonies had higher pathogen loads and were co-infected with a greater number of pathogens than control populations, suggesting either an increased exposure to pathogens or a reduced resistance of bees toward pathogens. Levels of the synthetic acaricide coumaphos (used by beekeepers to control the parasitic mite Varroa destructor) were higher in control colonies than CCD-affected colonies."

The following was stated in the *Scientific American*[53] as reported in the Huffington Post,

"'When you look at what's out there in the public press, the implication is that pollinators are all under threat, that there's some kind of mysterious decline across the board,' says Sam Droege, a biologist at U.S. Geological Survey's (USGS) Patuxent Wildlife Research Center. 'The problem is, there's really no data to show that either way.'"

A SAP focus on Varroa mites is in order. An enhanced understanding of the role Varroa mites in bee health decline would be common to all bee health decline strategies.

We applaud EPA for having an open and transparent process to vent the public policy and scientific issues related to bee health decline. Subsequent to the SAP meeting CRE will make a determination as to whether it should file a Request for Correction, pursuant to the DQA, on the Pettis study with the Department of Agriculture.

VI. Summary

1. The Data Quality Act and its guidelines apply to studies and data authored or collected by outside (or "third-party") entities. The agency will not be able to use such studies or data in a risk assessment unless they can meet the law's quality standards.

2. The SAP and the agency should be fully informed on the requirements of the DQA and its guidance, particularly the definitions of "objectivity," "utility," and "reproducibility."

[10] http://www.plosone.org/article/info:doi/10.1371/journal.pone.0006481

[53] http://www.thecre.com/oira_pd/?p=62

3. There are studies being touted in the media as "convincing," such as the very recent Lu *et al*. study from Harvard, that clearly cannot meet DQA standards, and therefore cannot be used by the agency to support risk assessment conclusions.

4. The subject pollinator risk assessment "framework" is intended to provide the foundation for, or be the first step in, a "highly influential" agency risk assessment subject to the DQA peer review guidance. Therefore, the SAP and the agency should begin applying the DQA guidance at this stage. One requirement of the peer review guidance of particular importance is that peer reviews should appraise scientific data objectively, and should not inject non-scientific, or "policy," considerations, into their judgments. The peer review guidance also affirms the need for peer reviews to adhere to all the DQA quality standards.

5. It is doubtful whether the Pettis study could be used by EPA since it is probably non-compliant with the DQA.

6. The SAP should focus on the role of Varroa mites in bee health decline. An enhanced understanding of the role Varroa mites would be common to all bee health decline strategies.

7. The SAP risk assessment regime should include an analytical survey which is DQA compliant that delineates the magnitude of the bee health decline.

We look forward to continuing to follow and comment on the work of the SAP and the agency on this subject.

Respectfully submitted,

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