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September 19, 2013

VIA ELECTRONIC MAIL
AND COURIER

< Minister_Ministre@hc-sc.gc.ca >
< rona.ambrose@parl.gc.ca >
The Honourable Rona Ambrose
Minister of Health
Health Canada
Brooke Claxton Building, Tunney's Pasture
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Ottawa, Ontario
K1A OK9

Dear Minister Ambrose:

Re: Notice of Objection to Registration Decision RD2013-14 – Clutch 50 WDG, Arena 50 WDG and Clothianidin Insecticides – July 23, 2013

We are counsel respectively to the Sierra Club Canada, the David Suzuki Foundation, the Western Canada Wilderness Committee, and Équiterre (hereinafter the "Objectors") in connection with the above matter.

This letter and attached material constitute a Notice of Objection by the Objectors to Registration Decision RD2013-14 respecting clothianidin and pest control products containing clothianidin as an active ingredient (the "Decision"), pursuant to section 35(1) of the *Pest Control Products Act*, S.C. 2002, c. 28 (the "Act" or "*PCPA*").

The Objectors file this Notice of Objection because the Decision is contrary to the Act's primary objective of preventing unacceptable risks to the environment as it unreasonably renews until December 2015 the conditional registration of clothianidin and pest control products containing clothianidin that (1) have lacked for some considerable period of time key information about environmental effects on bees, and (2) produce unacceptable environmental effects on bees based upon currently available information. In the circumstances, the Decision should be reviewed by an independent review panel established by the Minister pursuant to section 35(3) of the Act.

Attached to this letter are the following documents:

1. Appendix A – A completed form for each Objector of a Notice of Objection to the Decision under Section 35(1) of the *PCPA*;

2. Appendix B – A copy of the Decision;

3. Appendix C – A report prepared by Dr. Mark L. Chernaik, biochemist; and

4. Appendix D – A letter report prepared by Dr. Ralph V. Cartar, bee ecologist.

This letter plus the material contained in Appendices C and D provide evidence to support, and the scientific basis for, the objection as required by section 2 of the *Review Panel Regulations*, SOR/2008-22, promulgated under the *PCPA*.

I. THE OBJECTORS

The mission of the Objectors includes:

- *Sierra Club Canada*: protecting wild places, promoting responsible use of the earth's ecosystem and resources, protecting and restoring the quality of the natural and human environment, and developing conservation policies;

- *David Suzuki Foundation*: collaborating with Canadians from all walks of life, including governments and business, to conserve our environment and find solutions that will create a sustainable Canada through science-based research, education, and policy work;

- *Western Canada Wilderness Committee*: protecting wilderness areas, critical wildlife habitat, and old-growth temperate rainforest and boreal forest;

- *Équiterre*: encouraging individuals, organizations, and government to make ecological and equitable choices aimed at making Quebec a society where sustainable development and social economy are centre stage.

II. STATUTORY REGIME

The Notice of Objection contests the renewal of the conditional registrations for clothianidin and the pest control products containing clothianidin referred to in the Decision. The Decision itself, though not explicit on the statutory authority relied upon, appears to rest on the application of a combination of sections of the Act and regulations, including sections 8 and 12 of the Act and sections 14 and 16 of the *Pest Control Products Regulations*, SOR/2006-124. To better understand the Objectors' concerns with the Decision, the following provides a brief review of the *PCPA* regime itself.

A. Overview of Act's Objectives and Key Authorities

The *PCPA* is the federal law that establishes a regime for the registration of pest control products in Canada. In administering the Act, the "Minister's primary objective is to prevent unacceptable risks to people and the environment from the use of pest control products" [s. 4(1)]. Consistent with, and in furtherance of, the primary objective, the Minister also must, among other things (1) support sustainable development,[1] (2) seek to minimize health and environmental risks posed by pest control products, and (3) facilitate public access to relevant information and public participation in the decision-making process [s. 4(2)(a)-(c)]. The preamble to the Act further recognizes *inter alia* that:

- it is in the national interest that the primary objective of the federal regulatory system be to prevent unacceptable risks to people and the environment from the use of pest control products;
- a scientifically-based national registration system address risks both before and after registration;
- registration of pest control products should only occur if it can be shown that conditions of registration can be established to prevent pollution of the environment; and
- the federal regulatory system be designed to minimize environmental risks posed by pest control products and to encourage, among other things, alternative, non-toxic, approaches.

The Act is also clear that during an evaluation under the registration process, the applicant for a registration has the burden of persuading the Minister that, among other things, the environmental risks from a pest control product are acceptable [s. 7(6)(a)]. While the Minister is obliged under the *PCPA* to give effect to government policy in evaluating environmental risks [s. 7(8)], the Minister must apply the "precautionary principle" as a matter of law, in certain circumstances, such as during the course of a re-evaluation if there are reasonable grounds to believe that the environment is being endangered [s. 20(1)(2)].[2]

B. Statutory Basis for Renewal of Conditional Registrations

The particular type of registration that clothianidin and its associated pest control products possess pursuant to the Act and regulations also is relevant to this Notice of Objection. Conditional registrations, and their renewal, are meant to be time limited exceptions to the normal requirement that before a pest control product may be sold or used in Canada it must possess a full registration based on meeting all statutory information requirements.

In this regard, under section 8 of the Act, if the Minister considers the health and environmental risks and the value of the pest control product acceptable, after any required evaluations and consultations have been completed, the Minister is required to register the product in accordance with the regulations including specifying a period for which the registration is valid. Under the

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[1] Section 4(2)(a) adopts the internationally recognized definition for sustainable development as enabling the needs of the present to be met without compromising the ability of future generations to meet their own needs.
[2] Section 20(2) adopts the internationally recognized definition for the precautionary principle that: "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent adverse health impact or environmental degradation".

Pest Control Product Regulations, SOR/2006-124, the normal period of registration for a product is five years (s. 13). However, pursuant to section 14(1)(a) of the regulations, if a ministerial notice is delivered to the registrant under section 12 of the Act when a pest control product is registered, the registration becomes a conditional registration and is valid for a period of only three years. A section 12 notice from the Minister may require the registrant to "compile information, conduct tests and monitor experience with the pest control product for the purpose of obtaining additional information with respect to its effects on human health and safety or the environment or with respect to its value" and report this information to the Minister in the time specified in the notice.

A conditional registration may be extended for two years if the requirements of the section 12 notice are complied with. A conditional registration may also be extended for a period sufficient to allow the completion of a ministerial consultation with federal and provincial government departments and agencies under section 28 of the Act. A renewal of a conditional registration (the situation here) is authorized by section 16 of the regulations and is accompanied by a new notice pursuant to section 12 of the Act. Under section 16(2) of the regulations, the validity period for a renewed conditional registration is governed by section 14(1(a) of the regulations (i.e. three years).

Accordingly, a registrant in possession of a conditional registration that is renewed could maintain that status for approximately six years. A registrant in possession of a conditional registration that is extended and then renewed could maintain that status for at least eight years. By definition, a conditional registration signifies that the government lacks a full data package of information on the health, environmental, or safety effects, or efficacy of a product that would otherwise justify a full registration.

C. Notice of Objection

Where the Minister grants an application for registration for a pest control product under the Act, (or in this case renews a conditional registration), any person may file with the Minister a notice of objection to the decision pursuant to section 35(1) of the Act.

Pursuant to section 35(1), the Objectors file this Notice of Objection because the Decision is contrary to the Act's primary objective of preventing unacceptable risks to the environment as it unreasonably renews until December 2015 the conditional registration of clothianidin and pest control products containing clothianidin that (1) have lacked for some considerable period of time key information about environmental effects on bees, and (2) produce unacceptable environmental effects on bees based upon currently available information. The evidence to support, and the scientific basis for, this Notice of Objection follow.

III. SCIENTIFIC AND REGULATORY SITUATION RESPECTING CLOTHIANIDIN INTERNATIONALLY AND IN CANADA

A. International Situation

The Decision, which is identified in the registration decision document as a decision of the Pest Management Regulatory Agency ("PMRA") to grant a renewal of the conditional registration for the sale and certain uses of clothianidin in Canada,[3] comes at a time when the international scientific community is becoming increasingly concerned about the potential impact on bee populations of the neonicotinoid class of insecticides, of which clothianidin is a member.[4] While the evidence in support of, and scientific basis for, the Objectors' Notice of Objection is set out below and further illustrated in Appendices C and D herein, the following summary from just one recent peer-reviewed scientific paper captures the essence of international scientific concern:

> (1) Neonicotinoids are now the most widely used insecticides in the world. They act systemically, travelling through plant tissues and protecting all parts of the crop, and are widely applied as seed dressings. As neurotoxins with high toxicity to most arthropods, they provide effective pest control and have numerous uses in arable farming and horticulture;
>
> (2) However, the prophylactic use of broad-spectrum pesticides goes against the long-established principles of integrated pest management (IPM), leading to environmental concerns;
>
> (3) It has recently emerged that neonicotinoids can persist and accumulate in soils. They are water soluble and prone to leaching in waterways. Being systemic, they are found in nectar and pollen of treated crops. Reported levels in soils, waterways, field margin plants and floral resources overlap substantially with concentrations that are sufficient to control pests in crops, and commonly exceed the LC50 (the concentration which kills 50% of individuals) for beneficial organisms. Concentrations in nectar and pollen in crops are sufficient to impact substantially on colony reproduction in bumblebees;
>
> (4) Although vertebrates are less susceptible than arthropods, consumption of small numbers of dressed seeds offers a route to direct mortality in birds and mammals; and
>
> (5) Major knowledge gaps remain, but current use of neonicotinoids is likely to be impacting on a broad range of non-target taxa including pollinators and soil and aquatic invertebrates and hence threatens a range of ecosystem services.[5]

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[3] Health Canada, Clutch 50 WDG, Arena 50 WDG and Clothianidin Insecticides, Registration Decision RD2013-14 (Ottawa: PMRA, July 23, 2013) at 1 [hereinafter the "Decision"].

[4] See, for example, European Food Safety Authority, Conclusion on the peer review of the pesticide risk assessment for bees for the active substance clothianidin, *EFSA Journal* 2013, 11(1): 3066 [58 pp] doi:10.2903/j.efsa.2013.3066 (several data gaps were identified 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 authorized uses as seed treatment and granules; the risk assessment for pollinators other than honey bees, the risk assessment following exposure to insect honey dew and the risk assessment from exposure to succeeding crops could not be finalized on the basis of the available information; a high risk was indicated or could not be excluded in relation to certain aspects of the risk assessment for honey bees for some of the authorized uses; for some exposure routes it was possible to identify a low risk for some of the authorized uses).

[5] Dave Goulson, "An overview of the environmental risks posed by neonicotinoid insecticides", Journal of Applied Ecology 2013, Vol. 50, pages 977-987.

The international regulatory community also is becoming concerned and some multi-national agencies are taking action as recently evidenced in the decision of the European Commission, based on the findings of the European Food Safety Authority noted above, to restrict the sale and use for two years commencing December 1, 2013 of three neonicotinoid pesticides (one of them being clothianidin) on many, though not all, crops for which they are currently approved.[6] The scope of the restrictions to be imposed by the European Commission to protect bees is quite extensive,[7] though the restrictions are now the subject of litigation initiated by the manufacturers of neconicotinoid insecticides.

B. The Situation in Canada

1. The Registration Decision of July 23, 2013 ("Decision")

In contrast to what the European Commission has decided Canada has issued a renewal of the conditional registrations for clothianidin technical active, and three pest control products using it in foliar treatment applications (the Decision). The rationale provided in the Decision for this course of action is that "An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment".[8]

However, even the Decision document itself acknowledges that:

> "Clothianidin is largely stable in the environment…it will…not evaporate from soil or water. Field dissipation studies confirm clothianidin's persistence and…they show that a fraction of the applied active ingredient can remain in the top soil layers. Clothianidin is a systemic pesticide and can be absorbed from soil and transferred by plants into pollen and nectar.
>
> Clothianidin is highly toxic to bees and mammals and moderately toxic to birds. In water, it is very highly toxic to aquatic invertebrates, but only slightly toxic to fish.

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[6] European Commission, Press Release, "Bee-Health: EU-wide restrictions on pesticide use enter into force on 1 December" (Brussels: Europa, May 24, 2013). See also European Commission, Implementing Regulation (EU) No. 485/2013 amending Implementing Regulation (EU) No. 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances. Annex 1 to the regulation, pertaining to clothianidin, notes that the restriction applies to seed, soil, and foliar treatments for the crops listed in the regulation.

[7] European Commission, Implementing Regulation, *supra* note 5 at preamble 11(in order to minimize the exposure of bees it is appropriate to restrict the uses of clothianidin [and two other neonicotinoids], to provide for specific risk mitigation measures for the protection of bees, and to limit the use of plant protection products containing clothianidin [and two other neonicotinoids] to professional users; the uses as seed and soil treatment of plant protection products containing clothianidin [and two other neonicotinoids] should be prohibited for crops attractive to bees and for cereals except for uses in greenhouses and for winter cereals; foliar treatments with plant protection products containing clothianidin [and two other neonicotinoids] should be prohibited for crops attractive to bees and for cereals with the exception of uses in greenhouses and uses after flowering; crops that are harvested before flowering are not considered attractive to bees), preamble 14 (the use and the placing on the market of seeds treated with plant protection products containing clothianidin [and two other neonicotinoids] should be prohibited for seeds of crops attractive to bees and for seeds of cereals except for winter cereals used in greenhouses), and Article 2 (seeds of crops listed in Annex II which have been treated with plant protection products containing clothianidin [and two other neonicotinoids] shall not be used or placed on the market with the exception of seeds used in greenhouses).

[8] Decision, *supra* note 3 at 1.

> Because clothianidin is systemic, persistent and highly toxic to honey bees, the PMRA has requested additional data to fully assess the potential effects of chronic exposure of this pesticide, resulting from its potential movement into plant tissues and secretions such as pollen and nectar."[9]

The Decision notes, no doubt because of the above concerns, that PMRA has initiated a re-evaluation of clothianidin and other neonicotinoid insecticides that will focus on potential effects on pollinators and will include consideration of all new scientific evidence.[10]

The "key risk-reduction measures" identified in the Decision to protect the environment are described as follows:

> "Hazard statements are required for toxicity to aquatic organisms, wild mammals, bees and other beneficial insects with associated precautionary measures. Buffer zones are required to mitigate the risk to aquatic organisms. Precautionary measures are also required to address concerns related to carryover, runoff and leaching".[11]

Yet the Decision also acknowledges that: "Although the risks and value have been found acceptable when all risk-reduction measures are followed, the applicant must submit additional scientific information as a condition of registration…by December 2015".[12] In this regard, the additional scientific information to be provided by that date is as follows:

- Lysimeter study conducted in coarse textured soil with a water dispersible granule (WDG) formulation;
- Study of behaviour and fate of clothianidin in plants, including determination of concentrations in nectar and pollen;
- Hive study designed to assess the chronic toxicity of clothianidin to bees.[13]

It would appear that the above studies will play a role in the re-evaluation of clothianidin that is now underway. However, as noted below, the re-evaluation is not expected to be completed before 2017 or 2018.

2. The Position of the Objectors is that the Decision Should be Referred to a Review Panel Pursuant to Section 35(3) of the Act

For the reasons set out in this Notice of Objection, including in the material contained in Appendices C and D, the Objectors submit that the:

- Decision as it relates to clothianidin pest control products was unreasonable because key environmental effects data have been lacking for some time, and will not be

[9] *Ibid* at 4.
[10] *Ibid* at 5.
[11] *Ibid* at 6.
[12] *Ibid*.
[13] *Ibid*.

required to be submitted until December 2015 while the products remain available for sale and use in Canada;

- Decision as it relates to clothianidin technical insecticide was unreasonable because PMRA has been requesting since 2004 but may lack until December 2015, a valid study on the chronic toxicity of the insecticide to bees. This continuing information gap and correspondingly lengthy period of scientific uncertainty respecting whether the insecticide causes chronic toxic effects to bees casts doubt on whether the Minister could be said to have minimized environmental risks posed by clothianidin, as required by section 4(2)(b) of the Act. Accordingly, it was unreasonable in the circumstances to decide to renew the conditional registration for clothianidin in the face of this long-standing critical information gap; and

- available information on the effects of clothianidin on bees also suggests the unreasonableness of the Decision and supports, in its own right, the Notice of Objection.

