David Suzuki Foundation

équiterre

August 7, 2015

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

BY E-MAIL

To Whom It May Concern:

Re. Special Review of Fluazinam: Proposed Decision for Consultation

This letter is in response to the invitation for public comment on Re-evaluation Note REV2015-08, posted on June 30, 2015. The David Suzuki Foundation and Équiterre welcomed the Pest Management Regulatory Agency's (PMRA) announcement on December 30, 2013, that a special review of pest control products containing the active ingredient fluazinam would be initiated, as required by s. 17(2) of the *Pest Control Products Act*. However, we are concerned by apparent gaps in the Agency's review of certain aspects of concern, in particular those relating to persistence and carryover in soil, risks to earthworms, and human health effects.

Based on the available information, we disagree with the proposed special review decision and urge the PMRA to cancel the registration of fluazinam (i.e., ban it) to protect human health and the environment, as Norway did in 2010.

Apparent gaps in the special review of fluazinam

1. **Persistence and potential carryover in soil**
   The Rotterdam Convention Prior Informed Consent (PIC) Circular[1] explaining Norway's decision to ban fluazinam states persistence as an underlying reason for the ban. The PMRA agrees that fluazinam is persistent in aerobic soil conditions and that the potential for carryover into the next growing season. REV2015-08 provides no justification for the PMRA's proposed decision to accept this environmental hazard, which Norway has deemed unacceptable, other than to note that the

[1] UNEP. PIC Circular XXXII – December 2010. http://www.pic.int/Portals/5/en/Circular/CIRC32-En.pdf

hazard is stated on the product label, along with a recommendation to not apply the product if it was used in the previous season.[2] The PMRA does not provide any evidence that the recommended best practice is being followed and is effectively mitigating the environmental hazard. No information is given about the usage profile of Allegro in Canada or environmental monitoring to test for accumulation of fluazinam in Canadian soils.

2. Risk to earthworms

Another underlying reason for the Norwegian ban, according to the PIC Circular, was that "fluazinam is extremely reproductively toxic to earthworms and the risk of effects on earthworms is very high." The PMRA evaluation of acute risks to earthworms does not address the concerns about reproductive toxicity. With respect to chronic effects, REV2015-08 mentions only that the PMRA considered the results of one field study reported by Norway that indicated no statistically significant reduction in total biomass or population size. There is no discussion of the evidence that led Norway to conclude that fluazinam is extremely toxic to reproduction for earthworms, or of why the PMRA and the Norwegian Food Safety Authority have come to opposite conclusions regarding the chronic toxicity of fluazinam to earthworms.

Furthermore, in the assessment of acute risks to earthworms, it is not clear whether the PMRA has taken into account fluazinam's persistence in soil and potential to accumulate in soils. REV2015-08 states that the expected environmental concentration (EEC) is calculated based on the maximum registered application rates, but multiple applications (in the same growing season, or subsequent growing seasons) could result in greater exposure.

3. Human health effects (developmental and reproductive)

The PIC Circular explaining Norway's decision to ban fluazinam also states that fluazinam is "classified with possible risk of harm to the unborn child." The PMRA agrees that developmental studies indicate increased sensitivity of the fetus and applies 3-fold margin of safety in calculating the allowable level of human exposure, pursuant to the *Pest Control Products Act* (PCPA). Section 19(b)(iii) of the PCPA generally requires a 10-fold margin of safety to take into account potential prenatal toxicity "unless, on the basis of reliable scientific data, the Minister has determined that a different margin of safety would be appropriate." REV2015-08 provides no rationale for maintaining only a 3-fold margin of safety. In light of the Norwegian decision to ban fluazinam, citing risks to the fetus, a higher margin of safety should be considered. As REV2015-08 does not specify the exposure levels (doses) calculated for various scenarios, it is not clear whether applying higher margin of safety would change the outcome of the risk assessment.

[2] The label for Allegro 500F Agricultural Fungicide, for example, includes the following statement under Environmental Hazards,"Fluazinam is persistent and will carry over; it is recommended that the product, Allegro 500F Agricultural Fungicide containing fluazinam, not be used in areas treated with this product during the previous season." http://pr-rp.hc-sc.gc.ca/1_1/view_label?p_ukid=58218862

Also, REV2015-08 does not explain the PMRA's decision to base the Acute Reference Dose (RfD) for the general population on the no observed adverse effects level (NOAEL) of 4 mg/kg bw/day, rather than the lower intermediate-term dermal and inhalation NOAEL of 1.9 mg/kg bw/day that was identified for liver pathology. Has the PMRA conducted a risk assessment, including potential developmental effects, based on this alternative endpoint?

Furthermore, the PMRA appears to have overlooked chronic effects in its evaluation of human health effects for the special review of fluazinam. The SAgE Pesticides database maintained by the Quebec Ministry of Agriculture, Fisheries and Food (Ministre de l'Agriculture, des Pêcheries et de l'Alimentation du Québec) classifies fluazinam as very highly toxic in terms of long-term effects on mammals and states, *"Dans des études de toxicité subchronique et chronique, le fluaziname touchait les organes suivants : foie, poumons, utérus, testicules, pancréas, thymus, thyroïde, estomac, yeux et cerveau,"* as well as effects on the endocrine system.[3] The latter, in particular, may be relevant to the evaluation of developmental toxicity.

Finally, section 19(2)(b)(i) of the PCPA requires consideration of "cumulative effects of the pest control product and other pest control products that have a common mechanism of toxicity." Yet there is no indication that the PMRA has considered cumulative effects in this special review evaluation of potential developmental and reproductive effects.

In light of these unresolved issues, we believe the PMRA is wrong to conclude that "fluazinam does not pose unacceptable risks to human health and the environment." In keeping with the precautionary principle, as required by the *Pest Control Products Act,*[4] the PMRA should instead cancel the registration of fluazinam and pest control products containing this active ingredient.

We note as well that Norway banned fluazinam in 2010, yet the PMRA did not initiate the legally required special review until December 30, 2013. In the future, we hope the PMRA will initiate special reviews of pest control products containing active ingredients banned in another OECD member country through a systematic process that does not require non-governmental organizations to bring the ban to the PMRA's attention, and in a more timely fashion. For example, the PMRA initiating special reviews of affected pest control products of its own accord within six months of the passage of a ban would be a more reasonable timeline.

---

[3] http://www.sagepesticides.qc.ca/Recherche/Resultats.aspx?search=matiere&ID=132

[4] Section 20 of the PCPA states:

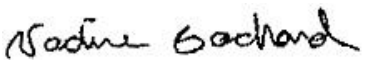
(1) The Minister may cancel or amend the registration of a pest control product if [...]

(b) in the course of a re-evaluation or special review, the Minister has reasonable grounds to believe that the cancellation or amendment is necessary to deal with a situation that endangers human health or safety or the environment, taking into account the precautionary principle set out in subsection (2).

(2) 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.

Thank you for considering these comments. Do not hesitate to contact us should you have any questions or to discuss these matters further.

Sincerely,



Lisa Gue
Senior Reseacher and Analyst
David Suzuki Foundation
2211 West 4th Ave., Suite 219
Vancouver, BC V6K 4S2
lgue@davidsuzuki.org

Nadine Bachand
Chargée de projet - choix collectifs, agriculture et pesticides
Équiterre
50 Sainte-Catherine Ouest, Suite 340
Montréal, QC H2X 3V4
nbachand@equiterre.org