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Response to Health Canada's Proposed Registration Decision (PRD) for the systemic pesticide Flupyradifurone (PRD2014-20)

Submitted by

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on

31 October 2014

The Proposed Registration Decision for Flupyradifurone (PRD2014-20; hereafter 'the PRD'), released on September 19, 2014, clearly states Health Canada Pest Management Regulatory Agency's (PMRA) inclination towards the registration of the chemical Flupyradifurone (and its end-use products BYI 02960 480 FS and Sivanto 200 SL) based on its purported value as a pesticide for certain crops as well as its supposed harmlessness towards human health and the environment.

Upon reading the PRD, however, it becomes clear that not only is this chemical not harmless, as claimed, but the studies conducted to determine its impacts are incomplete, inconclusive, and therefore grossly inadequate for the release of this pesticide into crop fields and eventually into the environment. Herein, we oppose the registration of Flupyradifurone in Canada, and our line of reasoning for this opposition is five-pronged — (1) the adverse impacts of Flupyradifurone, as reported in the PRD, (2) the lack of data on the long-term effects of Flupyradifurone, (3) the adverse impacts of the chemically-similar Neonicotinoids, (4) inadequate mitigation and risk management measures, and (5) insufficient economic justification for the release of Flupyradifurone.

1. Adverse Impacts of Flupyradifurone

The results of the studies reported in the PRD themselves do not absolve Flupyradifurone of its potential to harm the environment – both abiotic, and biodiversity. To list a few particular points of concern which the PRD reports:

1. **Human health** — Despite varied discrepancies in the study on the effects of Flupyradifurone on mammals (rats, mice and dogs), the general result is that toxicity increases in the body of the study subjects, and various organ and tissue-level negative impacts were observed. In short-term oral studies conducted in these 3 species, wherein Flupyradifurone was administered via the diet for 28 and 90 days, reductions in body weight were observed in all species. The liver was also a target of toxicity common to all three species – *pg 16*. Rodents also showed similar effects with long-term dosing – *pg 17*. These results suggest that human health impacts are not unlikely.
2. **Soil invertebrates:** In most cases, it is persistent in soil (via both aerobic and anaerobic transformation). It is also highly mobile in soil, including in soil leaching, and exerts impacts on soil fauna
    a. Earthworms — Laboratory studies on acute exposure showed that Flupyradifurone (Sivanto) killed earthworms but the soil-transformed products had little effect. This implies that in scenarios where Flupyradifurone is not transformed, earthworms are likely to die off. Results from the field study showed that there were "…no unacceptable adverse effects on the abundance and biomass of total earthworm population at 1500 g a.i./ha, more than three times of the maximum annual application rate…" – *pg 35*. It is unclear as to whether this field study addressed the effects of the major soil transformation products or of Flupyradifurone itself. It needs to be noted that the direct application of Flupyradifurone into the soil is likely to destroy the earthworm population with detrimental long-term effects on litter, and soil organic matter processing.
    b. Arthropods — One out of 3 soil arthropods tested showed increased mortality in response to Sivanto exposure – *pg 35*.
3. **Leaf arthropods** — "Flupyradifurone has the potential to pose a risk to foliar-dwelling arthropods based on the screening level assessment, and a refined assessment is needed" – *pg 36*.
4. **Bees** — Flupyradifurone is extremely toxic to bees when (a) bees are orally exposed to concentrations in excess of 1.2 µg a.i./bee (*pg 38*), and (b) bees are exposed to a combination of Flupyradifurone and azole fungicides. All forms of the chemical are toxic to bees when taken orally, especially within the 48h testing interval, and in combination with certain fungicides. Further, the effects of chronic/sub-lethal exposure of bees to Flupyradifurone were not properly assessed, despite the PMRA identifying the need to evaluate sub-lethal exposure of bees and pollinators to Neonicotinoids (Re-evaluation Note - REV2013-15).
5. **Aquatic fauna** — It is persistent in aerobic and anaerobic aquatic systems, especially when biotransformed, and is toxic to freshwater invertebrates, and at

least slightly toxic to freshwater fish. It is also slightly toxic to marine invertebrates with particularly high toxicity for certain shrimp species.

6. **Birds** — Except for the domestic chicken, it is toxic, to varying degrees, to all the birds tested.
7. **Mammals** — It is toxic to rats, which implies that other rodents, including species that are important prey for predatory birds, mammals and snakes, will also be adversely affected. The developmental toxicity study for mammals showed that both mother and foetus displayed negative responses to experimental doses. Small mammals and birds are bound to be exposed to toxic (treated) seeds, because about 1% of sown seeds do not get buried and may be foraged upon (Goulson 2013).

