Center for Regulatory Effectiveness

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April 10, 2013

Steven Bradbury
Office of Pesticide Programs
Environmental Protection Agency
Mail Code 7501P
1200 Pennsylvania Ave NW
Washington, DC 20460

RE: DQA Analysis on EFSA Report on Neonicotinoids

Dear Mr. Bradbury:

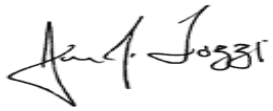
The Center for Regulatory Effectiveness (CRE), a regulatory watchdog, has performed a Data Quality Analysis (DQA) on the European Food and Safety Authority's (EFSA) report on neonicotinoids, in which EFSA concluded that neonicotinoids pose a risk to bees. Specifically, on January 16, 2013, EFSA published a report that identified a number of risks posed to bees by three neonicotinoids: clothianidin, thiamethoxam, and imidacloprid. Only two weeks after publishing the report the European Commission moved to implement a two-year ban on the use of the clothianidin, thiamethoxam, and imidacloprid.

Although the DQA does not apply to EFSA or the European Commission, the CRE has conducted a DQA analysis on the EFSA report to demonstrate the significant data deficiencies in the report. Specifically, the EFSA report failed to maximize the objectivity of the data by failing to reconcile numerous studies that had opposite conclusions of the EFSA report. In particular, the EFSA report did not 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.

The enclosed report outlines the serious DQA deficiencies in the EFSA report on neonicotinoids. Accordingly, the EPA cannot adopt the substance of the EFSA report without violating the DQA.

CRE is pleased to submit the enclosed report for your comments, *DQA Alert: The EFSA Report on Neonicotinoids Does Not Meet the Data Quality Standards of the Data Quality Act.* CRE will continue to monitor developments on its Review of Bee Health Decline Interactive Public Docket, which is available at http://www.thecre.com/oira_pd/ . Please contact me with any questions.

Respectfully submitted,



Jim Tozzi
Member, Board of Advisors
Center for Regulatory Effectiveness

DQA ALERT: THE EFSA REPORT ON NEONICOTINOIDS DOES NOT MEET THE DATA QUALITY STANDARDS OF THE DATA QUALITY ACT

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TABLE OF CONTENTS

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DQA ALERT: THE EFSA REPORT ON NEONICOTINOIDS DOES NOT MEET THE DATA QUALITY STANDARDS OF THE DATA QUALITY ACT

The Center for Regulatory Effectiveness (CRE), a regulatory watchdog, has performed a Data Quality Act (DQA) analysis on the European Food and Safety Authority's (EFSA) report on neonicotinoids, in which EFSA concluded that neonicotinoids pose a risk to bees. Based on the CRE's analysis, the CRE has identified serious DQA deficiencies with the report published by EFSA. As a U.S. law the DQA does not apply to European Union data disseminations; however, the CRE found it found it useful to view the dissemination of the EFSA report through a DQA perspective to demonstrate how the EFSA report, which is being used as the basis for a proposed ban neonicotinoids, would not meet the data quality guidelines in the United States.

I. OVERVIEW OF THE EFSA REPORT

On January 16, 2013 the European Food Safety Authority (EFSA) published a report that identified a number of risks posed to bees by three neonicotinoids: clothianidin,[1] thiamethoxam,[2] and imidacloprid.[3] EFSA found that neonicotinoids pose an unacceptable risk to honey bees. Pursuant to EFSA's report and only two weeks after receiving the EFSA report, the Standing Committee on the Food Chain and Animal Health (SCFCAH) of the European Commission proposed implementing a two-year ban on the use of clothianidin, thiamethoxam, and imidacloprid.

Despite proposing the ban on neonicotinoids only two weeks after the EFSA report was published, SCFCAH argued that the ban on neonicotinoids "are proportionate measures. We are giving the member states two years to see whether it's working. Then we will see if we need to review the legislation in Europe." The ban proposed by SCFCAH is far from a proportionate measure to the EFSA report. Instead, the ban is a rash decision that will have disastrous

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[1] European Food Safety Authority, *Conclusion on the Peer Review of the Pesticide Risk Assessment for Bees for the Active Substance Clothianidin*, available at http://www.efsa.europa.eu/en/efsajournal/doc/3066.pdf

[2] European Food Safety Authority, *Conclusion on the Peer Review of the Pesticide Risk Assessment for Bees for the Active Substance Thiamethoxam*, available at http://www.efsa.europa.eu/en/efsajournal/doc/3067.pdf

[3] European Food Safety Authority, *Conclusion on the Peer Review of the Pesticide Risk Assessment for Bees for the Active Substance* http://www.efsa.europa.eu/en/efsajournal/doc/3068.pdf

economic impacts on Europe. The proposed ban is a hasty one-size fits all approach that fails to account for the unique agronomic policies of the each EU member nation.

