

PROJECT SHEET

SUBCOMMITTEE: Joint Review

PROJECT TITLE: **Improved Coordination of Reregistration, *Food Quality Protection Act* (FQPA) and Re-evaluation Process**

PROJECT ID: JR05-98-1105

PROJECT TEAM: United States: Tom Myers
Canada: John Worgan

INITIATION: February 1998

UPDATE: June 2006

GOAL: To identify common re-evaluation/reregistration initiatives and opportunities for work sharing and increased efficiency, focussing on chemical groups most affected by the United States *Food Quality Protection Act* (FQPA).

PROJECT DESCRIPTION:

On an ongoing basis, to seek ways in which to coordinate the reregistration/re-evaluation process including communication, scheduling and work/information sharing.

The *Federal Insecticide, Fungicide and Rodenticide Act* (FIFRA), as amended by the *Food Quality Protection Act* (FQPA), establishes the schedule for reregistration in the United States. The FQPA also requires that all tolerances (maximum residue limits or MRLs in Canada) and exemptions from tolerances be reassessed by August 2006. Based on an assessment of those pesticides that appear to be of highest concern, the United States Environmental Protection Agency (EPA) has divided the chemicals for tolerance reassessment into three priority groups. Tolerance reassessment and reregistration of the organophosphate pesticides as well as some other selected pesticides are receiving highest priority. The EPA and the United States Department of Agriculture have established a new advisory group to ensure the broadest possible public involvement in the implementation of the FQPA, including tolerance reassessment.

Health Canada's Pest Management Regulatory Agency (PMRA) initiated a new re-evaluation process in 2001 to maximize the use of recent re-evaluations completed in other countries, in particular those of the EPA. The PMRA target for completion of the re-evaluation of all older pesticides is 2006–2007 for food use chemical and 2008–2009 for non-food chemicals. This schedule was established on the basis of making maximum use of international reviews of data, in particular those from the EPA, and will provide more opportunities to harmonize MRLs as much as practicable. Priorities for the re-evaluation program were established based on consideration of a number of factors including the following:

- the extent of use and toxicity profile for food use chemicals;
- the potential for cooperative re-evaluation under NAFTA (e.g., wood preservatives);
- Canadian specific concerns; and
- the availability of review conducted in the United States.

BACKGROUND / RATIONALE:

Joint reviews and work sharing activities have tended to focus on newer pest control products. As a result of discussion among members of the NAFTA Technical Working Group, it was concluded that reregistration (review of older compounds) would benefit from a similar approach. A well-defined process for coordinating reregistration and sharing information on currently registered products is needed, especially with respect to the potential impacts on Canada and Mexico of the implementation of the FQPA.

The FQPA requires the EPA to examine the aggregate risks of individual pesticides as well as the cumulative risks of chemical groups with a common mechanism of action. In accordance with the necessity to look at the more risky pesticides first, focus was initially placed on re-evaluation of the organophosphates, carbamates and B2 carcinogens. Re-evaluation is expanding to include other groups of compounds.

The re-evaluation of the active ingredients under the FQPA may result in changes in the uses and associated tolerances of these chemicals; thus, this process has the potential to affect trade with NAFTA partners. As a result, it is important that the United States, Canada and Mexico work closely together to ensure that the best possible information is used in making decisions and that all groups are kept fully informed throughout the re-evaluation process.

Both agencies will benefit from future cooperation in the registration review (15-year cyclical) process.

In 2004, NAFTA member countries agreed to formalize cooperative initiatives. Through informal arrangements, the following initiatives were undertaken:

- The EPA and the PMRA have harmonized several FQPA science policies (e.g., aggregate exposure assessment).
- Most PMRA re-evaluations build on EPA reviews (REDs), and most decisions are harmonized.
- The EPA participated on an expert panel convened by the PMRA for 2,4-D turf assessments.
- An aluminum and magnesium phosphine monitoring study was submitted to both the EPA and the PMRA, and the respective reviewers are discussing the results of the study.
- A Record of Understanding developed between the United States and Canada commits to ongoing cooperation with respect to the FQPA.

WORK PLAN

SUBCOMMITTEE: Joint Review

PROJECT TITLE: Improved Coordination of Reregistration, *Food Quality Protection Act (FQPA)* and Re-evaluation Process

UPDATE: October 2004

GOAL	ACTIVITIES	TIME FRAME
<p>1. Share experience of reviewing labels of selected organophosphates</p> <p>Canada contracted a review of whether efficacy data existed that would allow a refinement of the uses of certain organophosphates and, therefore, a lowering of label rates.</p> <p>Canada prepared consolidated summaries of Canadian label uses of all organophosphates, to be used as the basis for establishing the final use standard and carrying out label changes and improvements.</p>	<p>The PMRA forwarded information to the EPA.</p> <p>Results supplied to the EPA, as available.</p>	<p>Complete.</p> <p>The PMRA has forwarded label summaries for malathion, azinphos-methyl, ethion, naled, phorate and terbufos to the Biological and Economic Assessment Division (BEAD). Similar label summaries are available for all of the organophosphates currently registered for use in Canada.</p>
<p>2. Identify priority candidates</p> <p>Organophosphates, carbamates, B2 carcinogens</p>	<p>Scheduling of tolerance reassessment under the FQPA and reregistration schedules.</p>	<p>Complete. The PMRA re-evaluation priorities and schedules are largely linked to those of the EPA.</p>

GOAL	ACTIVITIES	TIME FRAME
<p>3. Identify common re-evaluation/re-registration initiatives and opportunities for work sharing and increased efficiency</p>	<p>Develop a communication strategy for NAFTA partners, explore avenues for their participation in the tolerance reassessment.</p> <p>Conduct monthly EPA/PMRA conference calls to discuss re-registration issues.</p> <p>Canadian participation in EPA working groups, Science Advisory Panels, technical sessions and discussions.</p> <p>PMRA attendance at CARAT and PPDC meetings.</p>	<p>Ongoing: Meeting held between PMRA and EPA co-chairs on February 17, 1998, to explore possibilities.</p> <p>Ongoing (initiated August 2002).</p> <p>The PMRA is keeping abreast of changes that are ongoing at the EPA as a result of the FQPA. The PMRA is actively participating with the EPA in certain areas, e.g., residential exposure to achieve harmonized approaches. The PMRA has harmonized several FQPA policy papers.</p> <p>Ongoing</p>
	<p>Opportunities for work sharing in registration review (15-year cycle) are being examined through the PMRA's participation at registration review meetings and the EPA attendance at PMRA stakeholder meetings on re-evaluation.</p> <p>Opportunities for harmonization of tolerances/MRLS are being explored.</p>	<p>Ongoing</p> <p>Ongoing</p>