The Objectors submit that as required by section 3 of the *Review Panel Regulations*, SOR/2008-22, the material set out in this Notice of Objection (1) raises scientifically founded doubt as to the validity of the evaluations on which the Decision was based respecting environmental risks of clothianidin to bees, and (2) suggests that the advice of expert scientists would assist in addressing the subject matter of the objection.

Accordingly, the establishment of a review panel pursuant to section 35(3) of the Act to review the Decision and recommend whether it should be confirmed, reversed, or varied, would appear warranted.

3. Canada's Reasons for not following the European Commission are not Persuasive

Three reasons advanced by Canada for not pursuing a ban on the use of neonicotinoids were set out by PMRA at May 2013 hearings before a committee of Parliament. When asked what could be the unintended consequences of a possible ban the PMRA witness stated as follows:

> "…First is the level of confidence the public as well as their stakeholders will have in the regulatory system in Canada, which is a significant unintended consequence. If we move too quickly to take regulatory action without the scientific weight of evidence to support those decisions, our credibility is diminished significantly. Right now, we are considered a world leader in terms of pesticide regulation.
>
> Second…the registrants require some level of predictability in the regulatory process. Again, to take action without the weight of evidence leaves the registrants questioning whether $100 million invested in developing a pesticide and bringing it to market is a good investment when it's not an outcome, if the way decisions are going to be made at the regulatory level isn't predictable.
>
> Third…in terms of crop production and the agricultural sector, the neonicotinoids are a very heavily relied upon group of chemicals. They have replaced some of the more, I would say, nasty chemicals that were registered before them, which were much more broadly toxic to a much wider variety of organisms as well

> as people. There is the possibility that getting rid of them and using more of these other chemicals, which have not been banned, may make – "[14]

The Objectors submit that the PMRA reasons for not implementing a ban, as given in testimony to the parliamentary committee, are not persuasive for several reasons. First, public confidence in Canada's regulatory system will be undermined if Canada moves too slowly – as we suggest is the case here – to obtain the scientific information necessary to fill long-outstanding gaps in understanding environmental impacts to bees. Moreover, failing to move quickly during a lengthy re-evaluation process may be contrary to the precautionary principle, enshrined in section 20(2) of the Act, which prohibits PMRA from relying on a lack of scientific certainty in postponing cost-effective measures to prevent environmental degradation.

Second, the *PCPA* places the burden of persuasion on the registrants, not the Minister, that environmental risks from a pest control product are acceptable, something that is difficult, if not impossible, for registrants to demonstrate in the face of vital gaps in information.

Third, it is not simply a question of moving from one chemical to another to find a solution because the *PCPA* recognizes that environmental risks posed by pest control products must be minimized and alternative, non-toxic, approaches encouraged. Indeed, the movement away from older, often highly toxic and persistent pesticides has not occurred with the worldwide movement towards registration and heavy use of neonicotinoid pesticides. Rather, this newer class of pesticides renews the approach of using chemicals that act systemically and that are highly persistent in the environment. These are two highly problematic features of pesticides that historical circumstances ought to have taught both pesticide manufacturers and regulatory agencies to avoid.

4. Long-Standing Information Gaps Exist With Respect to Environmental Effects

Despite the above statement to the parliamentary committee, PMRA recognizes the essential role played by bees in food production, the highly acute and oral toxicity of clothianidin to bees, and the information gaps with respect to its chronic toxicity and other effects on bees:

> "Bees play an essential role in crop production and, during bloom, orchards also attract a wide variety of wild pollinators. Clothianidin is highly toxic to honey bees on both acute contact and oral basis, and severe losses may be expected if it is used at the maximum application rate in orchards (210 mg a.i./ha) when bees are present at treatment time or within a few days thereafter (Appendix I, Table 14). Furthermore, because clothianidin is a persistent insecticide, the potential for chronic effects of exposure to residues translocated to plant tissues and secretions consumed by pollinators is of potential concern. Studies are therefore required to fully evaluate exposure scenarios linked with the translocation of clothianidin in treated plants and the potential for chronic effects of clothianidin to honey bee[s]".[15]

Yet, PMRA officials testifying before the parliamentary committee in May 2013 placed the regulatory situation respecting neonicotinoids in the wider context of an on-going re-evaluation

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[14] *House of Commons*, Standing Committee on Agriculture and Agri-Food, No. 80 (9 May 2013) (S. Kirby, Director, Environmental Assessment Directorate, PMRA, Health Canada).

[15] Health Canada, Clutch 50 WDG, Arena 50 WDG and Clothianidin Insecticides, Evaluation Report ERC2011-11 (Ottawa: PMRA, May 11, 2011) at 18.

of the insecticides under the *PCPA* that could last until 2017 or 2018 in order to fill information gaps:

> "That whole class of insecticides is being re-evaluated. We're doing that jointly with the United States Environmental Protection Agency. A data call-in has been issued on some of them. We have looked at the information that we have at hand. We've identified gaps in the information, and we are requiring the registrants to produce the information to fill those gaps. That step takes time. The registrants have to be able to generate that data. Depending on the type of study, it could take up to two years to generate data and submit it. Then our scientists would look at that. You're talking years to come to a finite conclusion.
> …
>
> I think the target is 2017 or 2018, but as I said, that is for the completion of the re-evaluation. Because this data is coming in at any time and we're reviewing it as it comes in, we can take action if we see something that is of concern".[16]

However, the PMRA testimony suggesting the need for approximately two years for registrants to generate information to fill data gaps plus additional time for PMRA to review that information must be understood in the context of how long it has been since the agency first began asking registrants for certain data. For example, and as noted above, because clothianidin is now, and has been, under a conditional registration the registrants would have been subject to a section 12 notice to provide additional information to the Minister. The Decision notes what the current obligations are on the registrants respecting the submission of additional information. As noted above, these include the submission of the following information by December 2015:

- a lysimeter study conducted in coarse textured soil with a water dispersible granule (WDG) formulation;
- a study of behaviour and fate of clothianidin in plants, including determination of concentrations in nectar and pollen; and
- a hive study designed to assess the chronic toxicity of clothianidin to bees.[17]

It is important to note though that it would appear from a review of the May 11, 2011 Health Canada Evaluation Report (ERC2011-11) on clothianidin that these same studies were originally to have been submitted by the end of September 2012 (page 26). Moreover, the Decision is a renewal of a conditional registration. Therefore, the three pest control products containing clothianidin at issue, have been under conditional registration for a long time[18] while lacking a full data package of information on environmental effects. By the time of the now December 2015 deadline for submission of the above referred to studies, it is possible that the three pest control products containing clothianidin will have been on the market over six years while environmental information has been lacking.

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[16] *House of Commons*, Standing Committee on Agriculture and Agri-Food, No. 80 (9 May 2013) (S. Kirby, Director, Environmental Assessment Directorate, PMRA, Health Canada).
[17] Decision, *supra* note 3 at 6.
[18] The three pest control products containing clothianidin that are the subject of this Notice of Objection have been registered for commercial use in Canada since October 2009. See Health Canada Pest Management Regulatory Agency, Clutch 50 WDG, Arena 50 WDG and Clothianidin Insecticides, Proposed Registration Decision PRD2012-24 (Ottawa: PMRA, November 26, 2012) at 1.

There is one other piece of relevant regulatory history applicable to clothianidin in Canada that underscores the existence of long-standing information gaps on environmental effects respecting bees. The active ingredient, clothianidin, was issued a temporary registration in September 2004 pursuant to section 17 of the former regulations (*PCP Regulations*, C.R.C. 1253, repealed in 2006 when the current version of the regulations came into force), along with a pest control product (seed treatment containing clothianidin). Under section 17 of the former regulations, a temporary registration could be issued where the applicant/registrant agreed to produce additional scientific or technical information or where the pesticide was to be sold "only for emergency control of infestations that are seriously detrimental to public health, domestic animals, natural resources or other things". The 2004 decision noted that technical grade clothianidin and the associated end-use product were granted temporary registration subject to the submission of the following data:

- batch data;
- storage stability data (product chemistry);
- genotoxicity studies;
- developmental immunotoxicity studies;
- passive dosimetry or biological monitoring study;
- field crop rotation study;
- analytical methodology for sediment;
- long-term hydrolysis study;
- leaching study;
- acute oral toxicity to bumblebees and leaf-cutter bees;
- chronic oral toxicity to hives of honey bees under field conditions;
- acute oral toxicity to the red-winged blackbird, house sparrow and mallard duck;
- toxicity to wild birds under field use conditions.[19]

While it is not clear whether the currently required lysimeter study in coarse textured soil, or plant behaviour and fate study, bear any resemblance to any of the studies required in 2004 (e.g. passive dosimetry or biological monitoring study, long-term hydrolysis, or leaching studies), the chronic toxicity study to honey bee hives does bear closer scrutiny. The following Table 1 sets out the history of deadlines with respect to production of this particular category of study:

[19] Health Canada Pest Management Regulatory Agency, Clothianidin Poncho 600 Seed Treatment Insecticide, Regulatory Note Reg2004-06 revision (Ottawa: PMRA, September 21, 2004) at 48.

Table 1: History of Deadlines Set By Health Canada-Pest Management Regulatory Agency (PMRA) for Production of Chronic Toxicity Honey Bee Hive Study by Clothianidin Registrants – 2004-2015

Name of Health Canada-PMRA Document	Registrant	How Study Requirement Characterized in Document/Page	Date Document Issued	Deadline Set by Health Canada-PMRA in Document for Production of Study
Regulatory Note - Clothianidin Poncho 600 Seed Treatment Insecticide	Sumitomo Chemical Takeda Agro Company, Ltd.;Bayer Cropscience Inc.	Chronic oral toxicity to hives of honey bees under field conditions/48	September 21, 2004	No deadline identified. Study submitted in 2007 but being repeated.
Evaluation Report – Clutch 50 WDG, Arena 50 WDG and Clothianidin Insecticides	Sumitomo Chemical Company, Limited; Valent Canada, Inc.	A hive study designed to assess the chronic toxicity of clothianidin to bees/26	May 19, 2011	September 30, 2012
Proposed Registration Decision – Clutch 50 WDG, Arena 50 WDG and Clothianidin Insecticides	Sumitomo Chemical Company, Limited; Valent Canada, Inc.	A hive study designed to assess the chronic toxicity of clothianidin to bees/7	November 26, 2012	December 2015
Registration Decision – Clutch 50 WDG, Arena 50 WDG and Clothianidin Insecticides	Sumitomo Chemical Company, Limited; Valent Canada, Inc.	A hive study designed to assess the chronic toxicity of clothianidin to bees/6	July 23, 2013	December 2015

On its face, Table 1 suggests that production of a valid chronic toxicity study on bees for the active ingredient clothianidin has been outstanding for a very long time. However, the government has continued to issue registrations of various types allowing clothianidin to be sold and used in various pest control products in Canada. In the case of this particular category of study, by the time the now December 2015 deadline for submission of the chronic toxicity bee hive study arrives, clothianidin will have been registered in Canada for well over a decade while this environmental information has been lacking.[20] Put simply, this approach puts bees and pollinators at unacceptable risk.

If this is the regulatory state of affairs in respect of this pesticide in 2013, then this is reminiscent of concerns identified in the late 1980s in a report prepared for the Law Reform Commission of Canada regarding gaps in the application of federal pesticide law of the day. The LRC report noted that the 1969 version of what is now the *PCPA* authorized departures from the meeting of full information requirements for registration (e.g. less-than-complete data and testing in the context of research permits and temporary registrations) that were meant to meet legitimate

[20] Pest Management Regulatory Agency registration label information indicates that clothianidin technical insecticide was registered on December 24, 2003 to the Sumitomo Chemical Company, Limited, registration number 27445. Clothianidin technical insecticide is one of the insecticides identified in the July 23, 2013 registration decision that is the subject of this Notice of Objection.

objectives such as the development and assessment of new pest control products, or controlling emergency pest infestations. However, the report noted that this approach could easily fall prey to abuse if allowed to persist over long periods of time while full environmental, health, and safety data remained lacking. The report also noted that the situation was much the same in the United States where explicit authority for conditional registrations existed but where it was clear that only possession of a full (not merely a conditional) registration under U.S. federal pesticide law ensured that the complete range of environmental, health, and safety test requirements had been met prior to issuance of a registration for a pesticide.[21]

5. Available Information Suggests Unacceptable Environmental Risks to Bees

While it is apparent that there are many key gaps in the information respecting the environmental effects of clothianidin on bees, and that some of these gaps are long-standing, the available information nonetheless also suggest problems. Some of these are set out below.

There are numerous unacceptable, harmful effects on bees and other pollinators, and on the ecosystem services that they provide. These effects are of serious concern to the Objectors, and include:

- acute, chronic and sub-chronic toxicity;
    - sub-lethal effects such as metabolic, immune, and reproductive impairments;
    - disruption of foraging and homing behaviour;
    - diminished colony reproductive performance;
    - effects on agricultural food production and wild plant reproduction from the loss of pollination service;
    - uncertainty with respect to transmission or exposure pathways (e.g. guttation fluids, nectar and pollen, dust and water);
    - on-going exposure concerns resulting from chemical persistence in soil and water; and
    - ineffectiveness of risk management measures.

Some of these are discussed above as well as in the material contained in Appendices C and D to this Notice of Objection.

i. Toxic Effects

A review prepared for the Objectors by Dr. Mark Chernaik, a biochemist, shows that 90 per cent of peer-reviewed scientific studies published in the last three years (2011-2013) relating to the effects of neonicotinoid insecticides on pollinators demonstrate adverse impacts at field-realistic levels of these insecticides, or in actual field experiments, constituting reasonable grounds to

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[21] J.F. Castrilli and T. Vigod, Pesticides in Canada: An Examination of Federal Law and Policy – Law Reform Commission of Canada Protection of Life Series Study Paper (Ottawa: LRC, 1987) at 61-65.

believe that the environmental risks of clothianidin are not acceptable. See Appendix C of this Notice of Objection for this review.

ii. Exposure Pathways

A second review prepared for the Objectors by Dr. Ralph V. Cartar, a bee ecologist, shows that better information on exposure pathways and impacts on bees is necessary before renewal of a conditional registration for systemic neonicotinoids is allowed. See Appendix D of this Notice of Objection for this review.

IV. SUMMARY OF OBJECTORS' OVERALL POSITION IN SUPPORT OF SECTION 35(1) NOTICE OF OBJECTION

The Objectors submit that the Decision as it relates to the clothianidin pest control products was unreasonable because key environmental effects data have been lacking for some time, and will not be required to be submitted until December 2015 while the products remain available for sale and use in Canada.

Furthermore, the Objectors submit that Decision as it relates to clothianidin technical insecticide was unreasonable because PMRA has been requesting since 2004 but may lack until December 2015, a valid study on the chronic toxicity of the insecticide to bees. This continuing information gap and correspondingly lengthy period of scientific uncertainty respecting whether the insecticide causes chronic toxic effects to bees casts doubt on whether the Minister could be said to have minimized environmental risks posed by clothianidin, as required by section 4(2)(b) of the Act. Accordingly, it was unreasonable in the circumstances to decide to renew the conditional registration for clothianidin in the face of this long-standing critical information gap.

Finally, the Objectors submit that the available information on clothianidin also suggests the unreasonableness of the Decision and supports, in its own right, the Notice of Objection.