European Union member states voted on the proposed ban on March 14, 2013. There was no qualified majority established supporting the ban, thus, the proposed ban failed to pass. Although the ban was not implemented by the EU, the EFSA report has been used to rally support for a similar ban within EU member states[4] and the United States.[5]

The disproportionate measure proposing to ban neonicotinoids in the EU was based on the flawed EFSA study. As such, no ban should be approved until conclusive evidence is established that neonicotinoids have an impact on bees.

II. OVERVIEW OF THE DATA QUALITY ACT

Enacted in 2000, the DQA requires that information disseminated by Federal agencies meet the standards of quality, objectivity, utility, and integrity of information (including statistical information."[6] In furtherance of this requirement, the DQA required the Office of Management and Budget (OMB) to issue government-wide guidelines to "ensur[e] and maximize[e] the quality, objectivity, utility and integrity of information."[7] The DQA further required agencies to establish their own guidelines that maximizes the objectivity, utility, and integrity of information the agency disseminates.[8]

In 2002, OMB published Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies ("OMB Guidelines"), implementing the Data Quality Act.[9] EPA (the relevant agency regulating pesticides) also adopted agency-specific Data Quality Act guidelines in 2002.[10]

The DQA also provides a relief mechanism where data does not comply with the DQA. Agencies are further required to "establish administrative mechanisms allowed affected person to

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4 *See* Andy McSmith, *Mps Call For Ban On 'Nerve Agent' Neonicotinoid Pesticides To Protect Dwindling Bee Population*, The Independent (April 5, 2013) available at http://www.independent.co.uk/environment/nature/mps-call-for-ban-on-nerve-agent-neonicotinoid-pesticides-to-protect-dwindling-bee-population-8560788.html

5 *Ellis v. EPA*, No. 13-1266 (U.S. Dist. Ct., N.D. Cal., filed March 21, 2013).

6 44 U.S.C § 3516(a)

7 *Id.*

8 *Id.*

9 Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies ("OMB Data Quality Guidelines"), 67 Fed. Reg. 8452 (Feb. 22, 2002) available at http://www.whitehouse.gov/omb/info_quality_iqg_oct2002/

10 U.S. Environmental Protection Agency, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by EPA, page 18 (Oct. 2002) ("EPA Guidelines")

seek and obtain correction of information" that the agencies maintain and disseminate if such information does not comply the agency guidelines.[11] The EPA Guidelines include a similar provision related to administrative mechanisms for correction of information.[12]

III. IF ADOPTED BY THE EPA, THE EFSA REPORT WOULD BE AN INFORMATION DISSEMINATION SUBJECT TO THE DQA

The DQA applies to information that is "disseminated" by federal agencies. OMB's government-wide guidelines define "dissemination" as "agency initiated or sponsored distribution of information to the public." "Agency initiated . . . distribution of information to the public" refers to information that the agency disseminates, e,g,, a risk assessment prepared by the agency to inform the agency's formulation of possible regulatory or other action."[13]

In the case of the EFSA report, although the European Commission did not publish the report or disseminate the report, the Commission did initiate the report by requesting EFSA to perform a risk assessment of neonicotinoids relating to bees.[14] Moreover, the European relied upon the findings in the report to form the basis of its proposed ban on neonicotinoids. Accordingly, if the DQA applied to the European Commission, its reliance upon the EFSA report would trigger the DQA. The dissemination that would be subject to the DQA would be the ban itself, and the data supporting it (e.g. the EFSA report).

Similarly, if the EPA were to rely upon the findings EFSA report, or its underlying data, in making any agency decisions or disseminations, then that dissemination would be subject to the DQA.

