Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

# Discussion Document

**DIS2003-01**

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

*(publié aussi en français)*

**January 10, 2003**

**This document is published by the Alternative Strategies and Regulatory Affairs Division, Pest Management Regulatory Agency. For further information, please contact:**

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

**Internet:** pmra_publications@hc-sc.gc.ca
www.hc-sc.gc.ca/pmra-arla/
**Information Service:**
**1-800-267-6315 or (613) 736-3799**
**Facsimile: (613) 736-3798**

ISBN: 0-662-33257-1
Catalogue number: H113-19/2003-1E-IN

## Foreword

The Consultation Document puts forward a proposal for a regulatory change that would result in the revocation of the General Maximum Residue Limit (MRL) Regulation which currently provides a default level of 0.1 parts per million (ppm) for pesticide residues on domestically grown and imported food unless specific MRLs are listed in Table II, Division 15 of the Food and Drugs Regulations (FDR). The default level of 0.1 ppm will be replaced by setting specific MRLs for each pesticide and food combination at levels at or below 0.1 ppm. A transition period is proposed during which contemporary U.S. tolerances at or below the 0.1 ppm level will serve as a basis for setting specific MRLs. Where appropriate, Codex MRLs at or below 0.1 ppm will also be considered. In cases for which no specific MRL can be established, quantifiable residues will no longer be permitted. The proposal will bring Canadian regulatory practice in line with world standards for setting MRLs.

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

## Information on submitting comments

Comments are welcome on any aspect of this proposal and, in particular, on the following four areas:

- areas that you agree with
- areas that concern you and the reasons for these concerns
- recommendations to address your concerns
- positive or negative impacts that the proposal may have on you or your organization.

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

Forward written comments and the completed Identification Profile (Appendix 2, attached at the end of this document) within 90 days of the date of this publication to:

Attention: Frank Wandelmaier
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:
Frank Wandelmaier, (613) 736-3668, e-mail: Frank_Wandelmaier@hc-sc.gc.ca.

Please visit the PMRA Web site at http://www.hc-sc.gc.ca/pmra-arla/english/pubs/dis-e.html for electronic copies of the proposal document.

# Table of Contents

# 1.0 Introduction

Under the authority of the *Food and Drugs Act* (FDA) and Regulations, the Pest Management Regulatory Agency (PMRA) establishes Maximum Residue Limits (MRLs), also known as tolerances in the U.S., for pesticides in food. The MRL for a particular pesticide and food specifies the maximum concentration in parts per million (ppm) of the pesticide that is allowed in or on that food.

Regulation B.15.002(1) of the Food and Drugs Regulations (FDR) establishes 0.1 ppm as the "General Maximum Residue Limit". This regulation states that a food is adulterated if it contains residues of a pesticide at a level greater than 0.1 ppm unless a specific MRL has been established in Table II, Division 15 of the FDR. The FDA prohibits the sale of adulterated food.

Most industrialized countries set specific MRLs for each pesticide on each food commodity. In a case where no residues are acceptable, those countries either do not establish an MRL or they set a specific MRL at a very low level. That low level can be the level of quantification (LOQ)[1] or the lower limit level that can be routinely detected in general food monitoring programs, e.g., 0.01 ppm. In any case, any residue detected by current or specified analytical methods would probably be a violation.

In Canada, a key consideration in making the General MRL Regulation in the late 1970s was that the analytical methodologies then available were not sufficiently sensitive to detect most pesticides at levels below 0.05 ppm in a general food monitoring and surveillance program for pesticide residues. Advances in analytical capabilities since then have improved to such an extent that residues in a general food monitoring and surveillance program can now be detected at or below 0.01 ppm levels.

A consequence of the General MRL Regulation is that the sale of foods with residues of any pesticide up to 0.1 ppm is allowed, even if good agricultural practices can result in much lower residue levels. The reliance on the 0.1 ppm default level thus allows the presence of higher than warranted pesticide residues.

