Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Discussion Document

DIS2006-01

Revocation of 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]

(publié aussi en français)

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: pmra_publications@hc-sc.gc.ca
www.pmra-arla.gc.ca
Information Service:
1 800 267-6315 or 613 736-3799
Facsimile: 613 736-3758

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Executive Summary

In January 2003, Health Canada's Pest Management Regulatory Agency (PMRA) proposed in a discussion document (www.pmra-arla.gc.ca/english/pdf/dis/dis2003-01-e.pdf) a regulatory change that would revoke 0.1 parts per million (ppm) as a General Maximum Residue Limit (MRL) Regulation for pesticide residues on foods.

The existing regulation, Food and Drug Regulation B.15.002(1), provides for a level of 0.1 ppm for residues of agricultural chemicals, including pesticides, on domestically grown and imported food, unless specific MRLs are listed in Table II, Division 15 of those Regulations. The intent of the regulation, to prohibit the sale of adulterated food, is not being fully met. This regulation can also lead to overestimates of exposure to a pesticide and no longer reflects analytical capabilities of food residue monitoring programs. Canada is one of very few countries to have a General MRL at this level. Finally, the use of a General MRL is inconsistent with the approach taken by the United States.

The proposed change is intended to achieve fully the intent of the General MRL, that is, to prohibit food that is adulterated because MRLs are exceeded or have not been established, and to maintain the safety of the Canadian food supply. The proposal is also meant to minimize the impact on existing registered Canadian food uses by continuing to allow residues on foods that result from the legitimate use of registered pesticides, and on trade through harmonization in a number of areas and through avoiding new trade irritants.

This second consultation document contains a revised proposal. In summary, the PMRA proposes that the general level of 0.1 ppm be replaced by specific MRLs for pesticide/food combinations at levels at or below 0.1 ppm. As a large number of specific MRLs will be required to replace the General MRL, the following one-time approach, specific to this issue, is proposed. American tolerances at or below 0.1 ppm that have been established after the *Food Quality and Protection Act* (FQPA) came into effect in the United States will guide the establishment of these Canadian MRLs. Codex MRLs at or below 0.1 ppm will also be considered for imported food. In a limited number of cases, specific MRLs cannot be established immediately, and transitional MRLs would be allowed. The transitional MRLs would be in effect for a maximum of seven years, beginning with publication of the final regulatory changes and continuing until an ongoing MRL is established. If no specific MRL can be established, any level of residue for that pesticide/food combination will no longer be permitted.

Tables that compare Canadian registered food uses, Canadian MRLs and American tolerances, are also included with this document. The database that was used to prepare these tables is available on the PMRA website (www.pmra-arla.gc.ca/english/pdf/mrl/dis2006-1/MRL_Table Master-e.xls) so that interested parties can determine how this proposal will affect specific pesticide-commodity combinations.

Affected parties and the public are invited to provide written comments on the proposal during the 90-day comment period.

Information on Submitting Comments

Comments are welcome on any aspect of this proposal to revoke the 0.1 ppm general regulation and, in particular, on the following:

- areas that you agree with
- areas that concern you and the reasons for these concerns
- recommendations to address your concerns
- suggestions you may have for innovative solutions to problems of access to pest control products in Canada and to trade irritants
- positive or negative impacts that the proposal may have on you or your organization
- amendments or additions that should be made to the tables or the database containing the detailed comparison of Canadian registered food uses and MRLs, and American tolerances that would be affected by revocation of the General MRL.

Whenever possible, please reference your comments to the applicable section(s) of this discussion document.

Forward written comments and a completed Identification Profile (Appendix I to this document) within 90 days of the date of this publication to:

Attention: Miriam Halevy
Pest Management Regulatory Agency, Health Canada
Sir Charles Tupper Building
2720 Riverside Drive, A.L. 6606D1
Ottawa, Ontario
K1A 0K9

Contact Information

If you have any questions regarding this proposal please contact:

Miriam Halevy, 613 736-3920, e-mail Miriam_Halevy@hc-sc.gc.ca.

Please visit the PMRA website at www.pmra-arla.gc.ca/english/pdf/dis/dis2006-01-e.pdf for electronic copies of this discussion document.

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1.0 Introduction

Before a pesticide is registered for use in Canada, Health Canada's Pest Management Regulatory Agency (PMRA) must determine that it does not pose any unacceptable risks to human health or the environment. This includes ensuring that consumption of the pesticide residues that may remain on or in the food will not pose an unacceptable health risk[1] and establishing MRLs.

A maximum residue limit is the maximum level of a pesticide that is likely to remain in or on a food at the farm gate when the pesticide is used according to label directions. This amount is established legally as an MRL. The MRL for a particular pesticide and food is the maximum concentration in parts per million (ppm) of the pesticide that is allowed in or on that food. MRLs are known as tolerances in the United States.

Regulation B.15.002(1) of the Food and Drug Regulations establishes 0.1 ppm as the "General Maximum Residue Limit". This regulation states that a food is adulterated and may not be sold if it contains residues of agricultural chemicals (including pesticides) at a level greater than 0.1 ppm, unless a specific MRL has been established in Table II, Division 15 of the Regulations. The *Food and Drugs Act* prohibits the sale of adulterated food.

The intent of the General MRL was to prohibit food that is adulterated because MRLs have not been established. However, in practice, consequences of the General MRL Regulation include the following.

- The sale of foods with residues of a pesticide up to 0.1 ppm is allowed, even if good agricultural practices can result in much lower residue levels. This potentially permits the presence of higher than warranted pesticide residues in the Canadian food supply.

- Foods can enter Canada with residues of pesticides for which no submission to request the establishment of an MRL has been made.

In the absence of specific MRLs below 0.1 ppm, prudent estimates of dietary exposure to a pesticide sometimes assume residues of 0.1 ppm. This may lead to overestimates of

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[1] The health risk posed by a pesticide depends on its toxicity and the amount of the pesticide to which a person is exposed from all sources. The total acceptable exposure is sometimes referred to as the "risk cup". As indicated in the previous discussion document, the stringent safety standards mandated by the *Food Quality Protection Act* in the United States and the new *Pest Control Products Act* in Canada require the regulatory agencies to consider aggregate and cumulative exposures to pesticides as well as to apply additional factors as required to ensure the protection of children and other sensitive groups. These standards can result in risk cups that are significantly smaller. It is important to ensure risk cups are not filled with residues from imported foods only, or by unrefined exposure assessments.

The PMRA is planning to publish a discussion document for comment on the use of uncertainty and safety factors in the human health risk assessment of pesticides.

exposure to the pesticide, particularly when residues from a large number of food commodities contribute to the overall exposure, so that new uses cannot be accommodated.

An important consideration in making the General MRL Regulation in the late 1970s was that the available analytical methodologies were not sufficiently sensitive to detect most pesticides at levels below 0.05 ppm in a general food monitoring and surveillance program. Analytical capabilities have improved to such an extent that residues in a general food monitoring and surveillance program can now routinely be detected at or below 0.01 ppm levels.

Most industrialized countries set specific MRLs for each pesticide on each food commodity. In 1998, the PMRA provided explicit guidance on the data the Agency requires to carry out dietary risk assessments and to establish specific MRLs in Regulatory Directive DIR98-02, *Residue Chemistry Guidelines*. Shortly thereafter, the PMRA began to establish specific MRLs in the Food and Drug Regulations for new pesticides registered in Canada for use on food in situations where the use of a pesticide may result in finite residues on food commodities, both above and below 0.1 ppm. Revocation of the General MRL will complete the move to setting specific MRLs for all pesticide/food combinations.

In a case where only very low levels of residues are acceptable, most industrialized countries either do not establish an MRL or they set a specific MRL at a very low level. The American approach is that any detectable residue is a violation unless there is a specific tolerance to cover it. This proposal, which would consider detectable residues to be violative unless specific MRLs have been established, would bring Canada in line with the approach of the United States.

In January 2003, the PMRA released a discussion document that proposed the revocation of the 0.1 ppm General MRL. Forty-two responses were received. This consultation document responds to the comments (Appendix II) and sets out a revised and more detailed proposal for the revocation of the General MRL. This document focuses on issues associated with establishing specific MRLs at or below 0.1 ppm; other issues, such as those related to MRLs above 0.1 ppm, are being addressed through other PMRA initiatives.

2.0 Revised Regulatory Proposal

The PMRA has carefully considered the comments that were received on the previous discussion paper and has developed a revised proposal based on the following principles.

- The intent of the General MRL, to prohibit the sale of food that is adulterated because MRLs are exceeded or have not been established, will be fully met.

- The safety of the Canadian food supply will be maintained. Setting pesticide-specific, food-specific MRLs below the current 0.1 ppm level will lower allowable residues overall and potentially reduce dietary exposure to pesticides.

- The impact on registered Canadian food uses will be minimized by continuing to allow residues on foods that result from the legitimate use of registered pesticides. Trade irritants will be minimized through harmonization in a number of areas, and new trade irritants will not be created. In particular, the proposal will contribute to the process of further harmonizing pesticide regulation in Canada and the United States.

The PMRA proposes that the general level of 0.1 ppm for pesticide residues in food be replaced by specific MRLs for pesticide/food combinations at levels at or below 0.1 ppm. The proposal is summarized in Chart 1 for commodities that are grown in Canada, and Chart 2 for commodities that are imported only.

As a large number of MRLs will be required to replace the General MRL, the following approach, specific to this issue, is proposed. American tolerances at or below 0.1 ppm that were established in the United States after the *Food Quality and Protection Act* came into effect will guide the establishment of these Canadian MRLs. Contemporary Codex MRLs at or below 0.1 ppm will also be considered for imported commodities.

Wherever possible, MRLs would be established on an ongoing rather than a transitional basis. In a limited number of cases, specific MRLs cannot be established immediately, and transitional MRLs would be allowed. Such MRLs would be in effect for a maximum of seven years, beginning when the final regulatory changes are published and continuing until an ongoing MRL is established. In cases for which no specific MRL can be established, any detectable residues will no longer be permitted.