To conclude this point, we quote the PRD which states that "Flupyradifurone and the transformation product DFA have the potential to move through the soil to enter groundwater, …[and] to enter aquatic environments through surface run-off...it may affect some species of aquatic invertebrates from soil and foliar applications, beneficial arthropods and bees from foliar applications…and may pose a risk to birds and small wild mammals when used for soybean seed treatment.". In other words, although some of the studies conducted showed little to no effects, other studies showed opposite, adverse effects on biodiversity, suggesting contradictory, and therefore, inconclusive findings.

2. Inadequate Data on the residual and long-term Effects of Flupyradifurone

At several places in the PRD it is clear that the long-term impact studies on people and the environment are ridden with gaps and unanswered questions, or throw up conflicting or contradictory points. Here are some examples:

1. No repeated-dosing regimen was included in the toxicokinetics studies for rats conducted with Flupyradifurone – *pg 15.* This is a major flaw in the testing methodology because pesticide application is, itself, an iterative process, and any exposure to local fauna is also likely to be repetitive. Therefore, information on just one time effects is not useful.
2. The periods of exposure to the chemical selected for the studies of effects on mammals were 1 year, 90 days, and 28 days. On what bases were these durations selected? In the case of study periods where no major effects were observed, could it be because the length of exposure period was too short for the effects to be manifested?
3. A repeated-exposure inhalation toxicity study on rats was not conducted with Flupyradifurone; "…owing to low volatility, this requirement was waived…" – *pg 16*. However, the PRD also says that "a repeated exposure inhalation study may be required for future use expansion of Flupyradifurone…" The two statements are contradictory.
4. For the studies on bees, residues for the various forms and application types were not measured. In the absence of data, the claim that the product is safe for bees is not only incorrect but also dishonest. Even the reported findings

acknowledge considerable gaps in the study and the uncertainty of conclusions drawn.

In general, the PRD provides no data on residues, which are a key component to understanding the long-term ecological impacts of Flupyradifurone. Although the PRD claims that "Residue trials conducted throughout Canada, the United States, and Brazil (coffee) using Flupyradifurone on a range of representative commodities were deemed acceptable", it is unclear as to who carried out these trials, what the results of these trials were and what their implications are for the environment.

It is important to note that this pesticide **has not yet been approved for use in Europe** and will not be until at least a year from now. In a joint effort, the United Nations World Health Organization (WHO) and the Food and Agriculture Organization (FAO) have called for diverse stakeholders ("…Governments, interested organizations, producers of these chemicals, and individuals…") to submit data on toxicological effects and residue evaluation for a variety of proposed pesticides including Flupyradifurone (FAO 2014). The call for data is still open and will close in December 2014. Thereafter, nearly a year of consideration will precede the joint meeting of the WHO and FAO in September 2015 (in Geneva) where Flupyradifurone, along with the other proposed pesticides, will be considered for registration. Why is Health Canada in a hurry to register a chemical which the rest of the developed world is approaching slowly and with caution? We strongly urge the PMRA to follow a similar protocol, and allow sufficient time for concerned stakeholders to submit the findings of independent studies, which can subsequently be carefully considered and deliberated before final registration.

3. Adverse Impacts of chemically-similar neonicotinoids

Flupyradifurone belongs to the Mode of Action (MoA) Subgroup (Subgroup 4D, the Butenolides) of chemicals which includes the neonicotoids (4A), nicotine (4B) and sulfoxaflor (4C). Like the Neonicotinoids, Flupyradifurone also interferes with the function of insect nerves, and is most potent when ingested either directly or through treated plant matter. Owing to its similarity to the Neonicotinoids, it is safe to imagine that the effects of Flupyradifurone on human health and the environment, are more likely to resemble those of the Neonicotinoids, than not.

When the Neonicotinoids were registered for use, their economic value was deemed great and their negative effects negligible. However, what we now know about the effects of these chemicals (Thiomethoxam, Imidacloprid, and Clothianidin) is clearly in contradiction to everything that we were led to believe when their registration was first justified. Consequently, in December 2013, PMRA re-evaluated the risks and risk mitigation measures for Neonicotinoid Insecticides (Health Canada 2013a; REV2013-15) and now they are being slowly phased out around the world due to their adverse environmental impacts:

1. Neonicotinoids are water-soluble and enter the soil. Their half-life in soil varies depending on soil type, weather conditions and active ingredient, and can range between 200 and well over 1000 days (Goulson, 2013).
2. Neonicotinoids have also been found to contaminate water ways and wetlands through agriculture runoff and may be acutely toxic to aquatic invertebrates, and may cause widespread groundwater contamination (Rexrode et al 2003, Main et al, 2014).
3. Despite being less toxic to vertebrates, in comparison to invertebrates, granivorous birds and small mammals may be more susceptible to toxicity due to the ingestion of treated seeds that are spilled or not buried. Acute toxicity, resulting in death, has been observed in small birds such as grey partridge (*Perdix perdix*), while in small mammals sub-lethal effects such as reduced reproduction and *in utero* development have been observed (Gibbons et al 2014).
4. Neonicotinoids are found in the nectar and pollen of plants and may negatively impact bees and beneficial arthropods through ingestion (Whitehorn et al 2012). In addition, the sowing of treated seeds releases aerial dust containing Neonicotinoids, which can lead to mortality of bees and other local pollinators (Goulson 2013). Health Canada's Interim Report on Canadian Bee Mortality (Health Canada 2013b) indicates that Clothianidin and/or Thiamethoxam may have been an important contributor to the high bee mortality found in Ontario and Quebec in 2012 and 2013. PMRA subsequently released new agricultural practices, vis-à-vis risks to bees, to be applied in the 2014 planting season (Health Canada 2013c; NOI2013-01).