Furthermore, in the absence of specific MRLs below the 0.1 ppm level and in the absence of monitoring data, current estimates of dietary exposure have to be built on the 0.1 ppm default assumption and lead to overestimates of exposure, particularly when residues from a large number of food commodities contribute to the overall exposure. Because more stringent safety standards require that total dietary exposure be kept low, inaccurate estimates, even when erring on the side of caution, have become increasingly problematic.

---

[1] Limit of Quantification (LOQ) is the minimum concentration or mass of the analyte that can be quantified with acceptable precision.

## 2.0 More stringent safety standards require more realistic exposure assessments

The introduction of more stringent safety standards in the U.S. through the *Food Quality Protection Act* (FQPA)(1996) and the need to offer equivalent protection to Canadians, initiated a rethinking of the approaches to estimating dietary exposures to pesticide residues on food commodities. The recent requirement to consider *aggregate*[2] and *cumulative*[3] exposures to pesticides and to apply greater safety factors for the protection of children and other sensitive groups, demands that the accuracy of exposure estimates that underlie regulatory decisions be improved.

The recent changes to estimating dietary exposure to pesticide residues are best visualized using the concept of a "risk cup".

The risk cup for a pesticide is determined by the toxicity of the pesticide and the safety factors required or deemed necessary for the protection of human health. The risk cup for each pesticide is of limited size, and, in order to be safe, all exposures to a pesticide must fit into the risk cup.

### 2.1 The size of the risk cup

In regulatory practice, the size of the risk cup is determined by two factors: (1) the highest dose that does not cause any adverse effects in test animals, i.e., the no observed adverse effect level (NOAEL), and (2) the safety factor (SF) used to further reduce the NOAEL by at least two orders of magnitude (100×).

The size of the risk cup for each pesticide, measured in milligrams of pesticide per kilogram of body weight (mg/kg bw), specifies the amount of a pesticide that can be ingested safely every day for a lifetime, the acceptable daily intake (ADI), and the amount that can be ingested safely for one day, the Acute Reference Dose (ARfD).

With the introduction of more stringent safety standards through the FQPA, toxicity assessments have frequently resulted in significantly lower ADIs and ARfDs, and therefore in smaller risk cups. While safety factors of 100 account for inter- and intra-species variability, higher safety factors are applied where there is a need to protect sensitive subpopulations. Today, safety factors range as high as 1000. The resultant smaller risk cups must still be able to hold the peak exposures that could be experienced in a single day and the average exposures that a person could receive each day for a lifetime.

---

2 *Aggregate* exposure is the sum of exposure to a pesticide from all dietary and non-dietary exposures.

3 *Cumulative* exposure is the sum of exposures of all pesticides with a common mechanism of toxicity.

## 2.2 The content of the risk cup

**Single pesticide exposure from food commodities**
Today, Canadian diets include a great variety of foods, both imported and locally grown. A single pesticide may now be used on more than 100 different food commodities. Pesticide residues on all these food commodities have to fit into risk cups that are getting significantly smaller.

As the number of Canadian food commodities with residues of the same pesticide increases, there comes a point where a full to "overflowing" risk cup would not allow the addition of new food uses. In order to keep a risk cup from overflowing, it is therefore of primary importance to fill it with exposure values that are as low and as accurate as possible.

Residues on imported food commodities are included in the Canadian exposure estimates when imported commodities contribute significantly to Canadian consumption or are considered specialty items that may be consumed to a greater extent by a specific sector of the Canadian population.

**Single pesticide from aggregate sources**
In addition to the reduced capacity of the risk cup and its rapid filling with exposures to food residues from numerous domestic and imported food commodities, there must now also be room for *aggregate* pesticide exposure resulting from non-occupational, non-dietary uses such as use in the home, lawn and garden, in recreational areas and schools and for potential pesticide residues in some sources of drinking water.

**Multiple pesticides from aggregate sources with cumulative toxicity**
Pesticides that share a common mechanism of toxicity must also share a common risk cup. When the *cumulative* exposures from all sources and routes for an entire group of pesticides must share one risk cup, there is obviously limited room for each pesticide and each use.

