

Status Report: 2001 Recommendations of the Canadian Horticultural Council
Crop Protection – A Better Future for Canada

<i>On the issue of....</i>	<i>2001 Recommendation....</i>	<i>2009 Status....</i>
1. a) User Requested Minor Use Registration Program (URMUR)	<ul style="list-style-type: none"> • establishment of an industry/government working group to negotiate an acceptable fee structure reflective of minor use criteria • adoption of the principles of transparency and responsiveness • to explore grower group endorsements in conjunction with registrant data submission 	<p>OUTSTANDING</p> <p>Accomplished, but within limitations of government confidentiality. To enhance this, grower groups should be notified when an URMUR submission has been submitted.</p> <p>Has been done, but within limits of regulatory authority.</p>
b) User Requested Minor Use Label Expansion Program (URMULE)	<ul style="list-style-type: none"> • 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 • 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 • that data requirements must reflect the risks inherent from the proposed use • a negotiable approach, particularly with respect to data requirements (i.e.: consideration of data that already exist in an OECD country) • that AAFC actively encourage and provide financial assistance for their research centres to become GLP compliant • 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 	<p>Done</p> <p>Done</p> <p>Done</p> <p>Done</p> <p>Done</p> <p>Done. However, backlog continues to exist, is in fact increasing and must be addressed.</p>

<p>c) Emergency Registration</p>	<ul style="list-style-type: none"> • 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 	<p>Improvements have been made. However, many annual requests continue. There is a need to consider unregistered actives and PMRA must be in a position to set emergency residue tolerances. More work is required</p> <p>OUTSTANDING</p> <p>Significant improvements, however timeliness remains an issue (ie: 6 months to schedule a pre-submission meeting).</p>
<p>2. Risk Cup</p>	<ul style="list-style-type: none"> • 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 	<p>PMRA committed to this at the 2008 NAFTA meeting; however, remains outstanding until we see specific examples. Canada would like to see concurrent acceptance of risk cup changes in the United States (such as for chlorothanil).</p> <p>Some improvements but better coordination of sampling for all of North America required. No comprehensive pesticide use database in place.</p> <p>Phase-in is under way.</p> <p>We are in an improved position vis-à-vis new joint submissions, but much more to be done on existing AIs (active ingredients).</p>

<p>3. Data Requirements</p>	<ul style="list-style-type: none"> • 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 • 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 	<p>Good improvement in communications and participation in pre-submission meetings have occurred. There is still an issue for resolving ongoing disputes over data requirements. Growers recognize the need for confidentiality and are prepared to sign agreements with companies to facilitate better resolution of these problems.</p> <p>Pre-submission meetings are improved, but better timelines and written terms of agreement should be circulated post-meeting.</p> <p>Some willingness is apparent, more is required.</p> <p>Possible with registrant approval; has not been a consistent practice.</p> <p>We need movement in this direction. While there has been some consideration, the practice is not consistently applied.</p> <p>Done; this is now policy.</p>
<p>4. Zone Maps</p>	<ul style="list-style-type: none"> • 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 	<p>Done</p> <p>Done</p>
<p>5. Crop Groupings</p>	<ul style="list-style-type: none"> • 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 	<p>Done for residue, but not consistently applied for efficacy and crop tolerance; need much greater flexibility than is current practice.</p> <p>Underway</p> <p>While not accepted per se, data is used to reach a decision.</p> <p>This is being done to a certain extent, but not nearly enough.</p>

<p>6. Seed Treatment Harmonization</p>	<ul style="list-style-type: none"> • 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 	<p>OUTSTANDING</p> <p>This is being done to some extent.</p> <p>This is being done to some extent. Major roadblocks continue to exist and must be addressed (ie: worker exposure).</p>
<p>7. Joint Reviews</p>	<ul style="list-style-type: none"> • flexibility and cooperation as key components of successful joint reviews • that Canada allow “Tailgating” • 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 	<p>Excellent improvement; must be creative to bring holdouts into the program.</p> <p>OUTSTANDING; must be permitted in specific cases and for minor use only.</p> <p>OUTSTANDING; must be permitted in specific cases and for minor use only.</p> <p>Performance in this area has improved, unfortunately at the expense of Category B and C submissions; resource shortfalls must be addressed.</p> <p>DONE</p>
<p>8. Food and Drugs Act</p>	<ul style="list-style-type: none"> • 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 <i>Food and Drugs Act</i> be amended to reflect the Canadian Horticultural Council’s recommendations regarding risk cup determinations 	<p>Still a goal; more work is required.</p> <p>See Emergency Registrations; not complete and critically important.</p> <p>DONE</p> <p>Phase-in is underway.</p> <p>OUTSTANDING; remains a goal.</p>

<p>9. Ombudsperson</p>	<ul style="list-style-type: none"> • 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 finalizes 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 	<p>This was undertaken and is no longer in place due to enhanced communication between the PMRA senior officials and industry leaders.</p> <p>PMAC address this; however, more dialogue is always welcome.</p> <p>There will always be an ongoing need for this.</p> <p>Still important and access to good data is critical to good decisions.</p>
<p>10. Other</p>	<ul style="list-style-type: none"> • the establishment of an infrastructure, independent from government, grower organizations and manufacturers, to coordinate and facilitate product registrations for all commodities. 	<p>The PMC was created. Unfortunately is not at arms length and shows signs of issues which would not have arisen if at arms length.</p>