Yours truly,

Joseph F. Castrilli
Counsel for Sierra Club Canada

Lara Tessaro
Counsel for David Suzuki Foundation,
Western Canada Wilderness Committee,
and Équiterre

c.c. John Bennett, Sierra Club Canada
c.c. Mara Kerry, David Suzuki Foundation
c.c. Joe Foy, Western Canada Wilderness Committee
c.c. Sidney Ribaux, Équiterre

and to:

< richard.aucoin@hc-sc.gc.ca >
Richard Aucoin
Executive Director
Pest Management Regulatory Agency
Postal Locator: 6606E
2720 Riverside Drive
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APPENDIX A

NOTICE OF OBJECTION FORMS FILED BY SIERRA CLUB CANADA, DAVID SUZUKI FOUNDATION, WESTERN CANADA WILDERNESS COMMITTEE, AND ÉQUITERRE PURSUANT TO SECTION 35(1) OF THE PEST CONTROL PRODUCTS ACT

Health Canada / Santé Canada

Notice of Objection to a Registration Decision under Subsection 35(1) of the *Pest Control Products Act*

Avis d'opposition à une décision d'homologation en vertu du paragraphe 35(1) de la Loi sur les produits antiparasitaires

Date received – Date reçue

Submission No. - N° de la demande

1. Objector Information – Information sur l'opposant

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Sierra Club Canada

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613 241 4611	613 241 2292	jb@sierriaclub.ca	

2. Product Information – Information sur le produit*

Name of active ingredient to which the decision relates – Nom de la matière active à laquelle la décision se rapporte*
CLOTHIANIDIN

Name of end-use product to which the decision relates – Nom de la préparation commerciale à laquelle la décision se rapporte*
CLUTCH 50WDG; ARENA 50WDG; CLOTHIANIDIN INSECTICIDES RD2013-14

3. Registration decision to which the objection relates – Décision d'homologation pour laquelle vous déposez un avis d'opposition*

Decision on application – Décision concernant la demande

- [X] Granting registration – Homologation accordée
- [ ] Denying registration – Homologation rejetée
- [ ] Granting an amendment of a registration – Modification à l'homologation accordée
- [ ] Denying an amendment of a registration – Modification à l'homologation rejetée

Decisions on re-evaluation or special review – Décision concernant la réévaluation ou l'examen spécial

- [ ] Confirming registration – Homologation confirmée
- [ ] Cancelling registration – Homologation annulée
- [ ] Amending registration – Modification à une homologation

4. Date the decision statement was made public – Date de la publication de l'énoncé de décision*

July 23, 2013

5. Area of scientific evaluation to which the objection relates – Volet de l'évaluation scientifique touché par l'avis d'opposition*

- [ ] Health risk assessment (toxicology, food residue, occupational exposure) – Évaluation des risques pour la santé (toxicologie, résidus dans les aliments, exposition professionnelle)
- [X] Environmental risk assessment (environmental fate, environmental toxicology) – Évaluation des risques pour l'environnement (devenir dans l'environnement, écotoxicologie)- **Environmental; Fate and Toxicology**
- [ ] Value and efficacy assessments (crop tolerance, value) – Évaluation de la valeur et de l'efficacité (tolérance des cultures, valeur)

6. Scientific basis for the objection – Fondement scientifique de l'opposition*

Attachment included? – Pièce jointe inclse?	Yes – Oui X	No – Non

7. Signature of objector or representative – Signature de l'opposant ou de son représentant	Printed Name – Nom en lettres moulées*	Date*
[signature]	John M Bennett	Sept 6, 2013

Objectors who submit confidential information (i.e., confidential business information, confidential test data) are responsible for identifying this information which is part of their submission.

Health Canada / Santé Canada

Notice of Objection to a Registration Decision under Subsection 35(1) of the *Pest Control Products Act*

Avis d'opposition à une décision d'homologation en vertu du paragraphe 35(1) de la Loi sur les produits antiparasitaires

Date received – Date reçue
Submission No. - N° de la demande

1. Objector Information – Information sur l'opposant

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Mara Kerry, David Suzuki Foundation

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2. Product Information – Information sur le produit*

Name of active ingredient to which the decision relates – Nom de la matière active à laquelle la décision se rapporte*
Clothianidin

Name of end-use product to which the decision relates – Nom de la préparation commerciale à laquelle la décision se rapporte*
Clutch 50 WDG; Arena 50 WDG; Clothianidin insecticides

3. Registration decision to which the objection relates – Décision d'homologation pour laquelle vous déposez un avis d'opposition*

Decision on application – Décision concernant la demande

- [X] Granting registration – Homologation accordée **RD 2013-14**
- [ ] Denying registration – Homologation rejetée
- [ ] Granting an amendment of a registration – Modification à l'homologation accordée
- [ ] Denying an amendment of a registration – Modification à l'homologation rejetée

Decisions on re-evaluation or special review – Décision concernant la réévaluation ou l'examen spécial

- [ ] Confirming registration – Homologation confirmée
- [ ] Cancelling registration – Homologation annulée
- [ ] Amending registration – Modification à une homologation

4. Date the decision statement was made public – Date de la publication de l'énoncé de décision*

July 23, 2013

5. Area of scientific evaluation to which the objection relates – Volet de l'évaluation scientifique touché par l'avis d'opposition*

- [ ] Health risk assessment (toxicology, food residue, occupational exposure) – Évaluation des risques pour la santé (toxicologie, résidus dans les aliments, exposition professionnelle)
- [X] Environmental risk assessment (environmental fate, environmental toxicology) – Évaluation des risques pour l'environnement (devenir dans l'environnement, écotoxicologie) **Envirionmental Fate and Toxicology**
- [ ] Value and efficacy assessments (crop tolerance, value) – Évaluation de la valeur et de l'efficacité (tolérance des cultures, valeur)

6. Scientific basis for the objection – Fondement scientifique de l'opposition*

Attachment included? – Pièce jointe inclse? X Yes – Oui   No – Non

7. Signature of objector or representative – Signature de l'opposant ou de son représentant	Printed Name – Nom en lettres moulées*	Date*
[signature]	Mara Kerry	Sept 12,2013

Objectors who submit confidential information (i.e., confidential business information, confidential test data) are responsible for identifying this information which is part of their submission.

Health Canada / Santé Canada

Notice of Objection to a Registration Decision under Subsection 35(1) of the *Pest Control Products Act*

Avis d'opposition à une décision d'homologation en vertu du paragraphe 35(1) de la Loi sur les produits antiparasitaires

Date received – Date reçue	
Submission No. - N° de la demande	

1. Objector Information – Information sur l'opposant

Name – Nom / Corporation – société / Organization – organisation*
Joe Foy -- Western Canada Wilderness Committee

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2. Product Information – Information sur le produit*

Name of active ingredient to which the decision relates – Nom de la matière active à laquelle la décision se rapporte*
Clothianidin

Name of end-use product to which the decision relates – Nom de la préparation commerciale à laquelle la décision se rapporte*
Clutch 50 WDG; Arean 50 WDG; Clothianidin insecticides

3. Registration decision to which the objection relates – Décision d'homologation pour laquelle vous déposez un avis d'opposition*

Decision on application – Décision concernant la demande

- [X] Granting registration – Homologation accordée **(RD 2013-14)**
- [ ] Denying registration – Homologation rejetée
- [ ] Granting an amendment of a registration – Modification à l'homologation accordée
- [ ] Denying an amendment of a registration – Modification à l'homologation rejetée

Decisions on re-evaluation or special review – Décision concernant la réévaluation ou l'examen spécial

- [ ] Confirming registration – Homologation confirmée
- [ ] Cancelling registration – Homologation annulée
- [ ] Amending registration – Modification à une homologation

4. Date the decision statement was made public – Date de la publication de l'énoncé de décision*

July 23, 2013

5. Area of scientific evaluation to which the objection relates – Volet de l'évaluation scientifique touché par l'avis d'opposition*

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- [X] Environmental risk assessment (environmental fate, environmental toxicology) – Évaluation des risques pour l'environnement (devenir dans l'environnement, écotoxicologie)
- [ ] Value and efficacy assessments (crop tolerance, value) – Évaluation de la valeur et de l'efficacité (tolérance des cultures, valeur)

6. Scientific basis for the objection – Fondement scientifique de l'opposition*

Attachment included? – Pièce jointe inclse?	X Yes – Oui	No – Non

7. Signature of objector or representative – Signature de l'opposant ou de son représentant	Printed Name – Nom en lettres moulées*	Date*
[signature]	Joe Foy	Sept. 11, 2013

Objectors who submit confidential information (i.e., confidential business information, confidential test data) are responsible for identifying this information which is part of their submission.

Health Canada / Santé Canada

Date received – Date reçue	
Submission No. - N° de la demande	

Notice of Objection to a Registration Decision under Subsection 35(1) of the *Pest Control Products Act*

Avis d'opposition à une décision d'homologation en vertu du paragraphe 35(1) de la Loi sur les produits antiparasitaires

1. Objector Information – Information sur l'opposant

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2. Product Information – Information sur le produit*

Name of active ingredient to which the decision relates – Nom de la matière active à laquelle la décision se rapporte*
Clothianidin

Name of end-use product to which the decision relates – Nom de la préparation commerciale à laquelle la décision se rapporte*
Clutch 50 wdg; Arena 50 wdg; Clothianidin insecticides.

3. Registration decision to which the objection relates – Décision d'homologation pour laquelle vous déposez un avis d'opposition*

Decision on application – Décision concernant la demande

- [x] Granting registration – Homologation accordée
- [ ] Denying registration – Homologation rejetée
- [ ] Granting an amendment of a registration – Modification à l'homologation accordée
- [ ] Denying an amendment of a registration – Modification à l'homologation rejetée

Decisions on re-evaluation or special review – Décision concernant la réévaluation ou l'examen spécial

- [ ] Confirming registration – Homologation confirmée
- [ ] Cancelling registration – Homologation annulée
- [ ] Amending registration – Modification à une homologation

4. Date the decision statement was made public – Date de la publication de l'énoncé de décision*

July 23, 2013

5. Area of scientific evaluation to which the objection relates – Volet de l'évaluation scientifique touché par l'avis d'opposition*

- [ ] Health risk assessment (toxicology, food residue, occupational exposure) – Évaluation des risques pour la santé (toxicologie, résidus dans les aliments, exposition professionnelle)
- [x] Environmental risk assessment (environmental fate, environmental toxicology) – Évaluation des risques pour l'environnement (devenir dans l'environnement, écotoxicologie) Environmental fate and toxicology
- [ ] Value and efficacy assessments (crop tolerance, value) – Évaluation de la valeur et de l'efficacité (tolérance des cultures, valeur)

6. Scientific basis for the objection – Fondement scientifique de l'opposition*

Attachment included? – Pièce jointe inclse?	Yes – **Oui**	No – Non

7. Signature of objector or representative – Signature de l'opposant ou de son représentant	Printed Name – Nom en lettres moulées*	Date*
[signature]	Sidney Ribaux	September 12, 2013

Objectors who submit confidential information (i.e., confidential business information, confidential test data) are responsible for identifying this information which is part of their submission.

APPENDIX B

REGISTRATION DECISION RD2013-14
CLUTCH 50 WDG, ARENA 50 WDG AND CLOTHIANIDIN INSECTICIDES
23 JULY 2013

Registration Decision RD2013-14

Clutch 50 WDG, Arena 50 WDG and Clothianidin Insecticides

(publié aussi en français)

23 July 2013

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
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Canada

ISSN: 1925-0932 (print)
1925-0940 (online)

Catalogue number: H113-25/2013-14E (print version)
H113-25/2013-14E-PDF (PDF version)

Registration Decision for Clothianidin Insecticide

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting a renewal of the conditional registration for the sale and use of Clothianidin Technical Insecticide, Clutch 50 WDG Insecticide, Arena 50 WDG Insecticide and Clothianidin Insecticide, containing the technical grade active ingredient clothianidin, to control a variety of insects on potato, grape, pome fruits, stone fruits and turf.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2012-24, *Clutch 50 WDG, Arena 50 WDG and Clothianidin Insecticides*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for clothianidin and summarizes the Agency's decision, the reasons for it. The PMRA received no comments on PRD2012-24. This decision is consistent with the proposed registration decision stated in PRD2012-24.

For more details on the information presented in this Registration Decision, please refer to PRD2012-24, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act.*

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act.*

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act.*

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Clothianidin?

Clothianidin is the active ingredient contained in Clothianidin Technical Insecticide, Clutch 50 WDG Insecticide, Arena 50 WDG Insecticide and Clothianidin Insecticide. It is an agricultural insecticide that can be applied to the foliage of plants or in-furrow to control a variety of important insect pests in several crops and turf. Clothianidin is a member of the neonicotinoid group of insecticides.

Health Considerations

Can Approved Uses of Clothianidin Affect Human Health?

Clothianidin is unlikely to affect your health when used according to label directions.

Exposure to clothianidin may occur through the diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when clothianidin products are used according to label directions.

The technical grade active ingredient clothianidin was highly acutely toxic to mice when ingested. Consequently, the statement "Danger Poison" was required on the label for the technical grade active ingredient.

Clothianidin did not cause cancer in laboratory animals and is non-genotoxic. The first signs of toxicity in animals given daily doses of clothianidin over longer periods of time were decreased food consumption, body weights, and body weight gains. Target organs of toxicity included the liver, kidney and reproductive organs, as well as the gastrointestinal tract and immune system.

Clothianidin did not cause birth defects in laboratory animals. There was evidence in animals that the young are more sensitive to the effects of clothianidin than adults. Effects on the young were observed at doses lower than those that caused effects in parental animals. In addition, signs of neurotoxicity were also seen in young animals at dose levels lower than those given to parental animals. Because of these observations, extra protective factors were applied during the risk assessment to further reduce the allowable level of human exposure to clothianidin.

The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and water are not of concern.

The aggregate refined chronic dietary intake estimates (food plus water) revealed that infants, the subpopulation which would ingest the most clothianidin relative to body weight, are expected to be exposed to less than 66% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from exposure to clothianidin residues is not of concern for any of the population subgroups.

A single dose of clothianidin is not likely to cause acute health effects in the general population (including infants and children). An aggregate (food and water) dietary exposure estimate of 31% of the acute reference dose is not considered to be a health concern for any of the population subgroups.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Crop field trials conducted in North American Free Trade Agreement geographical representative regions using the end-use product containing clothianidin in/on grapes, pome fruits and stone fruits were acceptable. The MRLs for this active ingredient can be found in the Science Evaluation of Evaluation Report ERC2011-01, *Clutch 50 WDG, Arena 50 WDG and Clothianidin Insecticides*.

Risks in Residential and Other Non-Occupational Environments

Exposure to the public in treated turfgrass and treated orchard areas is considered acceptable when clothianidin-containing products are used according to label directions.

Exposure of the general population to residues of clothianidin could occur from entering treated residential and municipal turf areas. The postapplication exposure to adults, youths, and children were considered acceptable.

Exposure of the general population to residues of clothianidin from treated orchards could occur by participating in pick-your-own (U-pick) activities for apple, pear, peaches, nectarines, sweet or sour cherries, and plums. The exposures from such activities are considered acceptable for adults, youths, and children.

Occupational Risks from Handling Arena 50 WDG Insecticide, Clutch 50 WDG Insecticide and Clothianidin Insecticide

Occupational risks are not of concern when the end-use products are used according to the label directions, which include protective measures.

Farmers, custom applicators, or professional lawn care operators who mix, load or apply Arena 50 WDG Insecticide, Clutch 50 WDG Insecticide, or Clothianidin Insecticide, as well as field workers re-entering freshly treated turf (including sod farm, golf course, residential, municipal, and industrial sites), crop fields, orchards and vineyards, can come in direct dermal contact with clothianidin residues. Therefore, the label specifies that anyone mixing/loading and applying Arena 50 WDG Insecticide, Clutch 50 WDG Insecticide and Clothianidin Insecticide must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes; and, for aerial application, additional protective equipment of coverall, and goggles or faceshield. The label also requires that workers do not enter treated fields for 12 hours after application. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for handlers and workers, the risk to these individuals is not a concern.

For bystanders, exposure is expected to be much less than that for workers and is not quantified. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Clothianidin Is Introduced Into the Environment?

Clothianidin is largely stable in the environment and could leach to groundwater in certain types of soils. It will, however, not evaporate from soil or water. Field dissipation studies confirm clothianidin’s persistence and, in spite of the predictions for high mobility from laboratory studies, they show that a fraction of the applied active ingredient can remain in the top soil layers. Clothianidin is a systemic pesticide and can be absorbed from soil and transferred by plants into pollen and nectar.

Clothianidin is highly toxic to bees and mammals and moderately toxic to birds. In water, it is very highly toxic to aquatic invertebrates, but only slightly toxic to fish.

Because clothianidin is systemic, persistent and highly toxic to honey bees, the PMRA has requested additional data to fully assess the potential effects of chronic exposure of this pesticide, resulting from its potential movement into plant tissues and secretions such as pollen and nectar.

