October 27, 2014

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

To Whom It May Concern:

Re: Special Review of Imazapyr: Proposed Decision for Consultation (REV2014-03)

This letter is in response to the invitation for public comment on Re-evaluation Note REV2014-03, posted on August 28, 2014. The laboratory of Dr. Luc Gaudreau of the Université de Sherbrooke contributed to the development of these comments.

The David Suzuki Foundation and Équiterre were pleased that on December 30, 2013, the Pest Management Regulatory Agency (PMRA) announced it would initiate a special review of pest control products containing the active ingredient imazapyr, as required by s. 17(2) of the *Pest Control Products Act*. However, we are again disappointed by the lack of rigour with which the Agency appears to have conducted this special review. As we stated previously in comments on the proposed special review decision of aminopyralid, a special review conducted pursuant to s. 17(2) should not merely rubber-stamp a pre-existing regulatory decision, in our view. Rather, it should give thorough consideration to the concerns leading to a ban on the active ingredient in another country in order to assess whether the risks and value of the pest control product are acceptable for continued registration in Canada. This should include obtaining and analyzing relevant data and examining the PMRA's approach to risk assessment in light of alternatives (i.e., the approach in the country with a ban). A special review may also provide an opportunity to consider new information or emerging issues related to health and environmental risks of the subject pest control product that may not have been available to or considered previously by the PMRA.

We ask the PMRA to conduct a more robust special review of registered use pest control products containing imazapyr and then issue a revised proposed decision for consultation. In particular, we hope a revised proposed decision will address the following issues, many of which mirror the concerns we raised in our previous comments on the proposed special review decision of aminopyralid:

The Agency has not evaluated the risks and value of each pest control product containing imazapyr

1. We remain concerned that the Agency is focusing special reviews on the active ingredients and not on registered end-use products as required by the *PCPA*. The proposed special review decision notes, "The proposed special review decision *is applicable* for all registered products containing imazapyr." However, at no place in the proposed decision does the PMRA ever evaluate, or summarize any evaluation of, any of these registered products.

   An evaluation of a registered pest control product would assess the product itself. For example, such an evaluation would assess the value of the product including consideration of its efficacy and alternatives. Additionally, an evaluation of a registered end-use product would consider the conditions of use as set out in the product's label. For example, the label for the product Arsenal includes instructions for mixing and using with Glyphosate which raises cumulative effects concerns from co-use with other products. There is nothing in the proposed special review document that suggests an evaluation of risks, value and specific use conditions was conducted for any registered products containing imazapyr.

   Further, we note that a pest control product containing imazapyr, Salute B Herbicide, was registered on September 18, 2014 and was not listed in Appendix 1. Another pest control product containing imazapyr, Habitat, was also not listed in Appendix 1 of the proposed special review decision. Presumably these products not listed in Appendix 1 were also not evaluated in the special review of imazapyr.

   We note here that we are very surprised and disappointed by the Agency's decision to register Salute B Herbicide at a time that all pest control products containing imazapyr are required to be undergoing a special review. To register new products containing imazapyr while conducting a special review to determine whether any products containing imazapyr should continue to be registered could reasonably be understood as an indication that the Agency has pre-determined the outcome of this special review.

The special review needs to evaluate environmental and health risks

2. Norway banned all uses of imazapyr in 2001 due mainly to groundwater contamination concerns caused by its persistence and high mobility in soil. Norwegian regulations state that no pesticide should contaminate drinking water in concentrations above 0.1 µg/L, and modelling suggests that imazapyr contamination in groundwater may exceed this threshold. It is striking that the maximum estimated environmental concentration calculated for imazapyr groundwater is 2.0 µg a.i./L and the maximum estimated drinking water concentration in Canada calculated in groundwater was 36 µg a.i./L. This is20 to 360 times greater than Norway's threshold value. Likewise, monitoring in the State of Montana identified some concentrations 110 times greater than Norway's threshold value. .

The proposed decision explains that the PMRA drinking water risk assessment takes into account toxicity, as well as estimated concentrations in drinking water, and that higher concentrations of imazapyr are considered acceptable because of its low toxicity at these concentrations. This approach ignores the cumulative and synergistic risks of multiple substances contaminating drinking water, combined with other pathways of exposure. The PMRA should give thorough consideration to the more precautionary rationale leading to a ban on the active ingredient in Canada.

