

Center for Regulatory Effectiveness

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May 2, 2014

Ms. Liz McIntosh
DEFRA Policy Lead – National Pollinator Strategy
National Pollinator Strategy Team
Room 11G35
Sand Hutton
York
United Kingdom YO41 1LZ

Re: CRE Comments on DEFRA Consultation on the National Pollinator Strategy: for bees and other pollinators in England

Dear Ms. McIntosh:

The Center for Regulatory Effectiveness (CRE) applauds DEFRA for its focus on “Evidence-gathering on pollinator status and impacts of pressures” as the first of its proposed three strategy elements. Table 1 of the consultation document¹ lists a series of planned research activities that are consistent with DEFRA’s plan to “create a ‘Call to Action’ message and package of evidence-based advice on how to support bees and other pollinators.”² CRE also applauds DEFRA’s commitment to regulate pesticides “based on scientific risk assessment.”³

All of the materials in these comments are to assist DEFRA in its commitment to building science-based pollinator protection policies. CRE’s comments assist DEFRA in their mission by providing three detailed analyses of pollinator health protection:

1. CRE’s Comments to the Welsh Government on their Draft Action Plan for Pollinators (May 2013; Appendix A);
2. CRE’s Comments to Health Canada’s Pest Management Regulatory Agency on their Consultation on Action to Protect Bees from Exposure to Neonicotinoid Pesticides (December 2013; Appendix B); and
3. The Australian Pesticides and Veterinary Medicines Authority’s *Overview Report: Neonicotinoids and the Health of Honey Bees in Australia* (February 2014; Appendix C).

We are providing DEFRA with our pollinator protection comments and other materials because of CRE’s extensive experience in:

¹ Department for Environment, Food & Agricultural Affairs, “A consultation on the National Pollinator Strategy: for bees and other pollinators in England,” March 2014, p. 7.

² Ibid., p. 16.

³ Ibid., p. 5.

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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 a *regulatory watchdog* promoting transparency in regulatory action by safeguarding the *good government* laws⁴ that *regulate the regulators*. CRE was established by former senior career officials from the White House Office of Management and Budget (OMB).⁵

CRE acts in its own name and does not represent any organization. For more information about CRE, please see the *About* section of our OIRA Watch Interactive Public Docket (IPD)⁶ focused on the OMB's regulatory office, the Office of Information and Regulatory Affairs (OIRA), http://www.thecre.com/oira/?page_id=8.

CRE's Review of Bee Health Decline Interactive Public Docket

CRE's Review of Bee Health Decline Interactive Public Docket (IPD) [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 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.⁷

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,⁸ academia,⁹ and National Public Radio (NPR).¹⁰ IPDs are also widely used by the

⁴ See, "Regulating the Regulatory State," <http://www.thecre.com/oira/?p=1559>.

⁵ For more information on CRE's leadership, please see http://thecre.com/ombpapers/OMB_Officials.htm.

⁶ See, Wikipedia entry for Interactive Public Dockets at http://en.wikipedia.org/wiki/Interactive_Public_Docket.

⁷ See, eRulemaking.US here, <http://www.fedfocus.org/science/Rulemaking.html>.

⁸ 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>.

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media as a data source for substantive reporting including Thompson Reuters¹¹ and a distinguished Spanish foreign policy journal.¹²

CRE's Comments to the Welsh Government

CRE's Comments to the Welsh Government, attached in Appendix A of this document, were in response to the Government's Consultation proceeding on their Draft Action Plan for Pollinators in Wales.¹³

Of particular relevance to DEFRA in this Consultation on a National Pollinator Strategy in England is a point CRE made to the Welsh Government which is that the Consultation process "provides the opportunity... to independently assess the conclusions reached in:

- DEFRA's Food and Environment Research Agency (fera) research which found that:
 - "The [fera] study did not show that neonicotinoids used within a normal agricultural setting have a major effect on bumble bee colonies."¹⁴
 - "The study underlines the importance of taking care in extrapolating laboratory toxicology studies to the field, as well as the great need of further studies under natural conditions."¹⁵
- DEFRA's March 2013 scientific assessment document, *An assessment of key evidence about Neonicotinoids and bees*, which determined:

⁹ 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>.

¹⁰ See, National Public Radio, Web Resources at <http://www.npr.org/templates/story/story.php?storyId=4599065>.

¹¹ 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/>.

¹² 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/>.

¹³ See, <http://wales.gov.uk/docs/desh/consultation/130409pollinators-action-plan-en.pdf>.

¹⁴ Food and Environment Research Agency, "Effects of neonicotinoid seed treatments on bumble bee colonies under field conditions," March 2013, p. 36, *available at* <http://www.fera.defra.gov.uk/scienceResearch/scienceCapabilities/chemicalsEnvironment/documents/reportPS2371Mar13.pdf>.

¹⁵ Ibid.

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.¹⁶ [Emphasis added.]*

CRE's comments to the Welsh Government made two additional key points:

1. ***Varroa Destructor is the major factor underlying colony loss.*** CRE's Welsh comments include extensive discussion of *V. destructor* supported by citations from the scientific literature. For example, the comments state,

“Recent research conducted by scientists at the Swiss Bee Research Centre in Bern, Switzerland and the USDA/Agricultural Research Service’s Bee Research Laboratory in Beltsville, MD found a close link between *Varroa* levels and Deformed Wing Virus (DWV) with associated loss of colonies:

There was a significant positive correlation between V. destructor infestation levels and the number of workers displaying DWV clinical signs, further supporting the mite's impact on virus infections at the colony level. A logistic regression model suggests that colony size, the number of workers with wing deformities and V. destructor infestation levels constitute predictive markers for winter colony losses in this order of importance and ease of evaluation.¹⁷”

CRE's Welsh comments also highlight a recent interview with the Director of the University of Illinois at Urbana-Champaign's Institute for Genomic Biology who is “an expert on honey bee behavior, genomics and biology.” The interview with the Institute's Director discussed bee health decline issues was with the Life Sciences editor of an online university publication. In a discussion of possible synergies between “between the sublethal effects of pesticides and the effects of a pathogen, or a parasite, or poor nutrition” the Director observed,

Here, [East Central Illinois] 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

¹⁶ Department for Environment, Food and Rural Affairs, “An assessment of key evidence about Neonicotinoids and bees,” March 2013, p. 1, available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/181841/pb13937-neonicotinoid-bees-20130326.pdf.pdf.

¹⁷ Benjamin Dainat and Peter Neumann, “Clinical signs of deformed wing virus infection are predictive markers for honey bee colony losses,” *Journal of Invertebrate Pathology*, Volume 112, Issue 3, March 2013, Pages 278–280, Abstract.

neonicotinoid use but we have no documented cases of Colony Collapse Disorder. [Emphasis added.]”

CRE comments also include a link to the complete interview in which the Director, in response to a question about the cause of bee health decline states, “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,” <http://illinois.edu/lb/article/72/73513>.

The United States Governments’ state of the science report on bee health¹⁸ also highlights the leading role of *V. destructor* in colony loss. The US Department of Agriculture (USDA) report, based on an interdisciplinary science conference sponsored by the National Honey Bee Health Stakeholder Conference Steering Committee, stated,

*The parasitic mite Varroa destructor remains the single most detrimental pest of honey bees, and is closely associated with overwintering colony declines.*¹⁹

The Conference’s Steering Committee consists of USDA, EPA and Pennsylvania State University scientists.

- 2. The US Government’s state of the science report emphasizes that neonics are safer for bees than the primary alternatives.** The National Honey Bee Health Stakeholder Conference report explained that neonicotinoids pose far lower hazards to bees than alternative crop protection products.

*Pesticide exposure to pollinators continues to be an area of research and concern, particularly the systemic pesticides such as neonicotinoids. Despite concerns regarding the potential hazard that systemic pesticides may represent to honey bee colonies, when pesticides are viewed in the aggregate at the national level, the frequency and quantity of residues of pyrethroids coupled with the toxicity of these insecticides to bees could pose a 3-fold greater hazard to the colony than the systemic neonicotinoids.*²⁰

- 3. The National Academy of Sciences provides guidance on adhering to data quality standards in assessing pesticide risks.** The National Academy of Sciences (NAS), which was established by Congress and President Abraham Lincoln in 1863 to provide “independent, objective advice to the nation on matters related to science and technology,”²¹ released a major report on assessing pesticide risks to species under the U.S. Endangered Species Act.²² The NAS prepared this report at the request of the US EPA, the U.S. National Oceanic and Atmospheric Administration (“NOAA”)/ National Marine Fisheries Service (“NMFS”), the U.S. Fish and

¹⁸ The complete conference report is available at <http://www.usda.gov/documents/ReportHoneyBeeHealth.pdf>.

¹⁹ Ibid., p. vi.

²⁰ Ibid.

²¹ <http://www.nasonline.org/about-nas/mission/>.

²² See, http://en.wikipedia.org/wiki/Endangered_Species_Act.

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Wildlife Service (“FWS”), and the USDA. This NAS Report provides the model for all ecological risk assessments, including pollinator risk assessments.

The complete NAS Report, *Assessing Risks to Endangered and Threatened Species from Pesticides* is available online here: <http://www.thecre.com/forum1/?p=6116>.

A fundamental issue discussed by the National Academies report is the need of regulators to adhere to the data quality standards established by the US Data Quality Act (DQA)²³ in their risk assessment activities. For example, on page 31, the NAS states,

[A]ll federal agencies are expected to comply with the Office of Management and Budget (OMB) guidelines on objectivity, utility, and integrity of disseminated information. OMB (67 Fed. Reg. 8452 [2002]) describes those attributes as follows....

The NAS report also provides the following additional guidance on data quality with is of relevance to DEFRA in their risk assessment work,

- *Given that stakeholders are aware of and can provide valuable and relevant data, the committee encourages provision for their involvement at the early stage and throughout the ERA [Environmental Risk Assessment] process. Stakeholder data are expected to meet the same data relevance and quality standards as all other data.*
- *To ensure that the best data available are used, information should first be screened for relevance and then subjected to quality review.*
- *The agencies should, at a minimum, subject all information to a review based on OMB criteria of ‘objectivity, utility and integrity.’ Information sources that fail any of the criteria can be used at the discretion of the risk assessor, provided that their limitations are clearly described.*
- *Comparisons of all information sources with the relevance and quality attributes should be documented in the risk assessment and described in the overall characterization of uncertainties.²⁴*

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²³ The White House Office of Management and Budget’s Guidelines implementing the Data Quality Act (also known as the Information Quality Act and by the legislative shorthand phrase Section 515) on a government-wide basis are found here, http://www.whitehouse.gov/omb/fedreg_reproducible.

²⁴ NAS Report, p. 34.

CRE's Comments to the Health Canada's Pest Management Regulatory Agency

CRE's pollinator protection comments to Health Canada, found complete in Appendix B of this document, include detailed analyses evaluating the data relating bees health to exposure to varroa mites and pesticides. The CRE comments include highlights of our comments on bee health regulation that we previously provided to the US EPA and to the European Food Safety Authority.

In addition to the above materials, CRE's comments focus on two additional key issues (1) the environmental hazards that would be amplified by a neonicotinoid ban and (2) an explanation of why the "precautionary principle" is not protective.

Banning Neonisc Creates 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."²⁵

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

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'Wildlife at risk' from incoming ban on pesticide linked to bee deaths

Farmers and beekeepers warn that crop-growers may turn to older pesticides when EU ban on neonicotinoids begins

Mark Riley Cardwell

theguardian.com, Wednesday 27 November 2013 07.00 EST

²⁵ [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>.

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....”

Neonic Bans Create an Environmental Threat

Regulatory officials in England, Canada, Wales and other countries need to give careful consideration to the broad environmental hazards that would be posed by restrictions on neonicotinoids. In the UK there is already 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.

The Guardian recently began an article by stating that “Wildlife could be at risk from an imminent ban on pesticides linked to bee deaths, farmers and beekeepers have warned.”²⁶

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.”

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

²⁶ [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 Precautionary Principle is Not Protective

Environmental protection of wildlife and human health is bolstered when regulators base their assessments on the best available science and apply quality standards to their data and analyses. Substituting “caution,” “prudence” or similar term for quality data in the face of uncertainty undermines, rather protects the public.

The need for government officials to apply quality standards to science was recently highlighted by the British government’s initiation of a 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 standards.” Currently, however, the “Regulator does not have statutory powers or the ability to enforce compliance with his standards.”²⁷

“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

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 quality standards.

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.

²⁷ 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.

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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.

CRE's comments discuss Britain's development of mandatory data quality standards because, US regulators are able to rely on and disseminate only data which meets the enforceable quality requirements set by the American Data Quality Act (DQA).²⁸

Australian Government Report: Neonicotinoids and the Health of Honey Bees in Australia

Australia's Pesticides and Veterinary Medicines Authority (APVMA) recently released a major assessment of neonicotinoids on honey bee health.²⁹ The complete study is found in Appendix C of this document. Australia has no varroa mites and is highly vigilant against their introduction.

The APVMA study is notable because Australian farmers use several popular neonicotinoids without the country having any instances of the hive failure commonly called colony collapse disorder (CCD).

The February 2014 Australian study was undertaken "to establish whether: (a) the use of the neonicotinoid insecticides in Australia is presenting any more of a risk to the health of honeybees than other pesticides which have been in use for many years..." The Australian study examined not only the bee health situation in Australia but also "regulatory actions taken in Europe and North America to date, in response to concerns about bee declines and the suggestion that neonicotinoid insecticides are the key culprits."

Of particular importance to DEFRA, The APVMA report concluded:

- **Neonicotinoids Reduce Risk.** "On the basis of information available to it, the APVMA is currently of the view that the introduction of the neonicotinoids has led to an overall reduction in the risks to the agricultural environment from the application of insecticides. This view is also balanced with the advice that Australian honeybee populations are not in decline, despite the increased use of this group of insecticides in agriculture and horticulture since the mid-1990s."³⁰ [Emphasis added]

Other notable finds from the report include:

²⁸ For a discussion of the applicability of the DQA in international regulatory proceedings, please see <http://www.foreffectivegov.org/node/925>.

²⁹ Australian Pesticides and Veterinary Medicines Authority, *Overview Report: Neonicotinoids and the Health of Honey Bees in Australia*, February 2014.

³⁰ APVMA Report, p. 2.

- **Neonicotinoids Don't Threaten Bee Health.** “Information and advice available to the APVMA suggests that, in Australia, honey bee populations are not in decline and insecticides are not a highly significant issue, even though they are clearly toxic to bees if used incorrectly. Incidents of beekeepers losing bee colonies as a result of insecticide use do occur, but this most often arises because there has been a break-down in communication between the farmer and the affected beekeeper.”³¹
- **Few Sub-Lethal Effects of Neonics Found in Field Studies.** “In general, monitoring data collected from a number of countries suggest that, despite a number of laboratory and semi-field studies describing sub-lethal effects of neonicotinoids on foraging behaviour, learning and memory, few adverse impacts have been observed at doses to which pollinators might be exposed in the field – with the exception of those well-documented cases in several European countries and in Canada of bee mortality caused by acute exposure of bees to neonicotinoid dusts generated during planting of insecticide-coated maize seed.”³²
- **Neonics Are Less Toxic Than Leading Alternatives.** “The introduction of the neonicotinoid insecticides has brought a number of benefits, including that they are considerably less toxic to humans (and other mammals) than the organophosphorus and carbamate insecticides they have significantly replaced.”³³
- **Neonics Benefit the Environment.** “On the basis of information available to it, the APVMA is currently of the view that the introduction of the neonicotinoids has led to an overall reduction in the risks to the agricultural environment from the application of insecticides.”³⁴

[This space intentionally blank.]

³¹ APVMA Report, p. 1 [Emphasis added.]

³² APVMA Report, p. 2 [Emphasis added.]

³³ APVMA Report, p. 2.

³⁴ APVMA Report, p. 2 [Emphasis added.]

CRE Conclusions

1. The precautionary principle is not protective; regulators cannot protect human and environmental health through biased and shoddy science.
2. Field use of neonicotinoids has few sub-lethal effects on bees.
3. Neonicotinoids benefit the environment, the Australian government found that the “introduction of the neonicotinoids has led to an overall reduction in the risks to the agricultural environment from the application of insecticides.”

CRE Recommendation

- DEFRA should finalize and carry out its evidence-based scientific assessment of pollinator protection policies.

Respectfully,

Jim Tozzi, Ph.D.
Member, Board of Advisors

Attachments

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30 May 2013

Biodiversity team
Nature, landscape and outdoor recreation branch
Welsh Government
Rhodfa Padarn
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SY23 3UR
biodiversity@wales.gsi.gov.uk

Re: Llywodraeth Cymru/Welsh Government: Draft Action Plan for Pollinators

Dear Biodiversity team:

Overview of the Welsh Government's Public Consultation

The Welsh Government has [declared](#), “Bee and pollinator health has been increasingly highlighted as a cause for concern in the UK and globally.” In an effort to reverse the decline in pollinator numbers,” the Welsh Government will be creating an Action Plan.

As part of the Action Plan, the Government recently opened a public comment period on a draft Action Plan it is developing to prevent the decline of pollinators, namely bees. The supporting documents identify neonicotinoids as a possible factor contributing to bee health decline. More specifically, the Welsh Government's Consultation Document states that “[t]he use of fertilisers and pesticides has been a part of the move towards more intensive farming in Wales. There is significant concern over the potential direct effects of pesticides on managed and unmanaged pollinators, such as neonicotinoids.”

The public comment period on the Wales Action Plan comes in the wake of the European Commission's decision to temporarily restrict three neonicotinoids. The Commission acted after “Member States did not reach a qualified majority – either in favour or against...a Commission proposal to restrict the use of 3 neonicotinoid insecticides.” 12 EU Member States declined to support the restrictions proposed by the Commission.¹

The Action Plan's development process, including this public consultation, provides the opportunity for Wales to independently assess the conclusions reached in:

- The Department for Environment, Food and Rural Affairs's (Defra's) Food and Environment Research Agency (fera) research which found that:

¹ http://europa.eu/rapid/press-release_IP-13-379_en.htm.

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- “The [fera] study did not show that neonicotinoids used within a normal agricultural setting have a major effect on bumble bee colonies.”²
- “The study underlines the importance of taking care in extrapolating laboratory toxicology studies to the field, as well as the great need of further studies under natural conditions.”³
- Defra’s March 2013 scientific assessment document “An assessment of key evidence about Neonicotinoids and bees,” which determined:

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.*⁴ [Emphasis added.]

It is important to also note Defra’s explanation of the deeply counterintuitive and unsupported complaints regarding neonicotinoids:

*Insects are significant pollinators of crops like oilseed rape where yields can collapse in the absence of pollinators [notes omitted]. In the UK, neonicotinoids have been used as seed treatments on OSR for 10 years. This suggests that if pesticide use was reducing pollinator effectiveness then this would also be detrimental to crop productivity. Consequently, the claim that treatment of OSR with neonicotinoids kills pollinators is partly countered by the success of the crops themselves.*⁵ [Emphasis in original.]

As we will discuss below, Defra’s findings are consistent with the observation of a distinguished entomologist and bee researcher at the University of Illinois who observed that the area the university is located in has zero confirmed cases of CCD even though it is “ground zero for neonicotinoid use.”

² Food and Environment Research Agency, “Effects of neonicotinoid seed treatments on bumble bee colonies under field conditions,” March 2013, p. 36, available at <http://www.fera.defra.gov.uk/scienceResearch/scienceCapabilities/chemicalsEnvironment/documents/reportPS2371Mar13.pdf>.

³ Ibid.

⁴ Department for Environment, Food and Rural Affairs, “An assessment of key evidence about Neonicotinoids and bees,” March 2013, p. 1, available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/181841/pb13937-neonicotinoid-bees-20130326.pdf.pdf.

⁵ Ibid., p. 5.

Summary of CRE Comments

About CRE

The Center for Regulatory Effectiveness (CRE), a non-governmental regulatory watchdog, fully supports the Welsh Government's announcement that it plans to develop an Action Plan to prevent the decline of bee health and other pollinators. CRE was established by former senior career officials from the White House Office of Management and Budget (OMB) who have been recognized for their contributions to [science](#). For more information about CRE, please see [here](#).

CRE appreciates the Welsh Government's commitment to science and transparency in public policy as evidenced by this public consultation. The CRE also appreciates the substantial impact that pollinators have on agriculture.

V. destructor: The Major Factor Underlying Colony Loss

According to the supporting documents for public consultation on the Action Plan, "the value of pollinators to UK agriculture is conservatively estimated to be £430 million per year." This is why it is necessary to direct to measures to effectively address "the major factor underlying colony loss,"⁶ varroa mites (*Varroa destructor*).

A recent study unequivocally state that the *Varroa destructor* "has resulted in the death of millions of honey bee (*Apis mellifera*) colonies."⁷ 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 the above-referenced study by researchers at the University of Sheffield and other institutions are 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."⁸

Recent research conducted by scientists at the Swiss Bee Research Centre in Bern, Switzerland and the USDA/Agricultural Research Service's Bee Research Laboratory in Beltsville,

⁶ United States Department of Agriculture/Agricultural Research Service, "Report on the National Stakeholders Conference on Honey Bee Health: Key Findings," available at <http://www.ars.usda.gov/is/pr/beereport.htm?pf=1>.

⁷ Stephen J. Martin, et al., *Global Honey Bee Viral Landscape Altered by a Parasitic Mite*, 336 Science 1304, (June 8, 2012).

⁸ Victoria Gill, *Honeybee Virus: Varroa Mite Spreads Lethal Disease*, BBC Nature, (June 7, 2012).

MD found a close link between *Varroa* levels and Deformed Wing Virus (DWV) with associated loss of colonies:

*There was a significant positive correlation between V. destructor infestation levels and the number of workers displaying DWV clinical signs, further supporting the mite's impact on virus infections at the colony level. A logistic regression model suggests that colony size, the number of workers with wing deformities and V. destructor infestation levels constitute predictive markers for winter colony losses in this order of importance and ease of evaluation.*⁹

Research funded jointly by the Dutch Ministry of Agriculture, Nature Conservation and Food Quality and the European Union also confirmed the close relation between *V. destructor* infestation levels and colony loss. More significantly, the research demonstrates that reducing the levels of mite infestation through treatment of colonies with an acaricide improved colony survival rates over the winter. The study concluded:

*This study contributes to theory about the multiple causes for the recent elevated colony losses in honey bees. Our study shows the correlation between long lifespan of winter bees and colony loss in spring. Moreover, we show that colonies treated earlier in the season had reduced V. destructor infestation during the development of winter bees resulting in longer bee lifespan and higher colony survival after winter.*¹⁰

Instead of addressing the *V. destructor* concern, the EU has been focusing on neonicotinoids as the cause. The EU recently passed a two year restriction on the use of neonicotinoids. The EU restrictions not only fail to address the impact of *Varroa* – and thus fail to protect pollinators –but also it will be economically harmful to European farmers and agricultural production.

According to a study by the Humboldt Forum for Food and Agriculture, neonicotinoid seed treatment contributes between 5.4 billion and 6.3 billion Euros to the GDP of the EU.¹¹ “To put the numbers into context: the immediate potential damages to the overall EU welfare if [neonicotinoid seed treatments] were banned or their use suspended (4.5 billion EUR) are approximately as large as

⁹ Benjamin Dainat and Peter Neumann, “Clinical signs of deformed wing virus infection are predictive markers for honey bee colony losses,” *Journal of Invertebrate Pathology*, Volume 112, Issue 3, March 2013, Pages 278–280, Abstract.

¹⁰ Coby van Dooremalen, Lonne Gerritsen, et al, “Winter survival of individual honey bees and honey bee colonies depends on level of *Varroa destructor* infestation,” *PLoS One*. 2012; 7(4): e36285, available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3338694/>.

¹¹ Steffen Noleppa and Thomas Hahn, *The Value of Neonicotinoid Seed Treatment in the European Union: A Socio-economic, Technological, and Environmental Review*, Humboldt Forum for Food and Agriculture, page 7, January 2013 available at <http://www.neonicreport.com/wp-content/uploads/2013/01/HFFA%20Report.pdf>.

the entire agricultural value added of some smaller EU member states, e.g. Austria or Finland.” Even worse, “over a five-year period, the EU could 17 billion EUR or more.”¹²

Moreover, the current research and data do not support the EU ban on neonicotinoids. In implementing the ban on neonicotinoids, the EU is relying on a report released by the European Food Safety Authority (EFSA) that has gaps in data, is biased, and fails to meet fundamental data quality standards.¹³

For the foregoing reasons, the Welsh Government needs to center its research efforts and the Action Plan on addressing the predominant cause of bee health decline, *V. destructor*.

The need for bee health regulators and researchers to focus on the role of *Varroa*, not neonicotinoids, was highlighted by a recent interview with the Director of the University of Illinois at Urbana-Champaign’s Institute for Genomic Biology who is “an expert on honey bee behavior, genomics and biology.”

As CRE noted above, the Institute’s Director discussed bee health decline issues in an interview with the Life Sciences editor of an online university publication. In a discussion of possible synergies between “between the sublethal effects of pesticides and the effects of a pathogen, or a parasite, or poor nutrition” the Director observed,

Here, [East Central Illinois] 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.
[Emphasis added.]

Prior to discussing the pesticides and bee health, Institute’s Director was asked about what causes CCD:

What factors do scientists think contribute to CCD?

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.

The complete interview may be found here, <http://illinois.edu/lb/article/72/73513>.

One issue researchers are investigating is whether there are environmental factors that may increase the susceptibility of bees to *V. destructor*. Research just published in a distinguished journal, the Proceedings of the National Academy of Sciences (“PNAS”), suggests that the common

¹² *Id.* at 18.

¹³ See *DQA Alert: The EFSA Report on Neonicotinoids Does Does Not Meet the Data Quality Standards of the Data Quality Act*, available at http://www.thecre.com/oira_pd/?p=5765

bee keeping practice of feeding bees high-fructose corn syrup instead of honey is harming the ability of bees to deal with environmental stresses by damaging their immune system. The researchers identified specific compounds of interest in honey, including *p*-coumaric acid, pinocembrin, and pinobanksin 5-methyl ether, that “specifically induce detoxification genes.” The researchers conclude that,

*As a major component of pollen grains, p-coumaric acid is ubiquitous in the natural diet of honey bees and may function as a nutraceutical regulating immune and detoxification processes. The widespread apicultural use of honey substitutes, including high-fructose corn syrup, may thus compromise the ability of honey bees to cope with pesticides and pathogens and contribute to colony losses.*¹⁴

The central role of the *Varroa destructor* in bee health decline was highlighted in a major US government science report, discussed below, prepared by scientists at the United States Department of Agriculture (“USDA”), the United States Environmental Protection Agency (“US EPA”) and Pennsylvania State University.

Any Welsh pollinator risk assessment should explicitly consider the conclusions and recommendations of a recent report by the United States National Academy of Sciences (NAS Report). The NAS Report is entitled *Assessing Risks to Endangered and Threatened Species from Pesticides*¹⁵ and is incorporated by reference as an integral part of CRE’s comments to the Welsh Government.

The NAS Report addresses U.S. regulation of pesticides under the Endangered Species Act (“ESA”).¹⁶ It should be noted that the U.S. government primarily regulates pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (“FIFRA”),¹⁷ which has a much more specific risk/benefit component than does the ESA. Currently, there are no bees on the ESA endangered and threatened lists. Consequently, the NAS Report does not specifically discuss bee risk assessments. The NAS Report does, however, reach conclusions and provide recommendations which are helpful in assessing risks to bees and other pollinators.

Of particular note, the NAS Report emphasizes the need for federal agencies to fully comply with White House’s government-wide guidelines implementing the federal Data Quality Act (“DQA”). The NAS Report provides excellent guidance on assessing all pollinator risks and in

¹⁴ Wenfu Maoa, Mary A. Schulerb, and May R. Berenbauma, “Honey constituents up-regulate detoxification and immunity genes in the western honey bee *Apis mellifera*,” <http://www.pnas.org/content/early/2013/04/26/1303884110>.

¹⁵ A prepublication copy of the complete NAS Report is available on CRE’s website here, http://thecre.com/pdf/NAS--Assessing_Risks.pdf.

¹⁶ See, US Fish & Wildlife Service, Endangered Species Act | Overview, *available at* <http://www.fws.gov/endangered/laws-policies/>.

¹⁷ See, US EPA’s Overview of FIFRA, http://www.epa.gov/agriculture/lfra.html#Summary_of_the_Federal_Insecticide,_Fungicide,_and_Rodenticide_Act.

particular it provides excellent guidance in assessing sublethal risks. This report's recommendations and conclusions are discussed in detail below in the section our comments titled, "National Academy of Sciences Provides the Model for Assessing Pollinator Risks."

US Government State of Science Report on Bee Health

The USDA-published document, "Report on the National Stakeholders Conference on Honey Bee Health" was based on "the proceedings of a stakeholder conference organized and conducted by members of the National Honey Bee Health Stakeholder Conference Steering Committee." The Steering Committee consists of USDA, EPA and Pennsylvania State University scientists.¹⁸

The conference which produced the Report focused on three objectives, the first of which was to synthesize the state of scientific knowledge on bee health decline, "bee pests, pathogens, and nutrition, potential pesticide effects on bees, and bee biology, genetics and breeding." Other purposes of the conference were to assist in the development of Best Management Practices guides and identify priority areas for research, education and outreach.

There were two key findings from the conference, one specific to *V. destructor* and a finding about the broad scientific consensus on the multi-factor nature of bee health decline.

After reviewing research from Conference participants, the Conference concluded that:

*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.*¹⁹

The primary implication from the USDA/EPA finding for the Welsh Government's development of an Action Plan to protect pollinator health is:

- To be effective, the Welsh Action Plan will need to take an integrated, science-based, multi-factor approach to protecting pollinator health.

The corollary to the above conclusion is that any simplistic plan with a focus on a "silver bullet," find-the-bad-actor-and-eliminate-it approach will fail.

