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*
Beatrice Olivastri, CEO, Friends of the Earth Canada

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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 and 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

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| 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***

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|---|---|
| | 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) |
| | 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 |
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## 1. Pollution of the Environment

Friends of the Earth (FOE) notes this statement in which we interpret "highly toxic" to mean acute toxicity in PMRA's report "Clothianidin is highly toxic to bees and mammals and moderately 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." (Health Canada, PMRA Evaluation Report – ERC2011-01, page 4, accessed September 8, 2013)

FOE asserts that acute toxicity as described by PMRA in its 2011 report should be considered pollution of the environment and thereby adequate cause for denial of conditional re-registration of this pesticide Clothianidin.

FOE also argues that the report *Evaluation of Canadian Bee Mortalities that Coincided with Corn Planting in Spring 2012* (Health Canada) demonstrates clear harm to the environment in documented bee mortality. "The information evaluated suggest that planting corn seeds treated with the nitroguanidine insecticides clothianidin and/or thiamethoxam contributed to the majority of the bee mortalities that ocurred in corn growing regions of Ontario and Quebec in Spring 2012."

## 2. Lack of due diligence by the applicant and by the Minister of Health

When the subject insecticide (Clothianidin) and products (Clutch 50 and Arena 50) were granted conditional registration, by the Minister of Health, for sale and use in 2009 (foliar or in-furrow use on potato, grape, pome fruits, stone fruits and turf as applicable), one of the conditions set down by the Minister for conditional registration was the requirement for the applicant to submit additional scientific information by September 2012(date quoted from ERC2011-01). These data included information on:

- 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.

The reason given for this (in PRD2012-24) was, "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 pesticides, resulting from its potential movement into plant tissues and secretions such as pollen and nectar."

To date, these crucial data have not been provided by the applicant, and, again, the Minister of Health is requiring submission, by the applicant, of the same information for December 2015 as a condition of the currently proposed renewal of the conditional registration (RD2013-14 Registration Decision *Clutch 50 WDG, Arena 50 WDG and Clothianidin Insecticides).* Document PRD2012-24 (*Proposed Registration Decision for Clutch 50 WDG, Arena 50 WDG and Clothianidin Insecticides)* states that a rationale was provided by the applicant for non-compliance (absence of required data or information) with the condition previously stipulated in accordance with s.7(4) of the PCPA . That rationale was accepted by the Pest Management Regulatory Agency (PMRA), acting for and on behalf of the Minister of Health.

FOE objects to the apparent lack of due diligence by the applicant, who apparently took no steps to generate the data that the applicant claimed were "absent". In addition, neither the Minister of Health nor PMRA has provided details of the applicant's rationale nor any information about their assessment of that rationale and why they found the rationale acceptable.

FOE questions whether the Minister of Health is on solid legal ground in proposing this renewal. The renewal could be a breach of s.7(5) of the *Pest Control Products Act* (PCPA), which states that the "Minister shall deny an application if the applicant does not comply with a notice under subsection (4)." Subsection (4) refers to information requested in support of the application with timeframes. It seems clear that the applicant did not comply with the previous condition respecting submission of studies and data, since the Minister is repeating that previous condition as part of the current, proposed renewal.

It is FOE's position that it is scientifically and socially irresponsible for the Minister of Health to continue to allow the use of these chemicals until the applicant completes the required studies and has submitted the required information and until PMRA scientists have completed their scientific assessment of the study results. The PCPA specifically requires the Minister of Health to take a scientifically based approach to assessment of applications for registration of pest control products. Please see s.7(7) reproduced below:

> "s.7(7) In evaluating the health and environmental risks of a pest control product and in determining whether those risks are acceptable, the Minister shall
>
> (*a*) apply a scientifically based approach;..."

**3. Government action in other OECD countries argues for comparable action in Canada**

FOE identifies the following state of affairs around the neonicotinoids that further support our call to deny conditional re-registration at this time:

-via Regulation (EU) No 485/2013, the suspension in the European Union for uses namely the prohibition of the sale and use of clothianidin, thiamethoxam and imidacloprid for crops attractive to bees, including pome and stone fruits (some of the targeted crops for this proposed renewal). Exceptions would include crops and seeds that do not attract bees and winter cereals. Regulation (EU) No 485/2013) enters into force on December 1, 2013 for two years.

