June 9, 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 Aminopyralid: Proposed Decision for Consultation

This letter is in response to the invitation for public comment on Re-evaluation Note REV2014-01, posted on April 24, 2014. The David Suzuki Foundation and Équiterre are 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 aminopyralid, as required by s. 17(2) of the *Pest Control Products Act*. However, we are disappointed by the lack of rigour with which the Agency appears to have conducted this special review. In our view, a special review conducted pursuant to s. 17(2) should not merely rubber-stamp a pre-existing regulatory decision. Rather, it should give thorough consideration to the concerns leading to a ban on the active ingredient in another country to assess whether the risks and value of the pest control product are acceptable for continued registration in Canada This could 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 PMRA or the country with a ban in place.

Moreover, the special review of aminopyralid focuses exclusively on the active ingredient and does not examine individual end-use pest control products containing aminopyralid as required by the Act. We note the PMRA's original assessment of aminopyralid in 2007 considered only one associated end-use product, Aminopyralid Liquid Concentrate Herbicide, whereas currently there are 11 aminopyralid products registered in Canada and one application pending.

We ask the PMRA to conduct a more robust special review of registered use pest control products containing aminopyralid and then issue a revised proposed decision for consultation. In particular, we hope a revised proposed decision will address the following issues:

1. Norway banned all uses of aminopyralid in 2011 due mainly to groundwater contamination concerns. Norwegian regulations state that no pesticide should contaminate drinking water in

concentrations above 0.1 µg/L, and modelling suggests that aminopyralid contamination in groundwater may exceed this threshold. It is striking that use of aminopyralid pesticides in Canada is estimated to result in groundwater concentrations of 66.7 µg/L – more than 600 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 aminopyralid 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 evaluate the appropriateness of its approach to managing drinking water contamination risks and assess alternative approaches (such as the Norwegian model), in light of the statutory requirement at s. 19(2)(b)(i) of the Act to take into account aggregate exposure and cumulative effects of the pest control product and other pest control products with a common mechanism of toxicity.

2. We would like to bring to the PMRA's attention laboratory results cited by the U.S. Environmental Protection Agency showing effects from chronic exposure at levels lower than those identified in the 2007 assessment (p. 34).[1]

3. We would like to know whether the PMRA applied the additional margin of safety of 10 required by the Act at s. 19(2)(b)(iii) in evaluating aminopyralid, given that the labelled used of some end use products suggest possible use near schools or homes.

4. The proposed decision suggests that the potential for aminopyralid contamination of groundwater in Canada is minimized by "precautionary statements" and measures (e.g., spray drift buffer zones) stated 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.

[1] "Longer term studies indicate that the stomach, ileum, and cecum are targets for aminopyralid. In a subchronic feeding study in rats (XDE-750), hyperplasia of the mucosal epithelium of the ileum and cecum was observed at the highest dose tested (HDT) of 1,000 milligrams/kilograms/day (mg/kg/day). Chronic exposure in rats (XDE-750) also resulted in hyperplasia of the mucosal epithelium, along with cecal enlargement and decreased body weights at a lower dose of 500 mg/kg/day. Hypertrophy and hyperplasia of the mucosal epithelium were seen after subchronic exposure in dogs (XDE-750) at the HDT of 929 mg/kg/day. Thickening of the stomach mucosa (females), hyperplasia and hypertrophy of the mucosal epithelium, slight lymphoid hyperplasia of the gastric mucosa, and very slight/slight chronic mucosal inflammation were observed in dogs after chronic exposure at the HDT of 967 mg/kg/day." Environmental Protection Agency, 2010. Vol. 75, Issue 066. Federal Information & News Dispatch, Inc., p. 17579.

5. The proposed decision states that no Canadian groundwater monitoring data on aminopyralid is available but does not indicate any efforts on the part of either the PMRA or the registrant to obtain such data. We note that the U.S. Environmental Protection Agency is planning a 12-month groundwater monitoring study to support its registration review of aminopyralid.[2] It is troubling that the Canadian regulator is not addressing this issue with the same level of diligence. The special review is an opportunity for the PMRA to obtain Canadian data on aminopyralid 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.

6. The PMRA should clarify its views on the persistence of aminopyralid. Regulatory Note REG2007-01 states that aminopyralid meets the criteria for persistence in soil and water/sediment systems (p. 51). Yet the proposed decision characterizes it as "non-persistent to slightly persistent in most soils" and persistent in aquatic environments (p. 2). We disagree with the assessment that dissipation through leaching equates to non-persistence. On the contrary, this signals the chemical's persistence in the wider environment. Persistence is a characteristic of the substance. Material balance must be met in analyzing persistence.

7. Recently, concerns have been raised about aminopyralid residue in compost and animal feed. This issue does not appear to have been foreseen in either the 2007 Canadian or the 2010 Norwegian assessments of aminopyralid. The U.S. Environmental Protection Agency has just announced plans to study the dissipation of aminopyralid in compost.[3] The PMRA should also examine this issue. In the context of the special review, the potential for groundwater contamination as a result of leaching in areas where contaminated compost has been applied or pastureland, in the case of animal feed, are particularly relevant.

8. We are concerned that key regulatory decisions concerning aminopyralid are difficult to find on the Health Canada web site. The proposed special review document states that aminopyralid was first registered in 2006. However, we have not been able to locate any record of this registration decision on the Health Canada web site and Regulatory Note REG2007-01, suggests that aminopyralid was in fact "proposed for temporary registration" in 2007. This Regulatory Note also specifies, "The applicant will be carrying out additional chemistry, storage stability, environmental chemistry and value studies as a condition of this temporary registration. Following the review of this information, the PMRA will publish a proposed registration decision document and request comments from interested parties before proceeding with a final regulatory decision" (p. 52).We have located, after some difficulty, a regulatory document from

[2] Aminopyralid Preliminary Work Plan, March 2014 http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2013-0749

[3] Aminopyralid Preliminary Work Plan, March 2014 http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2013-0749

2008 regarding the conversion of the registration of aminopyralid from temporary to full registration. However, we have not located any record of the 2008 document being subject to public consultation and are concerned that PMRA may have made a final regulatory decision about the registration of this active ingredient without undertaking the legally required consultations.

In future special review consultations, we recommend the PMRA provide a list of all related regulatory documents, including URLs, with the proposed decision and ensure these related documents are clearly posted in the list of decisions and updates on the Health Canada web site (http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_decisions/index-eng.php).

Finally, we note that Norway's ban on aminopyralid took effect in January 2, 2011, 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 pesti 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 aminopyralid and evaluates the risks and value of registered end-use products.

Sincerely,

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