

## **EXECUTIVE SUMMARY**

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The horticulture sector in Canada represents a value of \$4.2 billion (14.2% of agriculture); a workforce of 300,000 persons and farm cash receipts greater than grains and oilseeds crops in seven out of ten provinces<sup>1</sup>. It is the fastest growing agricultural sector in Canada. Horticulture is a highly diversified production, encompassing in excess of 120 species and sub-species of fruits, vegetables and herbs. Horticulture also includes the highly diversified floral and ornamental sector, with more than 1,500 nursery crops grown in Canada.

Recognized for their superior quality and wholesomeness, Canadian-grown fruits and vegetables are very much in demand in the United States and around the world. Fruits and vegetables are the basis of a healthy diet and are known to reduce disease risks. This important fact is supported and promoted by many organizations, including the Canadian Produce Marketing Association<sup>2</sup>, the Canadian Cancer Society and the Heart and Stroke Foundation. These health aspects are acknowledged and promoted in other countries as well.

The Canadian Horticultural Council and its members are committed to producing the safest and finest quality crops in the world. We have a long history of leadership and proactive initiatives in adopting and promoting production practices that support these objectives. However, we cannot continue to meet these objectives and remain competitive without access to the newer, safer technologies that are available to our counterparts in other jurisdictions. Access is not possible without a process and system based on logic, science and a commitment to serving the best interests of the public.

With respect to production practices and, in particular, crop protection, the horticulture sector is unique in that most of the crops are minor crops. Therefore, crop protection tools utilized in this sector are considered minor use<sup>3</sup> products.

The limited availability of minor use pesticides<sup>4</sup> in Canada is a chronic and increasingly acute concern among growers and agri-food stakeholders generally. This has been a major source of frustration for over 20 years. During this time considerable resources have been dedicated to the issue with little advancement in key areas. Industry and government are at a crossroads and action is needed now.

In Fiscal Year 2000, the United States Environmental Protection Agency (EPA) registered new pesticides and approved new uses of existing pesticides which provided growers in the United States with access to 901 new uses for minor crops<sup>5</sup>. In Canada during the period of March, 2000 to February, 2001 the number of registrations was 24<sup>6</sup>.

Canada's life sciences strategy to harvest and develop a broad range of food and non-food bioproducts suggests that we increase production of specialty/niche market crops, the majority of which require minor use pesticides. It is, therefore, imperative to develop and implement solutions to the challenges.

We acknowledge the efforts and accomplishments of the Pest Management Regulatory Agency and Agriculture and Agri-Food Canada, and appreciate the working relationship we have. However, major issues remain unresolved. It is apparent that despite this relationship and PMRA activity, that a growing array of problems and disruptions are eminent. We look forward to building on these alliances as we all work together to develop solutions.

This document provides an environmental scan of the issues and includes an inventory of possibilities and examples of how to approach and resolve the challenges, while respecting the role and the need for a regulatory process and associated regulations.

## 1.1 Recommendations

*On behalf of horticulture producers in Canada  
the Canadian Horticultural Council recommends:*

<b><i>On the issue of....</i></b>	<b><i>Recommendation....</i></b>
<b>1. a) User Requested Minor Use Registration Program (URMUR)</b>	<ul style="list-style-type: none"><li>• establishment of an industry/government working group to negotiate an acceptable fee structure reflective of minor use criteria</li><li>• adoption of the principles of transparency and responsiveness</li><li>• to explore grower group endorsements in conjunction with registrant data submission</li><li>• increased flexibility from the Pest Management Regulatory Agency (PMRA) in setting data requirements and accepting reviews conducted in the United States and other OECD countries</li><li>• that the PMRA adopt the United States reduced-risk classification and reduced data requirements for minor use products. This applies equally to URMULE and Emergency Registrations</li></ul>
<b>b) User Requested Minor Use Label Expansion Program (URMULE)</b>	<ul style="list-style-type: none"><li>• that data requirements must reflect the risks inherent from the proposed use</li><li>• a negotiable approach, particularly with respect to data requirements (i.e.: consideration of data that already exist in an OECD country)</li><li>• that AAFC actively encourage and provide financial assistance for their research centres to become GLP compliant</li><li>• implement major changes to the AAFC Minor Use Program Funding Initiative (MUPFI) to reflect the huge backlog of need, the increased costs and the grower industry's financial position vis-à-vis the cost share requirement</li></ul>

### **c) Emergency Registration**

- in considering an emergency registration request, if no Canadian data can be submitted, data available from other countries as well as regulatory decisions made in other countries be accepted in Canada
- emergency registration of new actives which have a recent (less than five years) data package (reduced-risk product) from the US Environmental Protection Agency (EPA) should be considered
- increased transparency and dialogue between and among the PMRA, the sponsors (grower groups and/or provincial governments) and the registrants<sup>7</sup>