- via the scientific opinion by the European Food Safety Authority's (EFSA), on which the decision by the EU to implement Regulation (EU No 485/2013 was, in part, based. (EFSA Panel on Plant Protection Products and their Residues (PPR); Scientific Opinion on the science behind the development of a risk assessment of Plant Protection Products on bees (Apis mellifera, Bombus spp. and solitary bees). EFSA Journal 2012; 10(5) 2668. (275 pp.)www.efsa.europa.eu/efsajournal)

- the ongoing re-evaluation (REV2012-2 *Re-evaluation Note. Re-evaluation of Neonicotinoid Insecticides*) of the family of neonicotinoids by the PMRA (in association with the United States Environmental Protection Agency (US EPA) with a reporting target date of 2018;

**4. Exercising Precaution**

Given the state of uncertainty in Canada as to what is causing honeybee deaths but with acknowledgement that neonicotinoids contribute to those deaths, we recommend, based in part on the precautionary principle, that the Minister of Health deny a conditional re-registration until the re-evaluation process is complete in 2018 and until the applicant has completed and submitted the required studies identified in the proposed decision document.

FOE also is concerned about wording on page 5 of the proposed decision document which states that "The PMRA is working with the United States (sic) Environmental Protection Agency and other international regulatory partners to develop *additional data requirements*" and, then, the requirement for "*additional scientific information*" from the applicant on page 6. What is the relationship between the additional data requirements mentioned on page 5 and the additional information required as per page 6? Is the additional scientific information required from the applicant as per page 5 related in any way to the additional data requirements that PMRA, the US EPA and other foreign regulatory bodies are trying to develop? FOE contends that these

bodies should do their work first to see if their results can be brought to bear on “additional scientific information” that may be required from the applicant in order for the Minister of Health to make a decision on conditional re-registration of Clothianidin.

FOE asserts that, in denying this conditional registration, the Minister of Health would be acting in accordance with s.7(5) of the PCPA and would be demonstrating use of the scientifically based approach set out in s.7(7). The Minister would thus relieve one pressure to Canada's pollinators' health, at least for the period until the PMRA/US EPA re-evalution report is available in 2018. A decision to deny renewal of this conditional registration would be a valid enactment of the precautionary principle while the science on the safety of these insecticides is clarified. The Minister would be acting in accordance with the following preambular statement from the *Pest Control Products Act:* “pest control products of acceptable risk be registered for use only if it is shown that their use would be efficacious and if conditions of registration can be established to prevent adverse health impact or pollution of the environment”, the environment including pollinators such as honeybees to which, by admission of the Minister of Health and PMRA, “Chlothianidin is systemic, persistent and highly toxic” (page 4 of the proposed decision document).

Further, FOE offers these comments on the scope of the proposed studies being requested (again) as terms of conditional re-registration:

- for the study on behaviour and fate in plants, we suggest that guttation fluids (where applicable) be added to nectar and pollen. Plants should include not only the crops but weeds that may have been exposed during application (and therefore contain the insecticide in their tissues and fluids).
- for the hive study, we request clarification of whether the study applies only to honeybees (*Aphis mellifora*) or whether the study’s scope is to include wild bees as we would advocate.

In summary, FOE objects to this proposed conditional re-registration for the following reasons:

- Pollution of the environment given the known adverse impacts of Chlothianidin on honeybees (highly toxic, systemic, persistent and bee deaths) already recorded under Canadian conditions for related products.
- Lack of due diligence by applicant and by the Minister of Health given the wording of s.7(5) of the PCPA which obliges the Minister to deny an application for registration where a Ministerial request under s.7(4) has not been complied with,
- Requirement for comparable action to that taken by other OECD countries
- Requirement to exercise precaution

FOE recommends that the Minister deny conditional re-registration of this pest control product and should only reconsider when the applicant has completed and submitted their required studies, and findings of the joint PMRA/US EPA re-evaluation slated for completion in 2018 can be considered and taken into account.

| 7. Signature of objector or representative – Signature de l’opposant ou de son représentant | Printed Name – Nom en lettres moulées* | Date* |
|---|---|---|
|  | Beatrice Olivastri | September 20, 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.