Although the USDA Report highlighted the multi-factor nature of bee health decline, the document also emphasized pre-eminent role of *Varroa destructor* in the loss of colonies:

*The parasitic mite Varroa destructor remains the single most detrimental pest of honey bees, and is closely associated with overwintering colony declines.*²⁰

¹⁸ The complete report is available at <http://www.usda.gov/documents/ReportHoneyBeeHealth.pdf>.

¹⁹ USDA, "Report on the National Stakeholders Conference on Honey Bee Health," ("USDA Report") p. v.

Moreover, the Report also found that “Multiple virus species have been associated with CCD” and that “Varroa is known to cause amplified levels of viruses.”²¹

USDA, on their website, summarized the Report’s “Key Findings” by stating,

*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.*²² [Emphasis added.]

The first detailed presentation at the Conference was a review of the “Current State of Knowledge of CCD and its Relation to Honey Bee Health” presented by researchers at USDA and the University of Maryland. The findings presented included discussion of *Varroa*:

*The parasitic mite Varroa destructor remains the single most detrimental pest of honey bees and can magnify the role of viruses in bee health.*²³

The Current State of Knowledge presentation and the USDA Report both discussed neonicotinoids, but in a way very different than viewing the category of compounds as being a cause of bee health decline. Instead, the federal scientists found that neonicotinoids pose far lower hazards to bees than alternative crop protection products.

*Pesticide exposure to pollinators continues to be an area of research and concern, particularly the systemic pesticides such as neonicotinoids. Despite concerns regarding the potential hazard that systemic pesticides may represent to honey bee colonies, when pesticides are viewed in the aggregate at the national level, the frequency and quantity of residues of pyrethroids coupled with the toxicity of these insecticides to bees could pose a 3-fold greater hazard to the colony than the systemic neonicotinoids.*²⁴

USDA did not even mention neonicotinoids on their Key Facts summary of the report. Instead, the researchers emphasize the need for actual exposure data in order to be able to determine whether pesticides are relevant to bee health decline.

²⁰ Ibid., p. vi.

²¹ Ibid.

²² USDA, Agricultural Research Service, “Report on the National Stakeholders Conference on Honey Bee Health: Key Findings,” available at <http://www.ars.usda.gov/is/pr/beereport.htm>.

²³ USDA Report, p. 6.

²⁴ Ibid.

Acute and sublethal effects of pesticides on honey bees have been increasingly documented, and are a concern but it is not clear, based on current research, whether a pesticide exposure is a major factor associated with U.S. honey bee health declines. [sic] The most pressing research questions relate to determining actual pesticide exposures bees receive in the field.²⁵ [Emphasis added]

The Report delved into the issue of the sublethal effects of pesticides on bees and emphasized the complexity of the research and the need to understand the actual exposures of bees to pesticides,

...it remains a challenge to measure the effects of low-level, field-relevant exposure where it matters most: in real honey bee colonies. The social complexity of honey bees and the uncontrollable aspects of field research present substantial challenges to determining pesticide effects in whole-colonies. While experiments using whole colonies have the potential to directly address the effects of pesticides on honey production and pollination services, challenges presented by field or semi-field experiments include:

- *Many colonies are needed per treatment due to high variability between honey bee colonies.*
- *The actual levels of exposure to pesticides that bees receive are still a big question.²⁶*

From a policy standpoint, the bee health question for the Welsh Government becomes, why focus on a class of chemical that has little or nothing to do with bee health decline? A neonicotinoid-centric strategy for protecting pollinators calls to mind a quote from legendary journalist H. L. Mencken²⁷ who explained that “For every complex problem there is an answer that is clear, simple, and wrong.”

From a science standpoint, the Welsh Government has the task of determining how to evaluate conflicting scientific data. Fortunately, federal officials have developed a set of standards for evaluating the quality of data. Unless the information under consideration by government agencies, irrespective of its source, can pass the federal data quality standards, agencies are prohibited from using or relying on the data in agency information disseminations such as reports and regulations.

The National Academy of Sciences (NAS), which was established by Congress and President Abraham Lincoln in 1863 to provide “independent, objective advice to the nation on matters related to science and technology,”²⁸ recently evaluated the role of the Data Quality Act standards on federal

²⁵ USDA Report: Key Facts, <http://www.ars.usda.gov/is/pr/beereport.htm>.

²⁶ NAS Report, p. 18.

²⁷ http://en.wikipedia.org/wiki/H._L._Mencken.

²⁸ <http://www.nasonline.org/about-nas/mission/>.

evaluation of science policy research. The NAS report, discussed below, is highly relevant to the Welsh government's Public Consultation on pollinator protection and to the science policy endeavors of virtually all organizations.

National Academy of Sciences Provides Guidance on Data Quality and Sublethal Risks

On April 30, 2013, the National Academy of Sciences released a major report on assessing risks to species under the U.S. ESA lists: *Assessing Risks to Endangered and Threatened Species from Pesticides* ("NAS Report"). The NAS prepared this report at the request of the US EPA, the U.S. National Oceanic and Atmospheric Administration ("NOAA"/National Marine Fisheries Service ("NMFS"), the U.S. Fish and Wildlife Service ("FWS"), and the USDA. This NAS Report provides the model for all ecological risk assessments, including pollinator risk assessments.

The complete NAS Report is available online here: <http://www.thecre.com/forum1/?p=6116>.

CRE submitted written comments to the NAS during its review and report preparation. CRE's comments to the NAS are available online here: <http://www.thecre.com/forum1/?p=4569>.

CRE's comments briefed the NAS on the four U.S. agencies' DQA implementing Guidelines. CRE is widely recognized as the leading champion of the DQA. An article in [Naval Law Review](#) explained that the Information (Data) Quality Act "is the result of lobby efforts by Dr. James Tozzi, Multinational Business Services and the Center for Regulatory Effectiveness (CRE)."

CRE's comments explained to the NAS that it was commenting on the DQA

because EPA, NMFS and FWS have not adequately briefed the Committee on the Government-wide data quality protocols and standards that govern their ecological risk assessments under FIFRA and the ESA. CRE has long been a proponent of these protocols and standards, and helped establish some of them.

We were gratified to see that the NAS Report, at page 31, acknowledges the importance of DQA Guidelines:

[A]ll federal agencies are expected to comply with the Office of Management and Budget (OMB) guidelines on objectivity, utility, and integrity of disseminated information. OMB (67 Fed. Reg. 8452 [2002]) describes those attributes as follows:

'Objectivity' focuses on the extent to which information is presented in an accurate, clear, complete and unbiased manner; and, as a matter of substance, the extent to which the information is accurate, reliable and unbiased. 'Utility' refers to the usefulness of the information to the intended users. 'Integrity' refers to security, such as the protection of information from unauthorized access or revision, to ensure the information is not compromised through corruption or falsification.'

The Services and EPA (EPA 2002; FWS 2007) have separately published information quality guidelines (IQGs) that follow closely the government-wide OMB guidelines. Similar basic principles for achieving a scientifically credible assessment are prescribed in the IQGs from the agencies; the agencies are committed to ensuring the quality of evaluations and the transparency of information from external sources used in their disseminated assessments and actions (EPA 2003; NMFS 2005). They also recognize that a high level of transparency and scrutiny is needed for influential information that is expected to have a substantial effect on policies and decisions (EPA 2002; NMFS 2004; FWS 2007) [citing the Agencies' DQA Guidelines].

The NAS report at page 34 provides the following additional guidance on data quality:

- *Given that stakeholders are aware of and can provide valuable and relevant data, the committee encourages provision for their involvement at the early stage and throughout the ERA process. Stakeholder data are expected to meet the same data relevance and quality standards as all other data.*
- *To ensure that the best data available are used, information should first be screened for relevance and then subjected to quality review.*
- *The agencies should, at a minimum, subject all information to a review based on OMB criteria of 'objectivity, utility and integrity.' Information sources that fail any of the criteria can be used at the discretion of the risk assessor, provided that their limitations are clearly described.*
- *Comparisons of all information sources with the relevance and quality attributes should be documented in the risk assessment and described in the overall characterization of uncertainties.*

In addition to data quality, the NAS report at pages 109-110 establishes the following principles for risk characterization:

- *Inclusion of uncertainty factors to account for lack of various data is unwarranted because there is no way to determine whether the assumptions being used substantially overestimate or underestimate the probability of adverse effect.*
- *RQs [risk quotients] are not appropriate for risk assessments or for any application in which it is desired to base a decision on the probabilities of the various possible outcomes.*
- *...established, scientifically defensible, statistical methods should be used to calculate risk as a probability to assist decision-makers' understanding of the potential consequences of their decisions.*

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- *A number of existing probabilistic methods have been shown to be applicable and practical for ecological risk assessments that involve pesticides.*
- *The transition from concentration-ratio to probabilistic approaches should begin now, focusing on a small set of sensitive key parameters, and drawing on the considerable literature and guidance on probabilistic approaches.*

Sublethal risks are a particular concern with pollinators. With regard to these risks, the NAS report concludes and recommends at page 96:

- *An adverse effect should be defined by the degree to which an organism's survival or reproduction is affected; thus, assessing the effects of a pesticide on a listed species requires quantifying the effect of the pesticide on survival and reproduction of the species in the wild. Any effect that results in a change in survival or reproduction is relevant to the assessment, and any effect that does not change either outcome is irrelevant with respect to a quantitative assessment of population effects.*
- *To determine whether a pesticide is "likely to adversely affect" a listed species, a broad search should be conducted to identify information on sublethal effects of the pesticide and possible concentration-response relationships.*
- *To provide information to support a jeopardy determination, the Services [NOAA/NMFS and FWS] should either (a) show how sublethal effects change survival or reproduction and incorporate such information into the population viability analysis or (b) state that such relationships are unknown but possible and include a qualitative discussion of uncertainty in the BiOp.*

The NAS report emphasizes on pages 8 and 9 that

Pesticides can kill organisms but can also affect reproduction or growth or make organisms less competitive. Although EPA and the Services agree that those sublethal (less-than-lethal) effects should be considered in the assessment process, they disagree on the extent to which they can be included. To address that issue, the committee first considered how to define objectively the degree to which observed effects are adverse. Defining adversity is essential for ERA because the mere existence of an effect is not sufficient to conclude that it is adverse. The committee concluded that the only way to determine whether an effect is adverse and how adverse it might be is to assess the degree to which it affects an organism's survival and reproductive success; any effect that results in a change in either survival or reproduction is relevant to the assessment, and any effect that does not change either outcome is irrelevant with respect to a quantitative assessment of population effects.... The inability to quantify the relationship between a sublethal effect and survival or reproductive success does not mean that the sublethal effect has no influence on population persistence; but in the absence of data, the relationship remains a hypothesis that can be

discussed only qualitatively with reference to the scientific literature to explain why such a hypothesis is tenable.

Defining and assessing ecological sublethal effects are among the most important issues addressed by the NAS Report. The report explains at page 68:

The committee considered how to assess objectively the degree to which observed effects of pesticides on organisms are adverse. Defining that concept is essential for ecological risk assessment because even if an effect is reliably observed, that alone might not be sufficient to conclude that the effect is adverse. The committee concluded that the only reasonable way to determine whether an effect is adverse and how adverse it might be is to assess the degree to which it affects the organism's survival and reproductive success. It then is possible to extrapolate from changes in an individual organism's survival or reproductive success to estimate population effects. If an adverse effect is large enough, it might lead to extinction of the species. EPA reached a similar conclusion in its overview of the ecological risk assessment process (EPA 2004, p. 31): "If the effects on the survival and reproduction of individuals are limited, it is assumed that the risk at the population level from such effects will be of minor consequence. However, as the risk of reductions in survival and/or reproduction rates increase, the greater the potential risk to populations."

At page 69, The NAS report

recommends that EPA in Step 2 (see Figure 2-1) cast a wide net and identify information about sublethal effects of a chemical. If possible, EPA's assessment should include information about responses at various chemical concentrations (a concentration-response curve) and, at a minimum, include a qualitative assessment of the relationship between sublethal effects and survival and reproduction. In Step 3 (see Figure 2-1), the Services should show how such effects change demographic measures (survival or reproduction) of a listed species and incorporate such information into the population viability analyses or should state that such relationships are unknown but possible and include a qualitative discussion in the uncertainty section of the biological opinion (BiOp). The Services [NOAA/NMFS and FWS] face the greatest challenge in Step 3 in determining whether an observed sublethal effect will change survival or reproduction in the natural population and, if so, the magnitude of such a change in relation to the predicted exposure.

On page 19, the Wales Action Plan states, "There are gaps in our knowledge of the status and trends of pollinator populations in Wales, and particularly in the interrelationships between impacts on them."

The Plan further states,

Area for Action 7: Building an evidence base to support future action for pollinators.

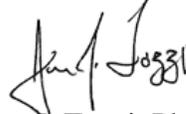
Although there is a large amount of research being carried out on pollinators there are many evidence gaps regarding their status and trends, the interactions between threats to pollinator populations, and mitigation methods. In Wales, we need to establish baseline data and monitor pollinator populations not least to monitor the outcomes of this plan. The value of retaining pollination services in Wales is one important area for future research. We will engage further with UK research initiatives to improve information for Wales.

The NAS report explains how to build “an evidence base to support future action for pollinators,” and on how to conduct “research initiatives to improve information for Wales.” We recommend and request that Wales use the NAS Report to help protect pollinators.

Conclusion

The protection of pollinators is far too important and complex an issue for the Welsh government to accept policy measures, such as banning neonicotinoids, that are “clear, simple, and wrong.” Instead, Welsh officials should evaluate all data presented to them to ensure it complies with Data Quality standards. The NAS Report also provides helpful guidance on assessing sublethal effects.

Respectfully,



Jim N. Tozzi, Ph.D.

Member, Board of Advisors

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December 11, 2013

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."¹

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*² that *regulate the regulators*. CRE was established by former senior career officials from the White House Office of Management and Budget (OMB).³ CRE acts in its own name and does not represent any organization. Instead, CRE is funded by

¹ 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>.

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

³ For more information on CRE's leadership, please see 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.⁴ For more information about CRE, please see the About section of our OIRA Watch Interactive Public Docket (IPD)⁵ focused on the OMB's regulatory office, the Office of Information and Regulatory Affairs (OIRA), 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/] 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.⁶

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,⁷ academia,⁸ and National Public Radio (NPR).⁹ IPDs are also widely used by the media as a data source for substantive reporting including Thompson Reuters¹⁰ and a distinguished Spanish foreign policy journal.¹¹

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

⁵ See, Wikipedia entry for Interactive Public Dockets at http://en.wikipedia.org/wiki/Interactive_Public_Docket.

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

⁷ 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>.

⁸ 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>.

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

¹⁰ 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/>.

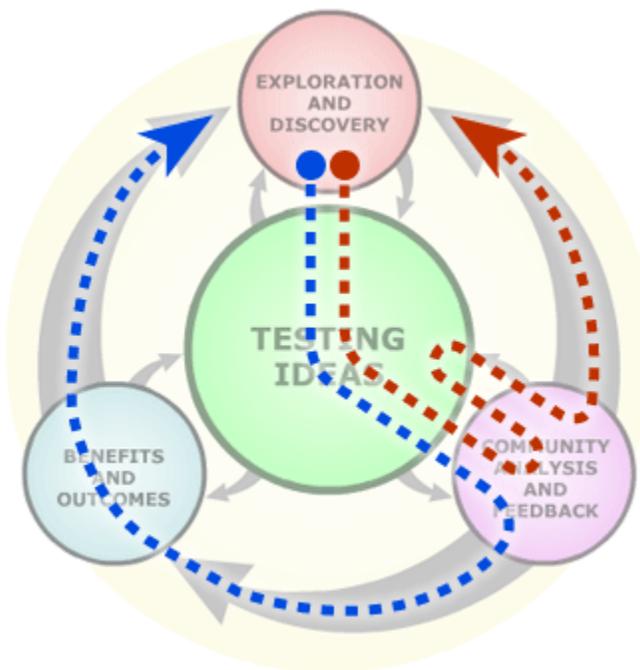
¹¹ See link from "Cyber Guard" in Acerca de Enrique Fojón Chamorro, "La transformación del U.S. Cyber Command," Elcano Blog – Analyses and debates on Spain's foreign affairs, available at <http://www.blog.rielcano.org/la-transformacion-del-us-cyber-command/>.

IPDs: The Real Process of Science

On their *Understanding Science – how science really works*, website,¹² the University of California at Berkeley¹³ 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.

The process of science is not predetermined.



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.¹⁴

¹² See, http://undsci.berkeley.edu/article/0_0_0/howscienceworks_02.

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

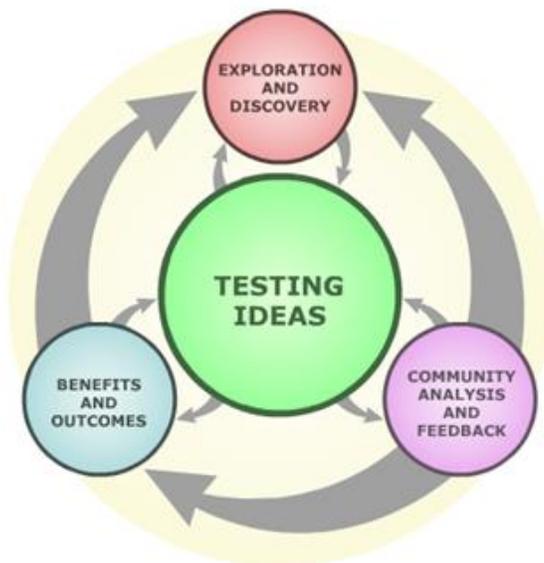
¹⁴ See, Wikipedia entry for Interactive Public Dockets, http://en.wikipedia.org/wiki/Interactive_Public_Docket.

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.¹⁵

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.

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:



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:

¹⁵ 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>.

Center for Regulatory Effectiveness

- 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.”¹⁶ 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.”¹⁷ 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.”¹⁸
- “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.”¹⁹

¹⁶ See, http://undsci.berkeley.edu/article/0_0_0/howscienceworks_02.

¹⁷ 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>.

¹⁸ Lalor and Hickey, Abstract.

¹⁹ Ibid.

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To these ends, CRE is using its Bee Health Interactive Public Docket 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/.²⁰

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.”²¹

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]

²⁰ 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>.

²¹ 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.”²²

“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.”²³

The University of Florida recently noted that at “this point, almost every conceivable and realistic cause [of CCD] remains a possibility.”²⁴ 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.”²⁵ 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.²⁶

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....”

²² 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>.

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

²⁴ 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.

²⁵ *Ibid.*, pp 2-3.

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

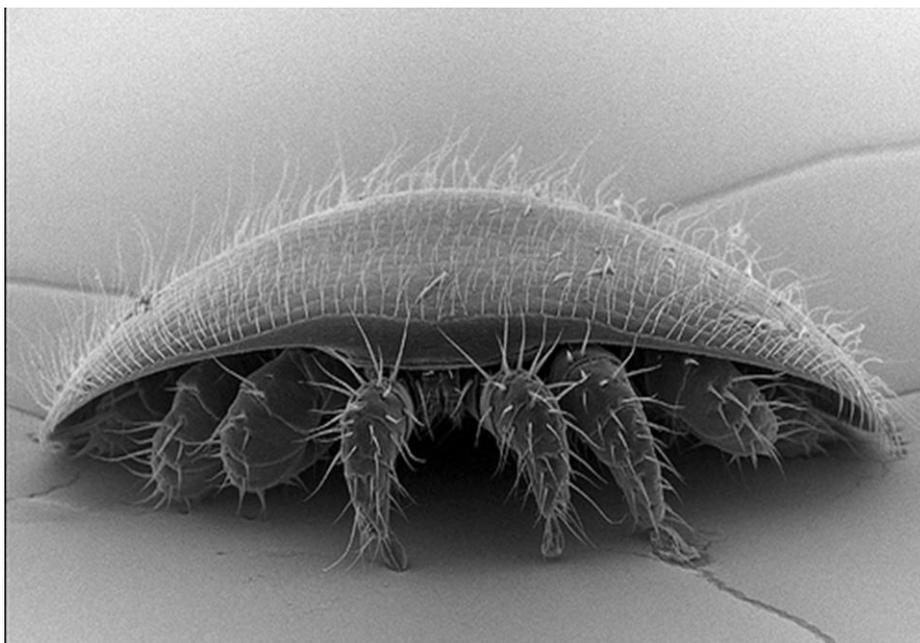
The definitive nature of the agency’s statement was particularly surprising since PMRA admitted that its policies based on its assumption that bee colonies declining because of pesticides *failed* to remedy the problem. Instead of analyzing why its policies didn’t work and keeping an open mind, PMRA 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.”²⁷

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.”²⁸ 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.²⁹

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.

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

²⁸ USDA, Report, p. vi.

²⁹ 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.

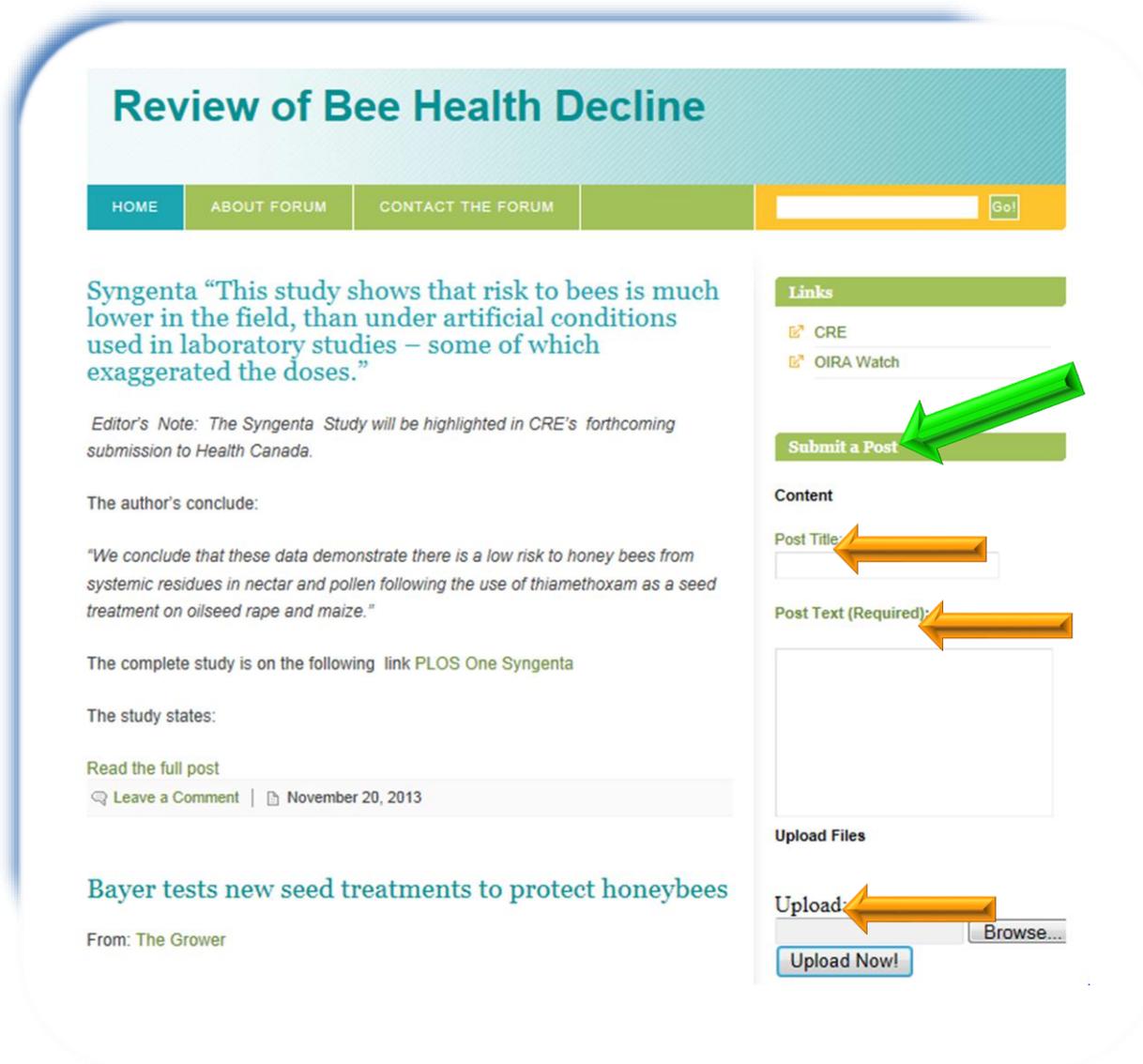
All of the forum's discussions, including those referenced in these comments, are available for public review and comment on an ongoing basis at http://www.thecre.com/oira_pd/. For instructions on how the Review of Bee Health Decline's readers are easily able to comment on articles and post their own 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. The post also includes a date of 'November 20, 2013'. To the right of the main content, there is a sidebar with sections for 'Links' (CRE, OIRA Watch), 'Submit a Post' (Content, Post Title, Post Text), and 'Upload Files' (Upload, Upload Now!, Browse...).

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.³⁰

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.

³⁰ See, 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

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...”³¹ The Review of Bee Health Decline evaluated the news story and found that it may several crucial points.³² 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:

³¹ [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>.

³² See, 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.³³

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"³⁴ 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."³⁵ 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.³⁶ One particular disease, deformed wing virus, can be directly linked to Varroa Mites' infestation of honey bee colonies.³⁷

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.³⁸ In contrast, "the island of Kauai and Maui remained mite-free, and no unusual colony losses or disease problems were reported there."³⁹ Specifically, "In Varroa-free areas, [deformed

³³ 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.

³⁴ EPA, Pesticide News Story.

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

³⁶ *Id.* at 1304.

³⁷ *Id.*

³⁸ *Id.*

³⁹ *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.⁴⁰

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.”⁴¹ Furthermore, Dr. Martin’s study mirrors similar findings by Yves Conte’s report in 2010.⁴² 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.

⁴⁰ *Id.* at 1305.

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

⁴² 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.”⁴³ 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.”⁴⁴

“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.eurekaalert.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.⁴⁵ 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.

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

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

⁴⁵ See, 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.”⁴⁶

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.

⁴⁶ 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.⁴⁷ 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.⁴⁸

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.”⁴⁹ 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.”⁵⁰

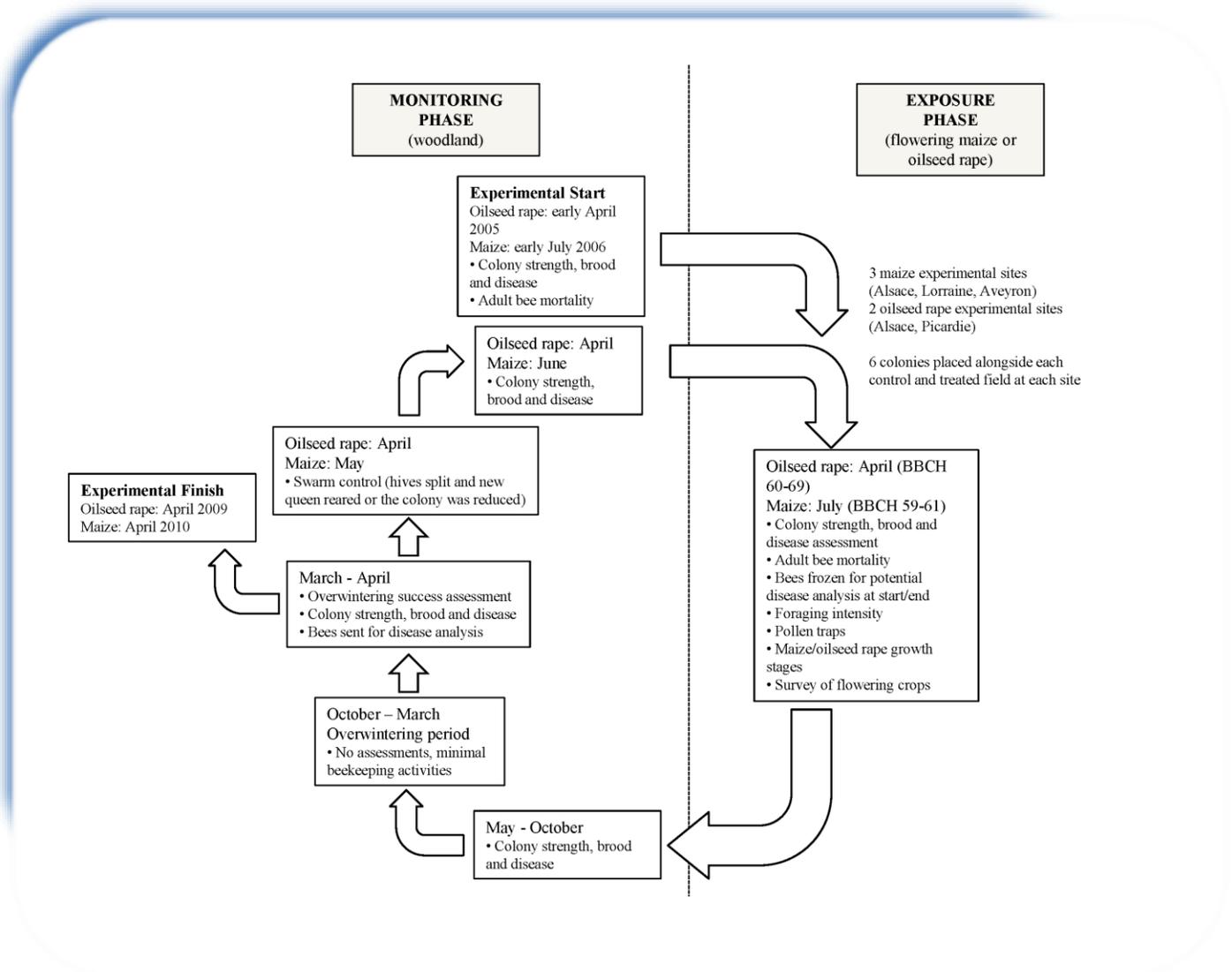
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⁴⁷ See, http://www.thecre.com/oira_pd/?p=11191.