3. Furthermore, it is unclear why the PMRA is using two different maximum application rates for assessing groundwater contamination concentrations versus drinking water concentrations. For the former, the the maximum food crop application rate is used (9 g a.i. /ha). For the latter, double the much higher maximum overall rate is used (1.69 kg a.i./ ha). While we can appreciate the need to be conservative on the drinking water assessment, we do not understand why the Agency would limit the environmental assessment to the much lower maximum food crop application rate. Clarification of the rationale for this decision is needed.

4. The proposed decision suggests that the potential for imazapyr contamination of groundwater in Canada is minimized by advisory environmental hazard statements on the label of end-use products. We are concerned that these measures are significantly less protective than the ban implemented in Norway to address the same issue. At a minimum, the PMRA should assess enforcement/compliance with labelled risk reduction measures and the effectiveness of precautionary statements in reducing contamination to groundwater.

5. According to the USEPA Reregistration Eligibility Decision for imazapyr (2006), "…there are ecological risks of concern associated with the use of imazapyr for non-target terrestrial plants and aquatic vascular plants, and potential risks to federally listed threatened and endangered species ("listed species") which include aquatic vascular plants, terrestrial and semi-aquatic monocots and dicots that cannot be precluded at this time. Imazapyr use at the labeled rates on non-crop areas when applied as a spray or as a granular to forestry areas present risks to non-target plants located adjacent to treated areas.". In light of concerns leading to a ban in Norway (noteably imazapyr's persistence and mobility in soil), the PMRA should assess the effectiveness of labelled risk reduction measures in protecting threatened and endangered species in Canada in particular.

6. The proposed decision states that no Canadian groundwater monitoring data on imazapyr is available but does not indicate any efforts on the part of either the PMRA or the registrant to obtain such data. The special review is an opportunity for the PMRA to obtain Canadian data on imazapyr contamination and total pesticide loading in groundwater. Once obtained and analyzed, the results should be made public and considered in a revised proposed decision for consultation.

7. We are also concerned that the proposed special review released for consultation lacks sufficient detail on its assumptions and methods to properly provide comments on certain issues. As mentioned above, it is not clear why the estimated environmental concentration of imazapyr was

based on the maximum yearly application rate of imazapyr on currently registered food crops, as opposed to the overall maximum Canadian application rate as was used in estimating drinking water concentrations.

The special review must evaluate available information on aggregate exposure including dietary exposure and exposure from drinking water

8. The Agency has assessed that chronic exposure is less than 0.1% of the acceptable daily maximum intake of 2.53 mg/kg bw/day for all population subgroups, below the level of concern. However, it is impossible to ascertain how all population subgroups were accounted for because the Agency does not disclosure the calculations on which this is based.

9. Similarly, the Agency does not disclose the source of the no observed adverse effects level (NOAEL), other than to say it was a 24-month rat combined chronic/carcinogenicity study.[1] It is therefore very difficult to assessthe safety and acceptability of the NOAEL. This has implications for the reasonableness of the Agency's decision to not apply the 10-fold PCPA factor under s. 19(2)(b)(iii), as discussed further below.

10. There is no consideration of other sources of aggregate exposures to pest control products containing imazapyr, such as dermal exposure and inhalation, both of which are typical exposures for persons applying imazapyr products. As required by law, the special review must evaluate available information on aggregate exposure including dietary exposure and exposure from drinking water

The special review must evaluate the cumulative effects of products containing imazapyr in combination with other pest control products with a common mechanism of toxicity

11. The *PCPA* requires, at s. 19(2)(b)(i), the Agency to evaluate the "cumulative effects of the pest control product and other pest control products that have a common mechanism of toxicity". As with aminopyralid, the proposed special review decision for imazapyr also declines to assess any cumulative effects. This failure to assess cumulative effects is three-fold.

    First, the Agency does not assess the cumulative effects of the many registered pest control products, listed in Appendix 1, that all contain imazapyr. Clearly these eight products, including Salute B Herbicide, have common mechanisms of toxicity.

[1] The acceptable daily intake of 2.53 mg/kg bw is based on a NOAEL of 253 mg/kg bw/day with an uncertainty factor of 100 applied to it (10 for interspecies variation and 10 for intraspecies variation).

Second, the Agency does not assess the cumulative effects of the three of these eight pest control products that also contain the second active ingredient of imazamox.[2] If products containing imazamox have a common mechanism of toxicity, cumulative effects should be assessed.

