David Suzuki Foundation

équiterre

September 5, 2015

Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
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Ottawa, ON K1A 0K9

BY E-MAIL

To Whom It May Concern:

Re: Special Review of Fluazifop-P-butyl: Proposed Decision for Consultation

This letter is in response to the invitation for public comment on Re-evaluation Note REV2015-09, posted on July 22, 2015. The David Suzuki Foundation and Équiterre welcomed the announcement on December 30, 2013, that the Pest Management Regulatory Agency (PMRA) had initiated a special review of pest control products containing the active ingredient fluazifop-P-butyl, as required by s. 17(2) of the *Pest Control Products Act*.[1] However, we are concerned that the special review fails to adequately address the concerns that led Norway to deny registration to pest control products containing this active ingredient — specifically, reproductive and developmental toxicity.

In particular, we believe the PMRA errs in not applying an extra margin of safety to take into account potential pre- and post-natal effects and uncertainties with respect to the vulnerability of infants and children. Based on the available information, it appears that application of an appropriate margin of safety would change the outcome of the PMRA's human health risk assessment.

We therefore disagree with the proposed special review decision and urge the PMRA to cancel the registration of fluazifop-P-butyl (i.e., ban it) to protect human health, as Norway did in 1995.

[1] PMRA. Re-evaluation Note: Special Review Initiation of 23 Active Ingredients (REV2013-06). December 30, 2013. http://www.hc-sc.gc.ca/cps-spc/alt_formats/pdf/pubs/pest/decisions/rev2013-06/rev2013-06-eng.pdf

Context for the special review

One technical-grade active ingredient and one commercial-class product (Venture L Herbicide) containing fluazifop-P-butyl are currently registered in Canada. Venture L Herbicide is approved for use on a large number of broadleaf crops and ornamentals to control grass weeds.

When a member country of the Organisation for Economic Co-operation and Development prohibits all uses of an active ingredient for health or environmental reasons, the *Pest Control Products Act* requires the minister of health to undertake a special review of registered pest control products containing that active ingredient (s. 17(2)).

According to information published pursuant to the Rotterdam Convention, Norway denied approval to products containing fluazifop-P-butyl in 1995 "because of its risk of effects on reproduction and its risk of teratogenesis at low doses." [2] These human health risks are summarized as follows in the Rotterdam Convention documentation:

> *Fluazifop-P-butyl has shown in animal studies, rat and rabbit, that it causes effects on reproduction and that it is a teratogen. This means that it also has the potential to cause these effects in humans. The risk of this happening is higher for the workers than for the consumers, although it is also possible that residues can be high and thus also be a risk to the consumer too.*

PMRA's review of the aspects of concern is inadequate

In REV2015-09, the PMRA acknowledges evidence of reproductive and developmental (teratogenic) effects. However, in contrast to Norway's conclusion, the PMRA considers that risks to workers are not a concern because the following precautionary statement is required on the label of products containing fluazifop-P-butyl:

> *Wear coveralls over long-sleeved shirt and long pants, chemical resistant gloves, socks and chemical resistant footwear during mixing, loading, application, clean-up and repair. Wear goggles or face shield during mixing/loading.*[3]

We find it difficult to understand — and REV2015-09 does not explain — how a label statement for personal protective equipment is considered adequate protection for Canadian workers, when Norway concluded that risks to workers (and potential risks to consumers) were unacceptable, and banned fluazifop-P-butyl.

Furthermore, REV2015-09 does not discuss risks of exposure to the general population or other workers (including vulnerable individuals) from residues when protective clothing is removed, transported and laundered, or from drift at the time of application.

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[2] PIC Circular XIII http://www.pic.int/Portals/5/en/Circular/CIRC13EN.pdf

[3] PMRA, Re-evaluation Decision: Fluazifop-P-butyl (RVD2012-05), April 23, 2012.

Instead, the PMRA limits its human health risk assessment to dietary exposures from food and drinking water and concludes that neither the acute reference dose (for acute dietary exposure) nor the acceptable daily intake (for chronic dietary exposure) are exceeded.