To give continued consideration to the needs of Canadian growers, proposals are outlined separately for commodities grown in Canada and for those that are imported only. A number of American tolerances have been set for pesticide use on commodities that are grown in Canada. However, Canadian growers cannot use these pesticides because the pesticides or the uses on those commodities have not been registered in Canada. If the PMRA were to simply establish import MRLs using the American tolerances, questions of fairness to Canadian growers would arise, and there would be no increase in availability in Canada of pesticides that are already available in the United States. Registrants are being encouraged to seek Canadian registrations at the same time they request import MRLs. In relevant cases, the PMRA is developing approaches to encourage registrants to seek registration in Canada; other innovative suggestions to narrow the gap in availability of products between Canada and the United States would be welcomed.

A database[2] with information regarding Canadian food uses, Canadian MRLs and American tolerances was generated to support the proposal to revoke the General MRL for food pesticide residues. The complete database can be found on the PMRA website at (www.pmra-arla.gc.ca/english/pdf/mrl/dis2006-1/MRL_Table Master-e.xls). In addition, a detailed comparison of Canadian pesticides and commodities that would be affected by revocation of the General MRL, with corresponding American tolerances, is contained in the tables in Appendix III. This information should assist stakeholders in determining the impact of replacing the General MRL. While significant care was taken in preparing the database and these tables, the Agency is aware that the information may not be current. We welcome any corrections or additions to the information.

The PMRA has worked closely with the United States Environmental Protection Agency (USEPA) for a number of years and has participated in developing the policies that guide the establishment of American tolerances. The PMRA and the USEPA have also jointly reviewed pesticide submissions that have led to specific MRLs and tolerances. Based on this experience, the PMRA has concluded that relying on American tolerances that are at or below 0.1 ppm and were set after the *Food Quality and Protection Act* came into force will reduce risks to the Canadian food supply, and will permit PMRA resources to be directed to areas of higher risk to health and the environment.

With respect to the potential for trade irritants, much of the food that is imported into Canada either comes from American sources or comes from a third country via the United States. This proposal will adopt American tolerances for imports to Canada and the United States from other countries. The PMRA will also consider Codex MRLs at or below 0.1 ppm for imported food

It should be noted that in Canada and the United States, a number of pesticides are currently being re-evaluated or are scheduled to undergo re-evaluation over the next few years. Changes to Canadian MRLs may result from these reassessments. The PMRA is establishing a tracking mechanism that will identify tolerances that change (either in level or residues of concern) are revoked or are established during implementation of the General MRL proposal.

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[2] Source information: May 2004 review of all Canadian product labels to identify all registered food uses; Table II (Agricultural Chemicals), Division 15 of the Food and Drug Regulations; and a tolerance table received from the USEPA in May 2004. Subsequent registrations of new active ingredients, changes to commodities of registered active ingredients and corresponding additions, revisions or revocations of tolerances are not necessarily reflected in the tables.

Chart 1 Commodities Grown in Canada

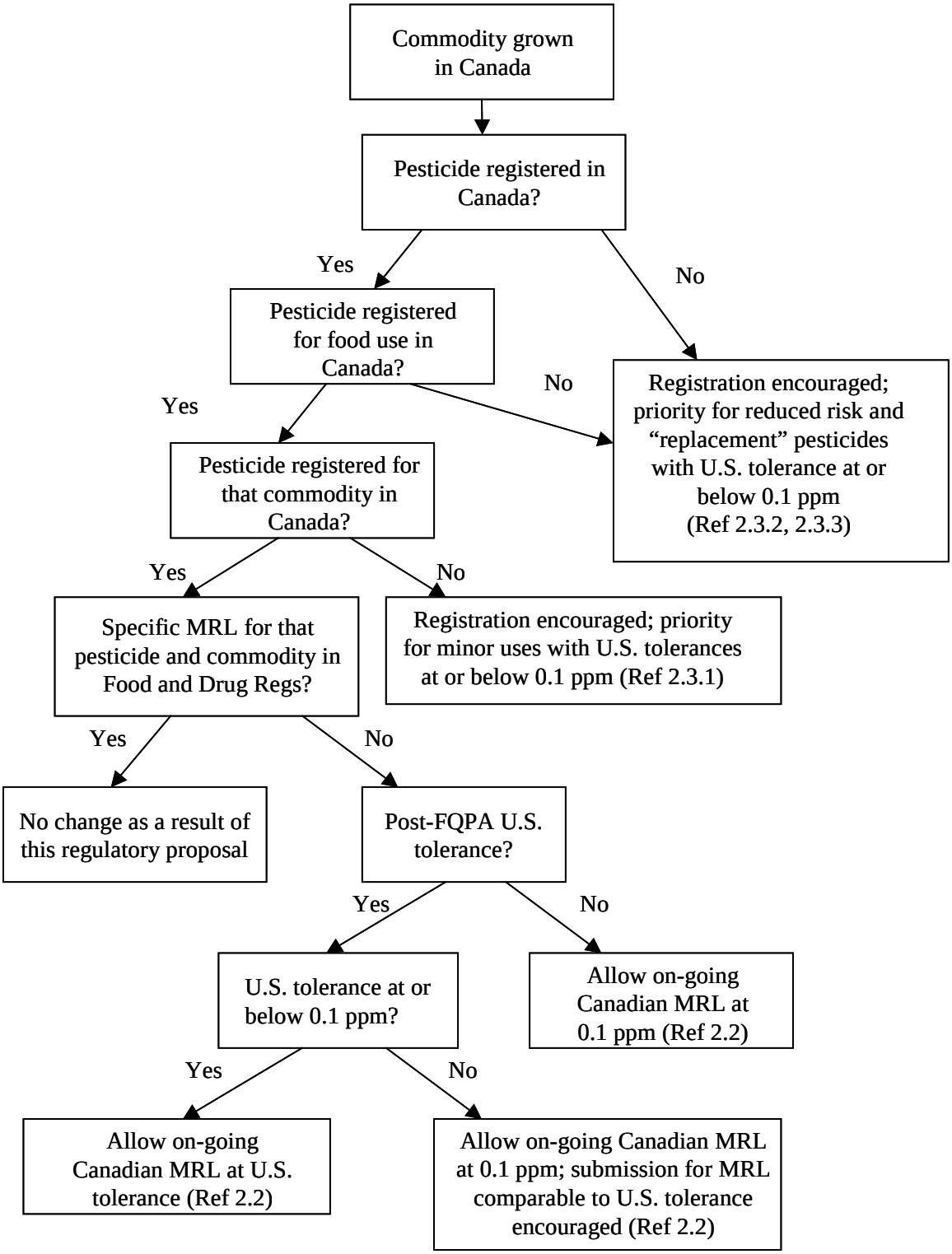
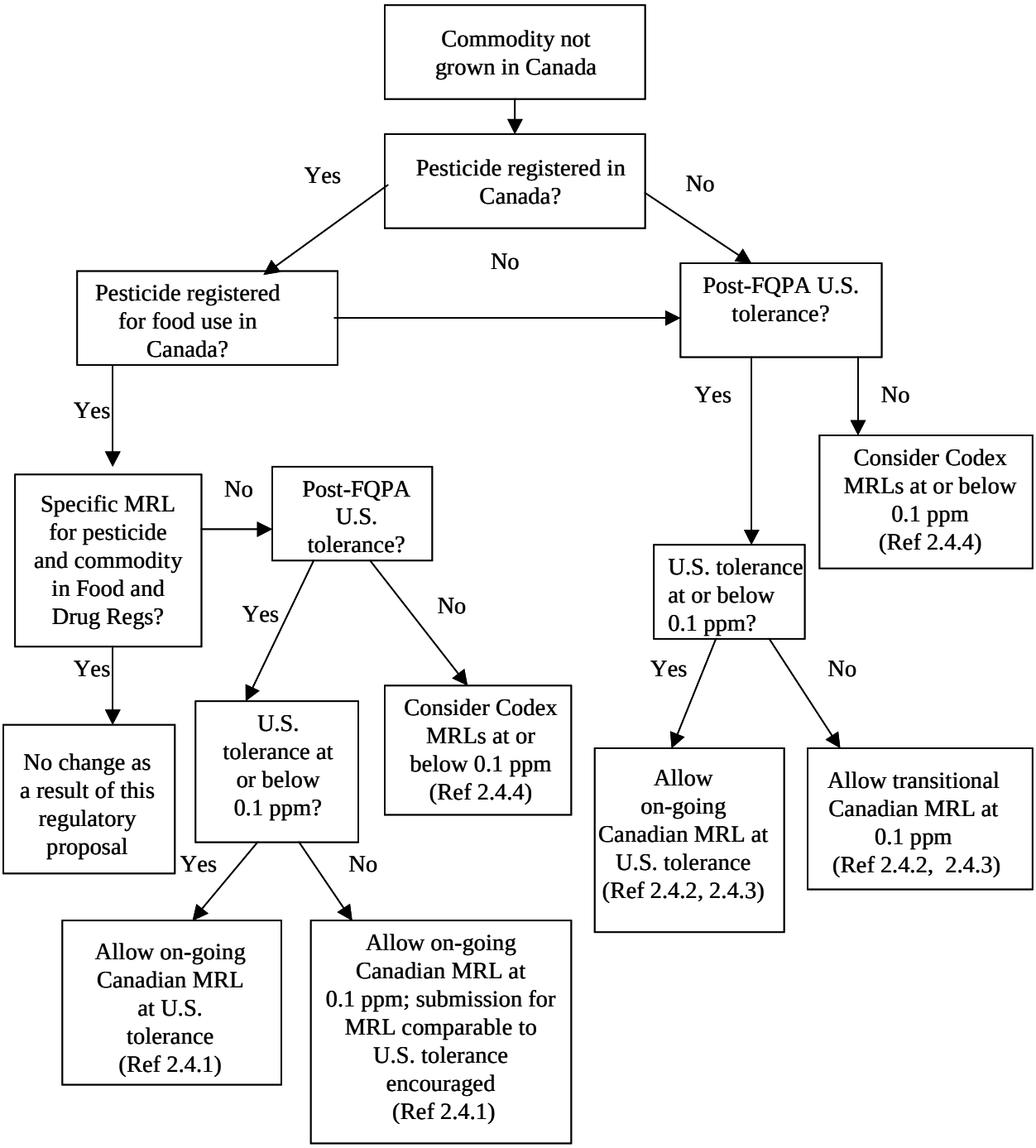


Chart 2 Commodities Not Grown in Canada



2.1 Transitional MRLs

The previous discussion document proposed that, in general, specific MRLs be set on a transitional basis. Based on the PMRA's analysis and comments received, the Agency now proposes that many of these specific MRLs be established on an ongoing rather than a transitional basis.

