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# Pest Management Regulatory Agency

## *Information Note*

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11 February 2005

### **Harmonization and International Regulatory Cooperation**

Health Canada's Pest Management Regulatory Agency (PMRA) is responsible for regulating pesticides in Canada and determining whether the risks associated with their use are acceptable before allowing their use in Canada. The 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 facilitate international regulatory cooperation in order to share the work of evaluating pesticides.

#### **The Goals of Harmonization**

Harmonization is a complex process that requires an understanding of the methods and practices used to regulate pesticides in other countries as well as 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.

Harmonization activities are aimed specifically at standardizing the following:

- 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);
- the methods used to evaluate submissions and prepare country reports (monograph);
- the methods used to transmit and archive submissions and country reports; and
- the methods used to carry out risk assessments.

#### **Important Accomplishments**

Significant progress on these fronts has facilitated international cooperation and, in particular, the Joint Review Program for new pesticides. Joint reviews provide the opportunity for companies to submit pesticide applications to Canada's PMRA and the United States Environmental Protection Agency (USEPA) at the same time. Because the work of reviewing the submission is shared between the two countries, the product becomes available on both sides of the border at the same time according to mutually agreed time frames.

In fact, about 50% of new pesticides submitted to Canada are reviewed jointly with the United States or by using reviews from other countries. As of March 2004, 55 pesticides were registered as a result of joint reviews or work shares with the USEPA, 31 of which were reduced risk products.



The PMRA also uses USEPA reviews to re-evaluate older pesticides more efficiently. In 2003–2004, 83% of the re-evaluation decisions were completed based on USEPA reviews, resulting in most decisions being harmonized with American decisions.

### **Who Benefits?**

Harmonization benefits everyone by reducing duplication of effort and streamlining the pesticide review process. The public will see health risks reduced as newer and safer pest control products are introduced. Growers have access to the same pest control products as their counterparts in the United States with the same maximum residue limit and more equitable access to a wider range of effective pest control products. The pesticide industry benefits from reduced submission costs as well as faster and broader access to international markets. Regulatory agencies achieve increased efficiency as a result of work sharing initiatives and joint reviews.

### **Next Steps**

Harmonization efforts are ongoing in the face of rapidly advancing and more complex science. The PMRA is continuing to work with the USEPA to resolve remaining differences and to make the joint review process more efficient, while encouraging active participation by industry. The PMRA will continue to improve the regulatory processes that make international cooperation possible, working to expand cooperation with the European Union, Australia as well as other regions and countries. Active industry participation will be critical to success in these areas.

Work sharing with other regulators will be facilitated under the new *Pest Control Product Act*, which will come into force as early as possible in 2005. Under the new Act, reviews related to a pesticide submission will be available as soon as a registration decision has been made.

### **Need More Information?**

Visit the following links on the PMRA's website to read more about the topics discussed in this document.

## **Harmonization**

### *Science policies on harmonization*

[www.pmra-arla.gc.ca/english/pubs/fqpa-e.html](http://www.pmra-arla.gc.ca/english/pubs/fqpa-e.html)

### *The PMRA Initiative for Reduced Risk Pesticides*

[www.pmra-arla.gc.ca/english/pdf/dir/dir2002-02-e.pdf](http://www.pmra-arla.gc.ca/english/pdf/dir/dir2002-02-e.pdf)

### *Fact Sheet on International Harmonization of Pesticide Regulation*

[www.pmra-arla.gc.ca/english/pdf/fact/fs\\_harmon-e.pdf](http://www.pmra-arla.gc.ca/english/pdf/fact/fs_harmon-e.pdf)



## **International Partners**

### *International Focus*

[www.pmra-arla.gc.ca/english/intern/intern-e.html](http://www.pmra-arla.gc.ca/english/intern/intern-e.html)

### *NAFTA Technical Working Group on Pesticides*

[www.pmra-arla.gc.ca/english/intern/twg-e.html](http://www.pmra-arla.gc.ca/english/intern/twg-e.html)

### *Organisation for Economic Cooperation and Development*

[www.pmra-arla.gc.ca/english/intern/oeecd-e.html](http://www.pmra-arla.gc.ca/english/intern/oeecd-e.html)

## **Risk Assessment Process**

### *Fact Sheet on The Regulation of Pesticides in Canada*

[www.pmra-arla.gc.ca/english/pdf/fact/fs\\_pestreg-e.pdf](http://www.pmra-arla.gc.ca/english/pdf/fact/fs_pestreg-e.pdf)

or for more information on the PMRA and pesticide regulation in html format

[www.pmra-arla.gc.ca/english/aboutpmra/about-e.html](http://www.pmra-arla.gc.ca/english/aboutpmra/about-e.html)

### *Children's Health Priorities within the Pest Management Regulatory Agency (SPN2002-01)*

[www.pmra-arla.gc.ca/english/pdf/spn/spn2002-01-e.pdf](http://www.pmra-arla.gc.ca/english/pdf/spn/spn2002-01-e.pdf)

### *A Decision Framework for Risk Assessment and Risk Management in the Pest Management Regulatory Agency (SPN2000-01)*

[www.pmra-arla.gc.ca/english/pdf/spn/spn2000-01-e.pdf](http://www.pmra-arla.gc.ca/english/pdf/spn/spn2000-01-e.pdf)

## **Government Regulations**

### *New Pest Control Products Act*

[www.pmra-arla.gc.ca/english/legis/pestcont-e.html](http://www.pmra-arla.gc.ca/english/legis/pestcont-e.html)

### *Government of Canada Smart Regulations*

[www.smartregulation.gc.ca/en/index.asp](http://www.smartregulation.gc.ca/en/index.asp)