Bees are a critical component of ecosystem function, providing a service – pollination – that cannot be easily replicated by any other method. When we already know the detrimental impacts of Neonicotinoids on bee populations in areas where they have been used, and we know that Flupyradifurone is similar to the Neonicotinoids, then should we not err on the side of caution, and defer the registration of this pesticide until its effects on bees (and other species) are more extensively and thoroughly studied?

We urge the PMRA to follow the 'Precautionary Principle', as mandated by Canada's policy on the environment – "…the absence of complete scientific evidence to take precautions does not mean that precautions should not be taken – especially when there is a possibility of irreversible damage..." (Environment Canada 2010).

4. INADEQUATE IMPACT MITIGATION AND RISK MANAGEMENT MEASURES

Leaching & Water Contamination — Flupyradifurone is moderately persistent to persistent in soil. It is mobile and is expected to leach into groundwater and reach aquatic ecosystems. The PRD requires a 1 to 10 m spray buffer zone to limit runoff into aquatic habitats. We are concerned that the proposed buffer zone is arbitrary

and completely unsupported by data, not taking into account soil type, rainfall and snowmelt, proximity to sensitive areas such as wetlands, and drainage (Main et al, 2014). From what we know of the mobility of this chemical and the leaching process, this buffer width is clearly insufficient.

Monitoring — Considering the expected persistence of Flupyradifurone, and the levels of other pesticides, namely Neonicotinoids, currently found in the environment, long-term monitoring is critical. However, the PMRA does not propose any monitoring studies of Flupyradifurone in soil and adjacent waterways following its registration and use, and this is a matter of serious concern to us.

Labelling — We are also concerned that simply informing users of the leaching potential of Flupyradifurone and its transformation products will not be sufficient in actively limiting groundwater contamination. Informing users of the carry-over potential of Flupyradifurone will not stem its persistence into the next growing season. What are the specific instructions of use that will minimize leaching into soil, and carry-over? How will the PMRA ensure that these instructions are understood and followed by users?

Protecting bees — The only measure to reduce the exposure of bees to Flupyradifurone (i.e., making foliar applications of Sivanto 200 SL when bees are not actively foraging) is more lenient than the measures imposed on the use of neoticotinoids (e.g., Thiamethoxam; Evaluation Report ERC2007-01). When the risks are similar why are the harm prevention measures less stringent? We are extremely concerned that the proposed measures will not protect bees from exposure and drift.

Protecting granivores — Finally, even if bags of treated seeds are labelled with hazard statements, it is unlikely that the labeling will curtail the use of treated seeds in order to reduce the accidental ingestion of these seeds by granivorous mammals and birds. Therefore, current proposed measures to avoid or mitigate spills are insufficient to protect granivores from the known toxicological effects of Flupyradifurone.

5. NO ECONOMIC JUSTIFICATION FOR ITS USE AS A PESTICIDE

The registration decisions for the Neonicotinoids as well as Flupyradifurone claim that the products have agricultural value. However, a recent US Environmental Protection Agency statement (EPA; Myers & Hill 2014) reports that Neonicotinoids have no real economic value for soybean production. Based on the similarity between the two, it is fair to assume that Flupyradifurone is not likely to have any greater economic value for soybean production than the Neonicotinoids which have just been shown to be useless. Until there are concrete data, from independent, peer-reviewed studies, that show that soy (and other crops) treated with Flupyradifurone have significantly greater yields than those that received no insect

control treatment, we believe that undertaking such environmental risks is economically unjustified.

We advise Health Canada to consider past research and regulations failures in the registration and use of insecticides. Organochlorides such as DDT and organophosphates were both widely used as pesticides before their negative impacts on human and environmental health were fully understood, and these chemicals were subsequently banned (van der Sluijs et al, 2014). Neonicotinoids, due to their potential negative impact on bees among other species, have been temporarily banned in the European Union, are now under review in Canada. We hope that, as a country, we will choose to encourage the research and adoption of non-harmful alternatives to pest management such as integrated pest management. Finally, we sincerely urge Health Canada to take a precautionary approach and extensively research the impacts of Flupyradifurone on the environment before allowing the full registration of a new systemic insecticide.

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