⁴⁸ See, http://www.ted.com/speakers/dennis_vanengelsdorp.html.

⁴⁹ Edward Pilling, 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.

⁵⁰ Pilling, 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”⁵¹

⁵¹ 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

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.”⁵² Similarly, the NGO Operation Bee defines CCD as the “rapid disappearance of bees as a multi-factor syndrome.”⁵³

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.

⁵² 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>.

⁵³ 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

- **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

- **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.

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

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.”⁵⁴

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.”⁵⁵ There is concern, however, that

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

⁵⁵ See, Wikipedia definition of 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.”⁵⁶

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....”⁵⁷

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.”⁵⁸

“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

⁵⁶ Syngenta/PLOS One, Abstract.

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

⁵⁸ 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*.⁵⁹ As noted by the best management practices identified by PMRA, most, if not all, neonicotinoid exposure comes from the dust during planting.⁶⁰ 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.⁶¹

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/>

⁵⁹ 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>

⁶⁰ Id.

⁶¹ 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.⁶² 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.⁶³

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.”⁶⁴ In contrast, in Vancouver Island, where annual colony losses have ranged between 60-76%, neonicotinoid use is relatively small.⁶⁵ 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.⁶⁶ 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

⁶² 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.

⁶³ *Id.*

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

⁶⁵ *Id.*

⁶⁶ 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.”⁶⁷

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.”⁶⁸ 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.”⁶⁹

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.

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⁶⁷ 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

⁶⁸ 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.

⁶⁹ 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/>

⁷⁰ 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.⁷¹

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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:⁷²

“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.”⁷³

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.⁷⁴ There has been recent field studies conducted in Europe which:

⁷¹ *Id.*

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

⁷³ 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>

⁷⁴ See the CRE’s IPD addressing this issue. 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.”⁷⁵

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.⁷⁶ 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.⁷⁷ 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).⁷⁸

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.⁷⁹ 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.”⁸⁰ 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.⁸¹ 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.”⁸²

⁷⁵ *Id.*

⁷⁶ 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

⁷⁷ *Id.*

⁷⁸ *Id.* at 12.

⁷⁹ 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/>.

⁸⁰ *Id.*

⁸¹ 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.

⁸² *Id.* at 28.

The findings by Dr. Scott-Dupree are also consistent with the research by Christian Krupke.⁸³ 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.⁸⁴ 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.”⁸⁵

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.⁸⁶ 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.”⁸⁷ 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.

⁸³ 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).

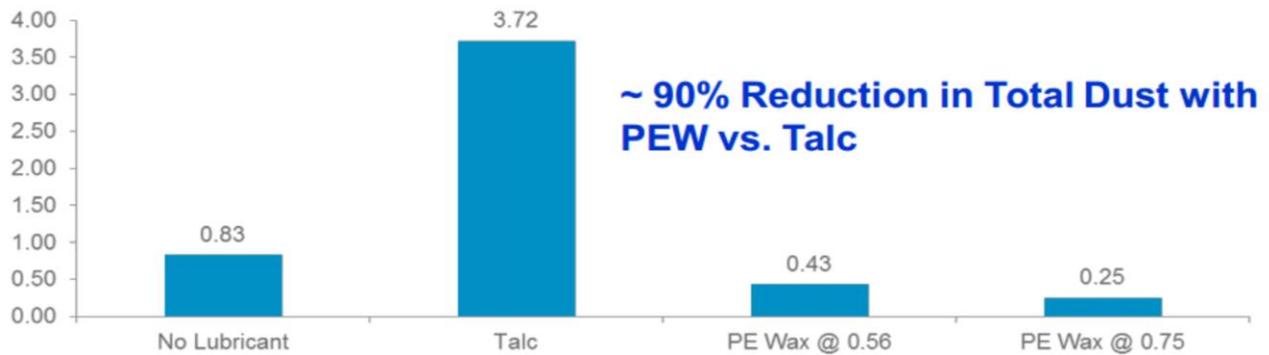
⁸⁴ *Id.*

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

⁸⁶ *Id.*

⁸⁷ *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%.”⁸⁸ 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.⁸⁹ 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.⁹⁰ 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.⁹¹ The results of the field studies mirror the laboratory studies, show a ninety percent (90%) reduction in dust.⁹²

⁸⁸ *Id.*

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

⁹⁰ *Id.*

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

⁹² 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.⁹³ 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.”⁹⁴

⁹³ 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”).

⁹⁴ [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.”⁹⁵

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

⁹⁵ 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>.

Center for Regulatory Effectiveness

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

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).⁹⁷

“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

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>

⁹⁶ 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.

⁹⁷ 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 protection 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.”⁹⁸

When seen in light of the UK’s forensic regulatory quality standards, the precautionary principle actually represents a threat to public safety. Who would be 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.

⁹⁸ See, Wikipedia entry, 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.

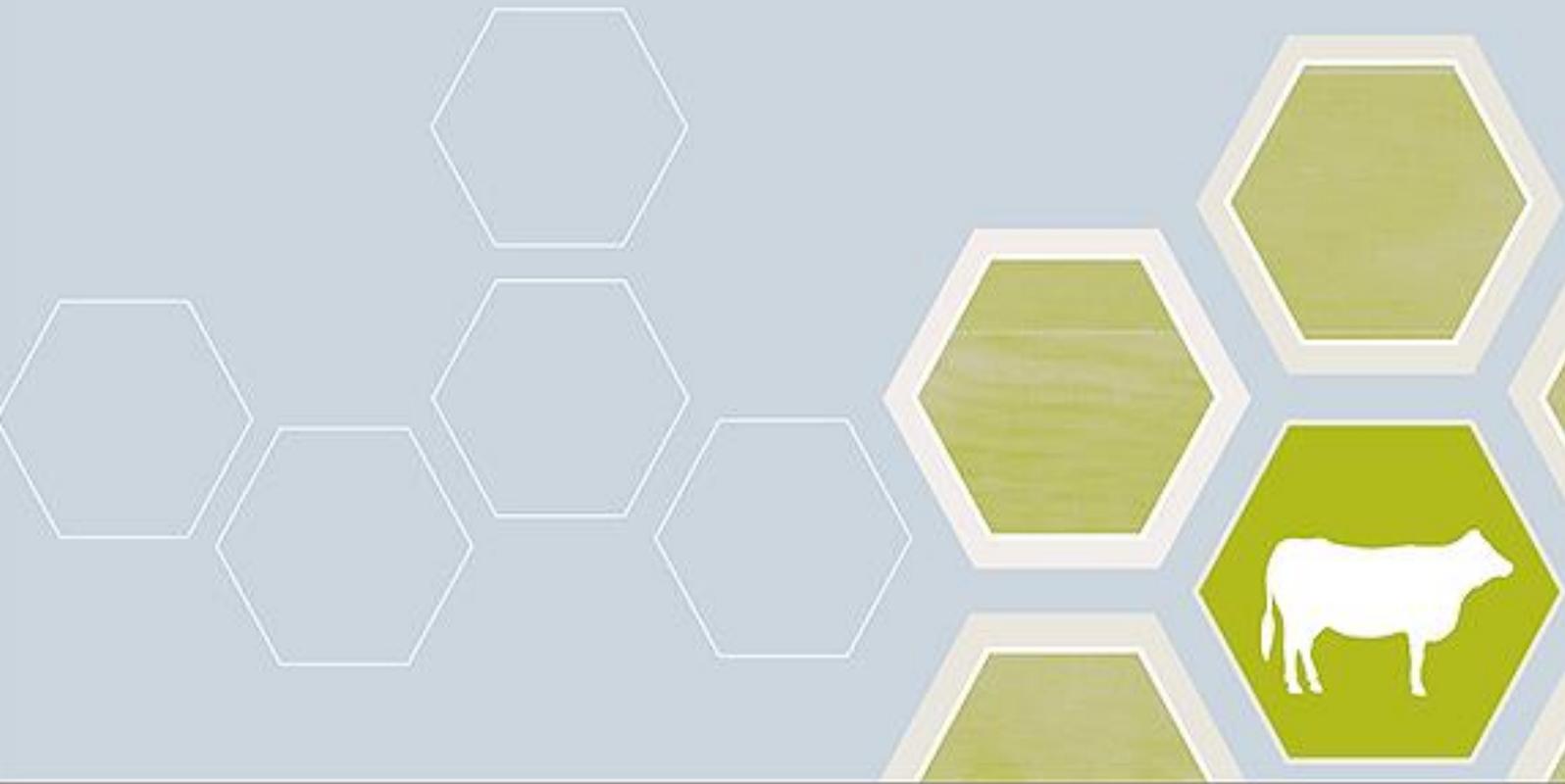
Respectfully,



Jim Tozzi
Member, Board of Advisors



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**



OVERVIEW REPORT

NEONICOTINOIDS AND THE HEALTH OF HONEY BEES IN AUSTRALIA

FEBRUARY 2014

If new information particularly relevant to neonicotinoid use in Australia becomes available, the APVMA may update this overview report. Any revision of the document will be indicated on the cover page.

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EXECUTIVE SUMMARY

This overview report was prepared as part of a project undertaken by the APVMA to establish whether:

- a) the use of the neonicotinoid insecticides in Australia is presenting any more of a risk to the health of honeybees than other pesticides which have been in use for many years; and
- b) the current APVMA data requirements for testing of insecticides are adequate to address scientific concerns about subtle effects of neonicotinoids (and other pesticides) on honey bees which have been suggested as impacting their ability to pollinate plants and collect honey.

The APVMA is aware of concerns that insecticides, especially those of the neonicotinoid ('neo-nicotin-oid') class, may be contributing to a decline in honeybee populations in Europe and the USA. Our current reading of the scientific literature is that there is lack of consensus on the causes of these regional declines, with a wide range of possible causes being actively investigated including pesticides, parasites, viruses, climate change, bee nutrition, lack of genetic diversity, and bee keeping practices. Furthermore, these declines are not universal, with evidence that global populations of honey bees are increasing (eg. Aizen & Harder, 2009a, b).

Information and advice available to the APVMA suggests that, in Australia, honey bee populations are not in decline and insecticides are not a highly significant issue, even though they are clearly toxic to bees if used incorrectly. Incidents of beekeepers losing bee colonies as a result of insecticide use do occur, but this most often arises because there has been a break-down in communication between the farmer and the affected beekeeper.

Different crops vary in how much they rely on pollination by bees - some crops such as apples, pears, cherries and almonds depend almost totally on bees for fruit and nut production. In Australia, the Rural Industries Research and Development Corporation (RIRDC) estimates that around 35 different crops are dependent on honeybee pollination for most of their production. However, because of the large number of wild (or feral) European honeybee colonies in Australia, RIRDC notes that the important role of managed pollination by honey bees is not widely recognised or valued and thus only a relatively small proportion of agricultural producers pay for pollination services from commercial beekeepers.

In Australia, beekeeping is undergoing a significant shift away from honey production and into pollination services. For example, increasing almond production will require a significant increase in the need for hives. However, as Australian beekeepers move away from traditional chemical-free sources of nectar and pollen (native scrub and forest) into providing agricultural and horticultural pollination services, there is a commensurate increase in the risk of exposure to agricultural chemicals.

While the neonicotinoids are acutely toxic to honey bees (ranging from slightly to highly toxic, dependent upon the neonicotinoid), this is not a property which differentiates them from many other insecticides which have been in use for many years. Other classes of insecticides will cause problems for bees and other insect pollinators, depending on how much is applied and when and how they are applied. Furthermore, some fungicides and herbicides used in agriculture and horticulture can be toxic to bees. It is not necessarily just the active constituent in pesticide products that can cause toxicity - other product excipients (ie. non-active

constituents in products), especially surfactants (wetting agents), can also be hazardous to bees (eg. Goodwin, 2012).

In general, monitoring data collected from a number of countries suggest that, despite a number of laboratory and semi-field studies describing sub-lethal effects of neonicotinoids on foraging behaviour, learning and memory, few adverse impacts have been observed at doses to which pollinators might be exposed in the field – with the exception of those well-documented cases in several European countries and in Canada of bee mortality caused by acute exposure of bees to neonicotinoid dusts generated during planting of insecticide-coated maize seed. Thus, other than dust generation during planting, there has been only a limited number of cases of poisoning of bees with neonicotinoids in countries where monitoring (either passive or active) has been carried out. Neonicotinoids appear to be less frequently involved in bee poisoning incidents than many other insecticide classes eg. pyrethroids, carbamates and organophosphorus insecticides. However, there are concerns that repeated exposures to sub-lethal concentrations of neonicotinoid residues in plants may make bees more susceptible to other stressors in the environment, including bee pests and diseases. Whereas tests to study the lethal effects of pesticides on bees are well defined and have been adopted into regulatory guidelines, studies related to sub-lethal effects are less well-defined and developed, and have generally not been incorporated into regulatory risk assessment schemes to date.

The introduction of the neonicotinoid insecticides has brought a number of benefits, including that they are considerably less toxic to humans (and other mammals) than the organophosphorus and carbamate insecticides they have significantly replaced. Furthermore, because of the physicochemical properties of a subset of the neonicotinoids, they can be used to coat crop seeds; this insecticide coating protects the seeds and the young plants while they are growing. This means that there is much less need for farmers to apply chemicals to the growing crops using in-field sprays (applied by ground boom or aerial spraying) which have the potential to lead to a greater spread of the pesticide in the environment. Nevertheless, care will have to be taken not to use seed treatments prophylactically, in the absence of a reasonable assessment of the likelihood of insect-pest attack during the development of the crop.

Conversely, there are some potential negatives. For a compound to be effective as a seed-treatment insecticide it needs to be able to be translocated from the seed into the growing plant and to have a reasonable level of stability in the soil and in the plant tissues. The greater environmental stability of certain neonicotinoids (ie. clothianidin, imidacloprid and thiamethoxam) and their ability to translocate within plants means that they do have the potential to present a greater environmental hazard than other less persistent and/or less mobile insecticides. This report summarises the main uses of neonicotinoids in different crops in Australia and the potential for exposure of managed honeybee colonies to these chemicals; this information should allow better targeting of local research on neonicotinoids.

On the basis of information available to it, the APVMA is currently of the view that the introduction of the neonicotinoids has led to an overall reduction in the risks to the agricultural environment from the application of insecticides. This view is also balanced with the advice that Australian honeybee populations are not in decline, despite the increased use of this group of insecticides in agriculture and horticulture since the mid-1990s.

Nevertheless, the APVMA recognises the importance of bees and other pollinators to Australian agriculture and ecosystems, and the risks that pesticides may pose. Thus it will continue to follow the research into

pesticide effects on bees, especially that on the neonicotinoids and related insecticides which act via the nicotinic acetylcholine receptor (nAChR); should research be generated that provides good evidence that a change in the risk management of any chemical is required, the regulatory system will respond accordingly.

The APVMA is working cooperatively with other government agencies, the chemical industry, the agricultural and horticultural industry and the bee-keeping industry to encourage more research and surveillance, to improve bee protection statements on product labels, to promote the use of our adverse experience reporting program (AERP), to encourage product stewardship, to ensure that suitable products are available for treatment of bee diseases, and to help prevent and manage incursions of exotic bee pests and parasites. The APVMA believes that the risks posed by currently-registered neonicotinoid use patterns can be appropriately managed by adopting a range of regulatory, industry stewardship, and educational measures.

Accepting that it is prudent policy to strengthen a range of risk management measures, this report makes a number of recommendations and research suggestions for consideration; some are addressed to the agricultural and horticultural industries, some to the chemical industry, and some to government agencies which support relevant research and extension services, and others to apiarists. This report also considers several recommendations made to the APVMA by a consultant contracted to review the adequacy of (1) the current battery of regulatory tests designed to investigate the effects of new pesticides on bees; and (2) bee protection statements on existing product labels,

As an overall conclusion, current scientific opinion is that pollinator declines in some parts of the world are likely to be caused by multiple interacting pressures including habitat loss and disappearance of floral resources, honeybee nutrition, climate change, bee pests and pathogens, agricultural/horticultural pesticides, miticides and other chemicals intentionally used in hives, and bee husbandry practices. Effective risk mitigation measures will be aided by ongoing collaborative research and monitoring which is directed at identifying and understanding the key risk factors. This will include research to translate test results on sub-lethal effects of pesticides on bees in a controlled laboratory setting to colonies/populations in the natural environment eg. what is the significance of a behavioural effect seen in the laboratory to the health of bees in the field?

If more information comes to light which suggests that there may be a concern with a particular use or uses of a pesticide (or group of pesticides), there are a number of regulatory options available to the APVMA, including a formal chemical review of the neonicotinoid insecticides, using its powers under the Agricultural and Veterinary Chemicals Code Act 1994. Alternatively, it may conduct a more limited label review of insecticide products; this will depend on the outcomes of APVMA's consideration of its current labelling requirements, recommended standard statements and information with respect to bee warnings and product use instructions on existing product labels.

1 INTRODUCTION

For several years now there has been a high level of research activity and a plethora of media articles and web blogs about the apparent severe decline of honeybee populations in the USA and parts of Europe. Reference is often made to 'Colony Collapse Disorder' (CCD), a syndrome first reported in the USA in late 2006.

Much of the focus of this recent research and commentary has been on a group of insecticides commonly known as 'neonicotinoids', with a lack of consensus on whether or not they present any more of a risk to insect pollinators than other insecticides. The focus on the neonicotinoid insecticides as the prime suspect arose from European reports of bee deaths coincident with planting corn seeds coated with these insecticides. In particular there were several reports from Italy in the early 2000's about problems arising during maize planting and in 2008 there was a mass poisoning of bee colonies in a maize-growing area of the Upper Rhine Valley in Germany. This incident, which gained widespread attention, resulted from neonicotinoid dusts emitted from vacuum seeders during planting operations depositing on nearby flowering crops and weeds.

Maini et al. (2010) noted that:-

"... many hypotheses are available on the problem of declining bee populations The problem is made worse by some in the media who sensationalize and report unsupported data and opinion. Such sensationalizing and the use of unsupported data are, unfortunately, not restricted to the media and can be made by scientists who report data that are not sufficiently verified, come from suspected sources, and/or fail to cite relevant research ... in some published manuscripts neither the author(s), reviewer(s), [or] editor(s) were acquainted with competing literature".

These comments convey quite well the level of discussion and debate that is occurring at the moment.

The Pesticide Action Network UK aptly summarised it in the comment that "environmental risk decision making is undoubtedly difficult in the context of scientific uncertainty, disputed values, high socioeconomic stakes and political pressure, as is the case for bees and neonicotinoids" (www.bees.pan-uk.org/assets/downloads/Bee_factsheet4.pdf).

Thus, in mid-2012 the APVMA commenced an investigation which sought to establish:-

- whether the use of neonicotinoid insecticides (clothianidin, imidacloprid, thiamethoxam) in Australia is presenting any more of a risk to the health of honey bees than other pesticides which have been in use for many years.
- whether the current APVMA data requirements for testing of insecticides are adequate to address scientific concerns about subtle effects of neonicotinoids (and other pesticides) on honey bees, which have been suggested as impacting their ability to pollinate plants and collect honey.

These investigations have been summarised in this overview report. Key questions considered included:-

- Is there a bee problem overseas?
- Is there a problem here?
- Does Australia's regulatory framework need to be revised in order to better protect insect pollinators?

The report also briefly summarises regulatory actions taken in Europe and North America to date, in response to concerns about bee declines and the suggestion that neonicotinoid insecticides are the key culprits.

The collapse of bee colonies is a very significant economic and environmental concern because of the role both commercial and feral bees play in pollinating crops and many plant species in the environment. Therefore it is important to try and gain an understanding of the cause, or causes, so that appropriate steps can be taken to help ensure their continued contribution to plant reproduction and agricultural production systems.

It should be noted that the APVMA's regulatory 'reach' is limited by the powers given to it under the Agvet Code. Following an appropriate evaluation the APVMA can approve new active constituents and register agricultural and veterinary chemical products (and approve their associated labels); review existing active constituents and agvet chemical products; issue permits for uses of agvet chemicals not included on the label; licence the manufacture of chemical products; and regulate the supply of chemical products. In summary, the APVMA is the Australian Government statutory authority responsible for the assessment and registration of pesticides and veterinary medicines, and for their regulation up to and including the point of retail sale. Thus, while a number of factors can impact bee health, the APVMA's risk management reach cannot address them all. For example, the APVMA does not manage the use of pesticides and veterinary medicines once they are sold (this control-of-use is the responsibility of the states and territories), it is not a research-funding organisation, and it does not have jurisdiction over industry codes-of-practice.

2 BEE COLONY DECLINES OVERSEAS

Examination of historical records shows that reports of significant regional declines in honeybee populations are not uncommon (vanEngelsdorp & Meixner, 2010; OPERA Research Centre, 2013). One such event was reported by beekeepers on the Isle of Wight in 1906. Within a few years all losses of bees in Britain were being ascribed to the “Isle of Wight Disease” (Neumann & Carreck, 2010).

More than a decade ago in Europe, French beekeepers suggested that hive weaknesses of a new type (viz. massive mortality within the few days of the first visits of foragers to sunflower crops or during the following winter) coincided with the 1994 introduction of the neonicotinoid insecticide imidacloprid as a coating for sunflower seeds (Aubert et al, 2004).

Concerns about the neonicotinoid insecticides increased in the 2000s when a number of incidents of bees being acutely poisoned by neonicotinoid dusts generated during planting of insecticide-coated maize seeds using vacuum seeders were reported in Austria, Germany and several other European countries.

Then in 2007 the term ‘Colony Collapse Disorder’ or CCD was first applied to a drastic increase in losses of honeybee colonies in parts of the USA in late 2006. Even though the term was coined to describe a specific set of symptoms (see below), subsequent bee colony losses in Europe and in several Asian countries were reported in the media as being part of a worldwide CCD ‘epidemic’.

Now there are regular media reports, both nationally and internationally, about the problem of declining honeybee populations, with many of these concluding that insecticides of the neonicotinoid class are the prime causal agents.

In summary, Aizen & Harder (2009b) note that claims of global bee disappearance are based on regional examples which are not necessarily representative of global trends. These examples usually come from parts of Western Europe and the USA where limited natural or semi-natural habitat remains. Any declines in stocks of domesticated honey bees in Western Europe and the USA over the 20th century have been more than offset by strong increases in Eastern Europe, Asia, Latin America and Africa. Indeed, it is reported that the number of managed honeybee hives worldwide is estimated to have increased by about 45% in the past five decades. Large bee losses resulting from CCD in the USA and the global spread of *Varroa* mites present significant problems but they are unlikely to be drivers of any long-term trend. Instead, the decline seen over many decades in the USA and Western Europe, in particular, are consistent with the economic dynamics of the honey industry, which is shifting to developing countries in search of cheaper production.

2.1 Colony Collapse Disorder (CCD)

CCD describes the abrupt disappearance of worker bees from beehives or colonies of the European honey bee. It should be noted that CCD as described in USA has not been observed in Europe (Hendrikx et al, 2009; Genersch et al, 2010a; OPERA Research Centre, 2013). In the USA, CCD is characterised by no adult bees and no corpses, with significant amount of capped brood and stores of honey and pollen (bee

bread) left in the hive, but a lack of healthy adult worker bees inside the hive (Ellis et al., 2010; vanEngelsdorp et al, 2009)¹. A collapsing colony shows too small a workforce for colony maintenance and that workforce is made up of young bees; this bee cluster seems reluctant to feed on either stored honey or pollen. A reported peculiar symptom is the lack of robbing behaviour by surviving colonies of colonies that have died out (Kevan et al, 2007).

Furthermore, there is little evidence for the occurrence of CCD in Canada (Kevan et al, 2007). There are differences between commercial beekeeping practices in the USA and Canada that may help explain this. For example, migratory beekeeping for pollination services is not such an important part of commercial beekeeping in Canada as it is in the USA, and hive moves are fewer and over shorter distances. And, by and large, Canadian beekeepers probably use fewer chemical and antibiotic control agents against pests and diseases than do their US counterparts and those chemicals that are used are applied more conservatively.

The observations commonly described as CCD are likely to be due to a combination of many factors rather than any single cause. Research by the US Department of Agriculture (USDA) suggests that a combination of environmental stressors may set off a cascade of events and contribute to colonies in which weakened worker bees are more susceptible to pests and pathogens (USDA, 2010; 2011; 2012).

2.2 Bee declines - possible contributing factors

A large number of factors negatively impact honeybee health. A summary list of honeybee stressors is given in the report of an EFSA bee health colloquium held in May 2013 (EFSA, 2013d). Some of these have been suggested as contributing to CCD, including:-

- *Varroa* mite: *Varroa destructor* is an external parasitic mite that attacks honey bees. (Note: Australia has been fortunate to date to avoid any incursion of *Varroa* which presents a major threat to the health of honey bees. Strategies are in place in case any outbreaks are detected.)
- *Nosema* fungus: *Nosema* (or nosemosis) is probably the most widespread of the adult honeybee diseases. *Nosema apis* and *Nosema ceranaea* are microsporidia, small, unicellular parasites recently reclassified as fungi.
- Other fungal diseases of bees: These include 'Chalkbrood' (*Ascosphaera apis*) that infests the gut of bee larvae and 'Stonebrood', caused by *Aspergillus fumigatus*, *Aspergillus flavus* and *Aspergillus niger*.
- Viral diseases: Eighteen viral diseases of honey bees have been described including: Israel Acute Paralysis Virus (IAPV); Deformed Wing Virus (DWV); and Invertebrate Iridescent Virus type 6 (IIV-6). Little is known about some of these viruses which are often associated with *Varroa* or *nosema*.

¹ In 2012 the US Department of Agriculture's Agricultural Research Service (ARS) noted that "The defining characteristic of CCD is the disappearance of most, if not all, of the adult honey bees in a colony, leaving behind honey and brood but no dead bee bodies. This definition has recently been revised to include low levels of *Varroa* mite and other pathogens, such as *Nosema*, as probable contributing factors (USDA-ARS, 2012).

- Small hive beetle (*Aethina tumida*)
- Acarine mites: *Acarapis woodi* is a small parasitic mite that infests the airways of honey bees.
- Bacterial diseases: American Foulbrood (AFB) and European Foulbrood are caused by *Paenibacillus larvae* ssp. *larvae* and by *Melissococcus plutonius*, respectively.
- Stresses related to environmental and climate changes
- Malnutrition: There is some reasonably strong evidence that CCD may not occur in healthy, well-nourished colonies. In the USA, honeybee colonies used for pollination services on large monocultures such as almonds, blueberries and alfalfa may be located in environments where little or no food choice is available to them. It is known that a diverse diet of a mixture of pollens from different plant sources is beneficial to bees, and the same would be true for nectar (Schmidt et al, 1987, 1995). Nutritional imbalance could explain, at least in part, some of the observed symptoms of CCD in the USA. Moreover, the situation for almonds is complicated by the potential toxicity of pollen and nectar from almond flowers, especially in large quantity and for prolonged durations (Kevan & Ebert, 2005; Kevan et al, 2007).
- Lack of genetic diversity: In the USA at least, it has been suggested that a limited gene pool from which nearly all queen bees have descended may be leading to a lack of 'hybrid vigour'.
- Pesticides: Any disappearance of an insect species would implicate pesticides as a potential cause, and CCD is no exception.
- Migratory beekeeping: Relocation of honey bees on a regular basis is likely to be stressful, possibly rendering them less resistant to pathogens. Furthermore, moving hives around the country (as routinely occurs in the USA) aids in the spread of bee pathogens. Migratory beekeeping involves the packing of large numbers of colonies onto the backs of trucks for transport over long distances. Mingling of bees between the hives increases transmission of pathogens. Transportation itself causes colony death - 10% to 30% losses are not uncommon as a result of moving colonies for pollination; migratory beekeepers then split hives into less numerically-sustainable colonies to compensate for the losses. These splits change the natural age structure of the colonies which is itself a further colony stressor. Rapid long-distance movement of bee colonies (e.g. across the USA) may cause disturbances equivalent to "jet-lag" since bees have diurnal rhythms of activity and do sleep. During long-distance moves, hives may be kept in 'staging apiaries' where hundreds of hives are placed cheek-by-jowl - often there is not enough food within the flight ranges of the foragers, hive robbing is common (leading to disease transmission), and hives become weakened despite the efforts of the beekeepers to provide food (pollen or pollen substitute and syrup). Other stressors include confinement in the hives (with stale air, higher carbon dioxide levels, and fluctuating temperatures and moisture levels) and mechanical vibrations. Even moving colonies short distances is well known by apiarists to cause the bees to become upset, so moves taking several days over thousands of kilometers would be considerably more stressful (Kevan et al, 2007; see references cited therein).

- Bee-keeping practices: Bee husbandry practices including the application of chemical miticides and antibiotics may compromise bee health. The difficult task for the apiarist is to differentially kill the pest while not killing the host.
- Electromagnetic radiation / mobile phone signals: This appears to have been largely discounted for a number of reasons, including the observations that CCD occurred in areas without mobile phone coverage and that many apiaries immediately adjacent to mobile phone towers and under high-voltage electrical transmission lines thrive without problem.
- Genetically modified (GM) crops with pest control characteristics

More recently (January 2014) researchers from the USA and China reported that Tobacco ringspot virus (TRSV), a viral pathogen that typically infects plants, has been found in honeybees and can replicate in this host, resulting in detections throughout the body. On the basis of their results, they concluded that the observed negative correlation between the level of TRSV infections and size of host bee populations suggests that this RNA virus, in combination with other viruses, is likely to be a contributing factor to poor survival of honeybee colonies and winter colony collapse (Lian et al, 2014).

An informative document on diseases of honey bees by Plant Health Australia and a number of other national organisations provides information and pictures of the diseases referred to above (PHA, 2012; see www.animalhealthaustralia.com.au/programs/biosecurity/biosecurity-planning/honey-bees/).

Other conditions of bees, not usually suggested as being possible contributing factors in CCD, include:-

Dysentery: This refers to a condition resulting from a combination of long periods of inability to make cleansing flights (generally due to cold weather) and food stores which contain a high proportion of indigestible matter.