IV. THE EPA WOULD NEED TO COMPLETE A PRE-DISSEMINATION REVIEW OF THE EFSA REPORT

OMB's government-wide data quality guidelines, implementing the DQA, require that agencies establish a pre-dissemination review process to "substantiate the quality of the information it [the agency] has disseminated...."[15] In discussing the need for the pre-dissemination review process, OMB explains, "Agencies shall treat information quality as integral to every step of an agency's development of information, including creation, collection, maintenance, and dissemination."[16] Thus, the pre-dissemination review process is far more than a simple tick-list of steps that are applied to existing data to determine if it is ready for release.

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11 44 U.S.C. §3516(b)(2)(B).

12 EPA Guidelines, Section 8.

13 *Data Quality Act*¸ 67 FR 8459, 8454.

14 European Food Safety Authority, *Conclusion on the Risk Assessment for Bees for the Active Substance Clothianidin*¸ page 1, available at http://www.efsa.europa.eu/en/efsajournal/doc/3066.pdf.

15 67 FR 8459

16 *Id.*

The pre-dissemination review is an essential quality assurance process that takes place throughout the development and analysis of information disseminated by an agency.

The EPA also gives special attention to DQA pre-dissemination requirements. Specifically, in 2006, the EPA issued the *Pre-dissemination Review Guidelines: Review Guidelines to Ensure that Disseminated Information is Consistent Information Quality Guidelines.*[17] The Guidelines state:

> [P]re-dissemination reviews are designed to provide additional assurance that information EPA disseminates to the public is consistent with the quality principles described in the [Data Quality Guidelines]. Agency Program Offices, Regions and Labs ("Agency Offices") should develop pre-dissemination review procedures consistent with the Guidelines and their respective authorities and activities.
>
> EPA's Office of Environmental Information (OEI) is providing these pre-dissemination review guidelines to help Agency Offices in developing their own procedures, if they haven't already done so, to allow for consistent cross-Agency pre-dissemination reviews while meeting each office's particular needs. These pre-dissemination review guidelines provide non-binding internal policy and procedural guidance intended solely for EPA management and staff.
>
> Systematic planning, typically part of a quality system, ensures that quality is built into information. The pre-dissemination review procedures outlined in this document are intended to ***provide assurance that quality has been built into the information we disseminate***, rather than to add another review stage at the end of the information development process. ***Ultimately, such reviews reinforce good government and common sense***.[18]

Notably the EPA Guidelines on pre-dissemination review also requires that the agency offices must "specify how the office retains pre-dissemination review records."

The EPA does have an admirable record adhering to it is pre-dissemination requirements. This is exemplified by the exhaustive pre-dissemination review for the Region 3 Quality Management Plan (QMP).[19]

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[17] Environmental Protection Agency, *Pre-dissemination Review Guidelines: Review Guidelines to Ensure that Disseminated Information is Consistent with EPA Information Quality Guidelines*, available at http://www.epa.gov/region2/science/qmp/pdfs/pdr-guidelines.pdf.

[18] *Id.* [emphasis added]

[19] See EPA, *Region 3 Quality Management Plan*, Appendix C, available at http://www.epa.gov/region03/esc/qa/eqmp/qmp.html#partAppC; The procedures for Region 3 QMP are quoted in length below:

A Pre-Dissemination review as defined in section 7 of the [Data Quality Guidelines] is intended to insure that information EPA disseminates is of the highest quality possible and meets standards for objectivity, utility and integrity. Any disseminated information not meeting these standards can be subject to a "request for correction" (RFC) and its appeal, a "request for reconsideration" (RFR) by any person. OEI has a formal process in place for the administration of RFCs and RFRs. Past and current RFCs and RFRs can be viewed on the EPA website.

EPA issued its Pre-Dissemination Review Guidelines in 2006 to assist offices and regions in implementing their own pre-dissemination review procedures. This document therefore serves as a basis for Region 3's procedure for conducting pre-dissemination reviews. Region 3 offices may expand upon the review procedure presented here.
Please note that EPA's pre-dissemination review guidelines provide non-binding internal policy and procedural guidance intended solely for EPA management and staff (EPA Final Pre-Dissemination Review Guidelines, September 2006).

Pre-Dissemination Review
One of the most important things to remember about conducting a pre-dissemination review is that it is not intended to consist solely of a final review in the development of a product. Rather, it should be conducted throughout a product's development life cycle. The Information Quality Guidelines Pre-Dissemination Review Checklist (PDF) (1 pg, 102K) can be used to document the results of pre-dissemination review during development.

