Information Note: Request for a Special Review of Glyphosate Herbicides Containing Polyethoxylated Tallowamine

Canada

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Health Canada's Pest Management Regulatory Agency (PMRA) may conduct special reviews to verify continued acceptability of registered pest control products. Section 17 of the *Pest Control Products Act* requires that the Minister initiate a special review if there are reasonable grounds to believe that the health or environmental risk associated with a product are, or its value is, unacceptable. While a re-evaluation is an overall reassessment of the health and environmental risks as well as the value of products, a special review typically targets a specific issue. This Information Note describes the PMRA's response to a recent application requesting that the agency initiate a special review.

What was the basis of this request?

On 25 May 2009, a member of the public requested that a special review be initiated, under Section 17 of the *Pest Control Product Act*, for glyphosate herbicides containing the formulant polyethoxylated tallowamine (POEA) on the grounds that they represent unacceptable risks to human health and the environment. Twelve documents were provided as justification for the request.

The PMRA's response to this request based on health concerns

The PMRA reviewed the submitted documents and recognizes that the overall conclusion reported by these health studies is that the POEA formulants present in certain glyphosate formulations make the product more toxic than glyphosate alone. However, it is important to note that all the studies were performed *in vitro* using cell cultures in a solution containing a glyphosate formulation; such an exposure scenario is not representative of what occurs with *in vivo* exposure of living organisms to glyphosate and POEA. Although information from *in vitro* studies is considered in the overall assessment of a product, *in vivo* studies by various routes (oral, dermal or inhalation) are more representative of the hazard potential. The PMRA assessments such as those that were conducted for glyphosate products containing POEA are based primarily on *in vivo* studies.

In addition, the PMRA concluded that the data presented in a submitted epidemiology study do not provide strong evidence of an important relationship between glyphosate exposure and spontaneous abortions due to unvalidated self-reported exposure information and lack of control for potentially important confounding factors such as maternal age.

Therefore, the PMRA did not find new evidence in this material to support a special review of health effects.

The PMRA's response to this request based on environmental concerns

The PMRA recognizes the toxicity of glyphosate formulations to aquatic organisms and that the toxicity of those formulations is at least in part attributable to the formulant POEA. However, it is important to note that in Canada, there are currently no registered uses of glyphosate for direct application to water. Based on the currently available

toxicity data, it is expected that the existing mitigation measures on labels that limit drift into aquatic systems from agricultural uses will be protective of amphibians in small ephemeral wetlands. Labels for forestry uses also indicate that appropriate "no-spray" buffer zones should be maintained to protect aquatic species.

The PMRA concluded that there is insufficient new evidence of unacceptable risk to amphibians in the submitted information to support a special review of environmental effects. The upcoming re-evaluation of glyphosate will include consideration of amphibians and POEA.

Additional comments

Subsection 17(2) of the *Pest Control Products Act* states that the Minister shall initiate a special review when a member country of the Organisation for Economic Co-operation and Development prohibits all uses of an active ingredient for health and environmental reasons.

A regulatory review by the Australian National Registration Authority was cited as the basis for needing a special review under subsection 17(2). However, Australia has not prohibited all uses of glyphosate but rather has restricted it by removing uses with direct application to water in order to minimize any possible aquatic contamination. Therefore, subsection 17(2) does not apply. As noted previously, there are no registered uses for direct application to water in Canada.

Subsection 17(3) of the *Pest Control Products Act* states that the Minister shall initiate a special review of the registration of a pest control product if a federal or provincial government department or agency has provided information to the Minister that relates to the health or environmental risks or the value of the product and if, after considering the information provided, the Minister has reasonable grounds to believe that the risk or value of a product is unacceptable.

A literature review published by the Government of British Columbia was cited as the basis for needing a special review under subsection 17(3). This document was considered with the other material regarding environmental concerns, and the conclusion was that a special review was not warranted.

Conclusion

Based on the overall assessment of the request, the PMRA has determined that the information submitted does not meet the requirements to invoke a special review. However, the PMRA will address the potential risks associated with both glyphosate and POEA within the broader re-evaluation of all glyphosate products. While this may entail additional work due to the broader scope, it will lead to a more complete consideration of the concerns.

The PMRA anticipates that the re-evaluation of glyphosate will be officially announced within the year. The PMRA will be working jointly with the United States Environmental Protection Agency on this re-evaluation.