This approach is consistent with the principles outlined previously. Furthermore, the new *Pest Control Products Act* requires that pesticides on the market be re-evaluated on a regular basis. During this re-evaluation, the risk cups for older pesticides will be assessed, data will be requested if required, and any necessary adjustments to MRLs will be undertaken.

Where transitional MRLs are suggested, the PMRA proposes that such MRLs be in effect for a maximum of seven years, beginning when the final regulatory changes are published and continuing until an ongoing MRL is established. Three years would be available to registrants to submit data, and four years for the PMRA to review the submissions. Submissions would not be subject to the review times established in Regulatory Proposal PRO96-01, *Management Of Submissions Policy*.

2.2 Residue Limits for Domestic Food Uses Currently Regulated Under the General MRL

A number of pesticides have been registered in Canada for use on specific commodities, but no specific MRLs have been established. For each of these situations, residues are currently regulated under the General MRL Regulation of 0.1 ppm.

The PMRA will allow an ongoing Canadian MRL at the level of the American tolerance for that use if there is an American tolerance at or below 0.1 ppm (Table 3A). Submission of data will not be required, but registrants are requested to indicate their interest in having such an MRL established.

If the American tolerance is above 0.1 ppm (Table 3B), an ongoing Canadian MRL will be allowed at 0.1 ppm. While submission of data will not be required to have an MRL established at 0.1 ppm, registrants are encouraged to make a submission to the PMRA to support an MRL in Canada that is comparable to the American tolerance.

For domestic food uses for which no American tolerance exists (Table 3C), an ongoing Canadian MRL of 0.1 ppm will be allowed, where warranted, given the nature of the pesticide and the use pattern. Submission of data will not be required, but registrants are requested to indicate their interest in having such an MRL established.

This approach will immediately facilitate a more realistic food residue exposure assessment. It will not compromise the safety of the Canadian food supply because the allowable residue limits in food will be at or lower than current practices under the 0.1 ppm General MRL Regulation. Furthermore, as American tolerances are generally

based on higher use rates than in Canada, there is little chance that the Canadian residues would exceed those found in the United States. Should these MRLs pose a problem for Canadian growers, however, the PMRA will consider higher MRLs.

The PMRA has tried to identify all cases in which a pesticide is registered for use in Canada for a commodity and no MRL has been established. Proposals to address these cases have been made to ensure all registrations have a corresponding MRL. If a particular use or pesticide has not been identified in Appendix III, please advise the PMRA.

2.3 Residue Limits for Foods Grown in Canada, but Uses Are Not Currently Registered in Canada

Foods containing residues of a number of pesticides for which MRLs have not been established can be imported into Canada if the residues are at or below 0.1 ppm, as a result of the General MRL. Under this proposal, a specific MRL will now be required for these foods.

Many of these foods are also grown in Canada, but the pesticides that give rise to the residues are not registered in Canada for use on these foods. A number of respondents commented that the challenges Canadian growers face should be recognized as the PMRA continues to develop the proposal to revoke the General MRL. As a result, the approach in the previous consultation document has been modified to address some of these concerns; this revised approach is outlined in some detail in the following sections.

The PMRA is exploring several ideas that would assist in encouraging the registration of pesticides and pesticide uses that meet a Canadian need. The Agency also invites comments and suggestions that offer innovative solutions to problems of access to pest control products in Canada and to trade irritants. Of particular interest are reduced-risk pesticides, including biopesticides, and replacements for critical older pesticides that may be phased out as a result of re-evaluation.

2.3.1 A Pesticide Is Registered in Canada for Food Use, but Not for Some of the Commodities for Which Tolerances Have Been Established in the United States

Where there is a recognized need, the PMRA is interested in encouraging Canadian registrations for pesticides that are registered in Canada for food use, but not for some of the commodities for which tolerances have been established in the United States.

If an American tolerance at or below 0.1 ppm was established after the *Food Quality and Protection Act* came into force (Table 4A), the Agency is interested in discussing the potential for Canadian registration with registrants. The Agency is prepared to explore with registrants how such registrations could be facilitated, including determining which data (value, residue, occupational) are essential and whether the PMRA already has sufficient data to allow a registration to take place should the registrant be supportive.

Should a registrant commit to seeking Canadian registration, the PMRA proposes to allow an ongoing Canadian MRL at the level of the relevant American tolerance.

In cases where there is a post *Food Quality and Protection Act* tolerance that is greater than 0.1 ppm (Table 4B), the Agency invites comments and suggestions for innovative solutions to the lack of Canadian registration. The Executive Board of the North American Free Trade Agreement (NAFTA) Technical Working Group on Pesticides has also recognized that some differences in product registration result in trade issues related to MRLs for traded commodities and has agreed to establish a government task force to develop options for a systematic approach to harmonize MRLs/registrations. In addition, the PMRA and the USEPA will coordinate their next cycle of re-evaluation/reregistration reviews and will look for opportunities during the process to harmonize MRLs and tolerances.

2.3.2 A Pesticide Is Registered in Canada but Not for Food Use; Tolerances for Such Uses Exist in the United States

The PMRA is interested in encouraging the registration of pesticides that are not currently registered in Canada for food uses and meet a recognized Canadian need.

In cases of American tolerances at or below 0.1 ppm that were established after the *Food Quality and Protection Act* came into force (Table 5A), the Agency is interested in discussing the potential for Canadian registration with registrants. The PMRA is prepared to explore how such registrations could be facilitated, based in part on the consistency between Canada and the United States of risk assessments and use patterns that would drive the health or environmental risk assessment. Should a registrant commit to seeking Canadian registration, the PMRA proposes to allow an ongoing Canadian MRL at the level of the relevant American tolerance.

In cases where there is a post *Food Quality and Protection Act* tolerance that is greater than 0.1 ppm (Table 5B), the Agency invites comments and suggestions that offer innovative solutions to the lack of Canadian registration. As noted in Section 2.3.1 above, the Executive Board of the NAFTA Technical Working Group on Pesticides is giving this issue priority.

2.3.3 A Pesticide Is Not Registered in Canada, but Tolerances for Food Use Have Been Established in the United States

The PMRA would like to encourage the registration of pesticides that are not currently registered in Canada and meet a recognized Canadian need. If the American tolerance was established or reassessed at levels at or below 0.1 ppm (Table 6A) after the *Food Quality and Protection Act* came into force, the Agency is interested in discussing the potential for Canadian registration with registrants. Should a registrant commit to seeking Canadian registration, the PMRA proposes to allow an ongoing Canadian MRL at the level of the relevant American tolerance.

In cases where there is a post *Food Quality and Protection Act* tolerance that is greater than 0.1 ppm (Table 6B), the Agency invites comments and suggestions for projects that offer innovative solutions to the lack of Canadian registration. As noted previously in Section 2.3.1, the Executive Board of the NAFTA Technical Working Group on Pesticides is giving this issue priority.

2.4 Residue Limits for Foods That Are Not Grown in Canada

There are a number of pesticides for which MRLs have not been established for foods that are only imported into Canada and not grown there. Foods containing residues of these pesticides have entered Canada if the residues are at or below 0.1 ppm. A specific import MRL will now be required.

2.4.1 A Pesticide Is Registered in Canada for Food Use; No Specific MRLs Have Been Set for Imported Foods but Tolerances Have Been Established in the United States

In cases of American tolerances at or below 0.1 ppm that were established or reassessed after the *Food Quality and Protection Act* came into force (Table 7A), the PMRA is prepared to allow the American tolerances as ongoing MRLs. Registrants are requested to indicate their interest in having an MRL established, but they will not be required to submit data.

If the post *Food Quality and Protection Act* tolerance is above 0.1 ppm (Table 7B), a Canadian MRL will be allowed at 0.1 ppm on an ongoing basis, provided that registrants request that an MRL be established. While submission of data will not be required to have an MRL established at 0.1 ppm, registrants are encouraged to make a submission to the PMRA to support an MRL in Canada that is comparable to the American tolerance.

This approach will immediately facilitate a more realistic food residue exposure assessment. It will not compromise the safety of the Canadian food supply because the allowable residue limits in food will be at or lower than current practices under the 0.1 ppm General MRL.

2.4.2 A Pesticide Is Registered in Canada but Not for Food Use; No Specific MRLs Have Been Set for Imported Foods, but Tolerances Have Been Established in the United States

In cases of American tolerances at or below 0.1 ppm that were established or reassessed after the *Food Quality and Protection Act* came into force (Table 8A), the PMRA is prepared to allow the American tolerances as ongoing MRLs. Registrants are requested to indicate their interest in having an MRL established, but submission of data will not be required.

If the post *Food Quality and Protection Act* tolerance is above 0.1 ppm (Table 8B), the PMRA will allow a Canadian MRL at 0.1 ppm as a transitional MRL, provided that registrants request an MRL be established. Registrants are also requested to submit the

data and USEPA Data Evaluation Reports that support the American tolerance. The transitional MRLs will be established as ongoing MRLs where there is sufficient information available to the PMRA. If there are insufficient data to allow the PMRA to establish an ongoing MRL, the transitional MRL will expire and any level of pesticide residue for that pesticide/food combination would be in violation of the *Food and Drugs Act*.