Determine Eligibility

- Determine if you need to conduct a pre-dissemination review using the IQG definitions of "information" and "dissemination" (Steps 2 and 3 below and IQG Section 5.3). The Region 3 IQG officer can be consulted should you have questions about whether the IQG apply (and thus a review is needed). Examples of non-applicability of the IQG are given in IQG Section 5.4.
- Determine whether the product to be reviewed is information. "Information" generally includes any communication or representation of knowledge such as facts or data, in any medium or form.
- Determine whether the product will be disseminated by EPA. EPA disseminates information to the public when EPA initiates or sponsors the distribution of information to the public.
- If neither step 2 or 3 applies then no PDR is necessary at this time. Otherwise continue to step 5. Note that under certain circumstances a product may become eligible for a review (e.g. EPA decides it would like to disseminate a report that had been only available within EPA).

Determine whether quality is maximized and IQG quality criteria are met

- Determine whether the product to be disseminated has maximized quality and has met the IQG criteria for utility, objectivity and integrity. "Utility" refers to the usefulness of the information to the intended users. "Objectivity" focuses on whether the disseminated information is being presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased. "Integrity" refers to security, such as the protection of information from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification. (See IQG, Sections 5.1 and 6.1).
- Determine whether the product is influential. "Influential," when used in the phrase "influential scientific, financial, or statistical information," means that the Agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact (i.e., potential change or effect) on important public policies or private sector decisions. If the product is influential then a higher degree of transparency for data and methods will be required. Consult IQG Section 6.3 on transparency requirements.

Approval of information prior to dissemination

The actions taken by the European Commission would clearly fail to meet any pre-dissemination review requirements under the DQA. In fact, the European Commission took EFSA's findings at face value without conducting any review of the findings. The European Commission proposed to ban neonicotinoids only two weeks after the report was published. In effect, the European Commission has conducted absolutely no review before embracing the EFSA report. If the EPA were to consider the findings of the EFSA report in regulating neonicotinoids, it would need to conduct an extensive pre-dissemination review of the report.

V. THE EFSA REPORT FAILS TO MAXIMIZE THE QUALITY OF THE INFORMATION REQUIRED BY THE DQA

In conducting a pre-dissemination review, EPA would need to confirm that the EFSA report relied on information that adheres to the rigorous quality standards required by the DQA. The DQA and EPA guidelines require that EPA ensures and maximizes the "objectivity, utility, and integrity of disseminated information."[20] "'Objectivity' focuses on whether the disseminated information is being presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased.[21] 'Integrity' refers to the protection of information from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification 'Utility' refers to the usefulness of the information to the intended users, including the public."[22]

Notably, the EFSA Report Fails to Meet the Objectivity Standard of the DQA. Specifically, "Objectivity" requires the "disseminated information is being presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased."[23] Information is presumed to be of acceptable objectivity "if data and

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- Obtain approval for the information to be disseminated from the appropriate program director. Approval can include other types of reviews such as legal reviews, peer reviews, programmatic reviews, scientific and technical review clearance processes, stakeholder reviews, and product review in accordance with the Office of Public Affairs guidelines.

Records management

- Pre-dissemination review records (such as the Information Quality Guidelines Pre-Dissemination Review Checklist (PDF) (1 pg, 102K)) should be retained with other product documents. Records should be retained using the appropriate records schedules.[19]

[20] Bureau of Land Management, Information Quality Guidelines, page 7 (Feb 2012) available at http://www.blm.gov/pgdata/etc/medialib/blm/national/national_page.Par.7549.File.dat/guidelines.pdf

[21] Environmental Protection Agency, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of the Information Disseminated by the Environmental Protection Agency*.