Additionally, the PMRA has initiated a re-evaluation of clothianidin and the other nitro-guanidine neonicotinoid insecticides (Re-evaluation Note REV2012-02, *Re-evaluation of Neonicotinoid Insecticides*) that will focus on potential effects on pollinators and will include consideration of all new scientific evidence. The PMRA is working with the United States Environmental Protection Agency and other international regulatory partners to develop additional data requirements and enhanced risk assessment methods and to develop and implement risk mitigation measures in a timely manner. Should evidence become available demonstrating reasonable grounds to believe that health or environmental risks of clothianidin are unacceptable, the PMRA will take appropriate regulatory action.

Value Considerations

What Is the Value of Clutch 50 WDG Insecticide, Arena 50 WDG Insecticide and Clothianidin Insecticide?

These end-use products control a variety of important insect pests on turfgrass, potatoes, grapes, and pome and stone fruits.

Sufficient efficacy data were provided to support the three products for the control of a variety of insect pests in potato, pome fruit, stone fruit, grapes and turf. The efficacy data confirmed the lowest effective rate for major pests and the data supported the rates for additional pests. The data support multiple methods of application including in-furrow on potato, foliar on potato, pome fruit, stone fruit, grapes and turf, and aerial application on potatoes.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the labels of Arena 50 WDG Insecticide, Clutch 50 WDG Insecticide or Clothianidin Insecticide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Anyone mixing, loading and applying the end-use products must wear a long-sleeved shirt, long pants, chemical-resistant gloves, and socks and shoes. Aerial applicators must also wear coveralls and goggles or faceshield. No human flaggers are permitted. In addition, precautionary measures are required to protect against drift during application. A 12-hour restricted-entry interval is required for all occupational postapplication tasks. There is no public access to treated areas until sprays have dried.

Environment

Hazard statements are required for toxicity to aquatic organisms, wild mammals, bees and other beneficial insects with associated precautionary measures. Buffer zones are required to mitigate the risk to aquatic organisms. Precautionary measures are also required to address concerns related to carryover, runoff and leaching.

What Additional Scientific Information Is Being Requested?

Although the risks and value have been found acceptable when all risk-reduction measures are followed, the applicant must submit additional scientific information as a condition of registration. More details are presented in the Science Evaluation of Evaluation Report ERC2011-01, *Clutch 50 WDG, Arena 50 WDG and Clothianidin Insecticides* or in the Section 12 Notice associated with the renewal of these conditional registrations. The applicant must submit the following information by December 2015.

Environment

- A lysimeter study conducted in coarse textured soil with a water dispersible granule (WDG) formulation.

- A study of behaviour and fate of clothianidin in plants, including determination of concentrations in nectar and pollen.

- A hive study designed to assess the chronic toxicity of clothianidin to bees.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2012-24, *Clutch 50 WDG, Arena 50 WDG and Clothianidin Insecticides*) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticide and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service.

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[5] As per subsection 35(1) of the *Pest Control Products Act.*

APPENDIX C

REVIEW PREPARED BY
DR. MARK L. CHERNAIK

Lack of Reasonable Certainty that Use of Clothianidin
Will Cause No Harm to the Environment: Unacceptable Risks to Pollinators

Prepared by:

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September 2013

At the request of the Canadian Environmental Law Association and Ecojustice, on behalf of their respective clients Sierra Club Canada, David Suzuki Foundation, Western Canada Wilderness Committee, and Equiterre, I prepared the following expert opinion[1] about the scientific evidence of the effects of neonicotinoids on pollinators as it relates to the decision of the Health Canada-Pest Management Regulatory Agency (PMRA) on 23 July 2013 to renew the conditional registration for the sale and use of clothianidin.

In my opinion, there is a clear lack of reasonable certainty that renewal of this conditional registration will cause no harm to the environment because of the demonstrated effects of neonicotinoids on pollinating insects, including bees.[2]

My opinion is based on **both** the inadequacy of the evidence that apparently PMRA relied on in reaching its decision, and a growing body of evidence from recent, peer-reviewed scientific studies that the PMRA has apparently not taken into account.

What follows below is brief introductory information about the mechanism of action of neonicotinoid insecticides and the vital services pollinators provide, followed by my review of the evidence that PMRA apparently relied on, and followed by my review of recently published original research articles a majority of which contain clear evidence that clothianidin poses unacceptable risks to pollinators.

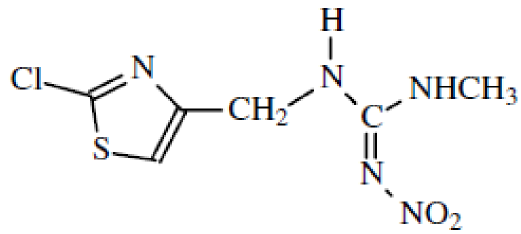
INTRODUCTION

The mechanism of the toxicity of clothianidin (and other neonicotinoid pesticides) is very well understood at a detailed, molecular level: clothianidin [(E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine] binds avidly to the nicotinic (acetylcholine) receptor (nAChR) on the surface of nerve cells in insect brains.[3] Extremely low concentrations of neonicotinoids exert potent effects. For example, neonicotinoids achieve 50% inhibition of nAChR at concentrations of less than 10 nanomoles (10 nM) per liter.[4] Inhibition of nAChR by neonicotinoid pesticides causes continuous, unabated nerve impulse transmission, leading to paralysis and death.

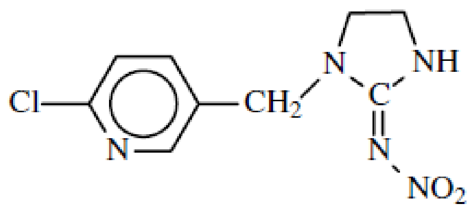
As depicted below, the chemical structure of clothianidin and other neonicotinoid pesticides – including imidacloprid and thiamethoxam – are similar in that they all make a tight, hand-in-glove fit with nAChR. Therefore, studies on the toxicity to bees of other neonicotinoid pesticide (e.g. imidacloprid and thiamethoxam) are directly relevant to the question of the toxicity to bees of clothianidin. In fact, the LD_{50} to the honey bee (*Apis Mellifera*) clothianidin, imidacloprid and

[1] I am grateful to Hayley Langmas and Nathan Toh for their research assistance in support of this report.
[2] Such reasonable certainty is a required finding for the decision made by the PMRA on 23 July 2013 to renew the conditional registration for the sale and use of clothianidin to control a variety of insects on potato, grape, pome fruits, stone fruits and turf. The Registration Decision states: "An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment."
[3] Iwasa, T., Motoyama, N., Ambrose, J. T., & Roe, R. M. (2004). Mechanism for the differential toxicity of neonicotinoid insecticides in the honey bee, *Apis mellifera*. *Crop Protection*, *23*(5), 371-378.
[4] Yamada,T., Takahashi, H., Hatano, R., 1999. A novel insecticide, acetamiprid. In: Yamamoto,I., Casida, J.E. (Eds.), Nicotinoid Insecticides and the Nicotinic Acetylcholine Receptor. Springer, Tokyo,pp. 149–176.

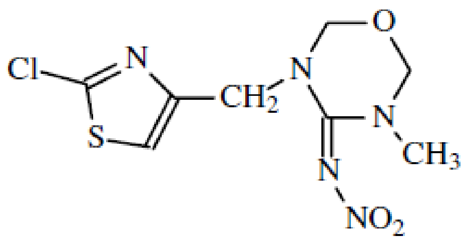
thiamethoxam are nearly identical – 0.022, 0.018 and 0.030 microgram (one-millionth of a gram) per bee, respectively.[5]



clothianidin



imidacloprid



thiamethoxam

Pollinators provide vital ecological and agricultural benefits that cannot be replaced. In a recent summary of the evidence about the effects of neonicotinoid insecticides, these benefits were described as follows:[6]

> "Ecosystem services of pollinators
>
> "Amongst the wide diversity of pollinating species [44], bees are the most important. Although bee research mostly focuses on the domesticated Apis mellifera, over 25,000 different bee species have been identified (FAO: Pollination; URL: http://www.fao.org/agriculture/crops/ core-themes/theme/biodiversity/pollination/en/). Bees provide a vital ecosystem service, playing a key role in the maintenance of biodiversity and in food and fibre production [45–47,48 ,49–51]. Pollination comprises an integrated system of interactions that

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5 Iwasa, et al. (2004), at page 375. To put this in perspective, a 25-kilogram container of Clutch 50 WDG (50% clothianidin) can theoretically deliver a lethal dose of clothianidin to more than 400 billion bees.

6 van der Sluijs, J. P., Simon-Delso, N., Goulson, D., Maxim, L., Bonmatin, J. M., & Belzunces, L. P. (2013). Neonicotinoids, bee disorders and the sustainability of pollinator services. *Current Opinion in Environmental Sustainability*.

links earth's vegetation, wildlife and human welfare [52]. Of all flowering plants on earth, 87.5% benefits from animal pollination [53]. Globally, 87 of the leading food crops (accounting for 35% of the world food production volume) depend on animal pollination [45]. Pollinator mediated crops are of key importance in providing essential nutrients in the human food supply [54]. The history of apiculture goes back to pre-agricultural times [55,56] and later co-developed with agriculture [57,58]. In addition, wild bees deliver a substantial and often unappreciated portion of pollination services to agriculture and wildflowers [59,60]. Bees and apiary products have a harmacological [61,62], scientific and technological [63], poetic [64], aesthetic (springs filled with buzzing bumblebees) culinary (e.g., keeping alive traditional cuisine of patisseries with honey) and cultural value."

EVIDENCE RELIED ON BY PMRA

The Registration Decision states:

> "Because clothianidin is systemic, persistent and highly toxic to honey bees, the PMRA has requested additional data to fully assess the potential effects of chronic exposure of this pesticide, resulting from its potential movement into plant tissues and secretions such as pollen and nectar. ….
>
> "Additionally, the PMRA has initiated a re-evaluation of clothianidin and the other nitroguanidine neonicotinoid insecticides (Re-evaluation Note REV2012-02, Re-evaluation of Neonicotinoid Insecticides) that will focus on potential effects on pollinators and will include consideration of all new scientific evidence. The PMRA is working with the United States Environmental Protection Agency and other international regulatory partners to develop additional data requirements and enhanced risk assessment methods and to develop and implement risk mitigation measures in a timely manner. Should evidence become available demonstrating reasonable grounds to believe that health or environmental risks of clothianidin are unacceptable, the PMRA will take appropriate regulatory action. …
>
> "Although the risks and value have been found acceptable when all risk-reduction measures are followed, the applicant must submit additional scientific information as a condition of registration. More details are presented in the Science Evaluation of Evaluation Report ERC2011-01, Clutch 50 WDG, Arena 50 WDG and Clothianidin Insecticides."

I reviewed Evaluation Report ERC2011-01 and Proposed Registration Decision PRD2012-24. In my opinion, these documents do not present any test data on clothianidin toxicity to pollinators that relates to foliar application of this product, or is not less than 10 years old, or involves anything more than tests on this product's acute toxicity.

Page 18 of the Evaluation Report states:

> "The effects of clothianidin and its relevant transformation products on several terrestrial

> organisms were evaluated during the review of seed treatment uses for this active ingredient. Refer to Regulatory Note REG2004-06, Clothianidin, Poncho 600 Seed Treatment Insecticide for details on the effects of clothianidin on honey bees, birds and mammals. ….”

It highly questionable whether information on the effects of clothianidin for seed treatment uses for this active ingredient is relevant to PMRA’s decision to renew the registration of clothianidin to control a variety of insects on potato, grape, pome fruits, stone fruits and turf, which would only encompass foliar applications of clothianidin. Please see the last section of this report “RELEVANT EVIDENCE NOT CONSIDERED BY PMRA: EFFECTS ON BEES OF NEONICOTINOID DRESSED SEEDS.”

Page 18 of the Evaluation Report further states:

> “Bees play an essential role in crop production and, during bloom, orchards also attract a wide variety of wild pollinators. Clothianidin is highly toxic to honey bees on both acute contact and oral basis, and severe losses may be expected if it is used at the maximum application rate in orchards (210 mg a.i./ha) when bees are present at treatment time or within a few days thereafter (Appendix I, Table 14). Furthermore, because clothianidin is a persistent systemic insecticide, the potential for chronic effects of exposure to residues translocated to plant tissues and secretions consumed by pollinators is of potential concern. Studies are therefore required to fully evaluate exposure scenarios linked with the translocation of clothianidin in treated plants and the potential for chronic effects of clothianidin to honey bee.”

Table 14 (Screening level risk assessment (direct overspray) on non-target species other than birds and mammals) of the Evaluation Report contains only information about the acute toxicity (the 50th percentile lethal dose [LD_{50}]) of clothianidin to honey bees. The acute toxicity of clothianidin is not in dispute. Such data fails to answer the fundamental question of “the potential for chronic effects of exposure to residues translocated to plant tissues and secretions consumed by pollinators.”

The References Section of the Evaluation Report contains the following:

> “A. List of Studies/Information Submitted by Registrant ...
> “3.0 Environment ...
> “PMRA Document Number: 1194190
> “Reference: 1998, TI-435 technical: Acute contact and oral toxicity to honey bees, Data Numbering Code: 9.2.4.2
> “PMRA Document Number: 1194193
> “Reference: 2000, TI-435 metabolite TMG: Acute oral toxicity to honey bees (Apis mellifera), Data Numbering Code: 9.2.4.2
> “PMRA Document Number: 1194194
> “Reference: 2000, TI-435 metabolite MNG: Acute oral toxicity to honey bees (Apis mellifera), Data Numbering Code: 9.2.4.2
> “PMRA Document Number: 1194196
> “Reference: 2000, TI-435 metabolite TZMU: Acute oral toxicity to honey bees (Apis mellifera), Data Numbering Code: 9.2.4.2

"PMRA Document Number: 1194197
"Reference: 2000, TI-435 metabolite TZNG: Acute oral toxicity to honey bees (Apis mellifera), Data Numbering Code: 9.2.4.2

Although the information from these studies is not discussed, it is apparent that such information, again, relates only to the acute toxicity of clothianidin.

The Registration Decision further states:

> "The relevant test data on which the decision is based (as referenced in PRD2012-24, Clutch 50 WDG, Arena 50 WDG and Clothianidin Insecticides) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa)."

Since I was unable to inspect PMRA's Reading Room in a timely manner, I was provided with "Notes from visit to Pesticide Management Regulatory Agency (PMRA) reading room" a Memorandum prepared by Mélanie Cousineau documenting her review of the 'relevant test data on which the decision is based' that is available for public inspection. In addition to the five studies on acute toxicity listed above, the 'relevant test data on which the decision is based' seems also to include seven studies on the environmental fate (e.g. the half-life) of clothianidin in soil and water,[7] none of which were conducted more recently than 2001, and nine studies on the effects of clothianidin for seed treatment uses (including three studies labeled "not used in the decision, as the PMRA deemed the study to be 'invalid' and 'not scientifically sound.'")[8]

Only **two** studies available for public inspection could be fairly considered as relating to the question of the potential for chronic effects of exposure to residues translocated to plant tissues and secretions consumed by pollinators, one of which was labeled not used in the decision, as the

[7] 1194671 (ERC2011-11), Aerobic degradation and metabolism of TI-435 in four soils, 2000; 1194675 (2001-1293), Aerobic degradation and metabolism of TI-435 in six soils. 2000; 1194678 (2001-1293), Photolysis of [guanidine 14C]TI-435 on soil surface, 1999; 1194679 (2001-1293), Degradation of 14C-MNG, degradate of TI-435, in three different soils, 2000 1194681 (2001-1293), Degradation of 14C-TZNG, degradate of TI-435, in three different soils, 2000; 1194690 (2001-1293); (14C)TI-435. Hydrolitic stability; and 1194854 (2001-1294) TI-435 Terrestrial field dissipation study, Ontario, Canada, 1998.