2.4.3 A Pesticide Is Not Registered in Canada; No Specific MRLs Have Been Set for Imported Foods, but Tolerances Have Been Established in the United States

In cases of American tolerances at or below 0.1 ppm that were established or reassessed after the *Food Quality and Protection Act* came into force (Table 9A), the PMRA is prepared to allow the American tolerances as ongoing MRLs. Registrants are requested to indicate their interest in having an MRL established, but submission of data will not be required.

If the post *Food Quality and Protection Act* tolerance is above 0.1 ppm (Table 9B), the PMRA will maintain the status quo and allow a Canadian MRL at 0.1 ppm as a transitional MRL. Registrants are requested to indicate their interest in having such an MRL established. Registrants are also requested to submit the data and USEPA Data Evaluation Reports that support the American tolerance. The transitional MRLs will be established as ongoing MRLs if there is sufficient information available to the PMRA. If there are insufficient data to allow the PMRA to establish an ongoing MRL, the transitional MRL will expire and any level of pesticide residue for that pesticide/food combination would be in violation of the *Food and Drugs Act*.

2.4.4 Residue Limits for Imported Foods When There Is No Specific Canadian MRL and No American Tolerance

Where there is no specific Canadian MRL and no American tolerance, Codex MRLs at or below 0.1 ppm will be considered for establishing an MRL on an on-going basis for imported food. Registrants are invited to indicate their interest in having an MRL established.

If the Codex MRL of interest is greater than 0.1 ppm, registrants are invited to contact the PMRA for discussions on a case-by-case basis.

This approach will not compromise the safety of the Canadian food supply because the allowable residue limits in food will be equal to or lower than current practices under the 0.1 ppm General MRL. It will also facilitate a more realistic food residue exposure assessment.

3.0 Proposals Regarding Issues Resulting from Revocation of the General MRL

3.1 Maintaining an MRL for Imported Food When a Registered Food Use Is Disallowed in Canada for Reasons Unrelated to Dietary Risk

The previous consultation document proposed that, when a domestic food use is no longer supported by Canadian registrants or is withdrawn following a pesticide re-evaluation or special review, the PMRA will revoke existing MRLs. With the revocation of the General MRL Regulation, domestic and imported food commodities with any detectable residues would be in violation of the *Food and Drugs Act*.

The PMRA has carefully considered the comments on this part of the proposal and proposes that the Agency will consider requests for maintaining or modifying the corresponding MRLs for imported food only where the basis for the Canadian action was not contingent on unacceptable dietary risk from food residues. The PMRA will base the decision to establish an MRL for imported food on current use patterns in the country of origin as well as on recent toxicology and relevant residue chemistry data. These data may already be available to the PMRA. If so, the PMRA will use them to establish MRLs. If the data are insufficient to establish an MRL, any detectable residues in the food would be in violation of the *Food and Drugs Act*.

3.2 Maintaining an MRL for Imported Food for an Active Ingredient Not Registered in Canada When the Registered Use Is Cancelled in the Country of Origin

The previous discussion paper proposed that Canadian MRLs for imported food will be revoked when the registrant in the country of origin no longer support the use or when regulatory authorities in the country of origin have cancelled the use because of unacceptable health risk.

A number of respondents raised questions regarding the original proposal. The discussion paper was not clear whether it is the intent of this policy to revoke MRLs if any country of origin cancels a registration.

The PMRA would like to clarify the proposal. An MRL for imported food would be revoked when:

- the use of the pesticide is no longer supported by the registrant in the country whose residue trials (at their Good Agricultural Practice levels) support the MRL; or
- the country whose residue trials supported the MRL cancels the registration for the pesticide for reasons of unacceptable health risk.

To maintain a Canadian MRL to support imports from other countries where the pesticide may be in use, a new submission for an MRL is required, accompanied by the necessary contemporary toxicology and residue chemistry data as well as labels from countries where the use is being maintained, to allow a dietary risk assessment.

3.3 Proposed Approach for Canadian Research Permits

The previous consultation document noted that, unlike the United States, Canada had no regulatory mechanism under the Food and Drug Regulations to establish MRLs in a timely manner to accommodate pesticide residues arising from pesticide research trials for food commodities.

Due to recent legislative changes, MRLs will be able to be established under the new *Pest Control Products Act* when it is proclaimed, and can be set more quickly than before. As a result, the PMRA proposes the following.

- If the active ingredient is registered in Canada, the General MRL of 0.1 ppm under the Food and Drug Regulations would be maintained for research involving such pesticides on food crops.

- If the active ingredient is not registered in Canada and the sponsor of the research trial does not wish to have the trial subject to a requirement to destroy the crop, the sponsor would suggest an MRL to PMRA for consideration, along with a rationale to support the MRL. The request should be made at the earliest possible date because the PMRA would publish the proposed MRL for consultation. The MRL would be specific to the research trial and would expire at the end of the trial.

- The foregoing would apply to all regulatory categories of research—research requiring authorization, research requiring notification and research that is exempt from notification or authorization.

It should be noted that the new Pest Control Product Regulations will prohibit the sale of treated food resulting from certain specific types of research. Further information is available at www.pmra-arla.gc.ca/english/pdf/legis/pcp_reg-e.pdf.

3.4 Proposed Approach for Emergency Uses

Under Section 18 of the new Pest Control Products Regulations, the PMRA may grant a registration for a period not exceeding one year to allow the use of a pesticide for the emergency control of a seriously detrimental pest infestation. Currently, emergency uses can only be approved when data from residue trials indicate that the residue level would be less than 0.1 ppm and the level is supported by an acceptable dietary risk assessment.

With the authority to establish MRLs under the new *Pest Control Products Act*, the PMRA can now set MRLs much more quickly than before. However, several months would still be required for consultation and the establishment of a new MRL. As a result, the Agency proposes to maintain a General MRL of 0.1 ppm under the Food and Drug Regulations, which will apply to residues resulting from emergency uses.

3.5 Establishing MRLs for Animal Commodities

Several respondents raised questions regarding MRLs for animal commodities that may have been previously subject to the 0.1 ppm General MRL. The PMRA proposes that, with respect to establishing MRLs for meat, milk and eggs when there is an expectation of a residue, the proposals outlined in Section 2.0 would apply as appropriate.

3.6 Limit of Quantitation[3]

The previous discussion document proposed that detectable residues will no longer be permitted in cases where no specific MRL can be established. In other circumstances, such as the expiry of a transitional MRL, any level of pesticide residue for that pesticide/food combination would be a violation of the *Food and Drugs Act*.

The PMRA has considered the comments on this issue and proposes the following.

- Where the use of pesticide may result in finite residues on a crop for which the pesticide is registered, but no residues are detected in the field trial data, the MRL for that food use is set at the limit of quantitation that is reported in the enforcement method and/or in the field trial method. This is current practice in the United States and Canada for new MRLs. The limit of quantitation is relatively easy to determine because it is a requirement of registration to provide a validated enforcement method.

- Where a pesticide is used illegally or where a pesticide is used in another country on food to be exported to Canada and the pesticide has no MRL or a submission to establish one has not been made, any level of residue is considered a violation. No level of quantitation will be specified and any residue above the limit of detection becomes a violation.

As this approach is also used in the United States, trade issues should be minimized. It is consistent with current PMRA practice for setting MRLs for new pesticides, so pesticides will be treated fairly.

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3 Limit of quantitation (LOQ) is the minimum concentration of a substance that can be quantified with precision.

3.7 Exemption from the Requirement for a Specific MRL

The USEPA has a number of ways of exempting pesticides from the requirement that MRLs be established. Food and Drug Regulation B.15.002 (2) lists several pesticides that are not considered to be adulterants of food. Residues of such pesticides are not subject to the General MRL, nor does a specific MRL have to be established.

The PMRA proposes the following:

- the current practice of listing specific pesticides to be exempted from the requirements to establish MRLs be continued under the Food and Drug Regulations; and

- specific uses (rather than all uses) of a particular pesticide also be exempted under those Regulations.

Exempting pesticides from the requirement to establish an MRL would be used when, for example, a pesticide cannot be defined chemically.

If a pesticide is not exempted from the requirement for a specific MRL and no specific MRLs have been established for that pesticide, no residues of the pesticide should be present on food that is sold in Canada.

4.0 Next Steps

Affected parties and the public are invited to provide written comments on this proposal within the 90-day comment period. The PMRA will analyze these comments and will prepare a regulatory proposal for consideration by the Governor-In-Council and publication in the *Canada Gazette,* Part I for a further comment period.

Registrants are invited to begin applying for the establishment of specific MRLs now, in particular if the American tolerance for the pesticide-food combination of interest is greater than 0.1 ppm. Registrants are also encouraged to seek registration in Canada of pesticides or uses that meet Canadian needs.

List of Abbreviations

CAN	Canada
Codex	Codex Alimentarius Commission
CFIA	Canadian Food Inspection Agency
ENV	environment
FED	federal
FRG	foreign
FQPA	*Food Quality and Protection Act*
HLTH	health
MRL	Maximum Residue Limit
NAFTA	North American Free Trade Agreement
ppm	parts per million
PROV	provincial
REG	registrant
U.S.	United States
USEPA	United States Environmental Protection Agency

Appendix I Submission of Comments

1) Identification Profile

Date of submission: _____

Name: _____

Address: _____

Telephone/email:_____

Please complete the following sections if you are submitting comments on behalf of an organization or association.

Type of organization: (e.g., professional, community, corporation, individual, etc.)

_____

Scope of organization: (e.g., municipal, provincial, regional, national, etc.)

_____

Description of organization: (e.g., size or membership, when established, etc.)

_____

Mandate of organization:_____

Objectives or activities related to pesticides: _____

Position/qualifications/interests held in organization: _____

2) Written Comments

Your written comments: _____

Forward comments to:

Attention: Miriam Halevy
Pest Management Regulatory Agency, Health Canada
Sir Charles Tupper Building
2720 Riverside Drive, A.L. 6606D1
Ottawa, Ontario
K1A 0K9

Appendix II Responses to Issues Raised in Comments

The PMRA received 42 responses to DIS2003-01, *Revocation of the 0.1 ppm General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. The following tables provide summary information regarding the source of comments.