Chilled brood: This is not a disease but can be caused by a sudden drop in temperature or when a beekeeper opens a hive and inadvertently prevents nurse bees from clustering over the brood to regulate temperature.

Wax moths (*Aphomia sociella*) and Greater wax moths (*Galleria mellonella*) cause destruction of the honeycomb and may kill bee larvae.

Environmental toxins: Chemicals other than those used in agriculture/horticulture or deliberately applied as miticides/acaricides cannot be discounted as having an impact on bee health; foraging bees may be impacted by urban, household or industrial chemicals.

Naturally-occurring toxins: There is an extensive literature on plants that have pollen which is toxic to honey bees² (eg. Vieira de Melo, 2013). There is also some evidence that under conditions of stress,

² Almond (*Amygdalus communis*) is commonly cited as a plant which is toxic to honey bees because its nectar and pollen contains the cyanogenic glycoside amygdalin. However, research (University of Haifa, 2010) suggests that even though amygdalin is toxic to mammals, it is not poisonous for honey bees, but rather is an insect attractant.

some plants can produce toxic components in pollen and/or nectar (e.g. some Australian Eucalyptus species may do so on occasion). Under certain weather conditions nectar can ferment to produce alcohol (ethanol) which can cause alcohol poisoning in bees [see Report 2 below under the section on 'Adverse Experience Reports (AERs)'].

2.3 Pesticides

With respect to pesticides, a number of scientists have been concerned that insecticides and possibly some fungicides may have sub-lethal effects on bees, not killing them outright but instead impairing their development, behaviour and immunity to parasites and diseases. While the N-nitroguanidine neonicotinoids (clothianidin, imidacloprid and thiamethoxam) are the focus of current attention with respect to sub-lethal effects (and have been for the past decade or so), there is an extensive literature on such effects of a number of other pesticides on honey bees eg. Maini et al. (2010) refer to studies on the insecticides acetamiprid, cyhalothrin, deltamethrin, fipronil and parathion, and the fungicides captan, chlorothalonil, myclobutanil and propiconazole, among others. Furthermore, it is quite likely that interactions (additive, synergistic, or antagonistic) may occur between different pesticides; in the UK, for example, advice has been issued not to spray pyrethroid insecticides together with EBI³ fungicides (Barnett et al, 2007). Laboratory studies indicate a synergistic effect occurring between EBI fungicide and a neonicotinoid insecticide in honey bees (Schmuck et al, 2003a). In laboratory studies Isawa et al. (2004) found that a number of fungicides (applied one hour before dosing with insecticides) significantly increased the 24-h acute topical toxicity of several neonicotinoids.

Mullin et al. (2010) found 121 different pesticides and metabolites within 887 wax, pollen, honeybee and associated hive samples taken in the USA, which indicates that attributing findings in bees to any one pesticide will prove to be a difficult task.⁴

Honey bees may be affected by neonicotinoids when they are used as a seed treatment because they are known to translocate through the plant up into the flowers and leave residues in the nectar and pollen, albeit at very low levels. The doses taken up by bees are not acutely toxic but it is feasible that there may be sub-lethal effects or chronic problems caused by cumulative exposure. Concerns about neonicotinoids have also arisen from direct poisoning of bees flying into dust from pneumatic seeding ('drilling') machines, and from dust drifting onto flowering plants near the field being planted. (These and other routes of exposure of bees to pesticides are discussed in more detail below.)

It also needs to be borne in mind that the chemicals deliberately used within hives to treat Varroa mites are insecticides; it is quite possible that the very nature of the Varroa treatments themselves are causing significant problems. For example, Williamson & Wright (2013) report that coumaphos, a commonly-used Varroa control chemical, affected important bee behaviours involved in foraging. In many countries (Including the USA) treatments for Varroa have been taking place over many years. If beekeepers don't regularly

³ Ergosterol biosynthesis inhibitor

⁴ By contrast, a sample of beeswax foundation purchased from a supplier in Brisbane and tested for 171 different chemicals in the same USDA laboratory only found one (1) chemical, chlorpyrifos, at 165 ppb (J Draper, 2011; *pers. comm.*)

change their brood combs – reports suggest that some can stay in a hive for many years – then there will be a build-up chemicals which have an affinity for beeswax, leading to increasing hive health problems over time.

3 WHAT ARE NEONICOTINOIDS?

Neonicotinoids are a class of insecticides which act on acetylcholine receptors (AChR) in the nervous system of insects. These receptors have been historically divided into two broad types, those activated by nicotine and those by muscarine. Neonicotinoids activate nicotinic acetylcholine receptors. These receptors are located in both the central (CNS) and peripheral nervous systems (PNS) of mammals but are limited to the CNS in insects. In normal synaptic transmission between nerve cells the naturally-occurring transmitter acetylcholine is broken down by an enzyme called acetylcholinesterase (AChE) and this ends nerve signalling. However, AChE cannot break down neonicotinoids which bind to AChR, leading to overstimulation of the insect nervous system, paralysis and death.

It is important to note that most neonicotinoids bind much more strongly to insect AChRs than to mammalian AChRs and thus are selectively more toxic to insects than to mammals (eg. Jeschke & Nauen, 2010).

Table 1 lists the neonicotinoid insecticides plus two related compounds which, while not classified as neonicotinoids (see footnote to Table 1), also act via nicotinic acetylcholine receptors. Neonicotinoid insecticides can be chemically classified as N-nitroguanidines (imidacloprid, thiamethoxam, clothianidin and dinotefuran), nitromethylenes (nithiazine, nitenpyram), and N-cyanoamidines (acetamiprid and thiacloprid) (Jeschke et al, 2011).

Clothianidin, imidacloprid and thiamethoxam are used as seed-treatment insecticides while the soil stability of dinotefuran, the other N-nitroguanidine neonicotinoid, is too limited for use as a seed treatment. The limited soil stability of nitenpyram and acetamiprid also mean that these compounds are not used as insecticide seed coatings.

In terms of bee toxicity, the N-cyanoamides acetamiprid and thiacloprid have a significantly more favorable profile than the N-nitroguanidine neonicotinoids and are usually applied to crops as foliar sprays.

Table 1 List of neonicotinoids and related compounds

GENERIC NAME	ORIGINATOR COMPANY	NOTES
Neonicotinoids		
Acetamiprid	Aventis Crop Sciences	
Clothianidin	Takeda Chemical Industries* & Bayer	
Dinotofuran	Mitsui Chemicals	
Imidacloprid	Bayer CropScience	
Nitenpyram	Novartis Animal Health	Veterinary uses only
Nithiazine	Shell Development Co.	Prototype neonicotinoid – early 1970s
Thiacloprid	Bayer CropScience	
Thiamethoxam	Syngenta	Active metabolite is clothianidin
Other related insecticides acting at nicotinic AChRs		
Sulfoxaflor ⁵	Dow AgroSciences	
Flupyradifurone	Bayer CropScience	

*Takeda's agrochemical interests were transferred to Sumitomo Chemical Co. Ltd in 2007

⁵ Like the neonicotinoids, sulfoxaflor acts as a nicotinic acetylcholine (nAChR) receptor agonist. Because of its chemical structure, the novel way it interacts with the nAChR, and its lack of insecticidal cross-resistance with the neonicotinoids, sulfoxaflor is not normally referred to as a neonicotinoid. Because of its lack of cross-resistance to neonicotinoids the international Insecticide Resistance Action Committee (IRAC) has separately categorised it within mode-of-action (MoA) Group 4 [nicotinic acetylcholine receptor agonists]; it has been placed in Group 4C while the neonicotinoids are in Group 4A (see the Mode-of-Action classification table (v 7.2; February 2012) at www.irac-online.org/content/uploads/MoA-classification.pdf).

4 REGISTERED USES OF NEONICOTINOIDS IN AUSTRALIA

Attachment 1 lists the neonicotinoids approved in Australia and their registered label uses (application method and crop type). In agriculture, the main routes of application include seed treatment, foliar spraying, soil spraying, and soil incorporation of granules.

The N-nitroguanidine neonicotinoids imidacloprid and thiamethoxam are used as seed dressings for a number of different crops. Imidacloprid⁶ and thiamethoxam products are registered for seed treatment of canola, cereals, cotton, maize, sweet corn, sorghum and sunflower; imidacloprid products are also registered for seed treatment of lentils and lupins, faba beans, field peas, pulses, forage and seed pasture (eg. red clover, subterranean clover, strawberry clover, white clover, ryegrass, phalaris, lucerne, medics), and forage brassicas (Kale, turnip, rape and swedes). At the time this report was prepared there were no registered seed-treatment uses for clothianidin in Australia.

In addition to seed-treatment uses, there are a number of neonicotinoid products approved for use as foliar or trunk sprays eg. products containing acetamiprid, clothianidin, imidacloprid and thiamethoxam are approved for foliar spraying of cotton while products containing clothianidin, imidacloprid and thiacloprid are approved as sprays for stone and pome fruit.

⁶ APVMA's PubCRIS lists at least 24 different imidacloprid products sold in Australia as seed treatments for canola.

5 AGRICULTURAL AND ECONOMIC IMPORTANCE OF NEONICOTINOIDS

Neonicotinoids are registered globally in more than 120 countries, and they are among the most effective insecticides available for control of sucking insect pests such as aphids, white flies, leaf- and plant-hoppers, thrips, some micro-lepidoptera, and a number of coleopteran (beetle) pests. They have broad-spectrum activity, with contact, stomach and systemic activity. Their physicochemical properties mean that they are very versatile in terms of application methodology, being used for foliar, seed treatment, soil drench and stem applications in a wide range of crops.

The neonicotinoids are the most significant chemical class of insecticides introduced to the global market since the synthetic pyrethroids.

Imidacloprid was the first neonicotinoid insecticide to come into commercial use, in 1991. It is currently the most widely used insecticide worldwide. It is applied against pests in/on soil, seed, timber and animals, and is in products for foliar application to turf and food crops including cereals, cotton, legumes, potatoes, pome fruits and vegetables. It is a systemic insecticide with particular efficacy against sucking insects and has quite a long residual activity. Because of its water solubility it can be added to the water used to irrigate plants.

In 1990 (before the launch of imidacloprid), the insecticide market was dominated by organophosphorus insecticides ('organophosphates' or OPs) (ca. 43%), pyrethroids (ca. 18%) and carbamates (ca. 16%). By 2008, neonicotinoids had gained around 24% share of the total insecticide market, mainly at the expense of the OPs and carbamates (which fell to around 13.6% and 10.8% of the insecticide market, respectively, at this time). In the past several years the use of neonicotinoid insecticides has grown further; in 2009 imidacloprid was estimated to account for ca. 41.5% of the global neonicotinoid market, making it the largest selling insecticide in the world. Thiamethoxam was second in terms of sales, followed closely by clothianidin. Together, the N-nitroguanidine class of neonicotinoids account for around 85% of the neonicotinoid insecticide market. Nevertheless, sales of other neonicotinoids have grown as well (Jenschke et al, 2011).

The application rates for neonicotinoid insecticides are commonly much lower than older classes of insecticides (eg. Jeschke et al, 2010).

When compared with OPs and carbamates, neonicotinoids pose lower risks to humans and other mammals.

As a result of their mechanism of action, there is no cross-resistance to other insecticide classes, including the so-called organochlorines (now superseded), OPs, carbamates and pyrethroids. Their introduction has increased the insecticide armamentarium available to farmers and horticulturalists, thus helping to prevent the build-up of resistance of insect pests to OPs and pyrethroids. Nevertheless, pests can evolve resistance to neonicotinoids; the first reported example was the silverleaf whitefly, *Bemisia tabaci* (Thany, 2010).

One problem with systemic insecticides is that the selection pressure placed on pests from the ongoing presence of the insecticide, coupled with their site-specific, mode of insecticidal action, may result in the development of resistant insect genotypes. Conversely, the benefits of using systemic insecticides like the neonicotinoid seed-treatment insecticides include (1) plants are continuously protected throughout most of the growing season without the need for repeat spray applications of insecticides; (2) these insecticides are

not susceptible to UV light degradation or 'wash off' during watering; (3) there is no surface residue on the crop and hence a reduced risk to agricultural workers performing in-crop activities.

A comprehensive review of the value of neonicotinoid seed treatments has been published by the Humboldt Forum for Food and Agriculture e.V. (Noleppa & Hahn, 2013). It investigated the socioeconomic and environmental contribution made by this technology to the European Union across major crops and key countries, and the significant economic and social impact should the technology no longer be available because of bans or suspensions.

An analysis of collated sales figures held by the APVMA suggest that the value of sales of neonicotinoid insecticide products is approximately 1/5th of total insecticide sales (including domestic-use insecticides). Over the past five financial years (from FY 2007/08) there has been a slight decline in this proportion because the value of overall insecticide sales has increased at a faster rate than the value of sales for insecticide products containing neonicotinoids. It should also be noted that more than half the sales value of neonicotinoid-containing products is made up of animal-treatment products (including domestic pet care products).

6 EXPOSURE OF POLLINATORS TO NEONICOTINOIDS

Arising from the registered uses of neonicotinoids, pollinators may be exposed to them by:-

- contact with neonicotinoid dusts arising during planting of seeds coated with the insecticide
- intake of systemic residues in nectar, pollen and guttation fluid of the plant, arising from neonicotinoid treatment of the seed used to grow the plant or from application of a neonicotinoid insecticide (as a spray or granule) to the soil in which the plant was grown
- contact with foliar sprays applied to the flowering plant (e.g. canola).

Since neonicotinoids are used in the same way around the world, these possible exposure routes could occur in Australia as in other countries.

6.1 Seed-treatment dusts

More than a decade ago there were reports from various European countries including Austria, Germany, Italy and Slovenia of honeybee poisonings which occurred at the same time as the spring sowing of maize seeds coated with neonicotinoids (see eg. Forster, 2011). In the most reported incident, approximately 12,000 bee colonies in Germany were poisoned in 2008 (Pistorius et al, 2008; Forster, 2009); these extensive poisonings in the Upper-Rhine Valley were attributable to high quantities of clothianidin-contaminated dusts from coated maize seeds being emitted into the air by vacuum-pneumatic seeders and depositing onto nearby flowering plants (eg. oilseed rape, fruits, weeds). It was subsequently established that the quality of the seed dressing was poor (inadequate stickers and binders), allowing the release of the abraded seed coating as fine dust. It appears that these corn seeds had been treated in controlled industrial facilities since there was negligible on-farm treatment of corn seeds in Central and Western Europe at the time. However there have been substantial improvements in seed treatment practices and quality standards since then (see below).

An Italian study found clothianidin and imidacloprid in the exhaust of pneumatic seeding equipment (Girolami et al, 2012). In the USA almost all Bt corn seed⁷ is treated with neonicotinoids and a 2010/11 study conducted in the USA found high levels of clothianidin and thiamethoxam in pneumatic planter exhaust and in the soil and on dandelions in unplanted fields nearby (Krupke et al, 2012). There is evidence from Canada that dusts from improperly formulated or applied seed treatments can acutely kill bees; in 2012 several provinces in Canada reported bee poisonings during the sowing of neonicotinoid-treated corn seed.

⁷ Bt corn is a genetically-modified corn containing a gene which codes for a protein from a naturally-occurring soil bacterium, *Bacillus thuringiensis*. This protein (called Bt delta endotoxin) is expressed in the corn plant and is highly effective at controlling caterpillars feeding on the corn but is generally not harmful to other insects such as beetles, flies, bees and wasps. Growers use Bt corn as a safer alternative to spraying insecticides.

Since 2008, regulations and product stewardship in Europe have largely eliminated this dust problem by controlling both the process of seed treatment and of planting (see eg. Nikolakis et al, 2009). For example, in Germany:-

- Seed treatment can only be performed in professional seed treatment facilities which are registered, have a quality control regime in place (covering staff training, improved coating technology, compliance with maximum permissible levels of dust, appropriate packing, storage and transport of treated seeds) and are subject to independent inspection.
- Packages of treated seed must bear a label advising that:-
 - the seed can only be sown using a pneumatic seeding machine of a type tested and registered by the German Federal Research Institute for Cultivated Plants
 - the seed can only be sown if the wind speed at planting does not exceed 5 m/sec
 - the treated seeds and any dust they produce must be completely incorporated in the soil
 - at least 48 h before seeding, the farmer/farm manager must notify beekeepers with hives located within 60 m of the sowing area (Forster, 2011).

However, concerns have been expressed that equipping maize planters with deflectors may still not have completely solved the dust problem arising during planting (Krupke et al, 2012; Sgolastra et al, 2012).

In Canada, product stewardship measures have been put in place (2012/13) to deal with the issue of neonicotinoid dusts arising from planting coated seeds.

The APVMA has not received any reports of bee poisonings arising from the generation of neonicotinoid dusts during planting of coated seeds in Australia. Saul Cunningham, a bee researcher and Group Leader in Ecology, Ecosystem Sciences / Sustainable Agriculture Flagship, the Commonwealth Scientific and Industrial Research Organisation (CSIRO) also advised that he was not aware of any such instances (*Pers. comm*, 4 Dec. 2013). [Further information about planting of treated seeds for specific crops can be found in Section 7 of this report.]

6.2 Systemic residues in plants

Pollinators may be exposed to neonicotinoids as systemic residues in plant tissues. These residues can arise from uptake via the roots of neonicotinoids applied as seed treatments, soil sprays or soil-incorporated granules or tablets. The absorbed insecticide is then translocated by the plant xylem from the roots to the foliage. Systemic residues may also arise following foliar application of neonicotinoid sprays. The following sections discuss systemic residues following these different insecticide application methods.

6.2.1 Seed treatments

There has been an extensive debate in the literature on whether the systemic levels of neonicotinoids occurring in nectar and pollen following seed-treatment uses of this class of insecticides are adequate to

acutely impair honey bees or other insect pollinators. The evidence is that they do not present an acute poisoning problem, but whether the levels are high enough (either alone or in combination with other pesticides to which bees might be exposed) to subtly affect bee behaviour (and ultimately affect colony health) is a subject of intense ongoing research (as the extent of the reference list associated with this overview report attests).

Frazier et al (2011) summarised a number of studies and noted that acute LD50s for imidacloprid and clothianidin in bees were around 28 and 24 ng/bee respectively, with sub-lethal effects reported at much lower levels. The lowest observed sublethal effects for imidacloprid in laboratory studies occur at doses around at 1 ng/bee, equivalent to 10 ppb for an average-size bee (100 mg). Achieving a 10 ppb dose would require consuming pollen with residues of 250 ppb imidacloprid at a consumption rate of 4 mg pollen/day (4% of bee's body weight). This level of residue is never found when label rates of 'Gaucho' (trade name for a key imidacloprid seed-treatment product) are used as a seed treatment (generally 1-5 ppb in pollen). Nectar residues of imidacloprid are usually less than in pollen, although more nectar than pollen is consumed over the bee's life. However, even if forager bees ingest 10% of their body weight in nectar per day, it would require 100 ppb of imidacloprid in the nectar to achieve a 10 ppb dose per day. Imidacloprid is known to be rapidly metabolised by bees and is excreted with a half-life of about 5 hours.

Thus, more than double the above doses of imidacloprid in the food would be required to maintain a level that keeps up with its rapid clearance from the bee. Thus, it appears unlikely that doses of neonicotinoids from routine systemic seed treatments would attain the necessary >100 ppb levels in pollen or nectar to acutely impair honey bees. However, it is possible that concentrations of neonicotinoids in guttation water from glandular exudations on young plants⁸ grown from treated seed⁹ could acutely kill bees.

Following the mass bee poisoning incident in the Upper-Rhine Valley in Germany in 2008 (in which clothianidin dust arising from planting of neonicotinoid-treated maize seed deposited on nearby flowering plants and poisoned ca. 12,000 bee colonies - see 'Seed-treatment dusts' section above), beekeepers in the region were concerned that when the maize flowered, systemically-translocated residues might cause new poisoning incidents. However, residue analyses following several poisoning reports concluded that they were not linked with maize but resulted from pesticide spray applications to other crops (Pistorius et al, 2009). Monitoring of damaged bee colonies in the region did not show any adverse effects on bee health during and after flowering of the maize, and there were no effects on overwintering strength, overwintering success and colony strength in the spring of 2009 (Liebig et al, 2008).

⁸ In corn, neonicotinoid (thiamethoxam, clothianidin, imidacloprid) concentrations in guttation drops have been shown to progressively decrease during the first 10-15 days after the emergence of the plant from the soil (Tapparo et al, 2011).

⁹ There appears to be a paucity of published information on guttation levels after other routes of application. Neonicotinoids move in the xylem sap flow of the plant in an upward direction and have most complete plant penetration by root uptake (seed or soil application). Theoretically, if a young plant is sprayed, any part of the plant (including guttation fluid) at or above the application point could contain the applied insecticide.

6.2.2 Soil-incorporated granules, soil sprays etc.

Systemic plant residues may arise from the use of neonicotinoids in granules incorporated in the soil at planting and from soil sprays and drenches.

Studies indicate that clothianidin degraded moderately under field conditions (Stupp & Fahl, 2003). Field trials in Europe and the USA on the degradation of imidacloprid demonstrate that it does not accumulate in the soil following repeated yearly applications (Krohn & Hellpointer, 2002). Thiamethoxam showed a moderate to fast degradation rate under field conditions (Maienfisch et al, 1999a). For thiacloprid, half-lives in soil measured under field conditions of northern Europe ranged from 9 - 27 days, and in southern Europe, from 10 - 16 days (Krohn, 2001).

Nevertheless, Krupke et al (2012) found neonicotinoids in the soil of sampled fields, including unplanted fields, near maize and soybean production fields in north western Indiana. Dandelions growing near these fields were also found to contain neonicotinoids. While this could have arisen from insecticide deposition on the flowers, uptake by the root system of neonicotinoids in the soil was suggested as a possibility.

Laboratory studies and field observations suggest that there could be conditions under which, depending on the neonicotinoid, a greater (or lesser) degree of soil persistence might occur. A 2005 field study (cited in Goulson, 2013) which randomly sampled farmland soil in France for imidacloprid found that nearly all soil samples from conventional farms contained detectable levels, even those that had not applied the chemical in the previous year; of the 67 samples from these farms, 9 contained between 10 and 100 ppb imidacloprid, and 3 exceeded 100 ppb.

Note that applications to the APVMA for the registration of plant protection products (including the neonicotinoids) require the submission of data from trials to determine the nature and amount of pesticide residues in crops (so-called follow crops) grown in soil previously used to grow a crop which was treated with the pesticide. Commonly, three different rotational intervals are used to be representative of immediate replanting after failure of the treated crop, a typical crop rotation following harvest of the treated crop, and a typical rotation in the following year.

6.2.3 Foliar sprays

As well as being systemic insecticides, neonicotinoids have trans-laminar or local systemic activity. Trans-laminar movement is the ability of the compound to penetrate the leaf cuticle and move into the leaf tissue, thus controlling insects feeding on the unexposed side of the leaf not directly exposed to the foliar spray, as well as sucking insects that feed on plant juices inside the leaf. Whether there is only local systemic activity in the leaf receiving the spray or whether there is xylem movement resulting in a broader distribution of residues in the whole plant will depend on the stage of the plant's growth when the spray is applied. In general, there is likely to be both trans-laminar activity and xylem movement when actively-growing plants are sprayed. If the plant has reached maturity and no more meristems are actively growing, then the movement of the insecticide will be trans-laminar and limited i.e. the residues will be largely confined to the leaves.

6.3 Contact with foliar sprays

Bees and other pollinators can be acutely poisoned by contact with insecticide sprays, either during spraying or to the un-dried spray on plant surfaces. Most insecticides are likely to be problematic in this regard, not just neonicotinoid sprays. The Rural Industries Research and Development Corporation (RIRDC), which has supported extensive research on crop pollination by honey bees¹⁰, notes (at www.rirdc.infoservices.com.au/items/10-116) that:-

One of the biggest drawbacks of placing bees near any agricultural crop is the possibility of colonies or field bees being affected by pesticides. Pesticides should be kept to a minimum while hives remain on the property. Most poisoning occurs when pesticides are applied to flowering crops, pastures and weeds.

It is strongly recommended that growers take the following steps to prevent or reduce bee losses:

- follow the warnings on pesticide container labels
- select the least harmful insecticide for bees and spray late in the afternoon or at night
- do not spray in conditions where spray might drift onto adjacent fields supporting foraging bees
- dispose of waste chemical or used containers correctly
- always warn nearby beekeepers of your intention to spray in time for steps to be taken to protect the bees; give at least two days' notice
- always advise nearby farmers.

¹⁰ See RIRDC's pollination website at www.rirdc.gov.au/research-programs/rural-people-issues/pollination for a large amount of extension information for farmers and bee keepers.

7 EXPOSURE OF POLLINATORS TO NEONICOTINOIDS IN AUSTRALIA

In considering which agricultural/horticultural situations in Australia might lead to insect pollinators being exposed to neonicotinoids, the following list summarises the possible scenarios:-

- plant/crop is grown from treated seed (or in treated soil) and is attractive to pollinators
- plant/crop has foliar spray applied but not at a time near flowering
- plant/crop has foliar spray applied at or near flowering
- plant/crop is treated but is not attractive to pollinators and/or (in the case of hive bees) is not used by apiarists - doesn't produce the required honey, or pollen/nectar is of poor nutritional quality
- plant/crop is not treated with neonicotinoids

The following section provides a brief overview of the main crops on which neonicotinoids may be used during the growing season, either as seed treatments, soil applied treatments, or foliar sprays. Where information is available to determine which of the above scenarios applies to a particular crop, the likelihood of insect pollinators being exposed to neonicotinoids from their use in that crop is assessed.

In addition to information about agricultural and horticultural uses of neonicotinoids (ie. crops applied to; method of application; see above under 'Registered uses of neonicotinoids in Australia'), it is important to have information about the importance of insect pollinators to the production of various crops ie. how dependent is a particular crop on pollination by insect pollinators and thus how likely is it that hives will be placed in or near the crop? This is summarised in the following summary table reproduced from the website Australian Government the Department of Agriculture (The Department of Agriculture, 2011) – see www.daff.gov.au/animal-plant-health/pests-diseases-weeds/bee_pests_and_diseases/honeybees-faqs).

Table 2 Dependence of different crops on pollination by insects (from Klein et al, 2007)

LEVEL OF BIOLOGICAL DEPENDENCE ON INSECT-MEDIATED POLLINATION				
ESSENTIAL	GREAT	MODEST	LITTLE	NONE
Kiwifruit	Apple	Cotton	Capsicum	Sugar cane
Passionfruit	Mango	Coffee	Tomato	Corn/Maize
Macadamia	Blackberries & related berries	Faba bean	Kidney bean	Wheat
Watermelon	Cherries	Soya bean	Peanut	Rice
Rockmelon	Plums	Sunflower	Papaya	Barley
Pumpkin, squash & zucchini	Avocado	Chestnut		Sorghum
	Almonds			Chickpea
	Canola			Grapes
	Cucumber			

Essential = pollinators essential for most varieties (production reduction by 90% or more comparing experiments with and without animal pollination)

Great = animal pollinators are strongly needed (40-90% reduction)

Modest = animal pollinators are clearly beneficial (10-40% reduction)

Little = Some evidence suggests that animal pollinators are beneficial (0-10% reduction)

None = no production increase with animal mediated pollination

Neonicotinoids are used in the following crops, as seed treatments and/or foliar sprays.

7.1 Canola

In Australia canola seems to be a crop of particular concern with respect to neonicotinoids and bee feeding because (1) it is now Australia's third-largest broad-acre crop after wheat and barley (>970,000 ha sown in 2008); (2) it is a crop which significantly relies on insect pollinators for good yields; (3) canola blossom is frequently one of the earliest floral species available in spring to commercial honey bees in the southern areas of Australia, flowering from September to October; (4) it produces abundant quantities of nectar and pollen with high protein content and thus is an important floral resource for beekeepers; and (5) almost all canola seed in Australia is treated with a neonicotinoid prior to planting.

There has been a difference of opinion over the need for insect pollination of canola. Some reports claim that canola is largely self-pollinated and does not need honey bees, whereas the weight of evidence indicates greater seed yields (more pods per plant, more seeds per pod, and higher rates of germination of resultant seed) when honey bees are present (Keogh et al, 2010b and references cited in this RIRDC 'Pollination

Aware' note; see also the Department of Agriculture's Q&A website at www.daff.gov.au/animal-plant-health/pests-diseases-weeds/bee_pests_and_diseases/honeybees-faqs). Honey bees in particular, whether feral or hive bees, represent a beneficial and important pollen vector for optimal canola yield. An informative NSW Agriculture 'Agnote' brochure titled Honey bees on canola (Somerville, 2002; available at www.dpi.nsw.gov.au/_data/assets/pdf_file/0013/117112/bee-on-canoloa.pdf) provides a concise overview of some key facts relating to bees and canola.

Insect pollinators working canola could potentially be exposed to neonicotinoids from (1) dust from seed coating arising during planting; (2) residues in nectar, pollen and guttation fluid arising from systemic absorption of the insecticide into the plant from the coated seed; and (3) direct exposure to foliar insecticide sprays applied around the time of canola flowering.

The risk of neonicotinoid dusts arising during canola planting appears to be very low because in Australia the low pressure air seeders which are used to plant canola vent directly into the furrow and there is no generation of dust clouds.

There has been considerable debate about whether the low levels of residues in canola nectar and pollen arising from seed treatment are having any impact on pollinators; this issue is considered elsewhere in this report (see above under 'Systemic residues in plants'). Advice provided to the APVMA during the preparation of this report suggests that, in the main, honey bees are doing well on canola in Australia. [See also further discussion on this issue in section 15.2 of this report ('Research Suggestions') under 'Canola'.]