Third, and most concerning, the Agency does not rule out the likelihood that these eight pest control products have common mechanisms of toxicity with other pest control products in Canada. Rather, the Agency simply concludes that no common mechanism of toxicity has been identified for imazapyr and other active ingredient. The Agency's failure to identify common mechanisms of toxicity does not mean these do not exist; again, to rely on a lack of full scientific certainty as a justification for not assessing cumulative effects would be inconsistent with the precautionary principle. Importantly, in deeming there to be no common mechanism of toxicity that would require a cumulative effects assessment, the mechanism of toxicity that the Agency considered is not disclosed. The PMRA must evaluate the cumulative effects of products containing imazapyr in combination with other pest control products with a common mechanism of toxicity.

If the PMRA does not apply the 10-fold margin of safety for protecting children and infants in this special review, the PMRA should explain its reasons why and indicate the data it relies on

12. Under s. 19(2)(b)(iii) of the *PCPA,* in respect of a threshold effect, the PMRA is obliged to apply a margin of safety that is ten times great than the margin of safety that would other apply under s. 19(2)(b)(ii) if the pest control product is used in or around homes or schools. The proposed special review decision advises that the Agency is *not* applying this higher margin of safety – that is, the "10-fold PCPA factor" – to imazapyr, or presumably to any pest control products containing imazapyr. Rather, the Agency decided to reduce the 10-fold PCPA factor to 1. However, it is unclear whether this decision is justified or precautionary. The Agency does not conclude that none of the many pest control products containing imazapry are *not* used in or around homes or schools. urthermore, it appears that the Agency's proposed decision not to use the 10-fold PCPA factor in this special review may be inconsistent with the Agency's published policy documents. According to the Agency's Uncertainty Factor Guideline,[3] the Agency "interprets the new PCPA provisions are requiring a presumption application of the 10-fold factor for the protection of infants and children. In other words, the onus is on the PMRA to provide a reliable scientific rationale in those cases where the 10-fold PCPA factor is reduced". The Agency has not provided any such reliable scientific rationale here, but merely stated that it assessed the toxicity database for children and infants to be complete and that there is "no indication of increased susceptibility to fetuses or offspring compared to parental animals in reproductive and developmental studies". Thus the Agency appears to rely on a lack of data to assume safety, which is inconsistent with a precautionary approach. Furthermore, the Agency does not address any data regarding *exposure* of infants and

[2] Salute B Herbicide, Ares and Ares Bulk Herbicide.
[3] *The Application of Uncertainty Factors and the Pest Control Products Act Factor in the Human Health Risk Assessment,* at http://www.hc-sc.gc.ca/cps-spc/alt_formats/pacrb-dgapcr/pdf/pubs/pest/pol-guide/spn/spn2008-01-eng.pdf.

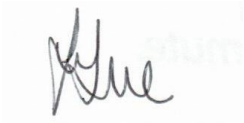
children, as is required under s. 19(2)(b)(iii). Nor does the Agency disclose which studies it relies on, making it impossible to assess if this rationale is reliable. Finally, the human health risk assessment of imazapyr conducted for Washington State provides contrary evidence, namely the existence of possible endocrine effects which could create greater susceptibility to fetuses[4].

To be clear, the application of the 10-fold PCPA factor may or may not be appropriate here, and may or may not change the Agency's assessment of human health risks of pest control products containing imazapyr. However, if the Agency continues to conclude that it is not appropriate to apply the 10-fold PCPA factor, a more transparent rationale is required, including an identification of the reliable scientific data relied upon with respect to both toxicity to and exposure of infants and children.

Finally, we note that Norway's ban on imazapyr took effect in December, 2001, but 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. We hope to have the opportunity to comment again on a revised proposed decision that addresses more completely the issues raised by the Norwegian ban on imazapyr and evaluates the risks and value of registered end-use products.

Sincerely,



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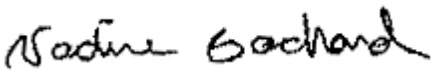

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[4] *Human Health and Ecological Effects Risk Assessment, Imazapyr Risk Assessment, Washington State*, at http://agr.wa.gov/plantsinsects/weeds/npdespermits/docs/2009AMECHumanHealthEcologicalEffectsRiskAssessmentImazapyr.pdf