Table 1 Responses by Organization

(I) Industry			(A) Association			(G) Government			NGO	
REG	CAN	FRGN	PROV	CAN	FRGN	PROV	FED	FRGN	HLTH	ENV
5	2	3	5	5	13	2	3	2	1	1

Table 2 Country of Origin of Responses

Canada				Foreign		
Industry	Association	Government	NGO	Industry	Association	Government
7	10	5	2	3	13	2

Codes	
CAN = Canadian **ENV** = Environment **FED** = Federal **FRGN** = Foreign	**HLTH** = Health **PROV** = Provincial **REG** = Registrant

Comments from respondents have been grouped into a number of issues, and the PMRA has considered these issues in developing the revised proposal outlined in the document. The Agency has also prepared responses to the issues.

1.0 Risk Cup

Comment(s)

One respondent commented that the factor used to reduce the no observed adverse effect level does not currently take children's and infant's safety adequately into account, and suggests that the factor used to reduce the no observed adverse effect level should be a minimum of at least three orders of magnitude (i.e. 1000×) to protect sensitive subpopulations.

Another respondent noted that the reduced size of the "risk cup" is the product of an excessive application of the precautionary principle. No benefits of this have been demonstrated and, within the sensitivities of epidemiological studies, it probably would not be possible to demonstrate any. The respondent concludes that the statement that these measures "… will significantly enhance the protection of all Canadians, including

infants, children and other vulnerable groups" is not substantiated by evidence and remains conjectural.

A third commenter noted that the size of the Canadian risk cup is sometimes substantially smaller than the American risk cup and suggested that the PMRA should review its risk assessment methods with the USEPA to avoid different sizes of risk cups and avoid these trade barriers.

Response
The PMRA has been conducting a case-by-case review of each pesticide to determine whether a 10-fold factor should be applied, or whether another factor adequately protects infants and children. Such a review will be mandatory under the new *Pest Control Products Act*. The PMRA is also planning to publish a discussion document for comment on the use of uncertainty and safety factors in the human health risk assessment of pesticides. With respect to comments about the size of the risk cup, the PMRA and the USEPA have largely harmonized the toxicology assessments that determine the acceptable acute and chronic doses. As a result the size of the risk cups in the two countries is usually similar. Work is underway through the NAFTA Technical Working Group on Pesticides, and through other planned consultations, to minimize remaining differences.

2.0 Dietary Risk Assessment

Comment(s)
One respondent noted that the international community has adopted the use of supervised trial median residue values, residue values at the limit of detection or, in some cases, zero values where there is no possibility of residues occurring. The PMRA should adopt international standards. Another respondent noted that usable data exist to allow a reasonably reliable estimation of actual Canadian dietary residue levels of many pesticides, including Health Canada's own monitoring data and American monitoring data. Another respondent suggested that MRLs should be developed from dietary risk assessments using data from the United States Department of Agriculture's Pesticide Data Program and the National Agricultural Statistics Service as well as consumption surveys conducted by the United States Department of Agriculture that are reasonably representative of consumption patterns of Canadians.

Another respondent commented that Science Policy Notice SPN2004-01, *Estimating the Water Component of a Dietary Exposure Assessment*, proposes using an unrefined concentration estimate, not unlike the 0.1 ppm default MRL, in an initial risk assessment. No further refinement of the concentration is required if the risk does not exceed the level of concern. The respondent suggested that this approach should be equally valid for estimating the food component of a dietary risk assessment, and further refinement of the concentration estimates for both water and food components would be warranted if the dietary risk assessment indicated the risk as calculated with these unrefined estimates exceeds the level of concern.

Response

The PMRA's approach to using monitoring data, including data from American sources, is outlined in Science Policy Notice SPN2003-03, *Assessing Exposure from Pesticides in Food: A User's Guide*. Data from registrants, from Canadian sources (federal and provincial) and from government sources in the United States are all used when they are available to refine dietary risk assessments. In the absence of sound monitoring data, however, the General MRL level is used. The PMRA does use a tiered approach in conducting risk assessments. If an assessment passes using protective, high-end residue estimates, no further refinement is warranted. Additional refinements may be considered if they are scientifically defensible and if they are needed to accommodate additional uses. Without refinement, a small number of foods could quickly fill the portion of the risk cup that is available after water exposure is considered.

3.0 Imports and Trade Irritants

Comment(s)

A number of respondents agreed with the intent of the approach in the previous document regarding imported food with residues of active ingredients not registered in Canada, encouraging registrants to seek Canadian registration at the same time as import MRLs are being requested.

Another respondent noted that for active ingredients not registered in Canada, the issue being more problematic; some foreign registrants will not be aware of the requirement for data submission to Canadian authorities before an MRL can be established on an imported food.

Some respondents stated that elimination of the 0.1 ppm will not increase the quality of Canada's food supply and that trade irritants may occur inadvertently. It was suggested that the PMRA should provide a discussion, based on the NAFTA and General Agreement on Tariffs and Trade Sanitary and Phytosanitary Agreements, on how this proposed action is scientifically acceptable under these agreements.

One respondent noted that the American process for *Food Quality and Protection Act* began in 1996 and continues today, through reregistration and a mandate to reassess the safety of all food tolerances, and that PMRA should follow a similar approach.

Another respondent suggested that, if no current MRLs exist either in the United States or in Canada, work towards a "North American" standard rather than a costly, two-track approach is encouraged.

One respondent commented that Canadian regulatory authorities should use Codex MRLs in cases where a product is of entirely import origin and no specific tolerance exists in the Food and Drug Regulations. Canada has a treaty obligation to first consider the use and application of Codex standards, guidelines and recommendations in terms of permitting market access in those areas involving health and safety.

Response
Importers are encouraged to make their suppliers aware of the proposed requirement for a specific MRL to be set in Canada in such cases and to contact the PMRA to alert the Agency to specific issues. With respect to comments about the contribution that this proposal will make to food safety, as noted earlier, setting pesticide-specific, food-specific MRLs below the current 0.1 ppm default will lower allowable residues overall and potentially reduce dietary exposure to pesticides.

With respect to trade concerns, trade irritants will be minimized through harmonization in a number of areas, and new trade irritants will not be created. In particular, the proposal will contribute to further harmonizing pesticide regulation in Canada and the United States. The PMRA is re-evaluating older pesticides on the Canadian market and is cooperating with the USEPA in their reregistration and tolerance assessment process. Revoking the General MRL regulation will bring the Canadian approach closer to that of the United States. The PMRA agrees with the suggestion to work towards a North American standard and welcomes joint submissions to the PMRA and the USEPA. Guidelines to assist in making such submissions can be found on the PMRA website under Applicants and Registrants, and data requirements can be found in the NAFTA Guidance Document entitled *NAFTA Guidance Document on Data Requirements for Tolerances for Imported Commodities*.

With respect to the use of Codex standards, the PMRA will consider Codex MRLs at or below 0.1 ppm in establishing a transitional MRL for imported food. If the Codex MRL of interest is greater than 0.1 ppm, registrants are invited to contact the PMRA for discussions on a case-by-case basis.

4.0 Transitional MRLs

Comment(s)
Respondents to the earlier discussion paper made a number of suggestions for transition approaches, including transition periods that would be set for each active ingredient or group of active ingredients and periods that would be individually negotiated with registrants. Others suggested a transition period of five to seven years.

The previous discussion document proposed that MRLs be set on a transitional basis, because a full complement of contemporary residue data as required by the Residue Chemistry Guidelines may not be available to establish ongoing MRLs immediately for all pesticide residues that are currently regulated under the General MRL. Many respondents commented on this approach.

Response
The PMRA has concluded that all transitional MRLs should be in effect for a maximum of seven years (Section 2.1) to treat all registrants in the same way, and to be able to communicate clearly and readily track progress. With respect to the comments on transitional MRLs, the Agency now proposes that a number of the specific MRLs be established on an ongoing, rather than a transitional basis.

5.0 Requirements and Process to Establish an MRL

Comment(s)
Respondents raised a series of questions regarding the process and requirements for setting MRLs, and the fees that would be charged.

Response
The submission process is outlined on the PMRA website at www.pmra-arla.gc.ca/english/appregis/appregis-e.html. For pesticides that are to be registered in Canada, the PMRA proposes MRLs that are based on data in the submission for registration. Data requirements are found at www.pmra-arla.gc.ca/english/appregis/appregis-e.html. Data requirements to establish MRLs for imported commodities can be found in the document "*NAFTA Guidance Document on Data Requirements for Tolerances for Imported Commodities*", www.pmra-arla.gc.ca/english/pdf/nafta/naftajr/nafta-jr2003-02-e.pdf. The target times to review submissions are published in Regulatory Proposal PRO96-01, *Management of Submissions Policy*, available at www.pmra-arla.gc.ca/english/pdf/pro/pro9601-e.pdf.

Comment(s)
The previous proposal contained references to "sufficient data", a term that also prompted questions. A respondent also noted there have been a number of uses that have been reviewed by the Canadian regulators and no MRL has been required as residues are less than or equal to 0.1 ppm. The respondent suggested that as data should be on file providing for a reduced MRL, these products should be treated differently than those which have never been reviewed by the Canadian regulators.

Response
This proposal significantly reduces the requirements for submission of data. In general, data that meets the requirements outlined in the NAFTA Guidance document referred to above will be sufficient. Registrants are encouraged to contact the PMRA at an early stage of planning their submission to determine what the data requirements would be in particular cases. The comment regarding reviews of previous data by Canadian regulators has been addressed with the revised proposal in Section 2.3.1.

Comment(s)
One respondent commented that, when a pesticide is no longer protected by patents, it may be produced and marketed by multiple companies, and there may be many different formulations in use. Often, only a subset of these companies will petition the PMRA for a Canadian MRL. However, they may not represent all those operating in a given market. The PMRA should encourage participation of parties who stand to benefit from an import MRL by communicating flexibility and reasonableness in the petition content.