There is no doubt that foliar application of neonicotinoid sprays (and indeed any other insecticide sprays) around the time of canola flowering will present a risk to pollinators. This is a risk that can be addressed, at least in part, by appropriate label warnings and by increasing grower awareness of the value of insect pollinators to improved canola yields – they will then be more inclined to consider whether there is a need to spray and, if so, the timing of spraying in relation to pollinator activity in the crop. In Australia there are currently no approved foliar spray uses in canola for any of the neonicotinoid insecticides listed in Table 1. A product (Dow AgroSciences 'Transform') containing sulfoxaflor which is related to the neonicotinoids (it targets the same receptors; see footnote to Table 1) is approved as a foliar spray in canola - its label contains the bolded caution that 'this product is highly toxic to bees: read the PROTECTION OF LIVESTOCK¹¹ section in this booklet before use'. The use instructions also advise that 'if honeybees are present in the target area during flowering, see the PROTECTION OF LIVESTOCK directions'. The text under the PROTECTION OF LIVESTOCK heading is as follows:-

Highly toxic to bees. Will kill foraging bees directly exposed through contact during spraying and while spray droplets are still wet. May harm bees in hives which are over-sprayed or reached by spray drift.

Do Not apply this product while bees are foraging in the crop to be treated.

Treatments made to crops in flower or upwind of adjacent plants in flower that are likely to be visited by bees at the time of application, should not occur during the daytime if temperatures within an hour

¹¹ Since honey bees are not native to Australia, they are classified as livestock.

after the completion of spraying are expected to exceed 12°C. It is recommended that orchard floors containing flowering plants be mown just prior to spraying. Beekeepers who are known to have hives in, or nearby, the area to be sprayed should be notified no less than 48 hours prior to the time of the planned application so that bees can be removed or otherwise protected prior to spraying.

7.2 Cereals

Imidacloprid and thiamethoxam seed treatment products are approved for treating cereal seeds. However, wheat, barley, oats, rice, corn etc. (the world's staple food crops ie. they provide more food energy than any other type of crop) are pollinated by wind and thus are not reliant on honey bees for seed set. Since they do not need to expend energy to produce colourful petals, nectar, or an attractive odour, they are not bee-attractive crops and are of no value to apiarists.

Therefore the risks to insect pollinators from neonicotinoid treatment of cereal crops are likely to be very low.

7.3 Clover & other pasture

Products containing imidacloprid are approved in Australia for coating forage and pasture seeds, including red clover, subterranean clover, strawberry clover, white clover, ryegrass, phalaris, lucerne and medics.

A wide range of clovers and sub-clovers are grown in Australia, in temperate, sub-tropical and tropical regions. Pollination of these mostly self-incompatible species is necessary for seed set. Pollination has consistently been identified as a major limiting factor to higher, more reliable clover seed yields and improved seed quality. Research in Victoria suggested that honey bees made up 88% of all insect visitors to white clover (Goodman & Williams, 1994). Red clover flowers are almost completely self-sterile and require cross-pollination to produce seed; it appears that honey bees are satisfactory pollinators of red clover provided that they are sufficiently numerous and that competing bloom is not too abundant. Little is known about the pollination of purple clover although the bright flower colour and observations of extensive bee activity suggest that it is also pollinated by bees (Keogh et al, 2010c and references cited in this RIRDC 'Pollination Aware' note).

Different clover species grown represent significant nectar resources for beekeepers, particularly in the New England area of NSW, Victoria and Tasmania. Somerville (2001) noted that pollen of white clover is of very reasonable quality and white clover produces choicest quality honey. Beekeepers are quite keen to work lucerne (T Weatherhead, AHBIC, 2013; *pers. comm.*)

Planting of pasture seed is by broadcasting (including aerial broadcasting) or shallow drilling.

The APVMA has no information about whether neonicotinoid seed treatment of clover and other forage and seed pasture (eg. ryegrass, phalaris, lucerne, medics) is causing any problems, arising either from dust generation during broadcasting or shallow drilling of coated seed, or from systemic residues occurring in the pollen and nectar. The potential for exposure of bees cannot be discounted.

7.4 Corn/Maize

In the USA corn is the number one broad-acre crop in terms of area under cultivation and economic value; the USA is by far the largest producer of corn in the world, producing over 30% of the world's corn.

In Australia sweet corn/maize¹² is a relatively minor crop, both in area and production compared to other summer crops such as sorghum and cotton. However, it has the widest geographical spread of all the field crops, being grown from tropical North Queensland to as far south as Tasmania. The total area of production varies from season to season, but over the 5 seasons to 2004 it averaged 72,000 ha (Maize Association of Australia website at www.maizeaustralia.com.au/austoverview.html).

The majority of the grain production is used domestically by a wide range of industries, ranging from stockfeed to human food uses including breakfast cereals, snack foods and for starch extraction. A significant area of maize is also grown for whole plant silage, especially for dairy farmers and cattle feedlots.

Over 90% of USA seed corn is treated with neonicotinoids (either clothianidin or thiamethoxam) and a similar statistic would apply to corn planted in Australia. As for canola, insect pollinators could potentially be exposed to neonicotinoids (1) from dust from seed coating arising during planting; (2) from residues in nectar, pollen and guttation fluid arising from systemic absorption into the plant from the coated seed; and (3) direct exposure to foliar insecticide sprays applied to the maturing crop. There is a significantly greater potential for dust generation during corn seeding (as cf. canola) because of the increasing use of vacuum seeders; fans which create a vacuum to 'suck' seeds onto a rotating seed plate vent directly to the air and hence there is a risk of generation of dusts which could poison flying pollinators directly or deposit on nearby flowering plants.

However, it appears that corn growing in Australia will present only a low risk to pollinators. As indicated in Table 1 (above) corn is not reliant on insect pollination for seed set or yield improvement. Furthermore, published research (eg. Höcherl et al, 2012) indicate that feeding bees on a pure maize pollen diet is linked to a reduction in brood rearing and lifespan; as a general rule any pollen from plants that are wind pollinated is low in protein and corn/maize has been confirmed as having low quality pollen. There is no nectar in corn and beekeepers report that bees on corn go backwards in hive strength if that is the only source of pollen (T Weatherhead, 2013; *pers comm*). Therefore Australian bee keepers advise that corn is not a crop that they are interested in putting their hives on.

The possible deposition of neonicotinoid dusts (arising from corn seeding) on flowering plants adjacent to the field may need to be investigated; since corn can be planted from August through to April/May depending on the region, it is likely that various other plants may be flowering sometime during this extended planting season.

¹² Maize is harvested at maturity when its kernels are dry and can be stored for stockfeed. Sweet corn is maize which is high in sugar and is harvested before maturity for human consumption; it must be eaten shortly after picking.

The risks to pollinators from direct foliar application of insecticides to maturing corn is likely to be low because it is not favoured as a nectar and pollen source by Australian beekeepers. Furthermore, there are currently no products containing neonicotinoids approved for foliar spraying of corn crops in Australia.

7.5 Cotton

Cotton is grown in southern and central Queensland and northern NSW. Although a relatively small producer on the world scale, Australia is the world's third-largest cotton exporter and thus cotton is a significant agricultural crop, with over 300,000 ha in production in 2008 (Keogh et al, 2010d and references therein).

In Australia imidacloprid and thiamethoxam seed treatment products are approved for cotton while acetamiprid, clothianidin, imidacloprid, thiacloprid and thiamethoxam products are approved as foliar sprays.

Since the introduction of GM cotton, there has been a very significant reduction in the total amount of pesticides applied to cotton – 96% of cotton planting in Australia is now 'Bollgard II' and the total amount of insecticide active constituent (ac) applied has decreased from ca. 6.24 kg ac/ha in 2000-01 to 0.54 kg ac/ha in 2010-11 (information provided by Cotton Australia, 7 Feb 2013). In Bollgard II cotton, foliar applications of the neonicotinoids acetamiprid, clothianidin, imidacloprid and thiamethoxam made up about 7.5% of the total foliar insecticide applications in 2010-11, with about 0.04 kg ac/ha of neonicotinoids applied by spray during this particular season.

Cotton Seed Distributors (CSD) advised (through Cotton Australia) that 92% of cotton seed planted in the 2012 season was treated with a neonicotinoid seed coating; CSD is currently the sole supplier of cotton planting seed in Australia and there does not appear to be any on-farm treatment of planting seed. The coating process for cotton appears to be tightly controlled, with industrial application of insecticide, fungicide and a colour polymer coating (for cotton variety identification purposes) that acts as an adhesive to improve uniformity of the coating and to reduce insecticide/fungicide dust.

Cotton is commonly regarded as being a partially cross-pollinated crop, and largely self-fertile and self-pollinating (McGregor 1976), although introducing insect pollinators into the crop during flowering has resulted in increased quantity and quality of cotton lint and seed (Keogh et al, 2010d and references cited therein; Rhodes, 2000). However, while cotton is a high-value crop for the grower, it is not considered to be a primary resource by apiarists and is not particularly attractive to bees. The nutritional value of cotton for bees is said to be 'acceptable' for honey bees although there appears to be limited research on its pollen and nectar characteristics.

The presence of bee-attractive extra-floral nectaries on cotton plants outside of flowering potentially provides an additional attraction to insect pollinators, particularly in the absence of other food sources¹³. Extra-floral nectaries are nectar-producing epidermal glands that are located on vegetative plant parts or on reproductive parts without being involved in pollination. Early in the season, when floral nectar is not yet available in

¹³ Little is known about the function and ecological role of extra-floral nectaries; they may help sustain beneficial insect parasitoids sufficiently to help reduce plant damage by sucking and chewing insects.

cotton, extra-floral nectaries are present and provide a nectar source well before the plants begin to flower. About 45–50 days prior to flowering of cotton, extra-floral nectar is provided by single foliar glands located on the mid-vein of the lower leaf surface. In later stages of cotton growth, extra-floral nectar is also found in three bracteal nectaries at the base of each of the three bracts (see eg. Röse et al, 2006). Thus, the risk to bees from insecticide application is not necessarily just at the time of flowering.

In drought periods, or protracted dry weather in Australia when other food and moisture sources are not easy to find, bees will be attracted to irrigated cotton.

Most beekeepers are aware that even Bollgard cotton needs to be sprayed with insecticides, albeit not as frequently as non-GM cotton. Therefore they have generally avoided cotton; one apiarist advised the APVMA that they were aware of reports from the USA of honey being produced from cotton but beekeepers in Australia will tend to 'steer clear' of this crop. There have been reports of bee kills in cotton but, in most cases, by insecticides other than the neonicotinoids.

Since use of honey bees in cotton has not been common in Australia, the risk to hive honey bees from neonicotinoid use in cotton would appear to be relatively low. Whether this is the case for feral honey bees, native bees and other insect pollinators is not clear from available information. Spraying with any foliarly-applied insecticide, whether it is a neonicotinoid or any other class of insecticide, will present a risk to bees and other pollinators when they are foraging.

While the APVMA has assessed residue data and set Maximum Residue Limits (MRLs) for the neonicotinoids (clothianidin, imidacloprid, thiacloprid and thiamethoxam) and the related compound, sulfoxaflor, in cotton seed (used for food-grade oil production) and cotton seed products used for animal feed (cotton seed meal and hulls), it has not seen any Australian data on the levels of neonicotinoid residues in cotton honey, pollen or guttation drops arising from seed-treatment with neonicotinoids. In a briefly-reported study in southern Europe, imidacloprid was detected at levels less than 10 ng/g in honeybee tissues, pollen and honey collected from bees placed on a cotton crop grown from imidacloprid-treated seed (Kasiotis et al, 2011).

The other possible risk is to pollinators which may be in the vicinity of cotton seeding activity. Advice from Crop Consultants Australia Inc (CCA) via Cotton Australia indicated that in the 2012 planting season around 95% of cotton was planted with vacuum seeders (with the remainder by gravity planters). As noted above (see under 'Corn/Maize'), vacuum seeders have the potential to blow insecticide/fungicide dust from the coated seed into the air which may directly affect flying insects (eg. Girolami et al, 2012) or deposit on any adjacent flowering plants. Cotton Australia suggested that the most common planter in use at the time of their limited survey of the 2012 planting was the John Deere 'MaxEmerge' row crop planter which has a centre-mounted fan behind the tractor that vents towards the ground to reduce the possibility of generating an airborne seed-coating dust cloud.

The cotton industry publishes a detailed pest management guide – the most recent one is *Cotton Pest Management Guide 2012-13* (The Australian Cotton Industry Development & Delivery Team, 2012). Table 3 of the guide ('Impact of insecticides and miticides on predators, parasitoids and bees in cotton'; pages 8-9) summarises the toxicity to pests, beneficial insects and bees of a range of pesticides potentially available to cotton growers. The following text is taken from pages 155-156:-

Protecting bees

The cotton growing environment is a high risk environment for bees. Bees are particularly susceptible to many of the insecticides used on cotton farms, such as abamectin, fipronil, indoxacarb, pyrethroids and profenofos. The productivity of hives can be damaged if bees or the hives are contaminated.

Insecticides that are particularly toxic to bees are identified as such with the following special statement on the label: Dangerous to bees. DO NOT spray any plants in flower while bees are foraging. The relative toxicities of cotton insecticides to honey bees are listed in Table 3 on pages 8–9. Table 3 ranks the acute toxicities of products to bees based on LD50 information. The residual toxicity of insecticides, that is, the amount of time the product remains toxic to bees after the time of application, should also be considered when information is available. For the majority of insecticides used in cotton the residual toxicities are unknown. Table 42 summarises the currently available information.

Bees are generally active between 7:00 am and 4:00 pm and most bees forage within a 2 to 4 km radius of their hive. They may travel up to 7 km away in search of pollen and nectar, though only when nearby pollen and nectar sources are in decline or are of poor quality. Bees collect nectar from extrafloral nectaries (eg under leaves) as well as from cotton flowers so they may forage in cotton crops before, during and after flowering. As well as bees foraging in cotton crops, damage may occur to bees when pesticides drift over hives or over neighbouring vegetation that is being foraged by bees eg. coolibah.

Coolibah trees (*Eucalyptus microtheca*) are a primary source of nectar and pollen for honey bees. These trees grow on the black soil plains along many of the river courses in the cotton growing areas. Budding and flowering occurs in response to good spring rains. In northern NSW the buds appear in November and the trees begin to flower mid-late December finishing about the end of January, budding and flowering times vary by a few weeks in both the southern and central Qld areas. When heavy budding occurs beekeepers often move large numbers of hives into cotton growing areas for honey production.

With good communication and good will, it is possible for apiarists and cotton growers to work together to minimise risks to bees, as both the honey industry and cotton industry are important to regional development.

The pesticide risk to bees can be reduced by:

- Applying pesticides toxic to bees in the evening when bees are not foraging;
- Notifying the apiarist when beehives are in the vicinity of crops to be sprayed to allow removal of the hives before spraying. Beekeepers require as much notice possible, preferably 48 hours, to move an apiary;

- Where possible, using EC¹⁴ and granular formulations in preference to wettable powders which are particularly hazardous to bees. Micro-encapsulated formulations such as that used for lambda-cyhalothrin are particularly hazardous to bees because of their persistence in the environment and because bees transport the micro-capsules back to the hive along with the pollen;
- Inform contract pesticide applicators operating on the property of the locations of apiaries;
- Paying particular attention to wind speed and direction, air temperature and time of day before applying pesticides;
- Using buffer zones as a mechanism to reduce the impact of spray drift or overspray; and,
- Avoiding drift and contamination of surface waters where bees may drink (see advice on risk management for aquatic organisms).

Bee Alert

The Cotton Catchment Communities CRC¹⁵ hosts a voluntary service on its website (www.cottoncrc.org.au/industry/Tools/Bee_Alert) called 'Bee Alert' which aims to improve communication between hive owners and cotton growers. The website allows beekeepers to regularly update information about their hives, for use by cotton growers. Each Bee Alert provides:-

- A description of where the hives are located
- The likely duration of their stay
- Contact details for the apiarist to be used in the event that hives may need to be moved.

The CRC oversees the placement of data, allowing the Regional Cotton Extension Officer to be notified when new listings are made in a region. Communication with growers and aerial operators can then be co-ordinated locally.

When communicating with beekeepers, encourage them to use this service, particularly when apiaries are being placed within bee flight range of flowering crops. [*End of text extract from Cotton Pest Management Guide 2012-13*]

The APVMA concludes that because apiarists avoid deliberately placing bees on cotton, the risks to managed hive bees will be low. However, there is the potential for bees to be poisoned if they are placed in cotton-growing areas in order to feed on native vegetation; Coolibah trees (*Eucalyptus microtheca*), which

¹⁴ Emulsifiable Concentrate

¹⁵ Cooperative Research Centre Limited

grow along many of the water courses in the key cotton growing areas of Australia are a primary source of nectar and pollen for honey bees.

7.6 Faba beans

Australia ranks about fourth as a global producer of faba beans. Faba beans have been used extensively in Australia for livestock feed but an emerging export market is becoming important; Australia is a major exporter to the Middle East where faba beans are a relatively high-value product.

Pollination has consistently been identified as a limiting factor to higher, more reliable seed yields and improved seed quality in faba beans. A number of studies have shown the value of honey bees as faba bean pollinators in Australia and overseas (Cunningham & LeFeuvre, 2013; Keogh et al, 2010e and references cited therein).

Pollen of faba beans is high in protein but the flowers have limited accessible nectar to attract bees (Birtchnell & Gibson, 2008). However, beekeepers do work faba beans, presumably because of pollination contracts and/or the supply of high-protein pollen for bee nutrition. (On faba bean crops, hives need to be charged with honey or sugar syrup supplied as a nectar source.)

The APVMA currently has no information about whether neonicotinoid seed treatment of faba beans is causing any problems, either with respect to dusts generating during seeding or systemic residues occurring in the pollen and nectar.

7.7 Sorghum

Sorghum is a summer crop grown in various areas throughout Australia. It has traditionally been used for human consumption and livestock feed although increasing amounts of sorghum are being used for ethanol production. Australia produces just over 2.5% of the global sorghum crop, but accounts for over 5% of global exports. In terms of tonnage of grain produced it is Australia's fourth-largest grain crop or sixth in terms of area planted after wheat, barley, canola, pulses ('grain legumes') and oats (PWC, 2011).

Imidacloprid and thiamethoxam seed treatment products are approved for sorghum. However, like wheat, barley, oats and corn/maize, sorghum is pollinated by wind and thus is not reliant on honey bees for seed set.

Sorghum is not a crop that is sought by beekeepers because of the low quality of its pollen.

As a cereal grain, the information provided above (under 'Cereals') is relevant to sorghum.

7.8 Sunflower

Sunflower seed is a source of high quality oil used for cooking, salads, paints and industrial lubricants. Non-oil varieties are used for birdseed or roasted for cereals, snack bars etc. Canola and cottonseed are the major oilseed crops (93% of total oilseed production in Australia) with sunflower and soybeans making up about 4% and 3% respectively.

Imidacloprid and thiamethoxam seed treatment products are approved for sunflower.

Sunflower nectar is collected by bees and pollination by bees produces significantly greater seed set and seed weight than crops not pollinated by bees; Australian studies suggest up to 60% more seeds were produced in the presence of bees (Keogh et al, 2010f). Greenleaf & Kreman (2006) found that behavioural interactions between honey bees and wild native bees significantly increased the pollination efficiency of honey bees, suggesting that conserving wild habitat could potentially increase sunflower production.

Sunflower is not favoured by apiarists as nectar or pollen resource. The quality of sunflower pollen and the quantity of nectar is limited; this low nutritional value requires apiarists to provide dietary supplements if they wish to maintain bee colonies on sunflower crops.

Since sunflower is not a major crop in Australia and is not a favoured source of nectar and pollen by beekeepers, any systemic neonicotinoid residues in this crop grown from treated seed are unlikely to present a significant risk to managed colonies of honey bees in Australia.

The APVMA is not aware of any Australian data on levels of residues of imidacloprid or thiamethoxam in pollen and nectar, arising from approved seed treatment uses. In field-based residue studies carried out on farms in Germany Schmuck et al (2001) did not detect any imidacloprid residues (limit of detection 1.5 microgram/kg, or 1.5 ng/g) in either nectar or pollen in sunflowers grown from treated seed, nor were there any detectable residues in nectar and pollen of sunflowers planted as a succeeding crop in soils which previously had been cropped with imidacloprid seed-treated plants. In a laboratory-based study, Laurent & Rathahao (2003) reported 13 ng/g in pollen grown from imidacloprid-treated seed. A set of 24 pollens was sampled and analysed from sunflowers grown from imidacloprid-treated seed (Bonmatin et al, 2003); imidacloprid was not detected (LOD 0.3 ng/g) in 17% of samples. A proportion (25%) had amounts of imidacloprid less than 1 ng/g, while 58% contained imidacloprid at levels ranging from 1 to 11 ng/g, with a mean 3 ng/g. At the approved seed treatment rate for imidacloprid, EFSA (2013b) estimated levels of imidacloprid in sunflower pollen of 3.9 ng/g and in nectar of 1.9 ng/g. On the basis of European data, EFSA (2013c) calculated that residues of thiamethoxam in pollen from sunflower seed-treatment would be between 2.4 – 3.0 ng/g pollen and 0.59-0.75 ng/g nectar.

Neonicotinoid products have not been registered for foliar application to sunflower crops in Australia and hence there will not be any exposure of bees feeding on sunflower crops to neonicotinoids applied by spraying.

The APVMA does not have information on the equipment used for planting sunflower and whether there is any potential for neonicotinoid dust generation during seeding.

7.9 Other crops

Imidacloprid products are approved for seed treatment of the following additional crops: lentils & lupins, field peas, pulses, and forage brassicas (Kale, turnip, rape and swedes).

The APVMA has not accessed data about insect pollination in these crops, whether they are attractive to bees, and whether apiarists place hives on them, either under pollination contracts or as sources of nectar

for honey production and bee nutrition. AHBIC advised that it was not aware of beekeepers working these particular crops other than under pollination contracts for seed production.

7.10 Horticultural crops

Products containing neonicotinoids are approved for a range of horticultural uses ie. fruit trees, vegetables, flowers, and ornamental plants.

Products containing the neonicotinoids listed in Attachment 1 are approved as foliar sprays and soil treatments/drenches for a range of fruit trees, ornamental shrubs and trees, and vegetables. The most significant risk would be from the application of sprays at the time plants are flowering and hence attractive to bees.

In this overview report, the APVMA has not ascertained whether there are any data on the levels of systemic residues which may occur in nectar of pollen of flowering trees and shrubs following application of soil treatments/drenches.

However the APVMA has received information [see eg. Report 3 under 'Adverse Experience Reports (AERs)' below] that bees have been poisoned by neonicotinoids applied by chemigation to horticultural crops. Quite clearly, application of any insecticide to a flowering crop by chemigation using a dripper system will present a significant risk to bees, particularly if there are no other readily-available sources of water.

8 LITERATURE RESEARCH ON THE EFFECTS OF PESTICIDES ON POLLINATOR HEALTH

There is a large body of publications relating to pesticides (particularly the neonicotinoid insecticides) and the health of insect pollinators. As discussed above, much of it has been stimulated by concerns in several parts of the world, including the USA and parts of Europe, about significant losses of honeybee colonies, particularly over winter. Furthermore, significant incidents of bee poisonings in Europe which were co-incident with spring planting of neonicotinoid-coated maize seed brought the focus of much research onto this group of insecticides.

This research falls into four types – laboratory-based toxicity tests, semi-field studies (including studies on bee colonies confined on a crop in tent enclosures – or ‘tunnels’ - for limited periods of time), field-based studies, and in-field observations (without any experimental intervention).

The following sections summarise just a few of the many hundreds of papers, in particular those which have attracted recent public attention. They also serve to illustrate the types of studies which have been, and are being conducted. No attempt has been in this overview report to evaluate the papers, although several targeted literature reviews have provided comment on the veracity of the methods and findings in some of these papers. Furthermore, it must be noted that this report is an overview report, not an in-depth regulatory evaluation. In a detailed regulatory review an assessment would be made of the adequacy of reporting of methods and results in published papers, in order to determine whether the authors’ conclusions were valid, and based on the reported findings.

8.1 Laboratory-based studies

Laboratory tests on individual honey bees suggest that sub-lethal doses of some pesticides can affect bee behaviour and possibly their susceptibility to disease. However, it remains a challenge to extend these findings to measure the effects of low-level, field-relevant exposure of bee colonies in the field; the social and biological complexity of honey bees and the many difficult-to-control parameters in conducting field research present substantial challenges to determining pesticide effects in whole colonies.

A number of laboratory studies have investigated sublethal effects of insecticides in individual bees, including:-

- Proboscis extension (related to learning) (Ciarlo et al, 2012)
- Waggle dance behaviour (Eiri & Nieh, 2012)
- Sucrose responsiveness (Eiri & Nieh, 2012)
- Mobility (Teeters et al, 2012)
- Foraging behaviour - short-term (3-h) effects of neonicotinoids (Schneider et al, 2012)
- Forager loss (Henry et al, 2012)

- Homing rate and foraging activity (Bortolotti et al, 2003; Schneider et al, 2012; Henry et al, 2012)
- Memory and learning (Williamson & Wright, 2013)

In addition, a number of tests looking at physiological parameters in bees have been reported in the literature including development of the hypopharyngeal glands (related to brood care); thermoregulation; respiration; age of first flight; lifespan; immunological functions; sperm viability; egg laying; enzymatic detoxification markers; flight ability; and pheromone production (EFSA, 2013d).

Lu et al. (2012) fed hives with high-fructose corn syrup (HFCS) at 0, 0.1, 1.1, 5.3 and 10.5 µg/kg HFCS for 4 weeks (starting 1 July 2010) then 0, 20, 40, 200 and 400 µg/kg HFCS for another 9 weeks. There were 4 control hives and 4 hives for each dose, and these 20 hives were held at 4 separate apiaries. The imidacloprid was dissolved in methanol before adding it to the corn syrup. There was a progression of bee mortality, with fifteen of the 16 imidacloprid-treated hives reported as dead 23 weeks after imidacloprid dosing. The authors – who presumed that the HFCS used by US bee keepers to feed their bees in 2006 was contaminated with residues of imidacloprid as a result of its use in US corn crops suggested that the delayed mortality seen in their experiments was reproducing CCD.

Note: This study by Lu et al, often referred to in the literature as ‘the Harvard study’, explicitly linked neonicotinoids to CCD and has been the subject of heavy criticism. It has been noted in particular that (1) bee colonies were fed ‘astronomical’ levels of imidacloprid-laced corn syrup; (2) that the sample sizes were far too small; and (3) that the symptoms the colonies subsequently suffered did not, in fact, mimic the symptoms of CCD. The flaws in this study are detailed in Randy Oliver’s *Scientific Beekeeping* website at <http://scientificbeekeeping.com/the-harvard-study-on-neonicotinoids-and-ccd/>. Oliver concluded that the Lu et al. results actually showed that feeding colonies for four weeks with HFCS spiked with imidacloprid at field-realistic levels (1) did not have any negative effects; and (2) then feeding the colonies with extremely high levels of the insecticide for another nine weeks still did not harm them enough to cause mortality during treatment or for three months thereafter (<http://scientificbeekeeping.com/neonicotinoids-trying-to-make-sense-of-the-science/>).

Williamson & Wright (2013) fed bees a sugar solution mixed with the neonicotinoid imidacloprid, the OP insecticide coumaphos, or mixtures of the two; coumaphos is one of the chemicals deliberately used by bee keepers to rid hives of the *Varroa* mite. Their study indicated that when bees were exposed to either of these pesticides or combinations of them, at doses they suggested mimicked levels that can be found in treated crops, as many as 30% of honey bees failed to learn or performed poorly in memory tests. What is noted from this study that the important behaviours involved in foraging were affected by an ‘old’ OP insecticide as well as by the neonicotinoid. It would have been an interesting comparison had they studied the effects of two other classes of neuroactive insecticides, namely the synthetic pyrethroids (SPs) which act on sodium channels in neural membranes and fipronil which acts on the gamma aminobutyric acid (GABA) receptor-chloride channel complex in neural membranes.

In a laboratory-based study honey bees were fed control pollen (free of pesticides) or pollen collected by honey bees placed on various horticultural crops in the USA and then tested for their susceptibility to

Nosema ceranae (Pettis et al, 2013). This study found that two fungicides (chlorothalonil and pyraclostrobin) had a pronounced effect on the bees' ability to withstand parasite infection. Two miticides deliberately used by beekeepers to control *Varroa* mite infestation (viz. DMPF¹⁶ and fluvalinate) had a similar adverse impact on bees' ability to cope with *Nosema*. (**Note:** The authors could not explain the path from in-hive application of these miticides to their presence in pollen collected by the forager bees.) Interestingly, for bees exposed to pollen containing carbaryl, neonicotinoids (acetamiprid, imidacloprid, thiacloprid), OP insecticides (coumaphos, diazinon, phosmet) or indoxacarb, the relative risk of succumbing to *Nosema* infection was significantly less than one ie. there was a reduced risk of *Nosema* infection after consuming pollen containing a specific pesticide.

Pettis et al (2013) noted that research on sub-lethal effects of pesticides on honey bees has focussed almost exclusively on insecticides, especially the neonicotinoids, and that more extensive research looking beyond just insecticides is needed, particularly research which endeavours to investigate synergistic and additive effects between different types of pesticides (including insecticides, acaricides/miticides and fungicides).

After exposure to sublethal doses of the neonicotinoid, thiacloprid, a higher mortality was observed in *Nosema ceranae*-infected honeybees than in uninfected ones (Vidau et al, 2011); this was not confined to neonicotinoids since fipronil also had a similar effect. Potential interactions between *Nosema* and pesticides were reported as early as 1972, well before the development of the neonicotinoids (Ladas, 1972). In another laboratory study by Aufauvre et al (2012), bees exposed to both sub-lethal doses of fipronil and *Nosema ceranae* had increased mortality than controls or bees exposed to either fipronil or *Nosema* alone. These data on the synergistic action of *Nosema* and insecticides indicate that such interactions are not restricted to neonicotinoids but extend to other classes of insecticides.