[8] 1194868 (2001-1294), Residues of TI-435 in nectar, blossoms, pollen and honey bees sampled from a summer rape field in Sweden and effects of these residues on foraging honeybees, 1999; 1194869 (2001-1294), Residues of TI-435 in nectar, blossoms, pollen and honey bees sampled from a British summer rape field and effects of these residues on foraging honeybees, 1999; 1194870 (2001-1294), Residues of TI-435 in nectar, blossoms, pollen and honey bees sampled from a French summer rape field and effects of these residues on foraging honeybees. 2000; 1194872 (2001-1294), The impact of Gaucho and TI-435 seed-treated canola on honey bees, Apis mellifera L. 2001; 1194873 (2001-1294), Residue levels of TI-435 FS600 and its relevant metabolites in nectar, blossoms and pollens of summer rape from dressed seeds and effects of those residues on foraging honey bees (test location: Farmland "Laacher Hof") 2001; 1194874 (2001-1294), Residue levels of TI-435 FS600 and its relevant metabolites in nectar, blossoms and pollens of summer rape from dressed seeds and effects of those residues on foraging honey bees (test location: Farmland Höfchen) 2001; 1194876 (2001-1294), Residue levels of TI-435 FS600 and its relevant metabolites in the pollen of maize plants from dressed seeds (test location: Farmland "Laacher Hof") 2001; 1194877 (2001-1294), Residue levels of TI-435 FS600 and its relevant metabolites in the pollen of maize plants from dressed seeds (test location: Farmland Hofchen). 2001, and 1464606 (2007-6051), An investigation of the potential long term impact of clothianidin seed treatment canola on honey bees, Apis mellifera L. 2001. (DACO 9.3.4.3)

PMRA deemed the study to be 'invalid' and 'not scientifically sound.'[9]

The studies on the environmental fate (e.g. the half-life) of clothianidin in soil and water confirm that the half-life of clothianidin in soil is typically greater than a year, meaning that application of clothianidin in the same field as earlier applications will result in significantly higher exposures to bees, a factor not addressed in most studies of the environmental effects of neonicotinoids.

As noted above, the nine studies on the effects of clothianidin for seed treatment uses seems irrelevant to a decision to renew the registration of clothianidin to control a variety of insects on potato, grape, pome fruits, stone fruits and turf, which would only encompass foliar applications of clothianidin. Moreover, none of the nine studies are based on data collected more recently than twelve years ago (2001). Finally, these studies on the effects of clothianidin for seed treatment uses are contradicted by more recent studies showing adverse effects. Please see the last section of this report "RELEVANT EVIDENCE NOT CONSIDERED BY PMRA: EFFECTS ON BEES OF NEONICOTINOID DRESSED SEEDS."

Of the two remaining studies that could fairly be considered as relating to the question of the potential for chronic effects on pollinators, one – "1194871 (2001-1294), Effects of diet (sugar solution) spiked with TI-435 Technical on behaviour and mortality of honey bees (Apis mellifera) and on the weight development of bee colonies under field conditions" – was labeled "not used in the decision, as the PMRA deemed the study to be 'invalid' and 'not scientifically sound.'" The other study is based on data collected more than twelve years ago (2001), and is contradicted by more recent studies showing adverse effects. Please see the following sections of this report.

RELEVANT EVIDENCE NOT CONSIDERED BY PMRA

In my opinion, the Registration Decision could not have evaluated all of the available scientific information because the decision overlooks a growing body of recent evidence in the peer-reviewed scientific literature[10] clearly showing that a decision to allow the use of clothianidin insecticides to control a variety of insects on potato, grape, pome fruits, stone fruits and turf would pose unacceptable risks to pollinators. These recently published original research articles involve either 'field-realistic' levels of exposure to neonicotinoid insecticides or direct field experiments. These recently published original research articles show the following adverse impacts of neonicotinoid insecticides on pollinators:

[9] 1194878 (2001-1294), Effects of TI-435 Technical residues in pollen on the development of small bee colonies and on the behaviour and mortality of honey bees, 2001. 1194871 (2001-1294), Effects of diet (sugar solution) spiked with TI-435 Technical on behaviour and mortality of honey bees (Apis mellifera) and on the weight development of bee colonies under field conditions.

[10] To formulate this opinion, I conducted a search of the peer-reviewed scientific literature for **all** original research articles published in the past three years (2011, 2012 and 2013) relating to the effects of neonicotinoid insecticides on pollinators. I exclude from my search articles that were only reviews or otherwise did not contribute new data to the body of scientific evidence on the effects of neonicotinoids. I made no attempt to exclude original research articles demonstrating no adverse effects. However, a large majority of such studies published in the past three years demonstrates adverse effects of neonicotinoid insecticides on pollinators.

- Direct lethality;
- Reproductive decline
- Impaired foraging and homing behavior;
- Immune suppression, causing increased susceptibility to pathogens; and
- Impaired metabolism

Therefore, consideration of all the new scientific evidence currently available should have led PMRA to conclude that there are already reasonable grounds to believe that the environmental risks of clothianidin are unacceptable.

RELEVANT EVIDENCE NOT CONSIDERED BY PMRA: DIRECT LETHALITY

A study published in 2013 by scientists with the University of Torino confirmed the potent lethality of clothianidin, imidacloprid and thiamethoxam to honey bees, finding only small differences in LD_{50} levels among different honey bee genotypes.[11] The publication states:

> "The results confirm that genetic differences in response to neonicotinoid toxic action exist in the honey bee, as firstly shown by Suchail et al. (2000), but no evident trend can be highlighted either in relation to subspecies or between AOT and ICT tests; additionally, differences were evidenced also between *A. m. ligustica* colonies."

A study published in 2012 by scientists with the Kanazawa University demonstrated the direct lethality of clothianidin and dinotefuran (another neonicotinoid insecticide) to entire honey bee colonies experimentally exposed to low, field-realistic concentrations of both insecticides.[12] This publication states:

> "Eight colonies consisting of about ten-thousand honeybees in each colony were investigated under the practical beekeeping conditions in our apiary. In this study foods containing dinotefuran of 1 ppm to 10 ppm or clothianidin of 0.4 ppm to 4 ppm were fed into a beehive. Three levels of concentration were 10 (high-conc.), 50 (middle-conc.) and 100 (low-conc.) times lower than that in practical use. The changes of adult bees, brood and the pesticide intake in each colony were directly examined. They suggest that each colony with the pesticide administered collapses to nothing after passing through a state of CCD, the high-concentration pesticides seem to work as an acute toxicity and the low- and middle-concentration ones do as a chronic toxicity."

A study published in 2012 by scientists principally with the National Veterinary Research Institute in Pulawy, Poland, found that bees set in fields of oilseed rape treated with foliar

[11] Laurino, D., Manino, A., Patetta, A., & Porporato, M. (2013). Toxicity of neonicotinoid insecticides on different honey bee genotypes. *Bulletin of Insectology*, *66*(1), 119-126.
[12] Yamada, T., Yamada, K., & Wada, N. (2012). Influence of dinotefuran and clothianidin on a bee colony. Jpn. J. Clin. Ecol., 21(1), 10-23.

applications of neonicotinoids did not suffer increased mortalities or adverse changes in behaviour.[13] This publication states:

> "We observed no adverse effect of detected residues on survival and overall colony health. The assessment of the health status of bee colonies during the flowering period and after their displacement to the stationary apiary showed no significant differences between those treated, the control and other bee colonies. None of the bees from any of the oilseed rape fields showed symptoms of lethal toxic effects of pesticide residues nor was there an increase in bee mortality. Bee colony population size and bee development were normal and appropriate for the time of the season in which the assessment took place. There was no statistical difference in the amount of capped and uncapped brood area or in the number of combs covered by bees. The assessment of overwintered colonies in spring 2011, found no chronic effect on their status. All bee colonies survived the 2010/2011 winter period, and bee strength and development were correct."
>
> "The study of the sublethal effects of the residues on the physiology and behavior of an individual (learning ability, olfactory memory, orientation, foraging activity) requires other methods e.g. proboscis extension reflex (PER) conditioning, (Decourtye et al., 2005) or radiofrequency identification (RFID) (Schneider et al., 2012; Henry et al., 2012). We did not use these methods in our research, however, chronic exposure to sublethal doses shown by impairment of food collection and/ or reproduction may also be the cause of the weakness of bee colonies. During the whole observation period, no abnormalities in colony development occurred. Thus, we can suppose that the residue levels determined in nectar and pollen did not have a sublethal effect on bees nor that the effect of the residue levels was relevant to the proper development and functioning of the bee colonies. Wallner and Engl (2004), Bailey et al. (2005), and Cutler and Scott-Dupree (2007) also did not observe any side-effects on the bee colonies from oilseed rape treated with clothianidin and imidacloprid."

RELEVANT EVIDENCE NOT CONSIDERED BY PMRA: SUBLETHAL ADVERSE IMPACTS: REPRODUCTIVE DECLINE

A study published in 2013 by scientists with the University of Exeter found that experimental colonies of bumble bees exposed to sub-lethal levels of imidacloprid suffered a dose-dependent decline in fecundity (reproduction).[14] This publication states:

> "The key result emerging from our work is that ingestion of imidacloprid at environmentally realistic levels substantively reduced the fecundity of worker bumble bees. This finding is consistent with those of previous studies, which have shown that exposure of B. terrestris workers to dietary imidacloprid at 10 ppb in feeder syrup

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[13] Pohorecka, K., Skubida, P., Miszczak, A., Semkiw, P., Sikorski, P., Zagibajło, K., ... & Bober, A. (2012). Residues of neonicotinoid insecticides in bee collected plant materials from oilseed rape crops and their effect on bee colonies. Journal of Apicultural Science, 56(2), 115-134.

[14] Laycock, I., Lenthall, K. M., Barratt, A. T., & Cresswell, J. E. (2012). Effects of imidacloprid, a neonicotinoid pesticide, on reproduction in worker bumble bees (Bombus terrestris). Ecotoxicology, 21(7), 1937-1945. doi:10.1007/s10646-012-0927-y

reduced larval production by 43 % (Tasei et al. 2000) and drone production by between 41 and 62 % (Tasei et al. 2000; Mommaerts et al. 2010). However, wild bees are probably exposed to imidacloprid residues lower than 10 ppb when they consume the nectar and pollen of treated crops (Bonmatin et al. 2003, 2005; Chauzat et al. 2006). We have now demonstrated that dietary trace residues of imidacloprid in the range of 1 ppb can reduce worker fecundity by at least one third.

"Our methodology is likely to have produced realistic exposures to dietary imidacloprid. The amount of imidacloprid ingested by foraging honey bees in nectar and pollen is estimated to be between 152 and 610 pg per day (Rortais et al. 2005). In our experiments, B. terrestris workers ingested on average 587 pg of imidacloprid per day when feeding on syrup dosed with imidacloprid at 1.63 ppb (1.28 lg L-1), which is in the lower range of field-realistic concentrations. In actuality, individual bumble bees probably consume more nectar in a day than honey bees (Thompson and Hunt 1999); therefore, our observations may be reasonably used as a minimum estimate of the effects on the fecundity of worker bumble bees that feed exclusively on real nectars containing imidacloprid residues."

A study published in 2012 by scientists principally with Harvard School of Public Health found that honey bees exposed *in situ* to sub-lethal doses of imidacloprid (doses reflecting residue levels reported in the environment) caused honey bees to exhibit symptoms consistent to colony collapse disorder months after imidacloprid exposure.[15] This publication states:

"All twenty hives were alive when they were assessed on December 22nd 2010, 12 weeks post imidacloprid dosing (PID), although at this time the strength of hives treated with the highest imidacloprid dose appeared to be weakening as observed by smaller clusters and frozen dead honey bees scattering (on snow) in front of the hives. The first observation of two dead hives was recorded 13 weeks PID (table 3). Additional imidacloprid- treated hives began to show signs of weakness throughout January 2011. Significant loss of hives did not occur until 18 weeks PID in which during the following 5-week period, additional 8 hives treated with various imidacloprid doses died. All control hives remained alive 18 weeks PID. Three additional imidacloprid-treated hives and the first control hive died 21 weeks PID. Twenty-three weeks PID, only 1 imidacloprid-treated hive remained alive, whereas 3 of the four control hives were alive."

A study published in 2012 by scientists principally with the University of Stirling found that bumble bees experimentally exposed to field realistic levels of imidacloprid suffered reduced growth rates and a dramatic reduction in the production of new queen bees.[16] This publication states:

"We exposed colonies of the bumble bee Bombus terrestris in the laboratory to field-realistic levels of the neonicotinoid imidacloprid, then allowed them to develop naturally under field conditions. Treated colonies had a significantly reduced growth rate and

[15] Lu, C. et al. (2012) *In situ* replication of honey bee colony collapse disorder. *Bulletin of Insectology* 65(1): 99-106
[16] Whitehorn, P. R., O'Connor, S., Wackers, F. L., & Goulson, D. (2012). Neonicotinoid pesticide reduces bumble bee colony growth and queen production. Science, 336(6079), 351-352. doi:10.1126/science.1215025

suffered an 85% reduction in production of new queens compared with control colonies. Given the scale of use of neonicotinoids, we suggest that they may be having a considerable negative impact on wild bumble bee populations across the developed world."

RELEVANT EVIDENCE NOT CONSIDERED BY PMRA: SUBLETHAL ADVERSE IMPACTS: IMPAIRED LEARNING AND BEHAVIOR

A study published in 2013 by scientists with UNESP-Universidade Estadual Paulista, found that honey bees exposed to sub-lethal doses of imidacloprid suffered adverse impacts in portions of their brains, especially their optic lobes.[17] The publication states:

> "The results of this study show that imidacloprid causes morphological, histochemical, and immunocytochemical alterations in optic lobes and mushroom bodies of bees. Therefore, sublethal doses of this insecticide can negatively affect honeybee physiology, possibly by disrupting their visual system and impairing their learning capacity ….. These changes could lead to abnormal behavior and possibly to the death of the affected bees."

A study published in 2013 by scientists principally with the University of Dundee found that cells of honey bees exposed to field-realistic concentrations of clothianidin and imidacloprid suffered deleterious changes that associated with cognitive function and were additive with exposure to organophosphate pesticides.[18] The publication states:

> "Here we show that two widely used neonicotinoids and an organophosphate miticide, by modulating the activity of nAChRs, potently affect the neurophysiological properties of [Kenyon cells] KCs. As a result, KCs will be rendered non-functional because of their inability to fire APs or respond appropriately to excitatory synaptic input. KCs are the major neuronal component of the mushroom bodies, which are particularly large in social bees compared with other insects. The effects of cholinergic pesticides on KCs are expected to lead to significant impairment of all cognitive functions that depend on this higher-order brain region, including multisensory integration, associative learning and memory, and spatial orientation. Consistent with this, sublethal exposure of honeybees to neonicotinoids significantly impairs olfactory learning in laboratory-based studies, and adversely affects navigation and foraging behaviour in the field."

A study published in 2013 by a scientist with the NARO Institute of Livestock and Grassland Science in Japan found that honey bees exposed under field conditions to sub-lethal levels of clothianidin suffered a reduction in homing flights following foraging.[19] The reduction in

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[17] de Almeida Rossi, C., Roat, T. C., Tavares, D. A., Cintra-Socolowski, P., & Malaspina, O. (2013). Brain Morphophysiology of Africanized Bee Apis mellifera Exposed to Sublethal Doses of Imidacloprid. Archives of environmental contamination and toxicology, 1-10.

[18] Palmer, M. J., Moffat, C., Saranzewa, N., Harvey, J., Wright, G. A., & Connolly, C. N. (2013). Cholinergic pesticides cause mushroom body neuronal inactivation in honeybees. *Nature communications*, *4*, 1634.

[19] Matsumato, T. (2013) Reduction in homing flights in the honey bee Apis mellifera after a sublethal dose of neonicotinoid insecticides. *Bulletin of Insectology* 66(1): 1-9

homing flights were observed at levels as low as 0.002 micrograms per bee. The publication states:

> "Among the side effects of pesticides on beneficial arthropods, sublethal effects have recently been gaining more attention (Desneux et al., 2007). Sublethal effects occur at levels far below the lethal dose, so damage from pesticides is greater than would be expected without such effects. .... This study is the first to show under field conditions that direct topical exposure to two types of neonicotinoid, at doses much lower than their LD50 values, caused sublethal effects although Bortolotti et al. (2003) and Henry et al. (2012) demonstrated that oral exposure of imidacloprid caused the sublethal effect under field condition."

