

Fact Sheet on International Harmonization of Pesticide Regulation

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What is Harmonization?

Health Canada's Pest Management Regulatory Agency (PMRA) is working with its counterparts in other countries in North America and abroad to harmonize the processes used to regulate pest control products. The purpose of harmonization is to develop a more efficient method of bringing safe and effective pesticides to the consumer, with the added benefit of promoting sound regulatory policies worldwide.

Harmonization is aimed specifically at standardizing:

- ' the type and scope of studies required to register a pesticide;
- ' the protocol followed in carrying out these required studies;
- ' the format and presentation of manufacturers' submissions for registration (dossier); and
- ' the methods used to evaluate submissions and prepare country reports (monograph).

Harmonization requires a complete understanding of the methods and practices used to regulate pesticides in other countries and a willingness on the part of all parties involved to work toward converging these approaches. This does not mean setting standards to the lowest common denominator, or simply accepting another country's decision, but rather finding an acceptable middle ground that will maintain our current high level of protection of the health of Canadians and of their environment. When agreement cannot be reached, the differences will be clearly delineated.

What Is Being Done?

Canada is pursuing a wide range of initiatives with the United States and Mexico through the North American Free Trade Agreement (NAFTA) Technical Working Group on Pesticides (TWG) and with other countries through the Organisation for Economic Co-operation and Development (OECD) Pesticides Forum.

Significant progress is being made on these fronts, but the work is proceeding with all the caution and attention to detail necessary for safeguarding health and the environment. Regulating pesticides is a complex responsibility, and harmonization has to take into consideration the wide range of ecological and cultural (dietary) factors amongst countries.

The NAFTA TWG met for the first time in March 1996. The members are devoting their energy to creating a more consistent basis for pesticide registration by 2002. Within five years, the NAFTA TWG aims to have work sharing become routine amongst Canada, the United States and Mexico (North American Initiative). This will build on the work sharing that has already started within the NAFTA TWG projects.

Targets for harmonizing pesticide regulatory processes in the NAFTA countries include:

- ' common data submissions for manufacturers;
- ' greater coordination of approval processes for pesticides;
- ' the elimination of trade problems related to differences in maximum residue limits (MRLs);
- ' a common labelling system; and
- ' concurrent access to products.

The NAFTA TWG's progress of specific interest to Canada includes:

- ' the launch of joint review of submissions by the PMRA and the U.S. Environmental Protection Agency (EPA) of reduced-risk chemical pesticides and biopesticides (microbials and pheromones);
- ' the resolution of specific trade irritants related to differences in MRLs between Canada and the U.S.;
- ' the creation of residue zones that are equivalent in Canada and the U.S., thereby reducing the need to redo residue trials;
- ' the launch of a Canada-U.S. initiative to develop mutually-acceptable models for predicting spray drift and deposit;
- ' a Canada-U.S. agreement on study protocols for environmental fate and toxicology;
- ' work sharing on the re-evaluation of wood preservatives; and
- ' a successfully completed Integrated Pest Management project between Canada and the U.S. on late blight in potatoes and ongoing work on Integrated Pest Management projects for the Colorado potato beetle and canola.

Internationally, the OECD Pesticides Forum is also working to improve efficiencies in its members' pesticide regulatory programs. Current efforts are focused on developing:

- ' a common format for industry data submissions and country review reports;
- ' a compatible electronic data submission and review process;
- ' common data sets and evaluation criteria;
- ' common data requirements for pheromones and microbials;
- ' comprehensive summary requirements;
- ' test guidelines; and
- ' effective risk reduction initiatives.

Updates on both NAFTA and OECD progress can be obtained on the PMRA web site at: <http://www.hwc.ca/pmra>, or by contacting the PMRA Pest Management Information Service at: 1-800-267-6315.

Who Will Benefit?

Harmonization benefits everyone by reducing duplication of effort and streamlining the pesticide review process.

Regulatory agencies will see increased efficiency as a result of work sharing initiatives and joint reviews. The pesticide industry will benefit from reduced submission costs and faster and broader access to international markets. Growers in all countries will have prompter and more equitable access to a wider range of more effective pest control products, and the public will see health risks reduced as newer and safer pest control products are introduced.

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