In a mechanistic study, Prisco et al (2013) reported that direct administration of sub-lethal doses of clothianidin and imidacloprid (but not the OP insecticide, chlorpyrifos) can modulate immune signalling in insects and adversely affect honeybee anti-viral defences; the researchers proposed a molecular mechanism for this effect and suggested the need for longer-term toxicity testing for the effects of pesticides on bees.

8.2 Semi-field studies

While semi-field or field studies using whole colonies have the potential to directly address the effects of pesticides on honey production and pollination services, challenges presented by these types of studies include:

- The fact that many colonies are needed per treatment due to the high variability between honeybee colonies
- The difficulty of determining actual levels of exposure of bees to pesticides

¹⁶ 2,4-dimethylphenylformamide, an amitraz metabolite

In a 2012 paper, the European Food Safety Authority (EFSA) assessed the results of semi-field studies conducted by APENET, a network for monitoring honeybee mortality and losses in Italy (EFSA, 2012c). Beehives situated in different geographic areas were periodically analysed, looking at pathogens and chemicals in dead bees, live bees, brood, honey, wax and pollen. EFSA concluded that, due to deficiencies in the study designs, weakness in the statistical analyses as documented and incompleteness in the reporting of results, it was not possible to draw any definitive conclusions from this monitoring. Other APENET studies looked at the effect of dusts arising during planting of maize seed (treated with a neonicotinoid or with fipronil) on free-flying bees and on bees housed inside mobile cages near planting machines. EFSA noted that exposures of caged bees to these insecticides were unrealistically high. However, the tests on free flying bees in the vicinity of unmodified planters (ie. pneumatic planters with no deflector to direct the air from the fan down to the ground) suggested that forager bees could be at risk if they fly through dust clouds emitted by seeders sowing maize seeds coated with either fipronil, or the neonicotinoids thiamethoxam, clothianidin or imidacloprid. The amount of deposition of dust decreased with distance from the planter although a similar reduction in air concentration was not seen; this was attributed the very fine nature of the dust which remained airborne.

Henry et al. (2012) used radiofrequency identification (RFID) methodology and microchipped bees to study the effects on homing behaviour of directly dosing honey bees with thiamethoxam. Results indicated that a dose of 1.34 ng thiamethoxam per bee led to a reduction in the number of foragers returning to the hive.

Schneider et al. (2012) used the same technology to study the effect of dosing honey bees with imidacloprid and clothianidin. Sub-lethal doses of clothianidin (>0.5 ng/bee) or imidacloprid (>1.5 ng/bee) led to a reduction in foraging activity and longer foraging flights.

In another study, in which bees were directly dosed in the laboratory, imidacloprid in sugar water and pollen was fed to bumblebees for two weeks, then their development was followed in the field for 6 weeks (Whitehorn et al, 2012). The weight gain of treated colonies was slightly lower than controls and the production of queens was slightly less.

EFSA compared the doses used in these three studies (viz. Henry et al, 2012; Schneider et al, 2012; Whitehorn et al, 2012) with doses that bees might receive from intake of residues in pollen and nectar from treated crops (EFSA, 2012b). Adequate data on crop residues was limited to pollen from maize, and nectar and pollen from canola, *Phacelia*, alfalfa and sunflower. EFSA concluded that the imidacloprid doses used by Schneider were higher than the potential residue intake by bees feeding on these crops. However the clothianidin doses tested by Schneider et al. and the thiamethoxam doses tested by Henry et al. were lower than potential field exposures from these crops. EFSA concluded that bumblebees would need to forage exclusively for two weeks on imidacloprid-treated crops before they would be exposed to the same insecticide dose they were given by Whitehorn et al.

EFSA's overarching conclusion was that "overall, before drawing definite conclusions on the behavioural effects regarding sub-lethal exposure of foragers exposed to actual doses of neonicotinoids, it would be necessary to repeat the experiments performed in the studies with other exposure levels or in other situations".

8.3 Field-based studies

A number of field studies are summarised in the Table at Attachment 2.

One of the most widely reported studies is that of Cutler & Scott-Dupree (2007) from Ontario, Canada. Bee colonies were placed in the middle of canola fields for 3 weeks during bloom (flowering); 4 colonies were placed in 4 fields grown from clothianidin-treated seed (total of 16 colonies) while another 16 colonies were placed in 4 control fields (ie. canola grown from untreated seed).

There were no differences in bee mortality, worker longevity, or brood development and no differences in colonies after overwintering. Very low levels of clothianidin residues were detected in nectar, pollen and honey, but not in beeswax, from treated fields.

Note: The Canadian PMRA had concerns about the size and separation of the plots in this study and the fact that some clothianidin residues were found in nectar from some colonies on control fields, albeit at very low levels. Therefore, a larger study with more hives, larger canola fields and more separation between sites was conducted in 2012/13. Parameters measured included colony weight gain, honey production, bee pest incidence, bee mortality, number of adults, and amount of sealed brood. Interim results (10 April 2013) indicate that there were no adverse effects on honeybee colonies over summer and autumn 2012. Overwintering success measured in April 2013 suggest that colony survival in the two groups was virtually equivalent; if anything, there was a slightly more favourable outcome in the colonies maintained on canola grown from neonicotinoid-treated seed. A final report is expected in September 2013 after over-wintering results are fully analysed (email advice from Bayer CropScience).

8.4 Field observations and monitoring

The Table at Attachment 2 also summarises the results of some monitoring studies.

Monitoring data may not provide a complete picture since it is difficult to monitor all the parameters which may be relevant, including pesticide exposure, climatic conditions, presence of diseases, and bee husbandry practices (eg. intentional use of chemicals in the hive to treat bee pests and disease). Furthermore, if an adverse effect is observed, it may be difficult to link it to a causal factor. However, if no differences are observed in the health of bee colonies between an area/region with treated crops and a similar area/region without treated crops, then it is possible to make a reasonable inference about the lack of effect of the crop treatment on bee health.

Internet commentaries on observations of bee populations include many conflicting reports. For example, several web posts suggest that in France, declines in the bee population in mountainous areas (where neonicotinoids are uncommon) are similar to those in agricultural areas (where neonicotinoids are widely used), and that in upland areas of Switzerland where neonicotinoids are not used, bee colony populations are under significant pressure. Yet another web post, in referring to Italy's 2011 ban on certain neonicotinoids, suggested that Italian beekeepers were already seeing a difference, with "much improved" bee survival rates.

In general, monitoring data collected from a number of European countries and Canada (see Attachment 2) suggest that, despite a number of laboratory and semi-field studies describing sub-lethal effects of neonicotinoids on foraging behaviour, learning and memory, few adverse impacts have been observed at doses to which pollinators might be exposed in the field. Thus, with the exception of those well-documented cases in several European countries and in Canada of bee mortality caused by exposure of bees to neonicotinoid dusts during planting of treated maize seed, there have been very few cases of intoxications of bees with neonicotinoids in all countries where monitoring (either passive or active) has been carried out. Neonicotinoids are less frequently involved in bee incidents than many other insecticide classes eg. pyrethroids and carbamates (eg. Maini et al, 2010; Thompson & Thorbahn, 2009).

Oliver (2012; 2013) reports that beekeepers in the heart of neonicotinoid seed-treatment areas of north America, namely the American Corn Belt and the Canadian canola fields, "uniformly report" that honey bees thrive in those areas, and that there are far fewer problems with pesticide poisonings since the introduction of neonicotinoid seed treatments.

A component of many monitoring studies is the measurement of pesticide residues in bee media, including pollen, nectar, bee bread, wax and bees themselves. In 2013 Pettis et al. reported that in 19 samples of pollen collected by bees foraging on six different US crops (where possible, sampling 3 hives from apple, blueberry, cranberry, cucumber, pumpkin and watermelon), insecticides and fungicides were found in all of them. Of the insecticides measured, pyrethroids were found in all (100%) of the samples, OP insecticides in 63.2%, DMPF in 52.6%, endosulfan in 52.6%, carbamates in 31.6%, neonicotinoids in 15.8%, and indoxacarb in 10.5%; the neonicotinoids and indoxacarb were only found in pollen collected by bees in apple orchards. Such monitoring data suggest that care needs to be taken not to unduly focus on neonicotinoids; exposure to residues of other pesticides could present similar or greater risks.

8.5 Overview of studies and observations to date

A review by Blacquière et al (2012) provides a reasonably concise summary and overview of 15 years of research on the hazards of neonicotinoids to bees. This paper includes a tabulated overview of lethal and sub-lethal side effects of a neonicotinoid (imidacloprid) reported in individual bees following oral or contact exposure in laboratory or semi-field studies and a tabulation of literature data on neonicotinoid residues in honey, bees, and bee-collected pollen. Their overall conclusions are as follows:-

- Many laboratory studies describe lethal and sub-lethal effects of neonicotinoids on foraging behaviour, learning and memory in bees but these effects have generally not been observed in the field at 'field-realistic' levels/dosages or at the colony level, or there is a discrepancy between field and laboratory tests for sub-lethal effects
- Causes of declines in bee health (especially heavy overwintering losses) are multi-factorial but crop protection chemicals may have contributed
- Increased use of neonicotinoids may cause an accumulation of some of these compounds in the environment.

Considering residues monitoring data, field observations of bee colonies, and investigations of pesticide poisoning incidents, neonicotinoids would appear to have been less frequently involved in bee incidents than many other insecticide classes. While most insecticides can present a risk to bees, depending on how and when they are used, evidence suggests that other pesticides including acarides/miticides (deliberately applied to hives to control bee pathogens), crop fungicides, and some herbicides can cause adverse effects in bees.

It is clear that a multitude of risk factors negatively impact colony survival including pesticide exposure, bee parasites and pathogens, foraging conditions before over-wintering, and beekeeper management. Furthermore, there is little doubt that various factors can interact with one another (vanEngelsdorp & Meixner, 2010; Williams et al, 2010). It has been noted that comprehensive empirical testing of the relative contribution of single and combined stressors to the decline of honeybees is limited by financial, logistical and time constraints (EFSA, 2013e).

9 REGULATION AND INVESTIGATIONS IN OTHER JURISDICTIONS

9.1 Europe

The following is taken from the Executive Summary of *Bee health in Europe - Facts & figures*, a report prepared by the European Observatory on Sustainable Agriculture (OPERA Research Centre, 2013) (<http://operaresearch.eu/en/documents/show/&tid=30>):-

Decline of honeybee colonies have been reported mainly in central Europe, but the situation is not universal, since in Mediterranean countries increases have been observed over the past decades. The media frequently reports alarming numbers of colony losses, but in many cases the reasons for decline - which are typically complex and multifactorial in effect - are poorly investigated and the information given on overwintering colony losses is often misleading. Typically the implication is that decline in honeybee colonies is affecting all bee species, when the causes and effects are more often specifically related to the keeping of hived bees.

Whilst overwintering colony losses have increased by trend in the last decade, these are not significantly different for single years registered in the past. When high colony losses are reported, most reports from Europe are about overwintering losses caused by the *Varroa* spp. mites, often linked with secondary infections by viruses and losses caused by *Nosema* spp.

The outcome of the multifactorial monitoring projects reported so far seems to suggest that the parasitic pest mite *Varroa* spp., which can be found in almost every apiary in Europe, is the main causative factor involved in honeybee colony weakening in Europe.

Other diseases like nosema, virus infections, or foulbrood, may also damage colonies during spring and summer. Due to the lack of veterinary treatments, parasites and diseases commonly affect these bee populations. Furthermore, it is also expected that diseases which are not currently present in Europe, such as the small hive beetle or the *Trolilaelaps* spp. mite may appear and spread. The efficacy of current treatment options, where they are used, varies based on beekeeping practices, climatic conditions and different seasonality.

Colony Collapse Disorder (CCD) as described in USA has not been observed in Europe.

Controlling bee pests and diseases is seen as the essential factor for successful beekeeping over the years.

Some countries made important efforts to implement specialized training programs for the recognition of diseases; in others this skill is gravely underdeveloped with beekeepers.

Additionally, as beekeeping techniques, cultural traditions and climatic conditions vary around Europe, greater attention should be paid from the policy side to the development and implementation of good beekeeping guidelines. New beekeeping techniques and improved knowledge have resulted in improved bee health and higher quality and quantity of honey yields. [End of text extract]

The European Commission (EC) asked the European Food Safety Authority (EFSA) to assess the risk to bees of the neonicotinoids clothianidin, imidacloprid and thiamethoxam. The conclusions laid down in these reports were reached on the basis of the evaluation of the studies submitted for the approval of the active substances at the European Union (EU) level and for the authorisation of products containing these compounds at Member State level. In addition, relevant literature and monitoring data were considered. The three risk assessments were published on 16 January 2013 (EFSA, 2013a, 2013b, 2013c).

Although products containing clothianidin, imidacloprid and thiamethoxam had been registered in various European countries for some years, clothianidin active constituent was formally added to Annex I on 1 August 2006, imidacloprid active constituent on 1 August 2009, and thiamethoxam active constituent on 1 February 2007. The provisions of their approval were amended in 2010 to permit use as a seed treatment only where the seed coating was performed in professional seed treatment facilities which must apply the best available technology to minimise the release of dust during seed treatment, storage and transport, and where seeding equipment used is such that it ensure a high degree of soil incorporation of the seed, and minimises spillage and dust generation.

EFSA's evaluations identified data gaps with regard to the risk to honey bees from exposure via dust, from consumption of contaminated nectar and pollen, and from exposure via guttation fluid for the authorised uses of clothianidin and imidacloprid as seed treatments and in granules for soil incorporation, and for the authorised uses of thiamethoxam as a seed treatment. Furthermore, risk assessments for pollinators other than honey bees, pollinators exposed to insect honey dew, and pollinators exposed to succeeding crops grown in soil previously used to grow treated crops, could not be finalised on the basis of the available information. For some authorised uses it was possible to identify a low risk for some exposure routes but for a number of other uses a risk to honey bees was either indicated or could not be excluded.

For all three substances, EFSA concluded the following:-

- Exposure from pollen and nectar. Only uses on crops not attractive to honey bees were considered acceptable.
- Exposure from dust. A risk to honey bees was indicated or could not be excluded, with some exceptions, such as use on sugar beet and crops planted in glasshouses, and for the use of some granules.
- Exposure from guttation. The only risk assessment that could be completed was for maize treated with thiamethoxam. In this case, field studies show an acute effect on honey bees exposed to the substance through guttation fluid.

On 29 April 2013 the European Commission (EC), in the absence of a majority vote by European member states, moved to suspend for two years (from 1 December 2013) the use of neonicotinoid insecticides on flowering crops such as corn, canola and sunflowers and cotton. The suspension will not apply to crops not attractive to bees, or to winter cereals. More information about the EC's actions and the restrictions which will apply can be found at http://ec.europa.eu/food/animal/liveanimals/bees/neonicotinoids_en.htm

9.2 The USA

On 2 May 2013 the US Department of Agriculture (USDA) and the US Environmental Protection Agency (USEPA) released a comprehensive scientific report on honeybee health. The report (USDA, 2013) details the deliberations and conclusions of a *National Stakeholders Conference on Honey Bee Health*, held in October 2012. The conference was convened to review the primary factors that scientists believe have the greatest impact on managed bee health.

The report (at www.usda.gov/documents/ReportHoneyBeeHealth.pdf) states that there are multiple factors playing a role in honeybee colony declines, including parasites and disease, genetics, poor nutrition and pesticide exposure:-

- The parasitic *Varroa* mite is recognised as the major factor underlying colony loss in the USA and other countries. There is widespread resistance to the chemicals beekeepers use to control mites within the hive. In addition to *Varroa*, new virus species have been found in the USA and several have been associated with Colony Collapse Disorder (CCD).
- US honeybee colonies need increased genetic diversity. Genetic variation improves the thermoregulation, disease resistance and worker productivity of bees. Breeding programs should emphasise traits such as hygienic behaviour that confers improved resistance to *Varroa* mites and diseases (eg. American foulbrood).
- Poor nutrition has a significant impact on individual bee and colony longevity. Bees need better forage and a variety of plants to support colony health and reduce their susceptibility to parasites and diseases. It was recommended that Federal and state partners should consider actions affecting land management to increase foraging sources for bees and provide an alternative to agricultural crops.
- There is a need for better communication between growers and beekeepers - collaboration between farmers/horticulturalists and apiarists/suppliers of pollination services will reduce the risk of pesticide poisoning of bees. Best Management Practices for pesticide use in different cropping industries need to be followed or developed.
- Beekeepers emphasised the need for accurate and timely bee kill incident reporting, monitoring, and enforcement of proper pesticide application.
- Research on pesticide impacts on bees needs to focus on field-based studies, both to determine actual pesticide exposure from approved uses, and whether there are any effects on bees which impact the health and productivity of the whole colony.

The report, representing the consensus view of the scientific community studying honey bees, can be downloaded from www.usda.gov/documents/ReportHoneyBeeHealth.pdf. It has been provided to the US Colony Collapse Steering Committee which was formed in response to the sudden and widespread disappearance of adult honey bees from beehives, which first occurred in 2006 (see above under 'Bee declines - possible contributing factors'). The Committee will update its CCD Action Plan which will outline major priorities to be addressed in the next 5-10 years; serve as a reference document for policy makers,

legislators and the public; and help coordinate Federal government strategy in responding to honeybee losses.

More recently, on 15 August 2013 the USEPA made the following announcement in relation to products containing imidacloprid, dinotefuran, clothianidin and thiamethoxam that have outdoor foliar use directions:-

In an ongoing effort to protect bees and other pollinators, the U.S. Environmental Protection Agency (EPA) has developed new pesticide labels that prohibit use of some neonicotinoid pesticide products where bees are present.

“Multiple factors play a role in bee colony declines, including pesticides. The Environmental Protection Agency is taking action to protect bees from pesticide exposure and these label changes will further our efforts,” said Jim Jones, assistant administrator for the Office of Chemical Safety and Pollution Prevention.

The new labels will have a bee advisory box and icon with information on routes of exposure and spray drift precautions. Today’s announcement affects products containing the neonicotinoids imidacloprid, dinotefuran, clothianidin and thiamethoxam. The EPA will work with pesticide manufacturers to change labels so that they will meet the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) safety standard.

In May, the U.S. Department of Agriculture (USDA) and EPA released a comprehensive scientific report on honey bee health, showing scientific consensus that there are a complex set of stressors associated with honey bee declines, including loss of habitat, parasites and disease, genetics, poor nutrition and pesticide exposure.

The agency continues to work with beekeepers, growers, pesticide applicators, pesticide and seed companies, and federal and state agencies to reduce pesticide drift dust and advance best management practices. The EPA recently released new enforcement guidance to federal, state and tribal enforcement officials to enhance investigations of beekill incidents.

More on the EPA’s label changes and pollinator protection efforts:

www.epa.gov/opp00001/ecosystem/pollinator/index.html

No applications of these regulated pesticides are allowed during flowering of pollinator-attractive crops unless certain conditions are met. For crops where bees are brought in for pollination services, applications during flowering are only allowed if the beekeeper providing the pollinator service is notified at least 48 h in advance. For pollinator-attractive crops where bee pollination services are not contracted, applications can be made at night, if air temperatures are less than 55°F (12.8°C), if there is a public health threat, if a documented pest pressure trigger has been met, or beekeepers in the area have been notified at least 48 h in advance. For residential uses, applications are not to be made when plants are flowering.

The US EPA has also devised a pollinator protection box with advisory language to go on product labels (see www.epa.gov/pesticides/ecosystem/pollinator/bee-label-info-graphic.pdf) – this is likely to be applied to other pesticide products.

9.3 Canada

An investigation into bee deaths in the maize-growing areas of Ontario and Quebec in the spring of 2012 implicated dust arising during planting of seed treated with the neonicotinoid insecticides clothianidin and/or thiamethoxam (see sections 6.1, 8.4, and 15.1.1 of this report). Following further reports of bee deaths in maize- and soybean-growing regions of Ontario, Quebec, and Manitoba in 2013, the Canadian Pest Management Regulatory Agency (PMRA) announced its intention, in September 2013, to place additional restrictions on the use of neonicotinoid insecticides used for seed coating. The measures proposed for the 2014 planting season include: the use of safer dust-reducing seed-flow lubricants; the use of best-practice seed planting methods and equipment; new pesticide and seed package labels with enhanced warnings; and provision of information on the necessity (or otherwise) for treatment of up to 100% of maize seed and 50% of soybean seed with insecticide.

The PMRA is working with provincial governments, growers, beekeepers, the chemical industry and Agriculture and Agri-Food Canada (AAFC) to determine if there are other risk-management options for the seeding dust incidents observed in 2012 and 2013.

The PMRA also proposes to implement label improvements on insecticide products similar to those set out by the EPA in August 2013 (see section 9.2); new US labels for the neonicotinoid insecticides imidacloprid, dinotefuran, clothianidin and thiamethoxam, include a bee advisory box and icon warning of potential risk to pollinators, with information on routes of exposure and spray drift precautions. They also prohibit applications when bees are foraging and plants are flowering, and require notifications to beekeepers prior to spraying.

The PMRA's proposed actions are open for public comment until 12 December 2013.

As other regulators have done, the PMRA concludes that bee health is a complex issue that involves many factors, including parasites, disease and climate. Nevertheless, it is reviewing all uses of neonicotinoid insecticides in co-operation with the US EPA.

10 TESTING REQUIREMENTS

In 2012 the APVMA contracted Chris Lee-Steere of the Australian Environment Agency Pty Ltd to conduct a review, *inter alia*, of (1) the adequacy of current APVMA data requirements related to testing the effects of new insecticides on honey bees; and (2) the value of new bee toxicity test protocols being developed internationally. His recommendations are included in a report dated 13 November 2012 titled *Consideration of Testing Requirements and Label Statements in Relation to the Impact of Pesticides on the Health of Honey bees and other Insect Pollinators* which was published on the APVMA's website in March 2013 (www.apvma.gov.au/news_media/chemicals/neonics.php).

This report notes that:-

- There has been significant discussion internationally over the last several years relating to data required to adequately assess the exposure and ecotoxicity of pesticides to bees and other pollinators. Currently there is a lack of harmonised guidelines for testing of pesticides on bees and other insect pollinators. However, there is ongoing consideration at an international level of a common suite of test data requirements to support the assessment of both exposure and toxicity.
- The regulatory data requirements for testing of insecticides have not been adequate to properly consider possible routes and extent of exposure of insect pollinators to pesticides or to assess the potential for adverse effects (including sub-lethal effects) of pesticides (including neonicotinoid pesticides) on honey bees and other insect pollinators; this conclusion applies to most pesticide regulatory agencies which are now actively working regionally and globally to develop and introduce new tests.

This consultant's report recommended that the APVMA and its advisory agency, the Department of the Environment, consider the tests available and under development that will improve knowledge of the exposure and effects of pesticides on bees and other insect pollinators, and ensure that, as internationally-harmonised tests are developed, they are reflected in relevant APVMA data guidelines.

This recommendation (Recommendation 1; full text given below in Section 15.3.1 on 'Next Steps – APVMA') was considered at a workshop for regulatory stakeholders on 24 July 2013. [**Note:** *At the time this overview report was published, workshop outcomes were being considered by the APVMA and the Department of the Environment.*]

11 PRODUCT LABELS

An agvet chemical product label is defined as the written, printed and related graphic matter on, or attached to, the container in which the chemical product is directly packed and the outside container or wrapper of the retail package. These labels contain important information about how to safely use products in accordance with legal requirements. Product labels are approved by the APVMA as part of the assessment process for agvet chemicals. The Agvet Code stipulates that a label must contain adequate instructions, including the following:

- circumstances in which the product should be used
- how the product should be used
- times when the product should be used
- frequency of the use of the product
- withholding period after use of the product
- re-entry period after use of the product
- disposal of the product when it is no longer required
- disposal of the containers of the product
- safe handling of the product and first aid in the event of an accident when handling the product.

Many insecticide products on the Australian market contain specific statements related to the protection of bees and other insect pollinators eg. 'Dangerous to bees and other beneficial insects. DO NOT spray any plants in flower while bees are foraging'.

A recommendation (Recommendation 4) from a report of the House of Representatives Standing Committee Inquiry into the Honey Bee and Pollination Industries (released 16 June 2008) was that "the Australian Government alter labelling requirements for agricultural chemicals to reflect their impact on honey bees and other pollinating insects" (see www.daff.gov.au/animal-plant-health/pests-diseases-weeds/animal/varroa-mite/sentinel-hive-program-review/inquiry-into-the-honey-bee-and-pollination-industries). In its response to the report (tabled in Parliament on 12 August 2009), the Government agreed with the recommendation to improve labelling of chemicals to reduce their impact on bees. The Government response noted that:-

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is progressing work to strengthen the existing label statement regarding agricultural chemicals and their impact on bees. This will include further directions to users which would describe steps to minimise the impact of pesticides on bees and to allow beekeepers to manage their bees if placed near crops that are likely to be sprayed with a chemical product. The APVMA is consulting with the Department of the Environment, Water, Heritage and the Arts (DEWHA), which assesses the effect of chemical products on non-target organisms, such as bees.

In addition to the standard label statements, further advice from DEWHA, beekeepers or other relevant stakeholders may be needed on a case by case basis to determine and develop management advice for specific hazards, such as the toxicity to bee larvae and/or claimed effects on pollinating ability and colony health at low doses, either at the time of registration of a new product or review of an existing product. Such advice from DEWHA would result in amendments to label directions approved by the APVMA. Advice from DEWHA would be considered for amendments to the Ag

Labelling Code published by the APVMA. All amendments to the Labelling Code are made in consultation with states and territories.

Following on from this enquiry, the APVMA met with representatives of the honey bee industry on 9 March 2011 to progress the implementation of revised pesticide product labelling to reflect the potential impact of pesticides on honey bees and other pollinating insects. The meeting brought together representatives of the Australian Honey Bee Industry Council, the Rural Industries and Research Development Cooperation, Capilano Honey, and state and territory government agencies to learn about the environmental assessment process as part of the registration of pesticides, and to consider the standardisation of product label statements and the provision of industry information on bee and pollinator hazards. Given the large differences in the environmental impacts affecting bee and honey production in Australia compared to overseas, the participants stressed the importance of easy access to pesticide-related information. The APVMA recognised that the issue was more than putting hazard statements on a product label and agreed to work with industry to make more product-specific information available to beekeepers (see meeting report at http://www.apvma.gov.au/news_media/news/2011/2011-03-10_labelling_bees.php).

The APVMA and the Department of the Environment (which conducts pesticide ecotoxicity risk assessments for the APVMA) negotiated rewording of bee advice for labels through the Labelling Code Working Group. It was agreed that the label statement proposed by the Department of the Environment when evaluating a pesticide product should indicate the nature of the hazard to bees (eg. "Dangerous to bees. Will kill bees foraging in the crop to be treated or in hives which are over-sprayed or reached by spray drift. Residues may remain toxic to bees for several days after application"). Such statements allow the users to determine an appropriate risk management strategy.

In addition to the use of standard label statements, it was agreed that further advice might be needed in specific cases, on a case-by-case basis, to indicate specific additional hazards (eg. toxicity to bee brood), with such label statements to appear under the heading PROTECTION OF LIVESTOCK:-

- If there is an unacceptable risk to bees:- "Highly toxic to bees. Will kill bees foraging in the crop to be treated or in hives which are over-sprayed or reached by spray drift."
- If residues are shown to be toxic:- "Residues may remain toxic to bees for several days after application."
- If bee brood effects are a concern:- "Bee brood development may be harmed by exposure to residues transported into the hive by foraging bees, overspray or spray drift."

In 2012, as part of the APVMA's more detailed investigation of the neonicotinoids and in recognition of the potential different routes of exposure of insect pollinators to these insecticides, the APVMA contracted the Australian Environment Agency Pty Ltd to (1) look at the labels of those Australian products which carry bee protection statements and review the consistency or inconsistency of the wording in those statements; and (2) advise the APVMA if changes need to be made to standard statements and to existing labels.

A report from AEA P/L dated titled *Consideration of Testing Requirements and Label Statements in Relation to the Impact of Pesticides on the Health of Honey Bees and other Insect Pollinators* (13 November 2012) which was published on the APVMA's website in March 2013 (www.apvma.gov.au/news_media/chemicals/neonics.php) noted the wide variety of bee protection statements on labels and the fact that they are not consistently applied across registered insecticide

products. AEA P/L recommended that the APVMA review the inconsistencies in bee protection statements found on Australian product labels, identify those products and use patterns that require bee protection statements, and determine those products which require warnings about residue toxicity to bees and bee brood (larvae) in addition to acute toxicity warnings to adult bees.

This detailed recommendation (Recommendation 3; full text given below in Section 15.3.1 on 'Next Steps – APVMA') were considered at a workshop for regulatory stakeholders on 24 July 2013. [**Note:** *At the time this overview report was published, the workshop outcomes and recommendations were being considered by the APVMA and the Department of the Environment.*]

12 ADVERSE EXPERIENCE REPORTS (AERs)

Since this investigation was commenced in late August 2012, only a handful of adverse experience reports (AERs¹⁷) relating to bee poisonings have come to the attention of the APVMA.

In an article titled 'To Australian Beekeepers from an Australian Beekeeper' by Jeffrey Gibbs in 'The Australian Beekeeper' (www.theabk.com.au/article/neonicotinoids-australia), he noted that it was difficult to get apiarists to report any problems with their hives and that "most beekeepers like to be out on the bees in preference to other duties" such as filling in forms and reports.

Therefore, it is possible that there is an under-reporting of bee poisonings in Australia. However, from discussions with the Australian Honey Bee Industry Council, relevant officers in State agriculture departments, academic bee researchers, and some apiarists, it appears that the number of incidents of chemical poisoning of bees is limited.

12.1 Report 1

In September 2008 the Victorian Department of Environment and Primary Industries (then the Department of Primary Industries) received a complaint about the death of bees from several apiarists in the Yarra Valley, Victoria. Sampling revealed the presence of low levels of clothianidin in some dead bees.