A study published in 2013 by scientists principally with Taiwan National University found that honey bee larvae briefly exposed to field-realistic levels of imidacloprid caused deficits in olfactory associative behavior at very low levels (0.00004 µg/larva).[20] The publication states:

> "In summary, this study demonstrated that the honeybee larvae are more tolerant to imidacloprid than the adult bees, but that their development, at least that of the [mushroom bodies] MBs, [antennal lobes] ALs and antennal nerves may be very easily interfered with by imidacloprid contamination. Honeybees depend on the MBs and ALs in the brain to learn and memorize food location as well as their homing routes when they are out collecting [74,78,79,82,83,84,85]. Our results infer that although imidacloprid does not kill the larvae, when these honeybees with both learning and memory impairments go out collecting, it is highly likely that they cannot learn and memorize food locations and homing routes and that therefore they fail to return to their hives, causing a reduction of bee products and getting even worse to induce [colony collapse disorder] CCD. Because honeybee larvae could be affected by a contamination of imidacloprid contamination as low as 0.04 ng/larva, neonicotinoid insecticides should be applied very carefully."

A study published in 2013 by scientists with the University of California found that honey bees exposed to field-realistic levels of imidacloprid and imidacloprid in field experiments caused behaviors – decreased sucrose responsiveness and decreased waggle dancing – that may impair fitness of honey bee colonies.[21] The publication states:

> "Nectar and pollen foragers treated with 0.21 or 2.16 ng of the nAChR agonist imidacloprid showed a significant decrease in their [sucrose responsiveness] SR 1 h after treatment. They extended their proboscises only for higher concentration sucrose solutions as compared with control bees. Analyses of two measures of SR yielded the same results. ….

[20] Matsumato, T. (2013) Reduction in homing flights in the honey bee Apis mellifera after a sublethal dose of neonicotinoid insecticides. *Bulletin of Insectology* 66(1): 1-9

[21] Eiri & Nieh (2012) A nicotinic acetylcholine receptor agonist affects honey bee sucrose responsiveness and decreases waggle dancing. The Journal of Experimental Biology.

"When tested 24 h after imidacloprid ingestion, foragers treated with 0.21 ng (24 p.p.b.) imidacloprid performed 10.5- and 4.5-fold fewer dance circuits, respectively, for 50% and 30% sucrose solutions at a feeder as compared with controls. Honey bee waggle dancing can significantly enhance colony fitness (Sherman and Visscher, 2002; Dornhaus and Chittka, 2004). Thus, decreased waggle dancing for relatively high quality nectar should negatively affect colony fitness. ….

"In summary, our results provide further insight into how imidacloprid affects honey bee foraging behavior. These effects are time dependent: SR decreased 1h after treatment, but foragers showed no change in the sucrose concentrations that they would collect when tested 24 h after treatment. Thus, foraging efficiency may be temporarily reduced if foragers have higher response thresholds (in the short term) and accept fewer available nectar sources. Over the long term, reductions in waggle dancing should affect colony fitness by reducing honey weight gain in situations where recruitment is important (Sherman and Visscher, 2002; Dornhaus and Chittka, 2004)"

A study published in 2012 by scientists with the University of Wurzburg found that honey bees exposed to field-realistic levels of clothianidin and imidacloprid suffered reduced foraging activity and longer foraging flights.[22] This publication states:

"Our study used the RFID-technology to analyze the impact of insecticide compounds on honeybee foraging behavior. ....

"This is the first study on foraging behavior of honeybees that presents sub-lethal effects after acute oral treatment with clothianidin. Dosages of 0.5 ng (38 ppb) negatively influence the foraging behavior and low dosages (0.05 ng; 3.8 ppb) can have effects on certain aspects of foraging behavior even if they did not have any significant effects on the number of feeder visits or on the total foraging time. Clothianidin elicited detrimental sub-lethal effects at somewhat lower doses (0.5 ng/bee) than imidacloprid (1.5 ng/bee). Bees disappeared at the level of 1 ng for clothianidin, while we could register the first bee losses for imidacloprid at doses exceeding 3 ng. This indicates a stronger impact of clothianidin compared to imidacloprid, which is in agreement with previous reports that both oral [7] and contact toxicity [25] levels are lower for clothianidin."

A study published in 2012 by scientists with the University of London found that exposure of bumble bees to a combination of imidacloprid and λ-cyhalothrin (a pyrethroid insecticide) at field-realistic levels caused declines in foraging performance that would lead to an increased propensity of colonies to fail.[23] This publication states:

"Here we show that chronic exposure of bumblebees to two pesticides (neonicotinoid and pyrethroid) at concentrations that could approximate field-level exposure impairs natural

[22] Schneider, C. W., Tautz, J., Grünewald, B., & Fuchs, S. (2012). RFID tracking of sublethal effects of two neonicotinoid insecticides on the foraging behaviour of *Apis mellifera*. *PLoS ONE*, *7*(1), e30023. doi:10.1371/journal.pone.0030023

[23] Gill, R. J., Ramos-Rodriquez, O., & Raine, N. E. (2012). Combined pesticide exposure severely affects individual- and colony-level traits in bees. Nature, 491(7422), 105-108. doi:10.1038/nature11585

foraging behaviour and increases worker mortality leading to significant reductions in brood development and colony success. We found that worker foraging performance, particularly pollen collecting efficiency, was significantly reduced with observed knock-on effects for forager recruitment, worker losses and overall worker productivity. Moreover, we provide evidence that combinatorial exposure to pesticides increases the propensity of colonies to fail."

A study published in 2013 by scientists principally with the Institut National de la Recherche Agronomique (INRA) in France found that individual honey bees exposed to field-realistic levels of thiamethoxam suffered declines in foraging success that could, in mathematical models, be associated with the collapse of honey bee colonies.[24] This publication states:

"Both experiments 1 and 2 evidenced substantial mortality due to postexposure homing failure, mhf, with the proportion of treated foragers returning to the colony being significantly lower than that of control foragers (exact binomial tests, P = 0.033 and P < 0.001, respectively) (Fig. 3 and table S1). Additionally, mhf was greater in treated foragers that tended to be unfamiliar with the foraging site, as indicated by their significantly lower homing proportions as compared with familiar foragers (exact binomial tests, P < 0.001). Experiments 1 and 2 returned mhf estimates of 0.102 and 0.316, respectively, potentially setting the lower and upper bounds for real mhf values. In other words, 10.2 to 31.6% of exposed honey bees would fail to return to their colony when foraging in treated crops on a daily basis. For the sake of comparison, foragers live ~6.5 days and therefore die at an average rate of 1/6.5 = 0.154 individual day−1 (27). Therefore, the probability that a forager would die because of homing failure during a day spent foraging on treated crops (up to 0.316) may attain twice the probability this same forager has to die naturally that day (~0.154).

"Such an additional mortality might represent a heavy burden to bear for colonies exposed to treated crops in their environment. When implementing mhf into a honey bee population dynamics model (21), all the tested scenarios predicted a major deviation from the expected dynamic (Fig. 4). In our simulations, we considered the evolution of a typical colony during the first 3 months of a beekeeping season, encompassing the oilseed rape blooming period, which was April to May in our study area (22). At this time of the year, colonies emerge from the wintering period. Population size is rather low (<20,000 individuals) and gradually expands in order to rapidly increase food storage and ensure colony sustainability. The daily egg-laying rate of the queen is a critical parameter in this colony dynamic because it determines the daily egg hatching rate and in turn the rate at which honey bees working in the hive will be replaced as they become themselves foragers. We simulated three scenarios with realistic levels of egg-laying rate (28), namely a rate allowing for a normal colony development (Fig. 4A), a rate ensuring equilibrium population (Fig. 4B), and a slightly deficient rate forcing the population to stabilize at a lower size (Fig. 4C). In each case, we also computed the expected trends if most foragers (90%) were exposed to nectar of treated oilseed rape each day and

[24] Henry, M., Béguin, M., Requier, F., Rollin, O., Odoux, J-F., Aupinel, P., Aptel, J., Tchamitchian, S., & Decourtye, A. (2012). A common pesticide decreases foraging success and survival in honey bees. Science, 336(6079), 348-350. doi:10.1126/science.1215039.

> therefore had a natural mortality increased by a homing failure probability mhf. Regardless of the queens' egg-laying rate, populations from colonies exposed to the treated nectar would follow a marked decline during the blooming period and would hardly recover afterward (Fig. 4, A to C). When combined with natural forager mortality, mhf raised total forager death rate up to a point that could hardly be compensated for by the rate at which new foragers are recruited. In the worse scenarios, populations would fall down to 5000 individuals, which is the lowest level one can usually observe in current beekeeping practices. With an exposure rate reduced to 50% of foragers exposed to treated nectar each day (Fig. 4, D to F), the model still predicts a major deviation from normal conditions."[25]

A study published in 2013 by scientists with Imperial College London found that bumblebees experimentally exposed to doses of thiamethoxam reflecting the highest level and mean level of exposure bees are likely to encounter in the field suffered reduced intake of artificial nectar, storage, nest building and larvae produced; however, no effects were observed with lower levels of thiamethoxam .[26] This publication states:

> "In this study, significant reductions in the intake of artificial nectar by micro-colonies fed on all dose rates of thiamethoxam or propiconazole were recorded. Micro-colonies exposed to thiamethoxam also exhibited reduced storage with only 10 % of colonies in the low-dose treatment building wax cells (honey pots) and no wax cells being produced in high-dose treatments…. In this study, 24 % of the observations made during the first week of exposure of microcolonies subject to the 10μg/kg thiamethoxam treatment recorded characteristic behavioural responses commonly associated with neurotoxic insecticides (e.g. uncoordinated movement and extensive grooming of the abdomen; Nauen et al. 2001; Colin et al. 2004). There was also a significant reduction in nest building activity in this treatment group with only two microcolonies building a nest within the 28 day experimental period and with no larvae being produced.

> "This study has highlighted that constant exposure to high levels of thiamethoxam in pollen and nectar has the potential to affect the initiation and development of bumble bee micro-colonies under laboratory conditions. However, these effects were not observed following constant exposure to more realistic residues of thiamethoxam or to propiconazole. The short flowering periods of treated crops, availability of alternative forage and any behavioural responses to contaminated pollen and nectar are likely to further reduce exposure of bumble bee colonies in the field."

[25] Also in 2012, scientists principally with the University of Exeter published a comment on the study of the scientists with INRA disputing the validity of the mathematical model. Cresswell, J. E., & Thompson, H. M. (2012). Comment on "A common pesticide decreases foraging success and survival in honey bees". Science, 337(6101), 1453. doi:10.1126/science.1224618. However, the comment published by the scientists principally with the University of Exeter did not add new data to the body of evidence on the impacts of neonicotinoid insecticides to bees.

[26] Elston, C. et al. (2013) Sub-lethal effects of thiamethoxam, a neonicotinoid pesticide, and propiconazole, a DMI fungicide, on colony initiation in bumblebee (Bombus terrestris) micro-colonies. *APIDOLOGIE* 44(5): 563-574

A study published in 2012 by scientist with Federal University of Vicosa found chronic ingestion of imidacloprid by stingless bees larvae resulted in high mortalities, decreased volume of mushroom bodies and impaired walking behavior.[27] The publication states:

> "The survival curves at doses between 0.28 and 28 mg a.i./bee were similar ($p>0.05$) and all of the worker larvae exposed to doses within this range died before reaching the pupa stage (Fig. 2). An even stronger effect of imidacloprid was observed at 56.00 ug a.i./ bee, where the larvae usually survive for less than five days. Survival rates were above 50% only at the lowest imidacloprid dose used (0.0056 ug a.i./bee) and among the control (97% survival), with a negative correlation between the insecticide dose and the median survival time.
>
> "The mushroom bodies of newly emerged adult workers (one day old) were not significantly affected by imidacloprid, but their development was thereafter significantly impaired by imidacloprid, as reflected by the reduced volume observed in older insects. As expected, the untreated insects exhibited an increase in mushroom body volume with aging (from $34.06 \pm 5.84 \times 10^{-3}$ mm^3 for one-day-old adults to $50.10 \pm 4.40 \times 10^{-3}$ mm^3 and $55.57 \pm 2.62 \times 10^{-3}$ mm^3 for four- and eight-day-old adults). In contrast, when the insects were exposed to the insecticide during larval development, this increase was compromised, even more so at higher doses, where a 36% reduction in volume was observed under the highest dose eight days after emergence.

RELEVANT EVIDENCE NOT CONSIDERED BY PMRA: SUBLEHTAL ADVERSE IMPACTS: INCREASED SUSCEPTIBILITY TO PATHOGENS

A study published in 2013 by scientists principally with the University of Maryland found that honey bees challenged experimentally to a honey bee pathogen (*Nosema ceranae* – a unicellular parasite tentatively linked to colony collapse disorder) **did not** show a positive correlation between infection rates and neonicotinoid levels in pollen samples collected from experimental hives.[28] In fact, neonicotinoid levels were inversely related to *Nosema ceranae* infection rates. This publication states:

> "Insecticide relative risk values showed an interesting pattern: directional separation by insecticide family. Within a family, relative risk values significantly different than one were almost all in the same direction. The formamidine (DMPF) and two of the three the pyrethroids (bifenthrin and fluvalinate, but not esfenvalerate) were associated with an increased risk of Nosema infection. The carbamate (carbaryl), all neonicotinoids (acetamiprid, imidacloprid and thiacloprid), organophosphates (coumaphos,diazinon and phosmet) and the oxadiazine (indoxacarb) were associated with reduced risk of Nosema infection."

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[27] Tome, H.V. et al. (2012) Imidacloprid-Induced Impairment of Mushroom Bodies and Behavior of the Native Stingless Bee *Melipona quadrifasciata anthidioides. PlosOne* 7(6).

[28] Pettis, J. S., Lichtenberg, E. M., Andree, M., Stitzinger, J., Rose, R., & vanEngelsdorp, D. (2013). Crop pollination exposes honey bees to pesticides which alters their susceptibility to the gut pathogen Nosema ceranae. PLoS ONE, 8(7), e70182. doi:10.1371/journal.pone.0070182

A study published in 2012 by scientists principally with Clermont University in France found that honey bees exposed experimentally to thiacloprid and a honey bee pathogen (*Nosema ceranae* – a unicellular parasite tentatively linked to colony collapse disorder) suffered increased mortality compared to honey bees exposed to *Nosema ceranae* alone.[29] This publication states:

> "In this study, we showed that sublethal doses of a neonicotinoid (thiacloprid) and of a phenylpyrazole (fipronil) highly increased mortality of honeybees previously infected by the microsporidian parasite N. ceranae. Although the exact mechanism involved in this synergistic effect remains unclear, our data suggest that the sensitization process is not strongly linked to a decrease of detoxification capacity in infected bees or necessarily by an enhancement of N. ceranae proliferation after exposure to insecticides. ….
>
> "To conclude, our study confirms that interactions between N. ceranae and insecticides constitute a significant risk for honeybee health. The increasing prevalence of N. ceranae in European apiary combined with the constant toxic pressure undergone by honeybees, appears to contribute to the honeybee colony depopulation."

RELEVANT EVIDENCE NOT CONSIDERED BY PMRA: SUBLETHAL ADVERSE IMPACTS: IMPAIRED METABOLISM

A study published in 2013 by scientists principally with the University of Nottingham found that honeybees briefly exposed to field-realistic levels of imidacloprid suffered changes in metabolism associated with fulfilling the high level of energy consumption bees require.[30] This publication states:

> "To mimic honey flow of a neonicotinoid-treated nectar source in bloom, we provided colonies of free-foraging honeybees in the field an additional, imidacloprid-tainted source of food. Over a 15- day period, three experimental, imidacloprid-exposed (IE) hives received a daily ration of 100 mls syrup containing imidacloprid, while three control (C) hives received 100 mls of untainted syrup. We provided a concentration of imidacloprid (2 mg imidacloprid/L21 syrup/<2 parts per billion) that lies within the range (0.5 ppb–10 pbb) detected in contaminated pollen and nectar of a variety of crops (reviewed in [15]). ….
>
> "Given the changes we observe at the RNA and lipid level, it is reasonable so suspect that the synthetic neonicotinoid-class of insecticides are a factor driving the global decline of pollinating insects. Species risk extinction if they fail to adjust effectively to the demands of a changing or new environment. <u>We find evidence that dietary traces of the insecticide imidacloprid impacts physiology of larvae from bee colonies located in a typical British</u>

[29] Vidau, C., Diogon, M., Aufauvre, J., Fontbonne, R., Viguès, B., Brunet, J-L., Texier, C., Biron, D. G., Blot, N., El Alaoui, H., Belzunces, L. P., & Frédéric, D. (2011). Exposure to sublethal doses of fipronil and thiacloprid highly increases mortality of honeybees previously infected by Nosema ceranae. PLoS ONE, 6(6), e21550. doi:10.1371/journal.pone.0021550
[30] Derecka, K., Blythe, M. J., Malla, S., Genereux, D. P., Guffanti, A., Pavan, P., Moles, A., Snart, C., Ryder, T., Ortori, C. A., Barrett, D. A., Schuster, E., & Stöger, R. (2013). Transient exposure to low levels of insecticide affects metabolic networks of honeybee larvae. PLoS ONE, 8(7), e68191. doi:10.1371/journal.pone.0068191

agricultural landscape. The genomic response to this novel environmental stressor mainly affects energy metabolism pathways. A probable involvement of Myc-regulated gene networks is suggestive of an altered growth rate of imidacloprid-exposed larvae. These findings, in concert with the detected decrease of Hsp90 expression may be interpreted as symptoms of a strained developmental buffering system. That is, larvae still grow and develop in the presence of the novel stressor although the stability of the developmental process is compromised. Depending on the genetic background, additional stressors would likely cause an increased rate of developmental failure.