Response
The PMRA recognizes that this is an issue whenever an MRL is sought for a pesticide that is no longer protected by patent. As is the case for pesticides that are subject to re-evaluation and are no longer protected by patent, the PMRA encourages the cooperation of all companies marketing a pesticide for which an MRL is being requested.

Comment(s)
One respondent noted that data developed overseas should be used for establishing or maintaining import MRLs when justified by sound science and resource efficiencies. However, the use of such data can also create situations where established legal practices for data protection may be compromised. When calling for foreign data outside of the Agency's control, the PMRA must assure that situations will not lead to compromising of affected registrants' intellectual proprietary rights.

Response
This issue is applicable to import MRLs in general and not only to those that would be subject to this process. The Agency can apply the data protection policy outlined in Trade Memorandum T-1-249, *Product-specific Registration and Proprietary Rights to Data*, when there is a Canadian registration, but this protection does not apply to data submitted to support import MRLs.

Comment(s)
Several respondents raised questions about cost recovery fees. There was concern that several fees could be charged when transitional MRLs are proposed. Some respondents felt that comparable fees should be charged for setting the import MRLs of new active ingredients as charged in the United States for similar activities. Others were interested in the level of the fees in Canada.

Response
The current proposal would require that a significantly smaller number of submissions be made to establish MRLs, so fees will be applicable to many fewer situations. Only one fee will be charged to establish an MRL, even if there is a transitional MRL and a submission for an ongoing MRL. Current fees are presented in *Guidance Document on Pest Control Product Cost Recovery Fees*, available at www.pmra-arla.gc.ca/english/pdf/cost/feeguide-e.pdf.

Comment(s)
One respondent pointed out that the Canadian promulgation of MRLs adds a significant delay time to the process of establishing MRLs, which far exceeds that of Canada's major trading partner, the United States.

Response
The PMRA is also concerned about the length of time that has been required to promulgate MRLs, and is seeking ways to address this issue while respecting the right of Canadians and other stakeholders to be consulted on proposed regulatory changes. One action that the Agency has taken is to establish a Memorandum of Understanding

involving Health Canada, the Privy Council Office and the Department of International Trade. Agreement has been reached on a streamlined process for establishing MRLs; further information is available at www.pmra-arla.gc.ca/english/pdf/mrl/MOU-HC-DIT-PCO-e.pdf. This Memorandum may be superceded by the changes outlined in the next paragraph.

Secondly, through a recent legislative change[4], foods containing residues of pesticides at or below the MRLs specified by the Minister under the new *Pest Control Products Act* would be exempted from the adulteration provisions of the *Food and Drugs Act.* As a result, MRLs will be established, changed and revoked much more quickly than at present because the Minister of Health, rather than the Governor-in-Council, will make such changes. Proposed MRL changes will continue to be based on a thorough scientific assessment, and the public will have an opportunity to comment on proposed changes before they become final.

6.0 Maintaining an MRL for Imported Food When a Registered Food Use Is Disallowed in Canada for Reasons Unrelated to Dietary Risk

Comment(s)

Some respondents disagreed with the previous proposal to revoke the MRL and then consider requests for a new MRL. A new submission is necessary because the PMRA needs to evaluate the MRL based on the use pattern in the country of origin and the corresponding residue data. If it differs from the Canadian use conditions, an amended MRL may be appropriate. There were suggestions that the Agency should take environmental considerations into account as part of the decision on establishing an import MRL; however, the new *Pest Control Products Act* specifies that only the health risks of the product may be considered in establishing an import MRL.

Response

The previous document did not specify the process that would be followed to revoke an MRL. Should the PMRA propose to revoke an MRL, the Agency will follow the same process that is used to establish an MRL. A proposal for comment will be published, comments will be considered, and the final decision will be announced. With the passage by Parliament of Bill C-28, the process of setting, modifying or revoking MRLs will be simpler and require significantly less time, while still providing for public consultation.

[4] Bill C-28, An Act to Amend the *Food and Drugs Act*, received Royal Assent on 27 November 2005, but has not yet been promulgated. A copy of this legislation can be found at www.parl.gc.ca/38/1/parlbus/chambus/house/bills/government/C-28/C-28_4/C-28_cover-E.html.

7.0 Maintaining an MRL for Imported Food for an Active Ingredient Not Registered in Canada When the Registered Use Is Cancelled in the Country of Origin

Comment(s)

Respondents questioned why a new import MRL application would be needed as MRLs are not currently tied to any specified country of origin. One respondent noted that there is a provision in the new *Pest Control Products Act* to initiate a special review if a product's registration is cancelled in another country that is a member of the Organisation for Economic Co-operation and Development; this provision can be used as the mechanism to reassess the MRLs, if warranted.

Response

The PMRA establishes MRLs based on a submission with country-specific data; as a result, the PMRA would need to consider the action in that country. With respect to the second comment, special review is intended for the review of the registration of a pesticide and not for situations in which the pesticide is not registered in Canada, as would be the case with an import MRL.

8.0 Proposed Approach for Canadian Research Permits

Comment(s)

Many respondents expressed concern about the effects of the previous proposal on research. They noted the importance of research in the development of any new product and major new use. Such research contributes to the ability of registrants to correct any problems that could arise from commercial use prior to the product reaching full-scale commercialization. They also noted the need to conduct operator exposure studies for some uses to meet Canadian regulatory requirements. Some respondents concluded that research permit trials will have to be performed on a destruct basis because quantifiable residues are at least a possibility. This would be very expensive. In addition, the proposal may also have any potential trials downsized to avoid a large crop-destruct cost, in turn affecting the usefulness of the trial.

One respondent noted that the limitations placed on uses of a pesticide by research permits can quantify and identify what was used and track residues for regulatory purposes. As all MRLs set are to meet a 70-year life span at worst-case scenario, the variation of relative exposure from a non-registered or emergency use within the good agricultural practices for a product already registered abroad is not a health risk.

Response

The PMRA shares the concerns expressed by respondents about the impact of the initial proposal on research that is conducted in Canada. The revised proposal (Section 3.3) enables research involving the use of pesticides on food crops to continue to be conducted in Canada if certain requirements are met, without increasing the risk to the safety of the food supply.

Comment(s)
One respondent proposed that the PMRA should consider allowing research crops to be marketed in other countries with tolerances.

Response
As outlined in Section 3.3, MRLs would be established for research crops in Canada, allowing them to be sold in Canada. As such, export would no longer be required.

9.0 Proposed Approach for Emergency Uses

Comment(s)
A number of respondents to the first consultation document noted the importance to Canadian growers of emergency registrations to respond to serious pest outbreaks. Similar emergency registration programs are in place in other countries that belong to the Organisation for Economic Co-operation and Development, and the lack of such a program in Canada would place growers at a competitive disadvantage.

Response
The Agency has examined available regulatory options with respect to emergency uses. When the authority to establish MRLs under the new *Pest Control Products Act* becomes available, the PMRA will be able to set MRLs much more quickly; however, several months would still be required. As a result, the Agency proposes to maintain a general MRL of 0.1 ppm under the Food and Drug Regulations, which will apply to residues resulting from emergency uses (Section 3.4).

Comment(s)
One respondent suggested that, as a condition of temporary registration for emergency control of a seriously detrimental pest infestation, the PMRA positively determine there are not other biological or cultural controls that could address the pest.

Response
Current requirements for an emergency to exist include the lack of an effective, alternative method to control the pest. An applicant is required to explain in depth why alternative methods are ineffective in controlling the pest, and the PMRA examines this information, along with other information outlined in Regulatory Directive DIR2001-05, *Emergency Registration*, when deciding whether to grant an emergency registration.

10.0 MRL Issues for Specific Commodities/Products

Comment(s)
Several respondents raised questions regarding MRLs for pesticide residues in processed and fresh-frozen products and multi-component foods.

Response
The Food and Drug Regulations indicate that MRLs are applicable to a food that contains a food listed for which an MRL has been established, or a food made from a product of any such food. This regulation would apply to processed products and multi-component foods, and to fresh-frozen products.

Comment(s)
One respondent expressed particular concern about MRLs for baby food, noting that the European Union has lowered its MRL on pesticide residues in baby foods to 0.01 ppm, which effectively establishes a ten-fold margin of safety for infants. Canada's MRLs on pesticide residues in baby foods should be equally as stringent.

Response
During the PMRA's risk assessment process for pesticides, sensitive subpopulations including infants are considered more explicitly than in the European Union, instead of setting MRLs specifically for baby food. This approach is also used by the United States.

Comment(s)
One respondent suggested that the proposal be revised to allow feed uses for cases where an MRL has been established elsewhere.

Response
The definition of "food" under the *Food and Drugs Act* does not include animal feed; there is no authority under this Act to establish MRLs for animal feed.

Comment(s)
Another respondent was concerned about seed treatments, which typically do not have detectable residues in harvested grain.

Response
Currently, the PMRA establishes MRLs when necessary for foods derived from treated seed.

11.0 Limit of Quantitation

Comment(s)
One respondent suggested that the previous proposal would require the Canadian government to establish a limit of quantitation. As science is steadily progressing and detection limits are constantly being lowered, the "quantifiable" residue level is a moving target.

Response
As proposed in Section 3.6, where the use of pesticide may result in finite residues on a crop for which the pesticide is registered, but none are detected in the field trial data, the MRL for that food use is set at the limit of quantitation that is reported in the enforcement method and/or in the field trial method.

12.0 Monitoring and Enforcement Issues

Comment(s)

Several respondents commented on the need for adequate monitoring and enforcement programs for pesticide residues in Canada. One respondent noted that, in theory, revoking the default MRL would not permit any residue of the pesticide in or on foods and is a positive move. However, in the absence of adequate monitoring and enforcement programs for pesticide residues in Canada, MRLs are almost moot. Another respondent noted that a zero default MRL for pesticide residues cannot be assumed given the fallibility of residue monitoring. Monitoring and surveillance efforts ought to be increased substantially to provide adequate incentive for MRL compliance. The respondent suggested that the PMRA should conduct, or contract out, spot checks of imported and domestic foods for pesticide residues to ensure that risk management decisions are not based on faulty assumptions that will present a risk to the public. Imported food deemed "adulterated" should be turned away at the border. Further, Canadian food deemed "adulterated" is unfit for consumption and should be confiscated and must be disposed of.