Following an investigation, it was concluded that the bee deaths were directly related to the inappropriate use of the clothianidin insecticide by the orchardist on whose property the majority of the affected bee hives were located. The grower used the product contrary to label advisory statements, viz:

- the product "should be sprayed at the first signs of infestation but after petal fall" (ie. after the fruit trees are no longer attractive to insect pollinators).
- the 'Protection of Livestock' statement "Dangerous to bees and will kill bees foraging in the crop to be treated or in hives which are over-sprayed or reached by spray drift, and residues may remain toxic for several days after application".

The Victorian DEPI advised that the wording of these label statements means they are considered advisory in nature (ie. they are not prohibitive 'Do not' statements) and thus are not enforceable under control-of-use legislation in the State of Victoria.

Other factors contributing factors to the death of the bees were an inadequate understanding of the impact of the insecticide product on bees by the orchardist and a lack of communication between the orchardist and

¹⁷ Information about APVMA's Adverse Experience Reporting Program (AERP) can be found at http://www.apvma.gov.au/news_media/community/2010-18_aerp.php. The general community, state and territory authorities and chemical manufacturers are encouraged to report 'adverse experiences'. These are unintended or unexpected negative effects on plants, animals, humans or the environment that flow from the use of pesticides and veterinary medicines when used according to label instructions.

the apiarist; the orchardist advised investigating officers that he had noticed some damage to the hives but didn't report it to the apiarist as he needed the bees to continue to pollinate his cherry crop¹⁸.

The Victorian DEPI noted that the existing label statements do not explicitly address the risk posed by use of this product in mixed orchards where blossoming is staggered across different fruits and varieties. Furthermore, they do not address the risk of flowering ground cover in orchards which may also be attracting bees to the target area¹⁹.

12.2 Report 2

In 2011 an apiarist placed a number of healthy hives throughout a large commercial orchard in SE Australia to provide pollination services. An AER was submitted to the APVMA because he considered they were harmed by the application of an insecticide product containing the neonicotinoid, thiacloprid.

The incident was investigated by the relevant state agriculture department which provided more detailed information to the APVMA. Healthy hives that had come off canola were placed in the orchard at times from early- to mid-October. At the end of the month a proportion of the hives had died and none had queen bees. The apiarist reported that other hives which came off the same canola but were not placed in the orchard were in good health.

Early in the month, parts of the orchard were sprayed with a thiacloprid insecticide product. For some blocks it was tank-mixed with a fungicide product and a potassium/ boron/calcium fertiliser, while for another block the insecticide was tank-mixed with another fungicide product and the same potassium/ boron/calcium fertiliser. Several days later a different insecticide was applied to parts of the orchard in a tank mix with magnesium/manganese. Other chemicals recorded as being used on different blocks in the orchard during the month included ammonium thiosulfate blossom thinner, a third fungicide product, and several different types of plant growth regulators.

In addition to the active constituents in the various products used, many formulations will contain wetting agents (surfactants) as excipients (non-active constituents) and the mixing instructions for one of the fungicide products requires it to be tank-mixed with a non-ionic wetting agent to increase its efficacy for certain fruit diseases. It is well known that surfactants - including soapy water - can cause harm to bees if they come in contact with the spray before it has dried (eg Goodwin, 2012).

The apiarist reported that the dead and dying hives had small hive beetle. Records of hive movements were not kept by the apiarist or orchardist.

¹⁸ The issue of communication between apiarist and farmer/horticulturalist is discussed elsewhere in this overview report.

¹⁹ This issue has been addressed in a recent (2013) label approval for a sulfoxaflor insecticide product which includes the following statement (under 'Risk management'): "It is recommended that orchard floors containing flowering plants be mown prior to spraying". The label also includes the advice that "Beekeepers who are known to have hives in, or nearby, the area to be sprayed should be notified no less than 48 hours prior to the time of the planned application so that bees can be removed or otherwise protected prior to spraying".

Detailed information about the incident is lacking eg. whether spraying took place during the day when bees were active; whether the hives were they placed such that direct over-spray or exposure from spray drift occurred; whether the dead hives came from all parts of the orchard or from specific blocks; etc. It is likely that direct spraying of the hives may have caused at least part of the problem but is also probable that forager bees took contaminated pollen/nectar to the hives and the larvae and/or queen were fed with this material.

Exposure to individual chemicals or a combination of them could have resulted in the deaths of the larvae and/or queen, followed by the death of the hive. However, on the basis of the information available to the APVMA, it is not possible to conclude with any degree of certainty that the deaths could be solely attributed to thiacloprid insecticide. The limited temporal information about spraying and bee deaths would suggest that there was no immediately lethal (acute) effect on the bees as a result of spraying the thiacloprid insecticide product.

Very limited additional information about insecticide and termiticide use in the area at the time was provided to the APVMA, but it was not possible to make any conclusions about the relevance of these particular applications to the bee kills reported.

12.3 Report 3

On Tuesday 26 February 2013 an article titled 'Beekeepers holding back on restricting *neonicotinoids*' was published in 'Pesticide & Chemical Policy'. The article included the following text:-

In a more recent case in Australia, bees that had been exposed to neonicotinoids through irrigation and delivery water languished and were removed to recover; "They sat there, and they sat there, and they sat there. Six months later, they got going. What happened there? We don't know," says Mussen²⁰, indicating the lack of data to support such behavior under the circumstances.

The APVMA made enquiries about this incident since it wasn't reported as an adverse experience report to APVMA's AERP. The APVMA was subsequently advised by a pesticide registrant that one of their field staff became aware of a case involving a commercial seed grower who used imidacloprid (and other products) off-label in surface watering system on crops grown in a covered cropping system; the grower used contract bees for pollination. It appears it took several bee poisoning episodes before a connection between the chemigation practice and the adverse event was established. The contract between the grower and the apiarists was subsequently amended to make sure that the products were not used in this manner while the bees are present.

It is not absolutely clear that this case relates to the PCP report since it is surprising that bees exposed to imidacloprid that was purposely added to irrigation water for insect control would survive.

²⁰ Eric Mussen, an apiculturist at the University of California, Davis, USA.

12.4 Report 4

In the autumn of 2013 the APVMA received a communication from a citizen living in/near Melbourne who stated that:-

The bees are falling out of my large flowering gum and struggling to fly or even stay on their feet. They have been dying in their hundreds and it is quite distressing to watch and not be able to help them. They seem drugged and just crawl on the ground until they die.

They were concerned that the bees might possibly have been poisoned by pesticides used on nearby farms or orchards.

The APVMA directed the correspondent to a booklet published by the Rural Industries Research & Development Corporation (RIRDC) at <https://rirdc.infoservices.com.au/downloads/08-098> titled *Flowering Ecology of Honey-producing Flora in South East Australia* (78 pages) (Birchneil & Gibson, 2008). Chapter 2 of this booklet, titled 'Drunken honeybees – fact or fiction?' reports that "nectar from several Australian melliferous [honey-producing] species is colonised by yeasts, which ferment nectar to varying extents, and this is likely to be influenced by high humidity [as can occur in autumn in SE Australia – and did occur in the autumn of 2013]. Honey bees will readily consume fermented nectar and will experience behavioural responses ultimately leading to those symptoms observed by apiarists, the authors and the general public".

The article's authors detected and quantified ethanol in nectar produced by Australian flowering plants. They noted the many reports of lorikeets as well as bees being affected by the ethanol in fermented nectar and discussed the symptoms of 'drunk' bees - which were very similar to those described by APVMA's correspondent. The chapter includes a photograph of dead honey bees carpeting the ground next to hives after humid conditions in Western Australia coincided with flowering of Wandoo (*Eucalyptus wandoo*) trees. [The booklet gives many other text examples of alcoholic poisoning of bees.]

12.5 Report 5

The following list does not relate to a specific report but includes signs suggested by a correspondent as indicating that hives in Australia had been poisoned by a neonicotinoid insecticide:-

1. Lack of thriving
2. Premature swarming
3. Bee brood out the front of the hive
4. Loss of the queen bee
5. Bees disappear – no bees evident
6. Collapse most evident in autumn

The APVMA sought advice from AHBIC, with the following response:-

1. *Lack of thriving* – there could be a multitude of reasons why a hive is not thriving (including neonicotinoids).
2. *Premature swarming* – unlikely association; if a hive was poisoned then it drops off and does not have the strength to swarm. For many years before the introduction of neonicotinoids reports of bees swarming on canola were common – the bees swarmed and did not leave a queen behind.
3. *Bee brood out the front of the hive* – there could be an association, but it could also be for a number of other reasons. The dead brood would need to be analysed for a proper diagnosis.
4. *Loss of the queen bee* – there could be an association, but queen bee loss can be associated with other pesticides (eg. dimethoate) and factors other than pesticides.
5. *Bees disappear – no bees evident* – unlikely; if there was pesticide poisoning then it is likely that there would be dead bees evident eg. photos from Europe showing masses of dead bees out the front of hives have been posted as evidence of poisoning by neonicotinoids. The disappearance of bees, with no sign of dead bees, is likely to be indicative of nosema, although sometimes with nosema there are crawling bees out the front of the hive. Some old bee journals contain reports of hives with no bees at springtime - it was then called ‘disappearing disease’ and considered to be most likely due to nosema.
6. *Collapse most evident in autumn* – there could be an association but hive ‘collapse’ could also be due to nosema or the bees working pollen-deficient nectar flows.

12.6 Report 6

Two large bee poisoning incidents in NSW in 2013 came to the attention of the APVMA.

In the first incident, more than 400 hives situated in three apiaries south of Darlington Point on the Murrumbidgee River in southern NSW were killed in early February 2013. The bee kills followed shortly after aerial pesticide application on nearby cotton crops.

The NSW Environment Protection Agency (NSW EPA) advised the APVMA that bees from all six sites where dead/dying bees were found had fipronil detections while clothianidin, a neonicotinoid, was only detected in bees from three of the six sites. Taking into account spraying dates, which chemicals were sprayed, and wind direction at the time of spraying, it appears that the bees were more likely to have been poisoned by foraging in the sprayed crops rather than the hives being directly impacted by spray drift. [Note that a clothianidin product is approved as a foliar spray in cotton in Australia but there are currently no clothianidin-based seed treatments in this country, so the detection of clothianidin, if it came from foraging on cotton, was from a foliarly-applied spray, not a systemic residue arising from cotton seed treatment.]

In the second incident in late December 2013, a large number of bees were killed along the Macquarie River between Gin Gin and Warren in central NSW. It was reported that over 200 hives were affected, with up to 90% mortality in many hives. The NSW Environment Protection Authority (EPA) commenced an investigation

after local beekeepers notified them of the bee deaths. It is understood that insecticide spraying of cotton crops took place in the area prior to the bee deaths.

It appears that the hives were sufficiently distant from the nearest cotton crop that spray drift can probably be ruled out and that bees were more likely to have been poisoned as a result of foraging on the cotton. Fipronil was suggested as the common insecticide in the applications but was not the only insecticide applied (G Kauter, Cotton Australia and Bryn Jones, Crop Pollination Association Inc, *pers. comm*).

The NSW EPA is currently investigating this matter, including reviewing pesticide-user application records in the area and undertaking chemical analysis of samples from the hives and plants.

As a result of these poisoning incidents in cotton, Cotton Australia has produced some targeted extension material (see '*Bee Aware*' of honey bees in the January 2014 'CottonInfo' newsletter at <https://www.mybmp.com.au/newsletter/2014/Jan/beeaware20140117.aspx> and is distributing a '*Bee Alert*' for Honey Bees factsheet (available at <https://www.mybmp.com.au/events/events.aspx?etid=4>). This material notes that "honey bees can travel up to 7 km in search of pollen and nectar when nearby sources are in decline or are of poor quality. Bees collect nectar from cotton's extra-floral nectaries (eg. under leaves) as well as from its flowers so they may forage in cotton crops before, during and after flowering". It appears the period of extended dry across the cotton growing region of NSW has made cotton crops a more attractive source of pollen and nectar for honey bees.

The NSW EPA is working with the NSW Apiarists Association and Cotton Australia to try and prevent bee kills in the future. The NSW EPA has advised that these incidents serve as timely reminders to landholders to take more care with pesticides. Apiarists also have a responsibility to communicate with landholders and let them know specifically when and where they are going to put the hives.

13 SURVEILLANCE PROGRAMS

A number of countries have programs in place to monitor the health of honeybee colonies. In the UK, Germany and the Netherlands, for example, post-registration schemes are in place to monitor incidents of poisoning of honey bees by pesticides. Thompson & Thorbahn (2009) stated that these incident schemes have been “invaluable” in identifying agronomic practices resulting in honeybee mortality, and changes to pesticide product labelling have been made as a result.

The UK Wildlife Incident Investigation Scheme (WIIS) monitors the effects of pesticides on wildlife, including beneficial invertebrates such as honey bees. Information gathered is fed into the approval process for pesticides and helps in the verification and improvement of pesticide risk assessments. It can also result in changes to label recommendations on pesticide products. It can lead to enforcement action if the misuse or abuse of a product is identified as part of the investigation (see <https://secure.fera.defra.gov.uk/beebase/index.cfm?sectionid=33>).

The German bee monitoring project (‘DeBiMo’) was initiated in the autumn of 2004 in response to significant winter bee losses in 2002/03 (Genersch et al, 2010).

Italy has had a national bee monitoring network since 2009, supported by two national projects, ApeNet (2009-2010) and BeeNet (2011-2013). Lodesani et al (2013) noted that “the establishment of a national monitoring network, covering geographically differentiated areas, is an essential tool to gather information on the health status of honey bees”.

The European Union has initiated a Pilot Surveillance Programme (PSP) to collect standard baseline data on colony losses and honey bee health from across the EU. In the autumn of 2011, Member States received an invitation to participate. The invitation stipulated monitoring procedures that would have to be rigorously followed, in order to ensure comparable data at the European level (see eg. http://ec.europa.eu/food/animal/liveanimals/bees/bee_health_en.htm).

In the USA the Bee Informed Partnership (<http://beeinformed.org/>) is funded by the National Institute of Food and Agriculture (NIFA) of the US Department of Agriculture (USDA) to monitor over-wintering losses.

The APVMA is not aware of any national honey bee colony surveillance scheme in Australia.

14 GUIDANCE DOCUMENTS FOR BEEKEEPERS, FARMERS AND HORTICULTURALISTS

14.1 Guidance relating to pesticides and their use

Pesticides — a guide to their effects on honey bees. John Rhodes, Livestock Officer – Bees, Intensive Industries Development, Tamworth & Mark Scott, Agricultural Chemicals Officer, Biological and Chemical Risk Management, Orange, NSW. May 2006. 'Primefacts' brochure no 149; available at www.dpi.nsw.gov.au/agriculture/livestock/honey-bees/management/pesticides/effects-pesticides-honeybees

Pesticides – reducing damage to honey bees. John Rhodes, Livestock Officer, Intensive Industries Development, Calala, NSW. July 2006. 'Primefacts' brochure no 148; available at www.dpi.nsw.gov.au/agriculture/livestock/honey-bees/management/pesticides/reducing-pesticide-damage-honeybees

Honeybee Pesticide Poisoning - A risk management tool for Australian farmers and beekeepers. Code: 12-043 Published: 28 May 2012 Daryl Connelly, TQA Australia. ISBN: 978-1-74254-386-4; available at <https://rirdc.infoservices.com.au/items/12-043>

This booklet was developed to help beekeepers and farmers identify pesticides that are toxic to bees, and to provide information that will help them manage the risk of honeybee poisoning. It is an excellent source of information and should be a primary reference for farmers, horticulturalists, beekeepers and others interested in the subject of bees and the effect of pesticides.

Products have been included on the basis that they either contain a bee related warning on the product label, or they have the same active constituent(s), active constituent(s) concentration, application rate and intended use as products which contain a bee related warning on the label. It contains the following sections:-

- The importance of commercial pollination to the horticultural industry
- The importance of commercial pollination to beekeepers
- List of pesticides toxic to honey bees
- Managing the risk of honeybee poisoning
- How bee poisoning occurs
- Things that farmers and beekeepers can do to reduce the risk
- Responding to a poisoning event; Investigation and reporting
- Identifying the symptoms of poisoning

- Managing affected hives

Cotton Pest Management Guide 2012-13. The Australian Cotton Industry Development & Delivery Team. ISSN 1442-8452; available at www.cottoncrc.org.au/industry/Publications/Pests_and_Beneficials

This guide includes a table (on pages 8 and 9) titled *Impact of insecticides and miticides on predators, parasitoids and bees in cotton*. It contains information about the pest control persistence of a number of insecticides (including the neonicotinoids acetamprid, clothianidin and imidacloprid) and miticides and their toxicity to a range of insects (including bees).

How to reduce bee poisoning from pesticides. Reidl H, Johansen E, Brewer L & J Barbour J (2006). A Pacific Northwest Extension Publication (Oregon State University, University of Idaho, Washington State University) PNW 591 (25 pp); available at <http://www.cdfr.ca.gov/files/pdf/ReduceBeePesticideEffects.pdf> . [This document was updated in October 2013 and is available at http://bit.ly/OSU_ReduceBeePoisoning](http://bit.ly/OSU_ReduceBeePoisoning).

This publication contains useful information about protecting bees (including honey bees, alfalfa leaf-cutting bees, alkali bees, and native wild bees), including:-

- Toxicity of different pesticides to pollinators
- Signs and symptoms of poisoning by different pesticides
- Causes of bee poisoning (including insecticides, miticides, blossom-thinning agents, oil sprays, and some fungicides)
- Ways to reduce bee poisoning – advice for bee keepers, growers, pesticide applicators
- Special precautions with particular products
- Precautionary application instructions for different pesticides

14.2 Information about diseases of honey bees

Biosecurity Manual for the Honey Bee Industry. Reducing the risk of exotic and established pests affecting honey bees. 2012) Plant Health Australia (PHA); Australian Honey Bee Industry Council (AHBIC); Horticulture Australia Limited (HAL); Rural Industries Research & Development Corporation (RIRDC); The Federal Council of Australian Apiarists' Associations (FCAAA) & The When Bee Foundation. ISBN: 978-0-9872309-2-8. Available at www.animalhealthaustralia.com.au/programs/biosecurity/biosecurity-planning/honey-bees/

This manual contains detailed information on diseases of honey bees. It is aimed at helping to prevent the introduction of new bee pests and diseases into Australia, and to reduce the impact of pests and diseases already established here.

14.3 Other useful Australian websites

The website *Honeybee pollination: technical data for potential honeybee-pollinated crops and orchards in Western Australia*. Website developed by Dr Rob Manning, WA Department of Agriculture and Food. Available at www.agric.wa.gov.au/PC_91801.html

This extensive website provides some excellent information about honey bees, crop pollination, and the provision of pollination services. It includes an example pollination contract for farmers and beekeepers.

Honey Bees & Pollination. Code of Practice.2012. Tasmanian Crop Pollination Association Incorporated. Available at [www.dpiw.tas.gov.au/inter.nsf/Attachments/JBAS-8X59BX/\\$FILE/Code%20of%20Practice%20%20Tas%20Crop%20Pollination%20Aug%2012.pdf](http://www.dpiw.tas.gov.au/inter.nsf/Attachments/JBAS-8X59BX/$FILE/Code%20of%20Practice%20%20Tas%20Crop%20Pollination%20Aug%2012.pdf)

This is a code of practice for apiarists who provide honeybee crop pollination services, growers, and advisers and consultants. It contains a proforma Pollination Agreement and a proforma 'Dispute Resolution Agreement'. It also contains a suggested list of pollination fees (per hive) for different crops.

Bee Friendly - A planting guide for European honeybees and Australian native pollinators. Mark Leech, Rural Industries Research & Development Corporation. 15 Jan 2013. Code: 12-014, ISBN: 978-1-74254-369-7; available at <https://rirdc.infoservices.com.au/items/12-014>

This planting guide for Individuals, gardeners, municipalities, government land management authorities and farmers describes planting choices to assist with increasing available bee food. The guide lists herbs, shrubs, trees and other plants, broken up into suggestions for domestic gardens, streetscapes, urban open spaces, rural environments and stationary beekeeping, and further categorised by type of climate.

Get *the Buzz on Bees*. Jerry Coleby-Williams. 'Gardening Australia' website of ABC Television, October 2009. Available at www.abc.net.au/gardening/stories/s2688801

This article provides advice on backyard bee-keeping. It explains the advantages of managing hives at home, the basics of backyard bee-keeping, and how to get started. It advises that adding a hive to the backyard makes a productive garden even more prolific and provides honey as well.

The website of the Australian Honey Bee Industry Council is at <http://www.honeybee.org.au/>. It has links to several useful factsheets, including:

- Bee Swarm Information
- Pollination Aware Fact Sheet
- National Best Management Practice for Beekeeping in an Australian Environment

The House of Representatives Standing Committee Inquiry into the Honey Bee and Pollination Industries (released 16 June 2008) and the Government's response to its 25 recommendations can be found at www.daff.gov.au/animal-plant-health/pests-diseases-weeds/animal/varroa-mite/sentinel-hive-program-review/inquiry-into-the-honey-bee-and-pollination-industries. Section 11 of this report ('Product Labels') contains summary information about this inquiry.

A RIRDC report, *Pollination Aware: The Real Value of Pollination in Australia*, (Keogh et al, 2010a) provides information on the size and importance of the honeybee industry in Australia. It estimates that Australia has almost 10,000 registered beekeepers, operating around 500,000 hives. While honey production provides the main focus for most beekeepers, the 2010 report indicated that about 28% of honeybee businesses provide pollination services. Pollination services to Australian horticulture and agriculture were valued at \$1.7 billion per annum in 1999-2000 for the 35 most important honeybee- dependent crops.

A manual titled *Pollination of Crops in Australia and New Zealand* by Dr Mark Goodwin, Plant & Food Research, Ruakura, New Zealand (Goodwin, 2012) provides growers with a range of tools that can be used to assess the levels of pollination their crops receive. It also provides growers and beekeepers with methods that can be used to better manage, and optimise, pollination. It also discusses how to protect pollinators introduced to orchards. It can be downloaded at <https://rirdc.infoservices.com.au/downloads/12-059>.

15 RECOMMENDATIONS, RESEARCH SUGGESTIONS & NEXT STEPS

In this section, several recommendations are made to various agencies/organisations in order to address data gaps and to help reduce potential risks to insect pollinators.

These recommendations are followed by several general suggestions for further research which might lead to a better understanding of the situation with respect to the use of neonicotinoids in Australia.

Finally, in Section 15.3 the APVMA outlines some of the further steps it is taking to help reduce the risks to insect pollinators arising from the use of insecticides in agriculture and horticulture.

15.1 Recommendations

15.1.1 Managing the release of neonicotinoid seed-treatment dusts at planting

As noted in this overview report, one of the potential routes of exposure of insect pollinators is to fine dust containing neonicotinoid arising from the process of planting seeds coated with these insecticides. The American Seed Trade Association (ASTA) and CropLife America have developed a best practice guide, *The Guide to Seed Treatment Stewardship* (www.seed-treatment-guide.com), which outlines good stewardship practices related to the use of seed treatments and treated seed (ASTA & CLA, 2013). Similarly, CropLife Canada has worked with their national regulator, the Pest Management Regulatory Agency (PMRA) to help manage the issue of neonicotinoid dusts, especially during corn planting, a major crop in Canada (see www.croplife.ca/issues/pollinators).

The APVMA is aware that in 2010 the EU amended the provisions of the approval for clothianidin, imidacloprid and thiamethoxam, permitting their use as seed treatments (1) only where the seed coating was performed in professional seed treatment facilities which apply the best available technology to minimise the release of dust during seed treatment, storage and transport; and (2) where seeding equipment used is such that it ensure a high degree of soil incorporation of the seed, and minimises spillage and dust generation.

Recommendation: *CropLife Australia could consider working together with relevant member companies to develop a best-management practice guide relevant to Australia and focussing on those industries where there is the potential for neonicotinoid dusts to be generated during the process of coating, transporting and planting of treated seeds. This may require liaison with relevant agricultural machinery manufacturers as well seed-treatment facilities and with agricultural commodity groups.*

While the APVMA does not have any information or evidence to hand to indicate that the generation of neonicotinoid dusts during planting of treated seeds has been an issue in Australia, the development of a best-management practice guide to help minimise any dust generation during the process of seed coating, transport of treated seed, and planting is considered to be a sensible and precautionary step. The APVMA is (1) liaising with CropLife Australia about the development of best management practice guidance; and (2) seeking any information, *via* its adverse experience reporting program (AERP), about any problems that might be occurring in agricultural areas with neonicotinoid seed treatment dusts.

15.1.2 Surveillance - bee poisoning incidents

The APVMA has received very few submitted reports of adverse effects of pesticides on bees and other pollinators in Australia; this issue is discussed in more detail in this overview report (see Section 12). During the preparation of this overview report discussions were held with a number of people associated with the honeybee industry and with some farmers about factors impacting bee health. However, the opportunity to consult with a larger number of apiarists, farmers and horticulturalists was limited.

Therefore, the following recommendation is directed to the Australian Honey Bee Industry Council (AHBIC; www.honeybee.org.au) and its member associations (including the various State apiarists' associations).

Recommendation: *AHBIC and its member associations could consider the feasibility of trialling an annual survey of apiarists in the different states/territories and agricultural/horticultural regions on the health of their hives. This information would then be collated into a national report, with assistance from the Department of Agriculture, RIRDC and/or state/territory agriculture departments, as appropriate. (The possibility of extending the survey to farmers and horticulturalists growing crops dependent on insect pollinators for production could be considered, depending on the outcomes of a 2-3-year trial of the survey of apiarists.)*

The APVMA's adverse experience reporting program (AERP) collects information on adverse effects arising from approved on-label uses of the pesticide products it regulates, but this does not extend to collecting information about other factors which may be impacting bees (eg. the ongoing drought in some regions and the lack of adequate nutrition for hive bees). Nevertheless, the APVMA would be in a position to provide advice to AHBIC if it did decide to trial a survey of Australian apiarists.

15.1.3 Residue monitoring for pesticide residues in bee media

Because of the physicochemical properties of the neonicotinoids, there is the potential for these systemic insecticides and/or their metabolites to be found as residues in plant components, including nectar and pollen.

The following recommendation is directed more broadly to relevant agencies/organisations and relates to the monitoring of pesticide residues in various bee media. In North America, over 800 samples of bees, pollen, and wax have been analysed for the presence of 171 different pesticides. Sixty percent of the 350 pollen samples contained at least one systemic insecticide and nearly half had two miticides (applied by apiarists to control mite affecting bees), as well as the agricultural fungicide chlorothalonil. In bee-collected pollen several insecticides, fungicides and an herbicide were detected. The pollen samples contained an average of 6 different pesticides. Almost all comb and foundation wax samples contained three pesticides used by beekeepers to control bee pests and diseases (Mullin et al, 2010; Frazier et al, 2011). Frazier et al. noted (www.extension.org/pages/60318/pesticides-and-their-involvement-in-colony-collapse-disorder) that:-

“Although our work represents the largest data set of pesticides in honey bee colonies to date, and was drawn from samples collected across 23 states and a Canadian province, it was not the product of a well-designed systematic survey of honey bee colonies in the US. It thus does not give us a clear picture of the current state of pesticide residues in honey bee colonies. Such a study is critically needed yet we know of no current plans to accomplish this expensive task.”

The APVMA is unaware that any such pesticide residue monitoring of various plant and bee media has been conducted in Australia.

Recommendation: *It is suggested that a research project be established and funded to analyse pesticide residues in various plant (nectar, pollen, guttation fluid) and bee (collected pollen, comb and foundation wax, bee bread, honey) media. It should be conducted in such a way to allow comparison with the quite extensive results collected in North America, in order to clarify whether conditions (climate, landscape), the absence of certain bee diseases, and different agricultural/ horticultural practices in Australia mean that there is a similar, or less of an issue with respect to pesticides. Such a project could involve RIRDC, State departments of agriculture, and agricultural/ horticultural research institutions.*

While the APVMA is not funded or resourced to conduct such monitoring, it could provide some advice on the conduct of such research, as well as information on the availability of published data from overseas monitoring studies.

A separate recommendation of this overview report was to be that the Australian Government's National Residue Survey (NRS; www.daff.gov.au/agriculture-food/nrs) extend the range of residues it tested in honey (www.daff.gov.au/agriculture-food/nrs/animal-product-testing/animal-results-2011-12) to include the neonicotinoids and relevant metabolites. However, in discussing the proposed recommendation with staff of the NRS, they advised the APVMA that such monitoring had already commenced and that the 2012-13 honey sampling program had tested 23 random samples of Australian honey for the following neonicotinoid insecticides and their metabolites: acetamiprid; N-demethyl acetamiprid; imidacloprid; 5-hydroxy imidacloprid; imidacloprid olefin, thiacloprid; and clothianidin. (Thiamethoxam was not assayed as its primary active metabolite is clothianidin.) Results of the first set of monitoring data for neonicotinoids in honey are likely to be published on the NRS website later in 2013.

15.1.4 Holding a national information symposium

An APVMA workshop for regulatory stakeholders was held on 24 July 2013 - attendance was primarily limited to regulatory staff from relevant federal and state government agencies (as partners in the National Registration Scheme for Agricultural and Veterinary Chemicals, or NRS). It was convened to address issues relating to bee protection statements on labels and the possible expansion of testing requirements for new insecticides being brought on to the Australian market.

Nevertheless, the APVMA sees value in holding a national bee/pesticide forum which could involve a wider range of stakeholders and at which issues related to bee health and pesticide impacts on pollinators could be more broadly discussed. Such a forum would recognise that protection of insect pollinators goes beyond farmers and horticulturalists but needs to include others, including local and regional authorities, private industry, the general public, and bee keepers themselves.

Recommendation: *Relevant agencies (eg. RIRDC, Plant Health Australia, the Department of Agriculture, the Department of the Environment) should consider holding a one-day symposium for a wide range of stakeholders to hear about issues relating to bee health from Australian and international experts. This would also provide an opportunity for the APVMA to provide a report of its overview of neonicotinoid insecticides*

and pollinator health, as well as a summary of the outcomes of the July 2013 workshop for regulatory stakeholders.