[22] *Id.*

[23] Environmental Protection Agency, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of the Information Disseminated by the Environmental Protection Agency*.

analytic results are subjected to formal independent, external peer review."[24] The EFSA report fails to meet the objectivity standard of the DQA, because the report ignores numerous recent studies on bees that contradict EFSA's conclusions.

a. EFSA Fails to Address the Varroa Mite Studies

There is very strong evidence that bee health decline is in fact caused by Varroa Mites, and not neonicotinoids. A recent study led by Dr. Stephen Martin from the University of Sheffield and published in the journal, Science, has concluded that the Varroa Mite "has resulted in the death of millions of honey bee (Apis Mellifera) colonies."[25] 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.[26] One particular disease, deformed wing virus, can be directly linked to Varroa Mites' infestation of honey bee colonies.[27]

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

Remarkably, during 2007 and 2008, independent researchers recorded the collapse of 274 of 419 colonies in the Varroa infected areas.[28] In contrast, "the island of Kauai and Maui remained mite-free, and no unusual colony losses or disease problems were reported there."[29] Specifically, "In Varroa-free areas, [deformed wing virus] was detected in 6 to 15% of colonies, but it increased to 75 to 100% where Varroa had been established," which was also accompanied by a millionfold viral load.[30]

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-

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24 *Id* at 19.

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

26 *Id.* at 1304.

27 *Id.*

28 *Id.*

29 *Id.*

30 *Id.* at 1305.

occur. The findings in this study is backed by the British Beekeepers Assocaition (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."[31] Furthermore, Dr. Martin's study mirrors similar findings by Yves Conte's report in 2010.[32] 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.

Regardless of these findings, 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 is biased and lacks objectivity. Thus, the Europeans Commission, and its member states, must very closely consider the implications of banning the use of neonicotinoids, particularly in light of the convincing evidence that neonicotinoids are not the cause of bee health decline.

b. EFSA Ignores James Creswell's Report "Comment on a 'Common Pesticide Decreased Foraging Success and Survival in Honey Bees"

On September 21, 2013, James Cresswell from the University of Exeter and Helen Thompson of the Food and Environment Research Agency published a report that found neonicotinoids are not lethal to honey bees.[33] The Cresswell study addresses the research by French scientist Mikaël Henry, which has been used as the primary evidence that neonicotinoids have been causing colony collapse. The Henry research showed that the death rate of bees increased when they drank nectar laced with a neonicotinoid pesticide, thiamethoxam. As such, the Henry report calculated that this would cause their colony to collapse. However, Dr. Cresswell's paper found that the calculation used by Henry used an inappropriate low birth rate.

Lead author Dr. James Cresswell of the University of Exeter said:

> 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.

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[31] Victoria Gill, *Honeybee Virus: Varroa Mite Spreads Lethal Disease*, BBC Nature, (June 7, 2012).

[32] 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.

[33] Cresswell *et al.*, *Comment on "A Common Pesticide Decreases Foraging Success and Survival in Honey Bees*, Science (21 Sept 2012) available at http://www.sciencemag.org/content/337/6101/1453.2.full#aff-3

> 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.**[34]

Dr. Cresswell further reported to the UK Parliament the following:

> 1.1. There is insufficient evidence to establish with high certainty that the residues of neonicotinoid pesticides in nectar and pollen threaten the sustainability of bee populations and the pollination services that they provide to crops and wild plants. But there is sufficient evidence to raise concern about bumble bees.
>
> 1.2. No experiment has demonstrated that neonicotinoids threaten the viability of honey bee colonies when delivered at realistic dietary levels. Experiments that have demonstrated impacts on colonies used unrealistically high dosages. The lack of evidence for impact is consistent with the observation that the global stock of honey bees has increased by 12% in the last decade.
>
> 1.3. Two experiments suggest that neonicotinoids threaten the viability of bumble bee colonies when delivered at realistic levels and I have medium certainty that these findings apply to agricultural landscapes in the UK. Other widely cited experiments are flawed because they used unrealistically high dosages. While there have been observable declines in certain bumble bee species coincident with the increasing use of neonicotinoids, pathogens and habitat degradation are also plausible culprits.
>
> 1.4. In the UK, oilseed rape is the principal vehicle for delivery of neonicotinoids to bees. Bumble bees can rapidly recover from neonicotinoid exposure after the crop's bloom subsides and also some/many colonies will escape the crop's peak bloom. If concern over bumble bees is justified, these details offer avenues to mitigation through smart land management.

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[34] James Cresswell, *Pesticides Not Yet Proven Guilty of Causing Honey Bee Declines*¸ Univerity of Exeter Press Release, 20 Sept 2012, available at http://www.eurekalert.org/pub_releases/2012-09/uoe-pny091812.php (emphasis added).