Response

The Canadian Food Inspection Agency (CFIA) is responsible for monitoring and enforcing Food and Drug Regulations regarding pesticide residues. The CFIA's monitoring program is prioritized on the basis of risk and targeting high consumption items. CFIA takes action when foods that exceed MRLs are identified. As with all such programs, not all residues and commodities are tested. The PMRA uses information from CFIA to determine whether pesticide users have complied with the conditions of registration of pesticides.

12.1 Enforcement Position Regarding Residues of Pesticides with No MRL or a Revoked MRL in Products with Long Shelf That Have Been Shipped to Canada Before Action Was Taken

Comment(s)

Several respondents commented that those who purchased inventories of food products under the current requirements should be allowed sufficient time to market the products. The American experience indicates time frames approaching four years to accommodate processed products may be necessary to allow legally treated commodities to transition to completely new tolerances or tolerance revocations.

Response

The PMRA will work with the Canadian Food Inspection Agency to determine appropriate timelines on a case-by-case basis for such products to continue to be marketed.

12.2 Enforcement Concerning Residues That May Be Found in Rotational Crops

Comment(s)
Some respondents raised questions concerning residues that may be found in rotational crops, and what consequences can be anticipated when the General MRL is no longer in place.

Response
With respect to rotational crops, specific MRLs based on current American tolerances for indirect or inadvertent residues at or below 0.1 ppm will be established as required to take unintentional residues into account, consistent with the approach that is taken for new pesticides. It is important to note that such MRLs do not imply that the pesticide can be used legally on such crops. Pesticide use in Canada is restricted to uses that have been registered and are listed on the product label.

12.3 Spray Drift and Pesticide Runoff

Comment(s)
Several questions were raised regarding pesticide residues in crops as well as in water and in fish resulting from spray drift or from the runoff of pesticides.

Response
The General MRL was not intended to permit such situations. Buffer zones are one of the methods used to protect the environment from contamination through spray drift. A proposal regarding the calculation of buffer zones, Regulatory Proposal PRO2005-06, *Agricultural Buffer Zone Strategy Proposal*, was recently published for comments.

Comment(s)
One respondent encouraged the PMRA to work with CFIA to establish a consistent enforcement policy on low levels of pesticide residues resulting from drift. Would a single pesticide residue detection be sufficient to impact the whole crop? If a general environmental sample taken prior to a product being shipped as a food showed a pesticide residue was present, would this be sufficient for action or would action only be taken when detections are found in the food product when it enters the market place?

Response
The Agency works regularly with CFIA on a number of issues and will discuss the enforcement policy on low levels of pesticide residues resulting from drift.

Comment(s)
One respondent noted that agricultural chemicals are also present in the form of environmental contaminants. For example, fish harvested in the Arctic may contain traces of persistent contaminants that may have originated in Asia, Europe or North America. Is there any intent to differentiate between persistent environmental contaminants and pesticides known to be currently used in the production of food for the purpose of food safety controls?

Response
The PMRA would have to consider each of the contaminants on a case-by-case basis for in light of the legislative mandate for establishing pesticide MRLs. The Agency would be pleased to discuss this issue further.

12.4 Public Health Uses

The USEPA establishes a "general tolerance", if required, when a public health use of a pesticide is involved. For example, a tolerance has been established for the pesticide naled on raw agricultural commodities (with certain exceptions) from use of the pesticide for area pest (mosquito and fly) control. Several groups asked whether the intent was to follow this practice in Canada; previously, the General MRL would have applied.

Response
The PMRA will address such situations as the need arises.

12.5 MRL Exceedances as a Signal to Investigate Environmental and Wildlife Effects

Comment(s)
One respondent suggested that the connection between MRLs and environmental exposure should not be ignored. Specifically, MRL exceedances can be a signal of something unacceptable happening in the environment, whereby wildlife would be negatively impacted. There should be a requirement that an investigation into adverse effects on the environment and wildlife must be triggered when MRLs are exceeded.

Response
The PMRA uses information from CFIA to determine whether pesticide users have complied with the conditions of registration of pesticides, including those designed to protect the environment.

13.0 Exemption from the Requirement for a Specific MRL

Comment(s)
One respondent noted that the USEPA has a process for the exemption from tolerance for lower toxicity pesticide chemicals that meet certain prescribed criteria. Once a chemical has been designated as exempt, specific tolerances are not required. The PMRA was urged to adopt a similar approach.

Another respondent expressed concerns when no MRL has been or can be established, and the consequences. It may be possible to have no MRL established for biological or other products where food or drug uses are currently allowed (e.g., acetic acid, vegetable oils, terpenes, natural food components). In this type of case, where human health impacts are deemed negligible, an MRL could well be set not to exceed a certain percentage of average food or drug use.

Response
The PMRA proposes that the current practice of listing specific agricultural chemicals to be exempted from the requirements to establish MRLs be continued under the Food and Drug Regulations, and, in addition, specific uses (rather than all uses) of a particular pesticide also be exempted under those Regulations (Section 3.7).

14.0 Minor Use Implications

Comment(s)
A number of respondents raised concerns about how elements of the previous discussion document could impact minor uses. That document indicated that the registrants are expected to identify and assess the residue data available as well as to propose MRLs. The respondents were concerned that, as many uses are currently registered under the minor use program, this puts these uses at risk where companies are not willing to spend additional money to do the research required to propose the MRL. Provincial governments and the user groups involved in minor uses may not have the skill, capabilities or resources to determine MRLs or to generate more data to determine MRLs. The support of these MRLs will place a significant burden on the fledgling minor use and risk-reduction process in Canada.

One respondent suggested that the proposal needs to recognize the importance of new or emerging crops and “micro” crops or those that are currently too small for provincial governments, manufacturers or growers to apply for or fund minor uses (i.e., specialty mushrooms, horseradish, spelt, artichokes and stevia (sweetener) as well as medicinal herbs such as echinacea, hawthorn, yarrow, Devil’s club, St. John’s wort and golden seal). These are extremely low volume crops. A potential solution could be to maintain the 0.1 MRL for emerging or “micro” commodities produced on less than a specific acreage.

Response
The PMRA shares the concerns of respondents and has modified the previous proposal to reduce the requirements for submissions to the PMRA by accepting American tolerances below 0.1 ppm as a basis for establishing ongoing MRLs. The Agency also wishes to encourage registrants to seek Canadian registration when requesting that specific import MRLs be established; some specific proposals have been made in earlier sections of the document. The PMRA recognizes the challenges associated with newly emerging crops. However, even if the General MRL were maintained, the PMRA would require a submission with data to support the registration of pesticides for use on such crops.

15.0 Priority Setting

Comment(s)
There were a number of comments regarding the amount of work that will be required to establish specific MRLs and the need for a workplan. Several respondents suggested ways in which priorities could be set in replacing the General MRL. One suggestion was to work with stakeholders to develop a list of the specific compounds and MRLs that

would need to be addressed. A prioritized schedule of needs for MRLs would be helpful in setting the time frame for any transitional periods for individual crop use sites. Hopefully, the most critical MRLs to avoid disruption of existing trade would receive the highest priority. A second suggestion was to use the results of preliminary dietary risk assessments based on the default MRL of 0.1 ppm in comparison to the current "risk cup" status of a compound, or group of compounds, as a means of setting priorities for the establishment of more refined MRLs. A third suggestion was to focus first on the pesticide/commodity combinations that would lead to the highest dietary exposures to pesticides or the pesticides that have the lowest margins of safety for dietary risk based on the 0.1 ppm default MRL.

Response
The PMRA appreciates these suggestions and agrees that an implementation plan is required. As a first step, the Agency has compared Canadian registered food uses and MRLs with American tolerances to provide a measure of the impact of replacing the General MRL. The Agency then developed the more detailed proposal, outlined in earlier sections of this document, that relies on American tolerances at or less than 0.1 ppm that have been set since the *Food Quality and Protection Act* was enacted. As a result, the workload for registrants as well as the PMRA has been greatly reduced.

16.0 Harmonization, Coordination and Work Sharing

Comment(s)
Comments from respondents were supportive of further harmonization with NAFTA countries for setting MRLs and registering pesticides.

One respondent suggested that MRLs should be progressively reduced across the continent, within the context of NAFTA harmonization of MRLs. Discrepancies between Canadian MRLs and American tolerances should be viewed as "health irritants". The goal should be to reduce residues in a wide range of continentally traded goods, including foods, wood and other consumer products, as the targeted means of addressing trade irritants (infractions of another country's residue limits). Trade irritants range from recurring crop/pesticide infractions to inevitable situations of zero allowable residues when one country de-registers a pesticide. One objective should be to set specific MRLs low enough to spur the adoption of ecologically sound agricultural practices. This approach also addresses the North American public's predominant health and environmental concerns about pesticides, i.e., residues in food.

Another respondent suggested MRLs for all new active ingredients should be harmonized with the American tolerance levels, with the understanding that the tolerances apply equally to imports and domestic uses. This would also require data sharing for market basket study data and crop use of active ingredients in both countries. A second comment supported further enhancement and expediting of joint registration efforts with the United States. A third comment noted that revoking of the Canadian default MRL presents an important opportunity for mutual acceptance of MRLs. The PMRA is interested in these

proposals and will pursue them with the USEPA, recognizing that the cooperation of industry and other stakeholders will be essential.

A respondent suggested that the PMRA should work with the NAFTA Technical Working Group on Pesticides to develop a harmonized approach on adapting residue data requirements for food uses to support new import MRLs. The PMRA should also harmonize approaches under NAFTA for modifying or maintaining existing domestic MRLs for import purposes when specific crop uses or product registrations have been cancelled. The approach for establishing import MRLs should emphasize the following:

- determining the amount of the potential exposure to consumers of the imported commodity;
- combining the residue trial guidance for MRLs where relevant; and
- having a basis for determining when the need for additional data is justified.