This brief outline of the recent changes to regulatory approaches in both the U.S. and in Canada to ensure food safety shows how strong the pressures are for the regulators and the regulated stakeholders to manage risks by keeping exposure as low as possible and within the confines of a risk cup that has become considerably smaller. Good risk management has to be founded on accurate exposure and risk assessment. In the absence of comprehensive monitoring data that provide a measure of the residues typically found on domestically grown and imported food, the regulator must assume that all pesticide residues are at least as high as the 0.1 ppm level, even though good agricultural practices result in actual residue levels far below this default value. This practice cannot be maintained without compromising good decision making.

## 3.0 Current approach for setting MRLs

In 1998, the PMRA provided explicit guidance to registrants and interested parties on the type of data that are required by the Agency to carry out dietary risk assessments (DRAs) and to establish specific MRLs. This guidance is available on the PMRA website: Regulatory Directive DIR98-02, *Residue Chemistry Guidelines* (http://www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir9802a-e.pdf).

Shortly thereafter, the PMRA began to establish specific MRLs below 0.1 ppm in Table II for new pesticides registered in Canada for use on food. The PMRA is now also applying this approach to the establishment of MRLs for pesticides under re-evaluation, pesticides considered under the Minor Use Programs, as well as to the establishment of MRLs on imported food. Therefore, when reviewing submissions, the PMRA no longer relies on the General MRL Regulation of 0.1 ppm and establishes specific MRLs when expected residues on Canadian and imported food commodities are at or below 0.1 ppm. This approach does not capture commodities being imported where the exporter does not request an MRL because of the expectation that the level of residue is at or below 0.1 ppm.

## 4.0 Regulatory proposal

The PMRA proposes that Regulation B.15.002(1) of the Food and Drug Regulations, the 0.1 ppm limit for pesticides, be revoked. The PMRA proposes instead to regulate pesticide residues on food by setting specific MRLs for all pesticide residues on domestically grown and imported food.

The practice of setting specific MRLs for each food commodity for both new pesticides and additional food uses of currently registered pesticides, and to pesticides under re-evaluation, is identical to approaches used by regulatory agencies of most industrialized nations.

Establishing specific MRLs for all existing food uses that are now covered under the General MRL Regulation cannot be done instantaneously. It is proposed that the revocation of the General MRL Regulation be followed by an appropriate transition period.

During this transition period, contemporary U.S. tolerances at or below the 0.1 ppm level will serve as a basis for setting MRLs. Where appropriate, Codex MRLs at or below 0.1 ppm will also be considered. In cases for which no specific MRL can be established for the transition period, quantifiable residues will no longer be permitted.

It should be noted that both in Canada and the U.S., a number of pesticides are currently undergoing or are scheduled to undergo re-assessment over the next few years. Any changes to MRLs as a result of these re-assessments may lead to changes in Canadian MRLs and U.S. tolerances during and after the transition period.

## 5.0 Details of the proposed approach

The PMRA recognizes that a full complement of contemporary residue data conducted at the registered use patterns in zones according to the Regulatory Directive DIR98-02 *Residue Chemistry Guidelines* may not be available to immediately establish permanent MRLs for all pesticide residues that are currently regulated under the General MRL Regulation of 0.1 ppm. Therefore, the Agency proposes a transition period of sufficient duration to allow registrants to identify and assess the residue data available to them, to propose an MRL on a permanent basis depending on the total body of information and data available, and to generate contemporary residue data where needed and allow the PMRA time for review, assessment of risk and promulgation of specific MRLs in Table II of the FDR.

### 5.1 Residue limits for domestic food uses

For each domestic food use currently regulated under the General MRL Regulation of 0.1 ppm, an MRL of less than 0.1 ppm will be established for the transition period wherever there is a contemporary U.S. tolerance of less than 0.1 ppm for that food commodity, provided that the registrant can demonstrate that the Canadian and the U.S. use patterns are similar, and data and data evaluation reports (DERs) are submitted that support the U.S. tolerance.