The APVMA has been holding discussions with RIRDC, Plant Health Australia, GRDC, the Department of Agriculture, and the Department of the Environment about the organisation of, and program for a one-day information symposium on issues relating to the protection of insect pollinators. **[Note: A symposium date has now been set down for Wednesday 9th April 2014 and will take place in Canberra; it is being organised by Plant Health Australia and jointly funded by RIRDC, GRDC and the APVMA.]**

15.2 Research suggestions

It became apparent while investigating the issues for this overview that there are a number of areas where targeted scientific research might help answer some questions relating to pollinator health and the use of neonicotinoids in Australia. While specific recommendations have not been formulated, the following list points to issues which could be gainfully investigated:-

Canola: The APVMA has seen and received several reports suggesting that there is a problem in Australia from bees feeding on canola grown from neonicotinoid-treated seed eg. “[in] the last couple of years we have stayed away from canola and we have had the best bees we’ve had for years” (see www.theabk.com.au/article/neonicotinoids-australia). Yet most other reports received suggest that canola was, and remains an excellent crop for apiarists. For example, the WA Department of Agriculture & Food advised the APVMA that, partly due to the abundant canola crops in that State, feral honey bees are multiplying and taking over tree hollows needed for nesting by native parrots (R Manning, *pers. com*).

It is possible that these different reports are a reflection of effects Somerville (2002) described viz:-

“A weak colony should benefit from being placed on canola blossom. The fresh nectar and pollen supply will encourage the colony to breed and to expand the brood area. If the colony experienced a particularly severe winter or is suffering from nosema disease, access to canola blossom could help the colony to overcome the disease by enabling the bees to rapidly expand the population, displacing the old bees and quickly populating the hive with young, healthy bees. However, the reverse can happen just as often, when the adult workers are placed under so much stress, foraging for pollen and nectar, ripening nectar and keeping the brood area warm, that the longevity of the bees is reduced and the hive population declines. This, particularly when combined with poor weather, will see the levels of *Nosema* increase.”

Nevertheless, there are indications that there may be a regional difference in these conflicting reports. Considering the different varieties/cultivars of canola grown in different parts of Australia (OGTR, 2002) and the fact that they have changed over time since there has been a rapid and extensive genetic development of ‘oilseed’ rape’ by the oilseed industry, it would be useful to know whether there are differences in the output and quality of the nectar and pollen from the current range of commercially-grown varieties/ cultivars which might help explain these different reports. [There has been some work to look at the issue of nectar quality in particular canola hybrids (eg. Pernal & Currie, 1998). By way of comparison, the APVMA has been advised that different soya bean and lucerne varieties can significantly vary in their attractiveness to bees.]

Neonicotinoid persistence: Because of the reasonably long soil half-lives of the N-nitroguanidine neonicotinoids (depending upon local conditions), more information on their potential to accumulate in the soil and in plants grown in fields used to grow crops treated with neonicotinoids (either as a seed or a soil treatment) in previous seasons would be useful. Australian field studies on whether accumulation is occurring, its extent, and whether it varies according to the neonicotinoid, soil type and application method, would help regulators to assess whether any additional controls on neonicotinoid use, especially in rotational crops, might be warranted. Such studies could be extended to investigate soil penetration and run-off in

areas where neonicotinoids are most heavily used. [Preliminary results (Sánchez-Bayo & Hyne, 2013) indicate the detection of several neonicotinoids, albeit at low levels, in river water samples taken around Sydney after a run-off event.]

Honey bee research: As one of the few remaining countries in the world without *Varroa*, Australia would be an ideal location to study the health of honey bee colonies without the confounding factors of *Varroa* mite and the chemicals deliberately used within hives to treat it. This fact suggests that Australia would be well placed as a location to contribute to studies on the complex interactions between the large number of factors which can adversely impact bee health.

15.3 Next Steps - APVMA

15.3.1 Bee protection goals, new tests for measuring hazard and exposure, labels

As noted above (see Section 10 – ‘Testing Requirements’ and Section 11 – ‘Product Labels’), in 2012 the APVMA, as part of its investigations into the use of neonicotinoids in Australia, contracted the Australian Environment Agency Pty Ltd (AEA PL) to investigate the issue of pollinator toxicity testing requirements, taking into account the work being done internationally on this subject.

In particular, AEA was requested to:

- advise whether the current APVMA data requirements for testing of insecticides are adequate to address scientific concerns about subtle effects of neonicotinoids (and other pesticides) on honey bees and other insect pollinators, which have been suggested as impacting their ability to pollinate plants and collect honey.
- propose additional data requirements in the event that the current ones are inadequate.
- consider the labels of those Australian products which carry bee protection statements and review the consistency or inconsistency of the wording in those statements and advise the APVMA if changes need to be made to standard statements and to existing labels.

The full AEA report, *Consideration of Testing Requirements and Label Statements in Relation to the Impact of Pesticides on the Health of Honey Bees and other Insect Pollinators* (dated 13 November 2012), is available on the APVMA’s website. It made five (5) recommendations to the APVMA; these are listed below, followed by a summary of APVMA’s responses to date.

Recommendation 1: *The APVMA and its advisory agency, the Department of the Environment, should consider the suite of tests currently available, and those being developed, to examine (1) the potential extent*

of exposure of bees and other insect pollinators to pesticides; and (2) the effects of pesticides on bees and other insect pollinators. These are not reflected in current Australian data requirements²¹.

Recommendation 2: The APVMA should request its environmental advisory agency, the Department of the Environment, to establish appropriate Australian protection goals for insect pollinators and link data requirements and risk assessment methodology to these protection goals.

Recommendation 3: Considering the large inconsistencies found in wording of bee protection statements on current Australian product labels, the APVMA needs to review them with a view to reducing the number of different statements currently available. The Department of the Environment has developed standard bee protection statements, but they are as yet only found on a limited number of products. In developing a more consistent label approach, related issues for consideration include:-

- identification of use patterns that will require labelling because of the potential for exposure of pollinators
- identification of uses that can be addressed through label statements (for example, products applied by foliar application) and those products (eg. seed treatments and soil-applied products) that might be better addressed through appropriate product stewardship
- detail of label statements compared to assessed risk. For example, active constituents shown to be acutely toxic to adult bees and where residues have been shown to remain toxic to larvae for extended periods of time will contain more detailed protection statements than actives that do not display residue toxicity.
- development of guidance for label statements for home garden products.

Recommendation 4: The APVMA and the Department of the Environment should consider convening a workshop to address the issues outlined in recommendations 1 to 3 above. The workshop should be attended by relevant stakeholders and include relevant staff from the APVMA, the Department of the Environment, the Department of Agriculture, Plant Health Australia and State/Territory departments of agriculture, as well as industry (apiarists and registrants).

APVMA Response: Recommendation 4 was acted upon and a workshop was held at the APVMA on 24 July 2013 to discuss Recommendations 1-3. Considering the regulatory focus of the workshop, invitees included those with a level of familiarity with the regulatory environment in Australia, and in particular, State partners in the National Registration Scheme for Agricultural and Veterinary Chemicals (the NRS) and Commonwealth government agencies which provide specialist technical advice to the APVMA. A report on the outcomes of that workshop has been prepared.

²¹ Current Australian data requirements for insect pollinator toxicity testing are those identified in the *Environmental Risk Assessment Guidance Manual for Agricultural and Veterinary Chemicals* (EPHC, 2009). The acute adult contact and oral toxicity tests are part of the standard data requirements. The need for the other two types of tests listed (viz. pollinator exposure to residues on foliage and a semi-field test) is considered on a case-by-case basis and depends on the toxicity and proposed use pattern of the chemical under consideration.

Recommendation 5: *In preparing to develop expanded risk assessment methodology to consider the impact of pesticides on insect pollinators, the APVMA should request the Department of the Environment to evaluate the increasing amount of data being submitted with pesticide applications (especially applications being submitted to multiple agencies as Global Joint Reviews, or GJRs) so that they can gain a better understanding of the additional studies being conducted to address the issue of pesticide effects on pollinators. This will assist in developing revised risk assessment approaches in Australia.*

APVMA Response: This recommendation has been actioned and the evaluation of expanded data packages is now taking place. As these data are evaluated, the relevant area of the Department of the Environment will be in a position to provide advice to the APVMA on the usefulness of new test methods being developed and introduced to better assess (1) the acute and sub-chronic impacts of pesticides on bees and bee brood; and (2) the extent of exposure of insect pollinators to neonicotinoids and other pesticides.

The Department of the Environment has been asked to consider the recommendations of the 24 July 2013 APVMA workshop (relating to bee toxicity test methodology, product labelling, and pollinator protection goals), together with the more recently-published (5 August 2013) European Food Safety Authority's *Guidance on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees)* (EFSA, 2013e); this latter document suggests a tiered risk assessment scheme for possible impacts of plant protection chemicals on bees, with a simple and cost-effective first tier to more complex higher-tier studies under field conditions. It is also expected that the US EPA's guidance document on their risk assessment for bees, based on their *White Paper in Support of the Proposed Risk Assessment Process for Bees* (USEPA, 2012) will be available early in 2014 for consideration.

Once the APVMA and the Department of the Environment have reached a final conclusion on additional bee toxicity testing methods and revised/updated product labelling to better protect insect pollinators, the APVMA will post regulatory advice on its website and also decide whether a formal review of the labels of current insecticide products is warranted.

15.3.2 Recommendations to external agencies/organisations - APVMA input

In Section 15.1 (above) the APVMA made four (4) recommendations which are directed to external agencies/organisations. The APVMA will continue to liaise with these agencies/organisations about the possible implementation of these recommendations.

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[Note: The five case studies listed below were prepared as part of *Pollination Aware – The Real Value of Pollination in Australia*, by RC Keogh, A Robinson and I Mullins, which consolidates the available information on pollination in Australia at a number of different levels: commodity/industry; regional/state; and national. The document and the accompanying case studies provide a base for more detailed decision making on the management of pollination across a broad range of commodities. The full report and individual case studies (35 in all) are available at www.rirdc.gov.au]

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17 ATTACHMENT 1: NEONICOTINOIDS (AND RELATED COMPOUNDS) APPROVED IN AUSTRALIA AND THEIR REGISTERED USES

ACTIVE INGREDIENT	REGISTERED USE IN AUSTRALIA
Neonicotinoids	
Acetamiprid	<p><i>Spray:</i> cotton</p> <p><i>Foliar spray:</i> potatoes, flowers, ornamental plants (indoor and outdoor), including roses, shrubs palms, bedding plants and trees</p> <p><i>Soil drench:</i> ornamental plants in potting mixes</p>
Clothianidin	<p><i>Soil drench & foliar spray:</i> pome fruit, stone fruit, grapes</p> <p><i>Water dispersible granules:</i> turf</p> <p><i>Spray:</i> cotton</p> <p><i>Stem spray & injection:</i> bananas</p> <p><i>Soil band spray:</i> sugar cane</p> <p><i>Soil injection:</i> eucalyptus seedlings and young trees</p>
Imidacloprid	<p><i>Spray:</i> cotton, fruit, stone fruit (including peach, plum, nectarine, apricot), apples, vegetables (capsicum, melon & other curcurbits, eggplant, sweet potato, potato, cucumber, tomatoes, brassicas), turf, ornamentals, shrubs, roses, Duboisia, Pandanus trees</p> <p><i>Seed treatment:</i> maize, sweet corn, lentils & lupins, faba beans, field peas, canola, sorghum, cereals, pulses, sunflower, cotton, forage & seed pasture (eg. red clover, subterranean clover, strawberry clover, white clover, ryegrass, phalaris, lucerne, medics), forage brassicas (Kale, turnip, rape and swedes)</p> <p><i>Soil treatment:</i> sugarcane, apples, citrus, vegetables (capsicum, curcurbits, eggplant, sweet potato, tomatoes), potatoes, Elm trees, eucalyptus seedlings, roses, azaleas and other ornamentals in pots</p> <p><i>Trunk injection:</i> bananas</p> <p><i>In-ground tablets:</i> roses, azaleas, Lillypillies, potted palms, magnolias, Eucalypt trees</p> <p><i>Soil spraying, trenching and rodding:</i> protecting buildings, fences and poles against termites</p> <p><i>Reticulation systems:</i> termite protection of buildings</p> <p><i>Wall, pole or tree injection:</i> termite nests</p> <p><i>Spray:</i> flowers, shrubs, trees, fruit trees, vegetables, lawn (home garden)</p> <p><i>Timber treatment:</i> manufacture of veneers, boards and plywood</p> <p><i>Topical paste:</i> flea control in cats and dogs</p> <p><i>Fly bait:</i> Houseflies in commercial, industrial and domestic areas</p> <p><i>Foam:</i> PCO use for termites, European wasps, ants, bed bugs, cockroaches</p> <p><i>Gel:</i> cockroaches</p> <p><i>Pour-on:</i> Lousicide for sheep</p>

ACTIVE INGREDIENT	REGISTERED USE IN AUSTRALIA
Nitenpyram	Tablets: fleas on cats and dogs. [No crop uses]
Thiacloprid	<p><i>Foliar spray:</i> pome fruit (including apples), stone fruit, maybush, roses, camellia (commercial nurseries only)</p> <p><i>Dip:</i> Lousicide for sheep</p> <p><i>[A product for use as an insecticide spray on cotton is approved but it is not marketed, nor is there any intention of the registrant to do so.]</i></p>
Thiamethoxam	<p><i>Spray:</i> cotton, citrus, tomatoes, turf & lawns, roses and ornamentals, home garden (indoor and outdoor)</p> <p><i>Soil-incorporated granules:</i> indoor and outdoor ornamental plants, shrubs and small trees (home garden)</p> <p><i>Seed treatment:</i> cotton, cereals, canola, maize, sweet corn, sorghum, sunflower</p> <p><i>Soil drench:</i> seedlings of fruiting vegetables, brassicas and leafy vegetables</p> <p><i>Fly spray, paint-on and bait:</i> House flies in commercial, industrial and domestic areas</p> <p><i>Bait gel:</i> ants (around buildings)</p>
Related insecticides acting at nicotinic AChRs (see footnote to Table 1)	
Sulfoxaflor	<i>Foliar spray:</i> Canola, cereals, cotton, soybeans, curcurbits, fruiting vegetables, leafy vegetables, root and tuber vegetables, vegetable brassicas

18 ATTACHMENT 2: SUMMARY OF SOME FIELD STUDIES AND MONITORING DATA

COUNTRY	MONITORING PROJECT	TIME	FOCUS	CONCLUSION FINDINGS
Europe				
Austria	MELISSA Project (Girsch & Moosbeckhofer, 2010).	2009-10	Investigation of bee –poisoning incidents in several regions	A number of incidents related to seed treatment dusts (maize) were recorded from certain regions - dust deposition from planting of small maize fields onto neighbouring flowering vegetation. No increased bee mortality was observed in areas growing neonicotinoid seed-treated canola (oilseed rape). Overwintering losses caused mainly by <i>Varroa</i> . Engineering controls etc. reduced the risks cf. planting 2009 season.
Belgium	Study on the influence of imidacloprid seed treatment in maize on bee health (Nguyen et al, 2009)	2004-05	Sixteen apiaries located in the vicinity of treated or untreated fields were surveyed over one year.	No adverse effects of imidacloprid seed treatment on exposed bee colonies were found. [Results suggested a correlation between the number of colonies per apiary and mortality rates in the respective apiary.]
Finland	Neomehi project – impact of neonicotinoid use in spring oilseed rape and turnip rape on honey bees (MTT & EVIRA, 2014)	2013-15	Beehives positioned in five different locations. Possible links between the proximity of the hives to rapeseed fields, death of beehives, and occurrence of bee diseases examined. Residues analysed in oilseed nectar, pollen, honey and in bees.	Initial results suggest that the insecticides do not cause immediate harm to honey bees and there was no connection between seed treatment and colony loss. Residues of neonicotinoids (in oilseed plants, nectar, pollen, honey and honeybees) were “fairly small and beneath the risk limit”.
France	Three-year field survey of bee colony mortalities (Chauzat et al, 2009; 2010a)	2002-05	Multi-factorial monitoring project involving 125 bee hives from 25 apiaries in five different regions of France.	No correlation between in-hive residues of pesticides (41 different chemicals assayed, including imidacloprid and its 6-chloronicotinic acid metabolite), abundance of brood and adults, or bee colony mortality was found. (Possible synergistic effects between different pesticides were not discounted.) Foulbrood and <i>Varroa destructor</i> infestation were the most severe conditions positively related to mortality.
	Case-control study of bee colony mortality (Chauzat et al, 2010b)	2005-06	Comparison of apiaries with high winter losses with neighbouring apiaries with no abnormal losses – apiaries homogenous with respect to climate, vegetation and pesticide exposure.	The cause of the high losses appeared to be absence of preventative treatment for <i>Varroa</i> .

COUNTRY	MONITORING PROJECT	TIME	FOCUS	CONCLUSION FINDINGS
	Survey of apiary mortality (Chauzat et al, 2010b)	2005-06	Overwintering mortality in 18 apiaries at 13 locations in France.	<i>Varroa</i> infection had a dominant role in over-wintering losses. Imidacloprid residues found in beebread samples from 3 apiaries (2 at levels <LOD).
	Monitoring for impacts of thiamethoxam seed treatment of maize in several regions (DGAL, 2012)	2008-12	Comparison of corn grown from treated and untreated seeds (across 3, 5 & 6 regions over the period). Monitoring of dust generation during seeding; residues of thiamethoxam and clothianidin metabolite in pollen; and health of bee colonies.	Normal bee behaviour was maintained and bee health and mortality was not affected. Use of dust collectors during seeding and paying attention to wind controlled the problem of airborne dusts. Bee exposure to the neonicotinoids during flowering (via pollen) was negligible and there was an absence of quantifiable residues in hives. There was no increase in bee pathogens (either viral or parasitic).
	Monitoring for impacts of thiamethoxam seed treatment of maize and oilseed rape (Pilling et al, 2013)	2005-2008	Effects of repeated exposure of bees to maize and oilseed rape crops grown from seed treated with thiamethoxam.	Mortality, foraging behaviour, colony strength and weight, brood development and food storage levels were similar between treatment and control colonies. Colonies exposed to treated crops successfully overwintered, with similar health status to controls in the following spring. The study concluded 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.
Germany	German Bee Monitoring (Genersch et al, 2010b)	2004/5 - 2007/8	Four-year monitoring project looking at overwintering losses in honeybee colonies	1200 hives monitored across ca. 120 apiaries. Winter losses related to (1) high <i>Varroa</i> infestations; (2) deformed wing virus and acute bee paralysis virus in autumn; (3) queen age; and (4) weakness of colonies in autumn. No correlation with <i>Nosema</i> or pesticides
	Monitoring of bee incidents by the Julius Kühn-Institut, Federal Research Centre for Cultivated Plants (Seefeld, 2005, 2006, 2008).	1960-2006	Ongoing monitoring of pesticide incidents involving bees	In several years, incidents were caused by off-label uses of neonicotinoid sprays, otherwise no significant incidents with neonicotinoids were observed before 2008. Imidacloprid was not found in any honey bee or plant sample. The numbers of incidents steadily declined since the mid-1970s and, since 1992, has been constant. "In summary, the damage to honey bees as a consequence of pesticide application has clearly decreased during the course of the past 20 years [1985-2006]"
	Monitoring of hives on corn grown from clothianidin-treated seed in south-western Germany (Liebig et al, 2008)	2008-09	Bee hives set up in different locations in a region with maize crops grown from clothianidin-treated seed - monitored during a season until the following spring. Extensive residue sampling conducted.	New colonies developed well ie. there were no adverse effects of feeding on crops grown from treated seed were reported. [The development of twelve productive colonies from two apiaries severely affected by high mortality following dust drift during planting in spring (April) was also monitored between May and October – they had recovered by early summer.]

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COUNTRY	MONITORING PROJECT	TIME	FOCUS	CONCLUSION FINDINGS
Hungary	Pesticide incident monitoring (Fazekas et al, 2012)	2007-11	Investigated 151 incidences of bee poisoning by pesticides (over 5 years).	222 bee samples and 129 plant samples assayed – 151 bee samples contained pesticide residues; in 64 cases, plant samples from the same poisoning incident contained the same pesticide(s) as in the bee sample. Poisonings were most frequently caused by chlorpyrifos, then dimethoate, fipronil and six different synthetic pyrethroids. Thiamethoxam was detected in one plant and one bee sample.
Italy	APENET - network for monitoring honeybee losses (see EFSA, 2012c).	2009-11	Network of beehives situated in different areas periodically analysed for pathogens and chemicals in dead bees, live bees, brood, honey, wax and pollen	EFSA concluded that it was not possible to draw any definitive conclusions from this monitoring. Tests on free flying bees in the vicinity of unmodified pneumatic planters (no deflector to direct the air from the fan down to the ground) suggested that forager bees could be at risk if they fly through dusts emitted by seeders sowing maize seeds coated with either fipronil, or the neonicotinoids thiamethoxam, clothianidin or imidacloprid.
	BEENET Monitoring (successor project of APENET)	2011-13	Survey on incidences of intoxication by pesticides, pesticide residues in bee hives and bee disease incidence in Italy	EFSA (2013b) reported that “no further data were available since their 2012 evaluation of APENET data (see row above).
Poland	Hives placed near oilseed rape crops seed treated or sprayed (Pohorecka et al, 2012)	2010 and 2012	Winter oilseed rape seed treated with thiamethoxam and imidacloprid and sprayed with acetamiprid and thiacloprid. Spring oilseed rape seed treated with clothianidin, thiamethoxam and imidacloprid, and sprayed with thiacloprid.	Study did not see any short-term or long-term effects of neonicotinoids in either winter or oilseed rape. However, because of various detections of neonicotinoid residues in nectar and/or pollen, the authors noted that there was a potential for adverse effects, especially from combined effects of exposure to insecticides and bee pathogens eg. <i>Nosema</i> .
Slovenia	Monitoring of pesticide residues in bee hives and bee colony health (Kozmus et al, 2011)	2009-10	Monitoring project including 90 colonies at 30 locations in different agricultural and horticultural areas. 50 pollen samples were analysed in 2009, 52 in 2010.	The highest number of residue detections was found in intensive viticultural and horticultural areas, with fungicides the most common. Insecticides (chlorpyrifos-ethyl, methoxifenozone, thiacloprid) were found in pollen samples from six of the 30 locations. The authors concluded that the pollen residues did not affect the honeybee colonies or infestation rate of <i>Varroa</i> , <i>Nosema</i> or bee viruses.

COUNTRY	MONITORING PROJECT	TIME	FOCUS	CONCLUSION FINDINGS
Spain	Large-scale survey on pesticide residues in bee hives and bee colony mortality (Bernal et al, 2010)	2006-07	Evaluation of the exposure of bees to pesticide residues in stored pollen and effects of pesticide exposure to colony mortality. 1,021 apiaries were surveyed.	Pesticide residues were detected in 42% of spring and 31% of autumn samples. Fluvalinate and chlorfenvinphos were the most frequently detected pesticides (as a consequence of the use of these acaricides in homemade formulations to control <i>Varroa</i>). Fipronil was detected in 3.7% of spring but not in autumn samples. Neonicotinoid residues were not detected. A direct relation between pesticide residues found in stored pollen samples and colony losses was not evident. Further studies would be necessary to investigate possible chemical synergism.
Switzerland	A series of field studies by the Swiss authorities to investigate insecticide seed treatments (BLW, 2009).	2009	Effects of neonicotinoid in dust during maize seeding, and in guttation liquid, on exposed honey bee colonies	No increased mortalities or other adverse effects of the treatment were seen, either during sowing of the crop - conducted in compliance with prescribed safety measures - or during the guttation phase of the crop.
UK	UK Wildlife Incident Investigation Scheme (WIIS) (Fletcher & Barnett 2003 and Barnett et al, 2007)	1988-2003	Incidents of possible acute poisoning of bees by pesticides investigated and recorded by the authorities	No cases of acute bee intoxication in which neonicotinoids were involved are reported from these years.
	Wildlife Incident Investigation Scheme (WIIS) (www.pesticides.gov.uk/guidance/industries/pesticides/topics/reducing-environmental-impact/wildlife)	2009-13	See above	Very few acute bee poisoning incidents in which neonicotinoids (imidacloprid, thiamethoxam, thiacloprid) were detected - between 1 to 6 per year from 2009-12. The following other pesticides were measured in the bee incidents investigated: fungicides (azoxystrobin, boscalid, carbendazim, prochloraz, propiconazole, prothioconazole, tebuconazole), insecticides/acaricides (bendiocarb, chlorpyrifos, cypermethrin, dieldrin, dimethoate, fipronil, fluvalinate, gamma-HCH, permethrin, lambda-cyhalothrin) and an herbicide (glyphosate) [These not necessarily implicated in the bee deaths investigated.]
	Investigation of the effects of neonicotinoid seed treatments on bumble bees by the UK Food and Environment Research Agency (Thompson et al, 2013)	2012	Field study conducted to investigate laboratory study of Whitehead et al (2012) suggesting that field-realistic levels of imidacloprid reduce bumble bee (<i>Bombus terrestris</i>) colony growth and queen production. The study monitored 60 buff-tailed bumblebee colonies over 3 UK sites.	Only 35-37% of the pollen collected by the bees was from oilseed rape ie. bumblebees were not feeding exclusively on oilseed rape. No consistent relationships were observed between colony mass, the number of new queens produced, and the observed variations in neonicotinoid residues across colonies (within and between sites). The absence of effects is "reassuring but not definitive". The study underlines the need to take care in extrapolating laboratory studies to the field, and the need for further field studies.

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COUNTRY	MONITORING PROJECT	TIME	FOCUS	CONCLUSION FINDINGS
America				
Canada	Monitoring of honeybee health in canola grown from clothianidin-treated seed (Cutler & Scott-Dupree, 2007)	2005-06	Bee mortality, worker longevity and brood development after 3 weeks on canola (grown from untreated and clothianidin-treated seed). Clothianidin levels in beeswax, honey, pollen and nectar.	Honey bees unaffected by exposure to clothianidin seed-treated canola. Clothianidin detected in honey, nectar and pollen but max. Concentrations were 8-22-times lower than no-observable-effect concentrations. No detects in beeswax. [Because of Canadian regulatory concerns about the size and separation of the plots and the detection of low levels of clothianidin in nectar from colonies in control fields, a larger study was conducted in 2012. A final report is due in late 2013 – see below.]
	Large-scale project to monitor honeybee health in canola grown from clothianidin-treated seed (Cutler et al, 2013).	2012-123	Colony weight gain, honey production, bee pest incidence, bee mortality, number of adults, amount of sealed brood.	No adverse effects on honeybee colonies over summer and autumn 2012. Overwintering success measured in April 2013 – colony survival virtually equivalent.
Argentina	Monitoring health of honey bees [<i>Apis mellifera ligustica</i> (Spin.) exposed to imidacloprid-treated sunflower during blooming	Field trial reported in 2003	Beehive weight, brood and honey production, foraging activity, pollen entrance, and mortality, residue analysis in soil, sunflower heads, pollen, wax and hives.	Parameters assessed after 10, 28 and 216 days. No residues of imidacloprid or its metabolites olefin-imidacloprid and hydroxy-imidacloprid were detected (lower detection limit = 1.5 µg/kg) in sunflower heads or bee media 10 days after exposure to treated sunflower. No adverse effects were observed after short-term or long-term monitoring. Hives were more productive (average weight, honey production, foraging activity, worker brood and comb foundation), considered to be due to the better condition of the treated crop.

19 ATTACHMENT 3: GLOSSARY

ac	active constituent
AChE	Acetylcholinesterase enzyme
AChR	acetylcholine receptors
AEA	Australian Environment Agency Pty Ltd
AER	adverse experience report
AERP	Adverse Experience Reporting Program
AFB	American Foulbrood
AHBIC	Australian Honey Bee Industry Council
APVMA	Australian Pesticides and Veterinary Medicines Authority
Bt corn	Genetically-modified corn containing a gene which codes for <i>Bt</i> delta endotoxin protein from a naturally-occurring soil bacterium, <i>Bacillus thuringiensis</i> . This protein is highly effective at controlling lepidopteran pests.
CCA	Crop Consultants Australia Inc
CCD	Colony Collapse Disorder
CNS	central nervous system
Cotton CRC	Cotton Catchment Communities
CSD	Cotton Seed Distributors
DWV	Deformed Wing Virus
EBI	Ergosterol biosynthesis inhibitor (a class of fungicides)
EC	European Commission
EC	Emulsifiable Concentrate
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
FCAAA	Federal Council of Australian Apiarists' Associations
GABA	gamma-amino-butyric acid
GJR	Global Joint Reviews
GM	genetically modified

HAL	Horticulture Australia Limited
HFCS	high-fructose corn syrup
IAPV	Israel Acute Paralysis Virus
IIV-6	Invertebrate Iridescent Virus type 6
IRAC	Insecticide Resistance Action Committee
LD50	Lethal Dose 50% - the estimated dose of a chemical which kills 50% of a test group of organisms dosed with the chemical
nAChR	nicotinic acetylcholine receptor
NRS	National Registration Scheme for Agricultural and Veterinary Chemicals
NRS	National Residue Survey
NSW	New South Wales, Australia
OPs	Organophosphorus insecticides, commonly called 'organophosphates'
PCP	'Pesticide & Chemical Policy', a weekly newsletter from Informa Ltd
PHA	Plant Health Australia
PMRA	Canadian Pest Management Regulatory Authority
PNS	peripheral nervous system
Qld	Queensland, Australia
RFID	radiofrequency identification
RIRDC	Rural Industries Research and Development Corporation
SPs	synthetic pyrethroids
USDA	United States Department of Agriculture
USEPA	United States Environmental Protection Agency
WIIS	United Kingdom Wildlife Incident Investigation Scheme