> 1.5. My recommendation is to fund further research to establish with high certainty whether bumble bees are affected by the dosages that originate from UK agriculture. If concern about bumble bees is justified, the government should fund investigations of smart mitigation strategies based on an understanding of the interplay of exposure, sensitivity, resilience and recovery.[35]

These findings by Dr. Cresswell undermine the research relied upon by EFSA in reaching its conclusion that neoncotinoids pose an unacceptable risk to bees. Nevertheless, EFSA fails to even consider Dr. Cresswell's research. Thus, the EFSA report falls well short of the DQA standards to maximize the objectivity of data. Accordingly, the EPA would not be able to rely upon the EFSA report for its DQA deficiencies.

c. EFSA Fails to Consider DEFRA's Findings on Neonicotinoids

The United Kingdom's Department for Environment, Food and Rural Affairs (DEFRA) conducted an extensive study on neonicotinoids' sub-lethal effects on bees, which was published in September 2012.[36] Responding to numerous scientific studies released in 2013 that stated neonicotinoids had sub-lethal effects on bees, DEFRA found the following:

- "none of the studies gives unequivocal evidence that sub-lethal effects with serious implications for colonies are likely to arise from current uses of neonicotinoids."[37]

- "Existing studies submitted in support of the present regulatory approvals fully meet current standards. They do not explicitly address all the sub-lethal effects suggested by the academic research. However, they do cover a wide range of important endpoints and, in these studies, hives exposed to treated crops did not show any gross effects when compared to control hives exposed to untreated crops."[38]

- "Further research will be carried out to fill identified evidence gaps, including the questions raised about the relevance of the recent studies to field conditions. The Government has already put new research in place to explore further the impacts of neonicotinoids on bumble bees in field

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[35] James Cresswell, *Written Evidence Submitted by Dr. James Cresswell, University of Exeter,* UK Parliament, Environmental Audit Committee (November 8, 2012) available at http://www.publications.parliament.uk/pa/cm201213/cmselect/cmenvaud/writev/668/m22.htm

[36] Department for Environment, Food and Rural Affairs, *Neonicotinoid Insecticides and Bees: The State of the Science and the Regulatory Response*, 13 Sept 2012, available at http://www.defra.gov.uk/publications/files/pb13818-neonicotinoid-bees-20120918.pdf

[37] *Id.* at 1.

[38] *Id.*

> conditions and to understand what levels of pesticide residues and disease in bees are normal."[39]

- "The recent studies do not justify changing existing regulation. However, the research that we have put in hand and the on-going work in Europe to develop the risk assessment could change the picture and it is always possible that further new evidence may emerge. As our knowledge develops, we will continue to consider the need for further research and for any changes to the regulation of neonicotinoids."[40]

EFSA failed to address any of the findings by DEFRA, despite the fact that DEFRA conducted nearly similar research just prior to EFSA's report. Thus, the EFSA report fails to meet the DQA's standard of objective.

d. The EFSA Report Has Substantial Data Gaps

One of the biggest shortcomings of the EFSA conclusion that neonicotinoids pose a risk to bees is that there are huge gaps in the data that EFSA relied upon. EFSA even acknowledges:

> As much of the data were generated before publication of the opinion, a number of shortcomings were identified. And, because the final guidance document for the risk assessment of plant protection products and bees is still under development, there is a high level of uncertainty in the latest evaluations.
>
> All of these factors mean that EFSA's scientists were unable to finalise risk assessments for some of the uses authorised in the EU, and identified a number of data gaps that would have to be filled to allow further evaluation of the potential risks to bees from clothianidin, imidacloprid and thiamethoxam. Finally, it is highlighted that limited information was available for pollinators other than honey bees; therefore the risk to these other pollinators should be further considered.[41]

EFSA further admitted that "there are still many shortfalls in the scientific data that were analysed."[42] Herman Fontier, head of the pesticides division of EFSA recently testified to the UK Parliament that "his organisation's recommendation two weeks ago that neonicotinoid pesticides, widely blamed for bee declines around the world, should be kept away from bees, was merely a risk assessment – and it was up to individual EU member states whether or not to act on

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39 *Id.*

40 *Id.* at 2.