The MRLs for the transition period will immediately facilitate a more realistic food residue exposure assessment. They will not compromise the safety of the Canadian food supply because the allowable residue limits in food will be lower than current practices under the 0.1 ppm General MRL Regulation. Furthermore, since U.S. tolerances are generally based on higher use rates than in Canada, there should be little chance that the Canadian residues would exceed the U.S. ones.

For domestic food uses for which no U.S. tolerance below 0.1 ppm exists, an MRL of 0.1 ppm will be established for the transition period.

After the transition period, permanent MRLs will be established and promulgated where there is sufficient information available to the PMRA. This would typically include either Canadian residue data or contemporary U.S. data generated under acceptable use pattern conditions. If at the end of the transition period there are no data that allow the PMRA to establish a permanent MRL, the MRL established for the transition period will expire and any level of pesticide residue for that pesticide and food combination would be in violation of the FDA.

## 5.2 Residue limits for imported food uses

There are numerous pesticides for which MRLs have not been established in Table II for foods that are imported into Canada. They have been accommodated under the 0.1 ppm General MRL Regulation. The revocation of the General MRL Regulation will require that a specific MRL be established for each food commodity. The PMRA proposes the following approach.

### 5.2.1 Imported food with residues of pesticides registered in Canada

The PMRA will consider setting an MRL for the imported food commodity when other food uses are already registered in Canada. In many cases, contemporary U.S. tolerances of equal to or less than 0.1 ppm for the food commodity will be the basis for setting the MRL for the transition period, provided that the Canadian risk cup is not full and the registrant submits the data and the DERs that support the U.S. tolerance. Most contemporary U.S. tolerances have undergone re-evaluation in the U.S. under the FQPA, are based on more stringent safety standards and have considered existing Codex MRLs.

In many cases, where Canadian and U.S. use patterns are similar, it would be desirable that registrants apply to expand the Canadian label at the same time as they are requesting an MRL for imported food. The condition for adding food uses to the Canadian label would be that a member of the same crop group is already on the Canadian label, that food tolerances have been re-assessed in the U.S. under the FQPA, and that the occupational and environmental safety and efficacy under Canadian use conditions would be acceptable. MRLs at or below 0.1 ppm for the added domestic food uses would be based on the same contemporary U.S. tolerances as the imported food.

Existing registration programs and processes for adding new uses to the Canadian label (e.g., Minor Use Label Expansion program) continue to be available for adding food crops to the Canadian label without a member of the same crop group being present.

Where there is no U.S. tolerance at or below 0.1 ppm, Codex MRLs will be considered for establishing an MRL for imported food for the transition period. Where no MRL can be established on this basis, any quantifiable residue on the food would cause this food to be in violation of the FDA.

After the transition period, permanent MRLs will be established and promulgated where there is sufficient information available to the PMRA.

If at the end of the transition period there are insufficient data to allow the PMRA to establish a permanent MRL, the MRL established for the transition period will expire and any level of pesticide residue for that pesticide and food combination would be in violation of the FDA.

### 5.2.2 Imported food with residues of active ingredients not registered in Canada

Canada imports a large number of food commodities that may have residues of pesticides not registered in Canada but that are currently covered under the General MRL Regulation. Upon revocation of the General MRL Regulation, any quantifiable residue of these pesticides in food would be in violation of the FDA, unless MRLs are established for the transition period.

Although the PMRA will consider in these cases the applicability of Codex MRLs as required under Article 3.1 of the WTO/SPS Agreement, there will in most cases be no basis for setting a transitional MRL, because the PMRA will lack adequate toxicology and residue data for assessing the health risks of the pesticide residues on the imported food.

To establish an MRL for a pesticide not registered in Canada, the petitioner must submit the required toxicology and residue chemistry data. These data requirements may be satisfied by a full complement of evaluation monographs, reviews or DERs for toxicology and residue chemistry from the exporting countries, or European Union (EU) or Joint Meeting on Pesticide Residues (JMPR) monographs where these reports are not older than five years and are comparable in quality to the DERs of the PMRA or the U.S. EPA.