> "Identifying that low levels of a neonicotinoid influences energy metabolism in worker bee larvae raises the question on the generality of our finding. How persistent is the effect? Recent evidence suggests that exposure in early life can influence associative ability of the adult honeybee workers [60]. Does insecticide-exposure alter expression of the same set of genes in adult pollinating insects? Downregulation of sugar metabolism in response to neonicotinoids could, for example, impact start and duration of foraging [61,62] and impair flight performance as flight muscles work at very high glycolytic rates [63,64]. In fact, it has already been observed that treatment of adult honey bees with imidacloprid can impair foraging and result in delayed return flights and an increase in the number of bees not returning from foraging [65]. Our study suggests that the pollinators' struggle to adjust to new environments can be influenced by anthropogenic activities."

A study published in 2013 by scientists with the University of Kentucky found that exposing colonies of bumble bees to white clover in turf treated with clothianidin at label rates caused a variety of adverse effects, including the inability of colonies to produce new queens.[31] This study is particularly relevant to PMRA's Registration Decision because it allows clothianidin use on turf. The publication states:

> "We exposed colonies of the bumble bee Bombus impatiens to turf intermixed with white clover where clothianidin or chlorantraniliprole had been applied at label rates to test the hypothesis that the latter is relatively less hazardous to colonies foraging on flowering weeds in treated lawns. ...
>
> "Colonies exposed to clothianidin-treated weedy turf showed reduced foraging activity and increased worker mortality in the hives within five days (Fig. 1). They also gained weight more slowly after being moved to an insecticide-free site where they were left to openly forage for six more weeks (Fig. 2). Although statistically significant differences were no longer detected by analysis of variance by the time the hives were dissected, there remained consistent trends for fewer live adults (workers and males), honey pots, and reduced colony weight of clothianidin-exposed colonies compared to the controls (P = 0.052, 0.09, 0.058, respectively; preplanned linear contrasts, Table 1). More importantly, clothianidin-exposed colonies failed to produce new queens (Fig. 3)."

[31] Larson, J. L., Redmond, C. T., & Potter, D. A. (2013). Assessing insecticide hazard to bumble bees foraging on flowering weeds in treated lawns. PLoS ONE, 8(6), e66375. doi:10.1371/journal.pone.0066375

A study published in 2013 by scientists principally with the University of Quebec found that honey bees exposed to sub-lethal doses of imidacloprid in field experiments suffered increased acetylcholinesterase (AChE) activity at levels (0.00008 micrograms per bee) several orders of magnitude below levels that cause direct lethality.[32] The publication states:

> "To our knowledge, this is the first time that an increased AChE activity is reported for both in-field and laboratory data implicating honey bees. While many laboratory experiments have been conducted to test the toxicity of several chemicals on honey bees, the real impact of sub-lethal exposures to a mixture of contaminants faced by the bees in wild environments is yet to be discovered. The precise concentration triggering the observed effects is difficult to predict. The results of the chronic exposure under controlled conditions suggest that the NOEL (no observable effects level) for imidacloprid alone is less than 0.08 ng per bee."

A study published in 2013 by scientists with Hellenic Institute of Apiculture, Mugla University and Agricultural University of Athens found honey bees exposed to sub-lethal doses of imidacloprid under laboratory conditions suffered underdevelopment of the hypopharyngeal glands (HPGs) and decreased respiratory rhythm. Development of HPGs was measured as a function of the size of the gland lobes or acini; respiration rhythm was measured in abdominal ventilation movements (AVM).[33] This publication states:

> "9-day-old treated honeybees had 14.5 % smaller acini than 9- day-old control honeybees and 14-day-old treated honeybees had 16.3 % smaller acini than 14-day-old control honeybees.
>
> "Imidacloprid significantly affected the bursting pattern of AVMs by causing a 59.4 % increase in the inter-burst interval from 4.56 to 7.27 s (Table I and Figure 3c). Therefore, fewer AVM bursts were recorded per minute from imidacloprid-treated honeybees (Figure 3c) than from untreated honeybees (Figure 3b). In addition, there was a 56.99 % decrease in the mean duration of AVM bursts, from 3.53 to 1.52 s (Table I). Taken together, these effects indicate a significant inhibitory effect on the generation of AVM bursts.
>
> "Our study demonstrates that in laboratory conditions, imidacloprid affects the development of HPGs and patterns of respiration rhythm and shows that the physiological effects must also be considered because they have negative consequences both for the individual honeybees and for the overall development of the colony."

[32] Bioly et al. (2013) Acetylcholinesterase in honey bees (Apis mellifera) exposed to neonicotinoids, atrazine and glyphosate: laboratory and field experiments. Environmental Science and Pollution Research International.
[33] Hatjina, F. et al. (2013) Sublethal doses of imidacloprid decreased size of hypopharyngeal glands and respiratory rhythm of honeybees in vivo. *Apidologie* 44: 467-480.

RELEVANT EVIDENCE NOT CONSIDERED BY PMRA: EFFECTS ON BEES OF NEONICOTINOID DRESSED SEEDS

A study published in 2012 by scientists with the University of Padova, Italy found that the application of neonicotinoid-coated seed by pneumatic drilling machines creates airborne plumes containing toxic levels of neonicotinoids.[34] This publication states:

> "Sudden losses of bees have been observed in spring during maize sowing. The death of bees has been correlated with the use of neonicotinoid-coated seed and the toxic particulates emitted by pneumatic drilling machines. The contamination of foragers in flight over the ploughed fields has been hypothesized. The airborne contamination has been proven, both with bees inside fixed cages around the field and in free flight near the driller. A new trial involving mobile cages has been established and consists of making rapid passes with single bees inside cages fixed to an aluminium bar. The bar was moved by two operators at different distances from the working drilling machine. A single pass was shown as sufficient to kill all the bees exposed to exhaust air on the emission side of the drill, when bees were subsequently held in high relative humidity. The extent of toxic cloud around driller was evaluated."

A study published in 2012 by scientists with University of Bologna, Italy found that honey bees exposed to clothianidin at concentrations reflecting the "mean concentration deposited on the ground at 5 meters distance from the field's edge, during sowing with a drilling machine equipped with dual pipe deflector" suffered increased mortality.[35] This publication states:

> "After dust application, the mortality level observed in the semi-field study increased about 10-11 times compared to the control. The mortality was significantly higher than in control during the first 2 days and was still ecologically relevant during the 3rd day."

A study published in 2012 by scientists with University of Padova found particulate matter emitted by drilling machines during the sowing of corn seeds coated with neonicotinoids exposes flying bees to lethal doses of insecticides.[36] This publication states:

> "The sowing (1.5 h) of Poncho 2010 corn seeds by the Gaspardo drilling machine (with the outlet air flow directed downward by an external deflector) induced the rapid death of more than 200 foraging bees flying across the sowing area, revealing a clothianidin content in the range of 0.5−11 μg/bee."

[34] Girolami, V. et al. (2012) Aerial powdering of bees inside mobile cages and the extent of neonicotinoid cloud surrounding corn drillers. *J. Appl. Entomol.*

[35] Sgolastra, F. et al. (2012) Effects of neonicotinoid dust from maize seed-dressing on honey bees. *Bulletin of Insectology* 65(2): 273-280.

[36] Tapparo, A. et al. (2012) Assessment of the environmental exposure of honey bees to particulate matter containing neonicotinoid insecticides coming from corn coated seeds. *Environ. Sci. Technol.* 46: 2592-2599.

CONCLUSION

Nineteen of twenty-one (90%) of studies[37] in the peer-reviewed scientific literature fitting the criteria of being an original research article published in the past three years (2011, 2012 and 2013) relating to the effects of neonicotinoid insecticides on pollinators showed adverse impacts at field-realistic levels of neonicotinoid insecticides, or in actual field experiments.

There are already reasonable grounds to believe that the environmental risks of clothianidin are unacceptable. The lack of reasonable certainty that renewal of the conditional registration of clothianidin will cause no harm to the environment is clear.

These conclusions are consistent with the recent recommendations of bee experts. Earlier this year, bee experts with Utrecht University in the Netherlands, the University of Sussex in the United Kingdom, and Orleans University in France provided the following opinion about the state of the scientific evidence and the need to curtail neonicotinoid use:[38]

> "At field realistic exposure levels, neonicotinoids produce a wide range of adverse sublethal effects in honeybee colonies and bumblebee colonies, affecting colony performance through impairment of foraging success, brood and larval development, memory and learning, damage to the central nervous system, susceptibility to diseases, hive hygiene etc. Neonicotinoids synergistically reinforce infectious agents such as N. ceranae and exhibit synergistic toxicity with other agrochemicals. The large impact of short term field realistic exposure of bumblebee colonies on long term bumblebee queen production (85% reduction) could be a key factor contributing to the global trends of bumblebee decline. Only a few studies assessed the toxicity to other wild pollinators, but the available data suggest that they are likely to exhibit similar toxicity to all wild insect pollinators. The worldwide production of neonicotinoids is still increasing. In view of the vital importance of the service insect pollinators provide to both natural ecosystems and farming, they require a high level of protection. <u>Therefore a transition to pollinator-friendly alternatives to neonicotinoids is urgently needed for the sake of the sustainability of pollinator ecosystem services. The recent decision by the European Commission to temporary ban the use of imidacloprid, thiamethoxam and clothianidin in crops attractive to bees is a first step in that direction</u> [163]."

[37] This metric does not include three studies relating to the effects on bees of planting neonicotinoid dressed seeds that show adverse effects.

[38] van der Sluijs, J. P., Simon-Delso, N., Goulson, D., Maxim, L., Bonmatin, J. M., & Belzunces, L. P. (2013). Neonicotinoids, bee disorders and the sustainability of pollinator services. *Current Opinion in Environmental Sustainability*.

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Helps more than four hundred public interest lawyers in more than sixty countries:

- obtain comprehensive and up-to-date scientific, technical, and medical information, publications, documents and analysis that are essential to the elements of a case;

- present scientific information in concise terms that judges and other decision-makers can most easily understand;

- critically evaluate the scientific and medical evidence presented by opposing parties

- identify and involve the best scientific and medical specialists;

- critically evaluate Environmental Impact Assessments for proposed projects;

- design, implement and interpret environmental testing projects;

- abate pollution from the aggregate industry, including stone crushing, concrete batching and cement plants.

This assistance has led to more than two hundred favorable judicial and administrative decisions, including:

- The High Court of Himachal Pradesh (*Him Privesh Environment Protection Society v. State of Himachal Pradesh*) regarding exposure to air pollution from a cement plant.

- The European Court of Human Rights (*Dubetska and others v. Ukraine*) regarding the rights of individuals exposed to air and water pollution from a coal washery.

- The European Court of Human Rights (*Fadeyeva v. Russia*) regarding the rights of individuals exposed to toxic substances.

- The Supreme Court of India (*M.C. Mehta v. Union of India*) regarding the operation of hazardous waste generating industries within the Delhi Metropolitan area

- The Supreme Court of Pakistan (*Zia v. WAPDA*) regarding the health effects of exposure to electromagnetic fields

- The Supreme Court of Bangladesh (*Bangladesh Environmental Lawyers Association v. Ministry of Housing and Public Works*) regarding exclusion of development within flood plain zones

- The High Court of South Africa (*Earthlife Africa v. Department of Environmental Affairs and Tourism and others*) regarding the adequacy of the Environmental Impact Assessment of for a proposed nuclear power plant

- The High Court of Nigeria (*Gbemre v. Shell Petroleum Development Corporation and others*) regarding the legality of gas flares at Niger River Delta oil fields

- The Supreme Court of Sri Lanka (*Lalanath M. de Silva v. Minister of Forestry and Environment*) regarding the necessity for establishing air pollutant emission standards.

- The High Court of Ipoh, Malaysia (*Chai Sing Chong v. Chip Lam Seng BHD*) regarding pollution abatement from a latex rubber processing factory.

On the issue of pesticides and agro-chemicals, my experience includes:

- Advising advocates in Argentina on the health effects of exposure to DDT and other pesticides in the SENASA abandoned pesticide warehouse case

- Advising advocates in Australia on the potential impacts and alternatives to the use of the pesticide chlopyralid (3,6-dichloro-2-pyridinecarboxylic acid) and atrazine

- Advising advocates in Guatemala on the potential environmental and health risks and regulatory status of Spinosad (*Saccharopolyspora spinosa*)

- Advising advocates in India on best practices for minimizing environmental releases from a cypermethrin pesticide manufacturing plant

- Advising advocates in India on necessary protocols for environmental monitoring following a fire at a pesticide manufacturing facility

- Advising advocates in Israel on least-toxic alternatives to field mice control and the toxicity of 2,4,5-TP and fluoracetic acid pesticides

- Advising advocates in Nepal on the human health risks of exposure to a mixture of abandoned pesticide stockpiles, leading to a judgment of the Supreme Court of Nepal directing the re-export of pesticide stockpiles to Germany

- Advising advocates in the Netherlands on the potential environmental and health of the pesticide quinoxyfen

- Advising advocates in the Philippines on the health effects and regulatory status of the pesticides chlordane, methomyl and methamidophos

- Advising advocates in South Africa on best practices for the prevention of drift during aerial application of pesticides

- Advising advocates in South Africa on the health and environmental risks of pesticide levels measured in the Upper Olifants River and its tributaries

- Advising advocates in Sri Lanka on the likely causative agent of pandemic chronic kidney disease of unknown etiology in North Central Province

- Advising advocates in Tanzania on the environmental health risks and least toxic alternatives to pesticides used on wheat crops near Lake Basuto

- Advising advocates in Uganda on the environmental and human health risk of perticides used by flower growers near Lake Victoria

SELECTED PUBLICATIONS AND REPORTS

Chernaik, M.L. (2012) "Evaluation of the Environmental Impact Assessment – Final Report Hongsa Power Plant, Mining Development and Transmission Project (June 2007) and Environmental Management Plan Honga Mine Mouth Power Project (March 2010)."

Chernaik, M.L., Weiskel (2012) "Evaluation of the Environmental and Social Impact Assessment (ESIA) for the Oyu Tolgoi Copper and Gold Project."

Chernaik, M.L (2011) "Interpretation of ambient air quality data near Jaypee Cement facility in Himachal Pradesh."

Chernaik, M.L. (2011) "Evaluation of the Preliminary Environmental Impact Assessment and Quantitative Risk Assessment for the Proposed Advanced Materials Plant Gebeng Industrial Estate, Kuantan Pahang."

Chernaik, M.L. (2011) Evaluation of the EIA for the proposed Cement Plant & Limestone Quarry at Port Esquivel Industrial Complex by Cement Jamaica Limited.

Chernaik, M.L. (2010) “Evaluation of the permit issued by the Ministry of Environment and Natural Resources of Ukraine to "Mikolayivtsement" on 31 December 2008

Chernaik, M.L. (2010) “Evaluation of the Environmental Impact Assessment for Operating a Asphalt Batch Plant at Layou Valley.”

Chernaik, M.L. (2007) “Evaluation of the Rapid Marine Environmental Impact Assessment (RMEIA) for Setting Up of a Captive Minor Port at Jatadharmohan Creek near Paradeep in Orissa; and Evaluation of the Rapid Environmental Impact Assessment (REIA) for 4 Metric Ton per Year (MTPY) Integrated Steel Project to be Set Up near Paradip in Orissa.”