The requirement for an extra margin of safety

The *Pest Control Products Act,* s.19(2)(b)(iii), states that in evaluating the health and environmental risks of a pest control product and in determining whether those risks are acceptable, the minister shall:

> *in the case of a threshold effect, if the product is used in or around homes or schools, apply a margin of safety that is ten times greater than the margin of safety that would otherwise be applicable under subparagraph (ii) in respect of that threshold effect, to take into account potential pre- and post-natal toxicity and completeness of the data with respect to the exposure of, and toxicity to, infants and children, unless, on the basis of reliable scientific data, the Minister has determined that a different margin of safety would be appropriate.*

However, in the special review of fluazifop-P-butyl, an additional safety factor of 1 is maintained. This is equivalent to not applying an additional safety factor and in our view is contrary to the intended purpose of s.19(b)(iii).

REV2015-09 suggests the PMRA relied on three considerations in selecting a "PCPA factor" of 1:

1. The dataset contains the full complement of required studies;
2. Observed pre- and post-natal effects are considered to be a developmental delay, as opposed to malformations, which the PMRA regards as a low-concern endpoint; and,
3. There is no residual uncertainty for pre- and post-natal toxicity.

We find this unconvincing, especially in light of Norway's decision to ban fluazifop-P-butyl because of reproductive and teratogenic effects. First, the PMRA acknowledges evidence of pre- and post-natal toxicity. PMRA policy identifies evidence of increased susceptibility or sensitivity of the young as a consideration that would generally lead to a determination of high concern and *retention* of the PCPA factor.[4] Second, completeness of the dataset is a basic requirement for evaluating the risks of any pesticide. The PCPA factor is not an alternative but rather an additional requirement of the act. In addition, REV2015-09 does not address the completeness of the dataset with respect to pre- and post-natal exposures. Third, we disagree with the PMRA's assessment of the seriousness of the endpoint. REV2015-09 does not explain or discuss in any detail why the PMRA considers evidence of developmental delay to be of low concern. Furthermore, the teratogenic effects cited by Norway

[4] PMRA, Science Policy Note: The Application of Uncertainty Factors and the *Pest Control Products Act* Factor in the Human Health Risk Assessment of Pesticides. July 29, 2008. http://www.hc-sc.gc.ca/cps-spc/alt_formats/pacrb-dgapcr/pdf/pubs/pest/pol-guide/spn/spn2008-01-eng.pdf

suggest that reproductive effects include malformations, which PMRA policy considers a high concern endpoint. REV2015-09 does not address this apparent contradiction, either. Fourth, 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 fluazifop-P-butyl as moderately toxic in terms of long-term effects on mammals and states that data are insufficient to determine whether certain developmental effects are linked to endocrine disruption.[5] This points to residual uncertainty in pre- and post-natal toxicity assessments that should be addressed through application of the PCPA factor.

In summary, neither REV2015-09 nor the underlying 2011 re-evaluation documents for fluazifop-P-butyl (PRVD2011-11 and RVD2012-05) provide adequate or convincing justification for reducing — much less obviating — the PCPA factor. This is despite the PMRA's recognition that the *Pest Control Products Act* requires "a presumptive application of the 10-fold factor for the protection of infants and children" and that "the onus is on the PMRA to provide a reliable scientific rationale in those cases where the 10-fold PCPA factor is reduced."[6]

We note that the application of any PCPA factor greater than 1 would result in a chronic dietary exposure estimate greater than the acceptable daily intake (ADI). REV2015-09 states that the highest chronic dietary exposure estimate from food and water is 61 per cent of the ADI with no PCPA factor applied. By our calculation, applying a PCPA factor of 2 would result in an exposure estimate of 122 per cent of the ADI — an unacceptable risk to human health. We are gravely concerned by the possibility that the PMRA has selected the PCPA factor to permit a determination of acceptable risk, rather than on the basis of reliable scientific data as required by the act.

Conclusion

In light of these unresolved issues, we believe the PMRA is wrong to conclude that "fluazifop-P-butyl 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*,[7] the PMRA should instead cancel the registration of fluazifop-P-butyl and pest control products containing this active ingredient.

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[5] http://www.sagepesticides.qc.ca/FicheSante.aspx?ID=59

[6] PMRA Science Policy Note

[7] Section 20 of the PCPA states:

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

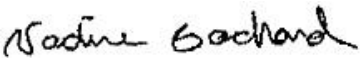
(b) in the course of a re-evaluation or special review, the Minister has reasonable grounds to believe that the cancellation or amendment is necessary to deal with a situation that endangers human health or safety or the environment, taking into account the precautionary principle set out in subsection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

We note as well that Norway banned fluazifop-P-butyl in 1995, 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.

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

Sincerely,



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