### 5.2.3 Maintaining an MRL for imported food when a registered food use is disallowed[4] in Canada

When a domestic food use is no longer supported by Canadian registrants or is not allowed following a pesticide re-evaluation or special review, the PMRA will revoke existing MRLs. With the revocation of the General MRL Regulation this would mean that both domestic and imported food commodities with quantifiable residues would be in violation of the FDA.

The PMRA 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.

In this case, the PMRA will base the decision to establish an MRL for imported food on current use patterns in the country of origin and recent toxicology and residue chemistry data. These data may already be available to the PMRA. If so, the PMRA will use them to establish MRLs for the transition period. If the PMRA cannot establish MRLs for the transition period, any quantifiable residues in the food would be in violation of the FDA.

[4] Disallowed for reasons unrelated to dietary risk.

In order to establish permanent MRLs, the PMRA requires a full complement of evaluation monographs, reviews or DERs for toxicology and residue chemistry from the exporting countries, or EU or JMPR monographs where these reports are not older than five years and are comparable in quality to the DERs of the PMRA or the U.S. EPA.

### 5.2.4 Maintaining an MRL for imported food for an active ingredient not registered in Canada when the registered use is cancelled in a country of origin

Canadian MRLs for imported food will be revoked when the use of a pesticide on a food commodity in a country of origin is no longer supported by a registrant or has been cancelled in a country of origin for reasons of unacceptable health risk. With the revocation of the General MRL Regulation this would mean that imported food commodities with quantifiable residues would be in violation of the FDA.

To maintain a Canadian MRL to support imports from other countries of origin, a new submission for an MRL for imported food must be made, accompanied by the necessary contemporary toxicology and residue chemistry data to allow a DRA.

## 5.3 Proposed approach for Canadian research permits

Unlike the U.S., Canada has no regulatory mechanism under the FDR to establish MRLs in a timely manner to accommodate pesticide residues for food commodities arising from pesticide research trials.

Upon revocation of the General MRL Regulation, research permit trials that result in quantifiable pesticide residues would violate the FDA if the food commodity were sold or used as feed. Therefore, because of the limited regulatory options, research trials will be permitted on a crop destruct basis only for crops where quantifiable residues are expected.

## 5.4 Proposed approach for emergency uses

Under Section 17 of the Pest Control Products Regulations, the PMRA may grant a temporary 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 have indicated that the residue level would be less than 0.1 ppm and the level is supported by an acceptable DRA.

With the revocation of the General MRL Regulation and the lack of a regulatory mechanism to establish MRLs within the short time required for emergencies, granting the emergency registration would be limited to cases in which no quantifiable residues were anticipated. The PMRA is exploring the possibility of maintaining a general MRL which would apply only to residues resulting from emergency uses.

## 6.0 Summary

In summary, the PMRA proposes to revoke the General Regulation (B.15.002(1)) and to establish specific Maximum Residue Limits (MRLs) for all pesticide residues that are permitted on food. Specific MRLs at less than 0.1 ppm will be established in Table II, Division 15 of the Food and Drug Regulations during and after an appropriate transition period. These changes will bring Canadian regulatory practice in line with world standards for setting MRLs. They will also enable the PMRA to perform more accurate dietary exposure and risk assessments and will significantly enhance the protection of all Canadians, including infants, children and other vulnerable groups.

## List of Abbreviations

| | |
|---|---|
| ADI | Acceptable Daily Intake |
| ARfD | Acute Reference Dose |
| CUP | Content under Protection |
| DER | Data Evaluation Report |
| FDA | *Food and Drugs Act* |
| FDR | Food and Drug Regulations |
| FQPA | *Food Quality Protection Act* |
| LOQ | Level of Quantification |
| MRL | Maximum Residue Limit |
| NOAEL | No Observed Adverse Effect Level |
| U.S. | United States of America |
| WTO/SPS | World Trade Organization/Sanitary and Phytosanitary Agreement |

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