## **2. Risk Cup**

- the development and implementation of a policy of Canadian use first, including MRLs (maximum residue levels) to create room in the 'risk cup', even if this results in the removal of import-only tolerances
- that a statistically valid cross section of imported commodities be monitored for residues, and only real life numbers be applied to the equation, not assumed worst-case numbers
- removal of the 'default' MRL of 0.1 ppm for all residues and use of 0 ppm as the default MRL. Many Canadian registrations are based on 'negligible' residues, and no discrete tolerance applies. That is, the default tolerance is applied. This also applies to a significant number of imported commodities and the pest control products used on them
- harmonization of residue tolerances with the United States on all new active ingredients, with the understanding that the tolerances apply equally to imports and domestic uses. This would also require data sharing for basket study data and crop use of active ingredients in both countries

## **3. Data Requirements**

- establishment of an interface (e.g.: ombudsperson) with the PMRA to discuss and resolve differences in interpretation of all data needs as they pertain to the minor use registration process
- that the PMRA clearly outline, articulate and communicate requirements and procedures to all applicants
- an openness to negotiation of data needs, of request for data waivers and usage of similar existing data packages

*Date Requirements continued...*

- that the provincial Minor Use Coordinators be copied consistently on data requirements to a sponsor, in order to allow discussions and consultations
- that when a product is registered in Canada for use on crops other than those for which the minor use is being sought and/or is registered in the United States for that same use, that the risk inherent with the additional minor use requested be taken into consideration when evaluating the data requirements
- that a new minor use request for an active ingredient that is used on the same commodity in the United States be considered in final data evaluation

**4. Zone Maps**

- amalgamation of similar Canadian sub-zones (1, 1A; 5,5A, 5B; 7,7A) with Zone 5 and Zone 5B as the top priority for this action
- that the PMRA recognize US Zone 5 as being equivalent to Canadian sub-zone 5B, thereby rendering data from US Zone 5 as acceptable for data purposes

**5. Crop Groupings**

- that the PMRA use crop groupings for registration as outlined in the Residue Chemistry Guidelines in Regulatory Directive 98-02; at present this is not done
- to implement crop group residue limits when data exists
- to accept US crop group tolerances if the risk cup is not significantly affected
- to accept scientific rationales for crop group efficacy

**6. Seed Treatment Harmonization**

- to re-visit the 93 unique Canadian requirements included in regulatory proposal PRO 2000-05 and make it truly harmonized with the United States
- acceptance of scientific rationales prepared by qualified experts
- acceptance of the principles of seed treatment harmonization requirements on minor use submissions

**7. Joint Reviews**

- flexibility and cooperation as a key components of successful joint reviews
- that Canada allow "Tailgating"

***Joint Reviews continued...***

- that no penalty (e.g.: loss of position in the queue) be applied to a “Tailgating” situation
- timeframe commitments established for the joint review process must be met
- registrants who are willing to participate in these “pilot projects” need to receive incentives (i.e. data protection, faster registration time, reduced fees) given the bad experiences to date. The intent is to encourage joint submissions

**8. Food and Drugs Act**

- harmonization and mutual acceptance of MRLs/tolerances between the NAFTA countries
- Establishment of a temporary tolerance process for Canada so as to allow immediate use of emergency registrations, and time limited or temporary registrations for use on food crops
- an amendment/change in the regulations so as to expedite the process of establishing MRLs, such as a limited delegation of authority to the Executive Director of the PMRA to sign for the promulgation of MRLs
- establishment of a common default value: that is, a reduction from 0.1 ppm to 0 ppm in Canada so as to harmonize with the United States and the OECD
- that the *Food and Drugs Act* be amended to reflect the Canadian Horticultural Council’s recommendations regarding risk cup determinations

**9. Ombudsperson**

- the appointment of an “ombudsperson” who will have the power to intervene in decisions and/or policies. There is a critical need for a person or a team to facilitate minor use activities, and
- ensure that growers and public health administrators have an opportunity to discuss their needs and concerns with PMRA before PMRA finalize regulatory decisions;
- work with AAFC, industry, growers, and other stakeholders to promote registration and use of reduced-risk pesticides for minor uses
- encourage development of real world pesticide use and residue data by growers, AAFC and other stakeholders for use in refined risk assessments

## 10. Other

- the establishment of an infrastructure, independent from government, grower organizations and manufacturers, to coordinate and facilitate product registrations for all commodities.

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<sup>1</sup> Agriculture and Agriculture Canada, 2000/2001 Overview of Canadian Horticultural Industry. Please refer to [www.agr.ca](http://www.agr.ca)

<sup>2</sup> The Canadian Produce Marketing Association has developed and implemented a program, *5 to 10 a day Are you getting enough?* advocating the consumption of *five to ten servings of fruit and vegetables per day as part of a healthy diet so as to reduce the risk of cancer, heart disease and stroke*. The Canadian Cancer Society and the Heart and Stroke Foundation support the program. For additional information please refer to [ww.5to10aday.com](http://ww.5to10aday.com).

<sup>3</sup> A minor use of a pesticide is defined as a necessary use of a pesticide for which the anticipated volume of sales is not sufficient to persuade a manufacturer to register products for sale in Canada.

<sup>4</sup> By definition, the term pesticide includes herbicides, insecticides, fungicides, rodenticides, sanitizers, plant growth regulators, and biological control products.

<sup>5</sup> Report on Minor Uses of Pesticides, USEPA, p.9

<sup>6</sup> Please refer to Section 6, Registration Performance

<sup>7</sup> Registrant, manufacturer and chemical company are used interchangeably in this document.