Chernaik, M.L. (2006) “Evaluation of The Rapid Environmental Impact Assessments: The Proposed Capacity Expansion of Bauxite Mines From 3.0 MTPA to 8.5 MTPA at Baphlimali Plateau Rayagada/Kalahandi District, Orissa; The Proposed Capacity Expansion of Utkal Refinery from 1.0 MTPA to 3.0 MTPA Doraguhra, Rayagada District, Orissa.”

Chernaik, M.L (2005) “Evaluation of The Environmental Impact Assessment Report Soapberry Wastewater Treatment Plant, St. Catherine, Jamaica.”

Chernaik, M.L (2005) “Evaluation of the Comprehensive Environmental Impact Assessment study for the Proposed Athirappilly Hydroelectric Project, India.”

Chernaik, M.L (2004) “Human Health Risk Assessment of Pollutant Levels in the Vicinity of the ‘Severstal’ Facility in Cherepovets, Russia.”

Chernaik, M.L (2003) “An Analysis of the Nuisance Odour and Health Problems in Chemor, Malaysia: Their Cause and Solutions.”

Chernaik, M.L. (1998) “Empowering Environmental Lawyers Worldwide with Scientific Expertise,” Journal of Environmental Law and Litigation 13:17-35

Chernaik, M.L., & Huang, P.C., (1991) “Differential Effect of Cysteine-to-Serine Substitutions in Metallothionein on Cadmium Resistance,” Proc. Natl. Acad. Sci. 88:3024-3028

FIELD EXPERIENCE

Traveled to the Philippines, Malaysia, Sri Lanka, India, Nepal, Bangladesh, Japan, Peru, Indonesia, Argentina, Israel, Slovakia, the Czech Republic and Ukraine to work with public interest lawyers and scientists to support their legal actions. Provided live expert witness testimony in the Philippine Court of Appeals (June 2012).

APPENDIX D

REVIEW PREPARED BY DR. RALPH V. CARTAR

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17 September 2013

Dr. Elaine MacDonald,
Senior Scientist, Ecojustice Canada

Dear Dr. MacDonald:

I'm a scientist at the University of Calgary, where my students and I study bumble bees, and frequently consider the impacts of anthropogenic disturbances on these native bees. My study of bumble bee ecology goes back 30 years. I have been asked to provide this brief opinion in response to the Pest Management Regulatory Agency's decision in July 2013 to register a neonicotinoid insecticide: clothianidin.

I have concerns about the potential impacts of systemic or sprayed neonicotinoid pesticides on non-target insects, in particular our native bees. All bees specialize in obtaining their food from flowers, making them ecologically important mutualists in both semi-natural and agricultural landscapes. The pollination service they provide, which is increasingly appreciated in the case of a range of agricultural crops, is potentially at risk from this class of pesticide.

One concern is the manner in which we assess risks; i.e., by focusing on individuals (like workers) rather than on reproductive entities (like colonies). In the social bees like bumble bees, most individuals are not reproductive, and are therefore more equivalent to plant leaves than to whole plants. Hence, lethal dose tests of toxicity performed on individual social bees miss a critical outcome. Instead, it is better to assess the reproductive performance of colonies (e.g., Whitehorn et al. 2012) which integrates the actions of well-known sub-lethal effects on their workers (e.g., disruptions of division of labour, orientation, memory, learning, foraging efficiency), but which still misses overwintering mortality. To further improve the assessment process, statistically powerful field tests made in the presence of high background noise should include blocked designs, and use techniques that increase sample size, such as micro-colonies (as advocated by Blacquiere et al. 2012).

Another concern is our uncertainty about pathways of pesticide transmission to non-target pollinating insects. Blacquiere et al. (2012) review some of these pathways: particularly guttation fluids, nectar & pollen, all of which contain the pesticide. But given that few neonicotinoids applied to seed coats or soil actually find their way into plants (~5%; Sur & Stork 2003), and given their season-long half life (34-75 days (in the lab); Maienfisch et al. 2001), the potential for dust-borne contact with neonicotinoids is non-trivial (e.g., Krupke et al. 2012). And because neonicotinoids accumulate in surface water, like ponds (van Dijk et al. 2013), where bees collect water in times of heat stress, surface water is another potential source of pesticide transmission. Finally, ephemeral ponds in the prairies often dry up in late summer, and become a potential source of dust-borne contamination. These possibilities remain unstudied.

The concern with uncertainty of pathways of transmission, and long persistence in the environment, also obtains even when pesticide use is discouraged in the presence of bees. Presence (or absence) of bees during pesticide application almost seems irrelevant for a material that persists for 1 to 4 years, depending on soil conditions, over which the potential for exposure to bees seems high.

For these reasons, I advocate the non-registration of systemic neonicotinoids until exposure pathways and long-term effects are better understood. I also advocate quantifying toxicological impacts on social insects in a manner that is more appropriate for their life histories (i.e., colony-level reproductive success). Overall, applying the precautionary principle to use of this pesticide seems essential.

Sincerely,

Ralph V. Cartar, PhD.
Associate Professor of Ecology & Director of the Natural Sciences Program

References:

Blacquiere, T. et al. 2012. Neonicotinoids in bees: a review on concentrations, side-effects and risk assessment. Ecotoxicology 21:973-992.
Krupke, C.H. et al. 2012. Multiple routes of pesticide exposure for honey bees living near agricultural fields. PLoS ONE 7:e29268.
Maienfisch, P. et al. 2001. Chemistry and biology of thiamethoxam: a second generation neonicotinoid. Pest Management Science 57:906-913.
Sur, R. & A. Stork. 2003. Uptake, translocation and metabolism of imidacloprid in plants. Bulletin of Insectology 56:35-40.
van Dijk, T.c. et al. 2013. Macro-invertebrate decline in surface water polluted with imidacloprid. PLoS ONE 8:e62374.
Whitehorn, P.R. et al. 2012. Neonicotinoid pesticide reduces bumble bee colony growth and queen production. Science 336:351-352.

Ralph Victor CARTAR

CURRICULUM VITAE

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Post-Secondary Education

PhD Simon Fraser University. (1990) Field: Behavioral Ecology.
Thesis: Condition-dependent foraging behaviour of bumble bees. Supervisor: Lawrence M. Dill
(University's nomination for the Canadian Society of Zoologists' Outstanding PhD Award)

MSc Queen's University. (1983) Field: Ecology.
Thesis: Incubation behaviour of white-rumped sandpipers. Supervisor: Robert D. Montgomerie

BSc University of Toronto. (1981) Field: Zoology.
Thesis: Morphometrics of two sibling sandpiper species. Supervisor: James D. Rising

Employment

Director of the Natural Sciences Program, Univeristy of Calgary. (July 2013 to present)
Acting Director of the Natural Sciences Program, Univeristy of Calgary. (Jan. 2013 to June 2013)

Associate Professor, Dept. Biological Sciences, University of Calgary (July 2005 to present)

Associate Professor, Dept. Biological Sciences, University of Lethbridge (July 2001 to 2005)
Assistant Professor, Dept. Biological Sciences, University of Lethbridge (July 1996-2001) and
Coordinator of University of Lethbridge's Environmental Science Program (July 1997-July 2002)

Faculty of Science Postdoctoral Fellow, University of Manitoba. (May 1994 to June 1996)
Topic: Spatial distribution of foraging organisms. Collaborator: Mark V. Abrahams

Sessional Lecturer--Part-time, Division of Zoology, Univ. of Calgary. (Jan. 1995-April 1995)
Sessional Lecturer--Full-time, Division of Zoology, Univ. of Calgary. (Sept. 1993-April 1994)

Postdoctoral Fellow. Indiana University (April-July 1993) Field: Behavioral Ecology
Topic: Decision-making under uncertainty. Principal Investigator: Leslie A. Real

Data analysis: Contract from the Canadian Wildlife Service (Nov. 1992 to March 1993)
Topic: Energetics of arctic-breeding shorebirds. Project supervisor: R.I. Guy Morrison

Visiting Scholar: Center for Population Biology, University of California at Davis
Sponsor: Marc Mangel. (April 1992-August 1994)

Sessional Lecturer: Simon Fraser University (January to April 1992)

NSERC Postdoctoral Fellow. The Australian Museum (1990-1991) Field: Behavioral Ecology
Topic: Theoretical & empirical studies of foraging in nectarivores. Collaborator: Graham H. Pyke

Research

Current Research Interests: Evolutionary Ecology & Applied Evolutionary Ecology
• Using the ideal free distribution as a tool for detecting environmental impacts and assessing populations.
• Linking foraging and life history traits in bumble bees with wing wear.
• Impacts of environmental stochasticity on organismal distributions and life histories.
• Resource-tracking by mobile competitors (studied using bumble bees competing for flowers).

Graduate Student Training (2000 to present)
7 MSc students (graduated)
3.5 MSc students (degrees in progress)

Research Grants held:
NSERC Discovery Grants (1996 to 2011; ~$19K per annum)
NSERC CANPOLIN grants (2009 to 2013; ~$14K per annum)
Shell & Husky grants (2004 to 2008; $40K total)
SARA/AESA grant (1998-1999; ~$11.5K per annum)

Publications

Kowal, V.A. & R.V. Cartar. 2012. Edge effects of three anthropogenic disturbances on spider communities in Alberta's boreal forest. Journal of Insect Conservation 16:613-627.

Owen, R.E., M.C. Otterstatter, R.V. Cartar, A. Farmer, S.R. Colla, N. O'Tolle. 2012. Significant expansion of the distribution of the bumble bee *Bombus moderatus* (Hymenoptera: Apidae) in Alberta over 20 years. Canadian Journal of Zoology 90:133-138.

Foster, D.J. & R.V. Cartar. 2011. What causes wing wear in foraging bumble bees? Journal of Experimental Biology 214:1896-1901.

Pengelly, C.J. & R.V. Cartar. 2011. Effect of boreal forest logging on nectar production of four understory herbs. Forest Ecology and Management 261:2068-2074.

Foster, D.J. & R.V. Cartar. 2011. Wing wear affects wing use and choice of floral density in foraging bumble bees. Behavioral Ecology 22:52-59.

Pengelly, C.J. & R.V. Cartar. 2010. Effects of variable retention logging in the boreal forest on the bumble bee-influenced pollination community, evaluated 8-9 years post-logging. Forest Ecology and Management 260:904-1002.

Cartar, R.V. 2009. Resource-tracking by bumble bees: What explains local responses to density of bergamot (*Monarda fistulosa*) flowers? Ecoscience 16:470-475.

Haas, C.A. & R.V. Cartar. 2008. Robust flight performance of bumble bees with artificially induced wing wear. Canadian Journal of Zoology 86:668-675.

Cartar, R.V. 2005. Short-term effects of experimental boreal forest logging on bumble bees, bee-pollinated flowers, and the bee-flower match. Biodiversity and Conservation 14:1895-1907.

Cartar, R.V. & R.I.G. Morrison. 2005. Metabolic correlates of leg length in breeding arctic shorebirds: The cost of getting high. Journal of Biogeography 32:377-382.

Cartar, R.V. 2004. Resource-tracking by bumble bees: Responses to plant-level differences in quality. Ecology 85:2764-2771.

Biernaskie, J.M. & R.V. Cartar. 2004. Variation in rate of nectar production depends on floral display size: a pollinator manipulation hypothesis. Functional Ecology 18:125-129.

Biernaskie, J.M., R.V. Cartar & T.A. Hurly. 2002. Risk-averse inflorescence departure in hummingbirds and bumble bees: Could plants benefit from variable nectar volumes? Oikos 98:98-104.

Cartar, R.V. 2002. Review of "Cognitive ecology of pollination: Animal behavior and floral evolution". Quarterly Review of Biology 77:185.

Cartar, R.V. & Abrahams, M.V. 2000. The infection of Pyrola (*Pyrola asarifolia*; Pyrolaceae) by spruce cone rust (Chrysomyxa pirolata; Uredinales): Morphological correlates in the host and consequences for spore dispersal. Écoscience 7: 357-364.

Abrahams, M.V. & R.V. Cartar. 2000. Within-group variation in the willingness to risk exposure to a predator: the influence of species and size. Oikos 89:340-344.

Cartar, R.V. & L.A. Real. 1997. Habitat structure and animal movement: the behavior of bumble bees in uniform vs random spatial resource distributions. Oecologia 112:430-434.

Cartar, R.V. & R.I.G. Morrison. 1997. Estimating metabolic costs of homeotherms from weather data and morphology: an example using Calidridine sandpipers. Canadian Journal of Zoology 75:94-101.

Cartar, R.V. & M.V. Abrahams. 1997. Predicting the distribution of organisms among a few patches: problems with detecting departures from the ideal free distribution. Oikos 78:388-393.

Smallwood, P.D. & R.V. Cartar. 1996. Risk-sensitivity in behaviour: where are we now? Introduction to the symposium. American Zoologist 36:389-391.

Cartar, R.V. and P.D. Smallwood. 1996. Risk-sensitive behavior: where do we go from here? American Zoologist 36:530-531.

Cartar, R.V. & M.V. Abrahams. 1996. Risk-sensitive foraging in a patch departure context: a test with worker bumble bees. American Zoologist 36:447-458.

Lyon, B.E. & R.V. Cartar. 1996. Functional significance of the cocoon in arctic woolly-bear moths. Proceedings of the Royal Society of London B 263:1159-1163.

Cartar, R.V. 1992. Adjustment of foraging effort and task switching in energy-manipulated wild bumble bee colonies. Animal Behaviour 44:75-87.

Pyke, G.H. & R.V. Cartar. 1992. The flight directionality of bumble bees: do they remember where they came from? Oikos 65:321-327.

Cartar, R.V. 1992. Morphological senescence and longevity: an experiment relating wing wear and life span in foraging bumble bees. Journal of Animal Ecology 61:225-231.

Cartar, R.V. 1991. A test of risk-sensitive foraging in wild bumble bees. Ecology 72:888-895.

Cartar, R.V. & L.M. Dill. 1991. Costs of energy shortfall for bumble bee colonies: predation, social parasitism, and brood development. Canadian Entomologist 123:283-293.

Cartar, R.V. 1991 Colony energy requirements affect response to predation risk in foraging bumble bees. Ethology 87:90-96.

Cartar, R.V. & L.M. Dill. 1990. Colony energy requirements affect the foraging currency of nectar-collecting bumble bees. Behavioral Ecology and Sociobiology 27:377-383.

Cartar, R.V. & L.M. Dill. 1990. Why are bumble bees risk-sensitive foragers? Behavioral Ecology and Sociobiology 26:121-127.

Cartar, R.V. & B.E. Lyon. 1988. The mating system of the buff-breasted sandpiper: lekking and resource defense polygyny. Ornis Scandinavica 19:74-76.

Cartar, R.V. & R.D. Montgomerie. 1987. Day-to-day variation in nest attentiveness of white-rumped sandpipers. Condor 89:252-260.

Cartar, R.V. 1985. Testis size in sandpipers: the fertilization frequency hypothesis. Naturwissenschaften 72:157-158.

Cartar, R.V. & R.D. Montgomerie. 1985. The influence of weather on incubation scheduling of the white-rumped sandpiper (*Calidris fuscicollis*): a uniparental incubator in a cold environment. Behaviour 95:261-289.

Cartar, R.V. 1984. A morphometric comparison of semipalmated and western sandpipers. Wilson Bulletin 96:277-286.

Knapton, R.W., R.V. Cartar & J.B. Falls. 1984. A comparison of breeding ecology and reproductive success between morphs of the white-throated sparrow. Wilson Bulletin 96:60-71.

Montgomerie, R.D., R.V. Cartar, R.L. McLaughlin & B. Lyon. 1983. Birds of Sarcpa Lake, Melville Peninsula, Northwest Territories: Breeding phenologies, densities, and biogeography. Arctic 30:42-45.

Cartar, R.V. 1976. The status of the piping plover at Long Point, Ontario, 1966-1975. Ontario Field Biologist 30:42-45.

Dunn, E.H., Howkins, H.F. & R.V. Cartar. 1975. Red-breasted nuthatches breeding in nest boxes in pine plantations on the north shore of Lake Erie. Canadian Field Naturalist 89:467-468.