Health Canada | Santé Canada

Pest Management Regulatory Agency | Agence de réglementation de la lutte antiparasitaire

January 25, 2001

MEMORANDUM TO REGISTRANTS, APPLICANTS AND AGENTS

As outlined in the North American Initiative Paper (November 1998), the Canadian Pest Management Regulatory Agency (PMRA) and the United States Environmental Protection Agency (EPA) have committed to the harmonization of their registration processes. The purpose of harmonization is to develop a more efficient method of assuring the safety and efficacy of pesticides, with the added benefit of promoting sound regulatory policies worldwide. Harmonization benefits everyone by encouraging availability of new and safer products, reducing duplication of effort, and streamlining the pesticide review process.

It is clear that one consequence of the implementation of the North American Initiative is the challenge of developing effective consultation mechanisms across all three North American Free Trade Agreement countries. Individually, countries have processes in place that meet their national needs. As closer cooperation amongst regulators increases, however, there is a need to encourage stakeholder input across countries.

For harmonization activities that result in the modification of data requirements, each country follows their national procedure for implementation. For the PMRA, this procedure includes an opportunity for public comment by putting out a Regulatory Proposal for comment, followed by subsequent publication as a Regulatory Directive.

The EPA has taken the lead in developing science policies related to the U.S. *Food Quality Protection Act* (FQPA). Harmonization of these policies between our agencies has been key to our ability to do joint reviews. Development of these policies required broad scientific input involving numerous scientists outside of regulatory agencies. The PMRA informed stakeholders at a meeting in Ottawa (July 1998) that it would be adopting the new science policies as they were implemented by the EPA. Members of the Pest Management Advisory Council were also advised of this at a meeting in February 1999.

To date, the PMRA has participated in the U.S. Tolerance Reassessment Advisory Committee (TRAC), which established a framework for the development and implementation of these science policies. The PMRA continues to be involved with the new U.S. Committee to Advise on Reassessment and Transition (CARAT), which has replaced TRAC, and has provided input to the U.S. science policies during their development.

The key considerations of these science policies are as follows:

1. In the case of threshold effects, an additional tenfold margin of safety for the pesticide chemical residues from dietary and other non-occupational sources of exposure shall be applied to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. A different margin of safety for the pesticide chemical residue may be used only if, on the basis of reliable data, such a margin will be safe for infants and children.

2. Available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue, including dietary exposure under the maximum residue limit (MRL) and all other MRLs in effect for the pesticide chemical residue, and exposure from other non-occupational sources shall be considered. This includes dietary food and drinking water exposure and other non-occupational exposures such as those from pesticide use in and around homes.

3. Available information concerning the cumulative effects of such pesticide chemical residues that have a common mechanism of toxicity shall be considered.

To ensure that Canadian stakeholders are aware of the harmonization with the EPA on these science policies, the PMRA has implemented the following process:

1. The PMRA will post a notice on its web site (www.hc-sc.gc.ca/pmra-arla, under FQPA announcements) when the EPA puts an FQPA-related document on the EPA science policies web site (www.epa.gov/pesticides/trac/science/). Canadian stakeholders are encouraged to send comments directly to the EPA in response to the U.S. Federal Register notices that solicit comments on each of the specific science policies. The U.S. Federal Register notice of availability can also be

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found at www.epa.gov/pesticides/trac/science/. A pesticide manufacturer with offices in the U.S. and Canada may wish to submit a joint response to the EPA. Copies of these comments can also be provided to the PMRA and should be directed to the Submission Management and Information Division.

2. When the U.S. EPA has finalized their position, the PMRA will review the science policy and adapt it as appropriate to the Canadian regulatory framework. Any areas where the PMRA has used an alternative approach based on science and other harmonization obligations will be highlighted.

3. A list of the science policies related to the FQPA that will be used by the PMRA can be found on the PMRA web site and is included here for your convenience.