All efforts should be made to maximize the use of existing data, accelerating the benefits of global harmonization of MRLs and of standardization of residue zone maps. The respondent would also like to remind the PMRA of the NAFTA Industry Working Group's proposal to consolidate the number of residue trials needed to support a NAFTA registration. This project has the potential to significantly reduce the number of residue trials needed to support continued registration of pesticides having minor crop uses in Canada.

One respondent commented that the international community is formulating and harmonizing food standards under the Codex discipline and ensuring their global implementation. The Food Code has become the seminal global reference point for consumers, food producers and processors, national food control agencies and international food traders. The PMRA should take an active role in establishing new MRLs by participating in an international initiative that is being lead by Food and Agriculture Organization (Intergovernmental Group on Tea under the auspices of the Committee on Commodity Problems); this initiative aims to bring about a global policy respecting the regulation of agricultural chemicals on tea.

Response

The PMRA appreciates the support from respondents for the work that has been undertaken with the USEPA and Mexican regulatory authorities. The Agency will continue to give priority to projects of the NAFTA Technical Working Group on Pesticides, which include work in harmonizing methodology and addressing trade irritants. The revocation of the General MRL will contribute to harmonizing the approach to regulating low levels of pesticide residues among NAFTA countries. Neither the United States or Mexico use a default MRL; with the change of approach in Canada, the three countries will be more harmonized. This consultation document proposes the acceptance of a number of contemporary American tolerances and some contemporary Codex MRLs, which will thereby continue progress to harmonization. The PMRA is also interested in the initiative to improve the setting of MRLs for tea on an international basis and welcomes other such suggestions.

Appendix III Database of Canadian Uses, Canadian MRLs and American Tolerances

A database with information regarding Canadian food uses, Canadian MRLs and American tolerances was generated to support the proposal to revoke the 0.1 ppm General Maximum Residue Limit for Food Pesticide Residues. The complete database can be found on the PMRA website at (www.pmra-arla.gc.ca/english/pdf/mrl/dis2006-1/MRL_Table Master-e.xls) and is the source of the tables that follow.

While significant care was taken in preparing these tables, the Agency is aware that the information is somewhat dated. Subsequent registrations of new active ingredients, changes to commodities of registered active ingredients and corresponding additions, revisions or revocations of tolerances are not necessarily reflected in the tables.

1.0 Description of Column Headings

Heading	Description	Source
CAS #	The Chemical Abstract Service (CAS) number of the pesticide chemical. Note that the chemical *registered* in a product may be different from the *residue* regulated in Table II, Division 15, of the Food and Drug Regulations.	Chemical Abstract Service
CDN Common Name	The common name for the pesticide in Canada.	Electronic Labels: Search and Evaluation (ELSE)
Commodity Descriptor on Canadian Label	Food commodity descriptors as extracted from Canadian labels.	Electronic Labels: Search and Evaluation (ELSE)
US CFR Citation	Reference to the Code of Federal Regulations (CFR), Title 40 (Protection of Environment), Part 180 entitled “Tolerances and Exemptions from Tolerances for Pesticide Chemicals in Food”, citation where American tolerances for each pesticide are codified (www.access.gpo.gov/nara/cfr/waisidx_05/40cfr180_05.html).	UESPA table, May 2004
U.S. Commodity	American commodities as codified in 40 CFR Part 180. Commodities reflect individual crops and animal commodities or crop groups or subgroups.	UESPA table, May 2004

Heading	Description	Source
U.S. Current Status	Description of the American tolerances status and corresponding date.	UESPA table, May 2004
U.S. Ingredient Name	The common name for the pesticide in the United States as identified in 40 CFR Part 180.	UESPA table, May 2004
U.S. Tolerance Granted (ppm)	American tolerances for the identified commodities codified in 40 CFR Part 180.	UESPA table, May 2004
U.S. Tolerance Type	Description of the nature of the American tolerance. USEPA 40 CFR Part 180 citations includes the following sections under which tolerances are listed: (a) General (reflects "Permanent tolerance" description in the database); (b) Section 18 emergency exemptions; (c) Tolerances with regional registrations; or (d) Indirect or inadvertent residues. These sections may also include temporary or time-limited tolerances with identified expiration/revocation dates. A few citations also include "(e) Revoked tolerances subject to the channel of trade provisions" (currently only vinclozalin and methyl parathion) or "(f) Import tolerances" (currently only mepanipyrim).	UESPA table, May 2004

2.0 Explanatory Comments

- The information in the tables is somewhat dated, and the PMRA has not attempted to update the information due to the extensive effort that would be required. Submissions to update this information are welcomed.

- Table comparisons are based upon parent compounds only; metabolites have not been included at this time.

- The tables are separated according to crops grown in Canada and those that are not. The basis for this information was primarily *Food and Feed Crops of the United States*[5]. Other sources include internet documents and limited informal communication with provincial minor use coordinators. The identification of any inaccuracies is welcomed.

- Tolerances for indirect or inadvertent residues are designated as such in the tables. There are situations in which American and Canadian uses are matched in the tables, but the American tolerance represents indirect residues, typically a lower value resulting from direct use on registered commodities; these would be inappropriate as the basis for an MRL for the direct application to a Canadian commodity.

- A crop group tolerance in the United States may be linked to a specific crop within that group in the "Commodity Descriptor on Canadian Label" column although the remaining crops in the group are not registered for use in Canada; this is not captured elsewhere in the database. However, an American tolerance for a crop group does not necessarily mean that all crops within that group are labelled for use in the United States either.

- Canadian food uses that do not have corresponding American tolerances for the active and commodity were incorporated into a separate database capturing:
  - unique to Canada active ingredients,
  - unique commodities for active ingredients registered in both countries, and
  - Canadian uses for active ingredients that are exempt in the United States from the requirement for a tolerance.

  These registered uses, previously captured under the General MRL regulation, will have MRLs established at 0.1 ppm in accordance with Table 3C.

- American tolerances listed are those that were in place when the table was prepared. They do not necessarily reflect post *Food Quality and Protection Act* values.

3.0 Tables

3.1 Domestic Food Uses Currently Regulated Under the General MRL (Reference Section 2.2)

Table 3A	Canadian Labelled Commodities Previously Covered Under the General MRL with American tolerances at or below 0.1 ppm (491 entries)
Table 3B	Canadian Labelled Commodities Previously Covered Under the General MRL with American tolerances above 0.1 ppm (617 entries)
Table 3C	Canadian Labelled Commodities Previously Covered Under the General MRL Without Corresponding American Tolerances (733 entries)

[5] Markle, G.M., J.J. Baron, and B.A. Schneider. 1998. *Food and Feed Crops of the United States.* Second Edition, Revised. Meister Publishing Co. ISBN 1-892829-00-2

3.2 Foods Grown in Canada, but Uses Are Not Currently Registered in Canada (Reference Section 2.3)

A Pesticide Is Registered in Canada for Food Use, but Not for Uses for Which Tolerances Have Been Established in the United States (Reference Section 2.3.1)

Table 4A — Pesticides Registered in Canada for Food Use, but Not on the Listed Canadian-grown Commodities, with American Tolerances at or below 0.1 ppm (1206 entries)

Table 4B — Pesticides Registered in Canada for Food Use, but Not on the Listed Canadian-grown Commodities, with American tolerances above 0.1 ppm (1390 entries)

A Pesticide Is Registered in Canada but Not for Food Uses; Tolerances for Such Uses Exist in the United States (Reference Section 2.3.2)

Table 5A — Pesticides Registered in Canada, but Not for Use on Food, with American Tolerances at or below 0.1 ppm for Canadian-grown Commodities (105 entries)

Table 5B — Pesticides Registered in Canada but Not for Use on Food, with American Tolerances above 0.1 ppm for Canadian-grown Commodities (79 entries)

A pesticide is not registered in Canada, but tolerances for food uses have been established in the U.S. (Reference Section 2.3.3)

Table 6A — Pesticides Not Registered in Canada with American Tolerances at or below 0.1 ppm for Canadian-grown Commodities (748 entries)

Table 6B — Pesticides Not Registered in Canada with American Tolerances above 0.1 ppm for Canadian-grown Commodities (698 entries)

3.3 Residue Limits for Foods That Are Not Grown in Canada (Reference Section 2.4)

A Pesticide Is Registered in Canada for Food Uses; No Specific MRLs Have Been Set for the Imported Foods but Tolerances Have Been Established in the United States (Reference Section 2.4.1)

Table 7A — Pesticides Registered in Canada for Food Use with American Tolerances at or below 0.1 ppm for Commodities Imported into, but Not Grown in, Canada (147 entries)

Table 7B — Pesticides Registered in Canada for Food Use with American Tolerances above 0.1 ppm for Commodities Imported into, but Not Grown in, Canada (380 entries)

A Pesticide Is Registered in Canada but Not for Food Uses; No Specific MRLs Have Been Set for the Imported Foods but Tolerances Have Been Established in the United States (Reference Section 2.4.2)

Table 8A — Pesticides Registered in Canada but Not for Use on Food, with American Tolerances at or below 0.1 ppm for Commodities Imported Into, but Not Grown In, Canada (14 entries)

Table 8B — Pesticides Registered in Canada but Not for Use on Food, with American Tolerances above 0.1 ppm for Commodities Imported into, but Not Grown in, Canada (33 entries)

A Pesticide Is Not Registered in Canada; No Specific MRLs Have Been Set for the Imported Foods but Tolerances Have Been Established in the United States (Reference Section 2.4.3)

Table 9A — Pesticides Not Registered in Canada with American Tolerances at or below 0.1 ppm for Commodities Imported Into, but Not Grown, in Canada (52 entries)

Table 9B — Pesticides Not Registered in Canada with American Tolerances above 0.1 ppm for Commodities Imported Into, but Not Grown In, Canada (89 entries)