41 European Food Safety Authority, *Press Release: EFSA Identifies Risks to Bees From Neonicotinoids* (Jan 16, 2013) available at http://www.efsa.europa.eu/en/press/news/130116.htm

42 Daniel Cressey, *Reports spark row over bee-bothering insecticides:Pesticide manufacturer brands risk assessment 'hurried and inadequate',* Nature (Jan 16, 2013) available at http://www.nature.com/news/reports-spark-row-over-bee-bothering-insecticides-1.12234

it."[43] Accordingly, SCFCAH should heed the advice of EFSA and leave the decision of whether to ban neonicotinoids to the individual EU member states.

e. The EFSA Report is Influential Information that Must be Held to More Rigorous Standards

Under the DQA and its related government-wide guidance, if information is considered "influential," it should be held to higher standards. Information is "influential" if it would have a "clear and substantial impact on important public policies or important private sector decisions."[44] The EPA DQA Guidelines state, "'Influential,' when used in the phrase 'influential scientific, financial, or statistical information,' means that the Agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact (i.e., potential change or effect) on important public policies or private sector decisions."[45] The EPA Guidelines further state:

> A higher degree of transparency about data and methods will facilitate the reproducibility of such information by qualified third parties, to an acceptable degree of imprecision. For disseminated influential original and supporting data, EPA intends to ensure reproducibility according to commonly accepted scientific, financial, or statistical standards. It is important that analytic results for influential information have a higher degree of transparency regarding (1) the source of the data used, (2) the various assumptions employed, (3) the analytic methods applied, and (4) the statistical procedures employed. It is also important that the degree of rigor with which each of these factors is presented and discussed be scaled as appropriate, and that all factors be presented and discussed.

For influential information the EPA requires, much more rigorous standards for the data that focuses on a higher degree of transparency and the capability for the data to be easily reproduced. Moreover, as it pertains to scientific risk assessments, the EPA Guidelines outlines specific requirements for the data:

> In our dissemination of influential scientific information regarding human health, safety1 or environmental risk assessments, EPA will ensure… the objectivity of such information disseminated by the Agency by applying the following adaptation of the quality principles found in the Safe Drinking Water Act20 (SDWA) Amendments of 199621:
>
> > (A) The substance of the information is accurate, reliable and unbiased. This involves the use of:

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[43] Michael McCarthy, *Government To Ignore European Ban On Neonicotinoid Pesticides,* The Independent (Feb 6, 2013) available at http://www.independent.co.uk/environment/green-living/government-to-ignore-european-ban-on-neonicotinoid-pesticides-8483916.html

[44] *Data Quality Act*¸ 67 FR 8459, 8455

[45] EPA Guidelines, at 20-21

> (i) 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
>
> (ii) 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).
>
> (B) The presentation of information on human health, safety, or environmental risks, consistent with the purpose of the information, is comprehensive, informative, and understandable. In a document made available to the public, EPA specifies:
>
> > (i) each population addressed by any estimate of applicable human health risk or each risk assessment endpoint, including populations if applicable, addressed by any estimate of applicable ecological risk;
> >
> > (ii) the expected risk or central estimate of human health risk for the specific populations affected or the ecological assessment endpoints, including populations if applicable;
> >
> > (iii) each appropriate upper-bound or lower-bound estimate of risk;
> >
> > (iv) each significant uncertainty identified in the process of the assessment of risk and studies that would assist in resolving the uncertainty; and
> >
> > (v) peer-reviewed studies known to the Administrator 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.[46]

Under the EPA DQA guidelines, the information disseminated in the EFSA Report will certainly be "influential" information and thus held to more rigorous standards. As such, in order to rely upon the findings in the EFSA report, the EPA would need to specify which studies "fail to support any estimate of risk." In this case, the study by Dr. Cresswell and the varroa mite research would need to be addressed if the EPA were to use the EFSA study. Moreover, the EPA would need to specify the "methodology used to reconcile the inconsistencies" between the EFSA report and Dr. Cresswell research—something the SCFCAH has failed to do. Accordingly, the EFSA report falls well short of the rigorous standards required by the DQA.

[46] *Id.* at 22.

VI. CONCLUSION

On January 16, 2013, EFSA released a report that concluded that neonicotinoids pose a risk to bees. Only two weeks after the EFSA report, SCFCAH of the European Commission hastily moved to ban clothianidin, thiamethoxam, and imidacloprid based on the findings of the EFSA report. SCFCAH performed no analysis of the EFSA report, did consulted the public on the report, and it did not verified the quality of the data. As demonstrated, the EFSA report would fail to meet the data quality standards of the DQA. Thus, the EPA cannot adopt the substance of the EFSA report without violating the DQA.