Ministry for Primary Industries
Manatū Ahu Matua

Proposals to Amend (No.2) the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2012

MPI Discussion Paper No: 2012/20

Prepared by the Biosecurity, Food and Animal Welfare Directorate of the Ministry for Primary Industries

ISBN No: 978-0-478-40424-1 (Online)
ISSN No: 2253-3907 (Online)

October 2012

New Zealand Government

Growing and Protecting New Zealand

Disclaimer

Every effort has been made to ensure the information in this document is accurate.

MPI does not accept any responsibility or liability whatsoever for any error of fact, omission, interpretation or opinion that may be present, however it may have occurred.

Requests for further copies should be directed to:

Publications Logistics Officer
Ministry for Primary Industries
PO Box 2526
WELLINGTON 6140

Email: brand@mpi.govt.nz
Telephone: 0800 00 83 33
Facsimile: 04-894 0300

This publication is also available on the Ministry for Primary Industries website at
http://www.mpi.govt.nz/news-resources/publications.aspx

Contents

Page

Submission **1**

1 Introduction **2**

1.1 Background 2

1.2 Summary of proposed amendment 3

2 Proposals **4**

2.1 Proposal to set an MRL for boscalid 4

2.2 Proposal to set an MRL for pyraclostrobin 6

Submission

The Ministry for Primary Industries (MPI) invites public comment on this discussion document, which outlines proposals to amend the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards.

The following points may be of assistance in preparing comments:

- Wherever possible, comment should be specific to a particular section in the document. All major sections are numbered and these numbers should be used to link comments to the document.
- Where possible, reasons and data to support comments are requested.
- The use of examples to illustrate particular points is encouraged.
- As a number of copies may be made of your comments, please use good quality type, or make sure the comments are clearly hand-written in black or blue ink.

Please include the following information in your submission:

- the title of the discussion document;
- your name and title (if applicable);
- your organisation's name (if applicable); and
- your address.

Please submit your response by 5:00pm 26 October 2012. Your comments should be sent to:

MRL Amendments
MPI Food Policy
PO Box 2835
Wellington

Email: FoodPolicy@mpi.govt.nz
Fax: (04) 894 2530

The Official Information Act

The Official Information Act 1982 (the OIA) states that information is to be made available unless there are grounds for withholding it. The grounds for withholding information are outlined in the OIA. Submitters may wish to indicate any grounds for withholding information contained in their submission. Reasons for withholding information could include that information is commercially sensitive or that the submitters wish personal information such as names or contact details to be withheld. MPI will take such indications into account when determining whether or not to release information. Any decision to withhold information requested under the OIA may be reviewed by the Ombudsman.

1 Introduction

Maximum residue limits (MRLs) are the maximum legal limits for residues of agricultural compounds and veterinary medicines in food for sale in New Zealand. MRLs are primarily a tool for monitoring the use of agricultural compounds in accordance with good agricultural practice (GAP). GAP is not explicitly defined or regulated, but is the generally accepted means for producing safe primary produce in a particular location while taking account of climate, pests or diseases and other environmental factors. MRLs are used to minimise risks to public health by ensuring that chemical residues in food are as low as practicable, without compromising the ability of the chemical to successfully do what is intended.

1.1 BACKGROUND

MRLs are set out in the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards (the MRL Standards). The MRL Standards are amended a number of times each year to reflect changes in the use of agricultural compounds in the production of food. The MRL Standards are available from the Ministry for Primary Industries (MPI) Foodsafety website at: http://www.foodsafety.govt.nz/elibrary/industry/register-list-mrl-agricultural-compounds.htm.

The MRLs set out in the MRL Standards apply to residues in food produced in New Zealand. The MRL Standards allow countries exporting food to New Zealand to comply with Codex MRLs rather than New Zealand's domestic MRLs.

MPI administers the MRL Standards, but the final decision on any changes to the MRL Standards rests with the Minister for Food Safety. Under section 11E and 11L of the Food Act 1981, when amending or issuing the MRL Standards, the Minister must take into account the following:

- The need to protect public health.
- The desirability of avoiding unnecessary restrictions on trade.
- The desirability of maintaining consistency between New Zealand's food standards and those applying internationally.
- New Zealand's obligations under any relevant international treaty, agreement, convention, or protocol, and, in particular, under the Australia-New Zealand Joint Food Standards Agreement.
- Such other matters as the Minister considers appropriate.

Possible implications for public health are considered during the toxicological and dietary risk assessments, by comparing the estimated dietary intake with a Potential Daily Exposure (food) (PDE (food)). Where there is no PDE (food), the estimated dietary intake is compared with the Acceptable Daily Intake (ADI). PDE (food) and ADI are described below.

A PDE (food) is a value determined by a toxicological evaluation by the Environmental Protection Authority (EPA) as part of its responsibility for managing public health under the Hazardous Substances and New Organisms Act 1996 (the HSNO Act). A PDE (food) gives the potential daily exposure a person may be subject to from a substance, via food. MPI uses a PDE (food) where it is available, rather than the internationally-determined ADI, as required by the HSNO Act in New Zealand. The ADI and PDE (food) are largely equivalent, as they are determined using the same set of toxicology data and through a very similar scientific process.

An ADI is defined by the World Health Organization (WHO) as: "the daily intake which, during an entire lifetime, appears to be without appreciable risk on the basis of all the known facts at the time". "Without appreciable risk" has been further defined as: "the practical certainty that injury will not result even after a lifetime of exposure". ADIs are established by the WHO and Food and Agriculture Organization (FAO) of the United Nations joint expert committees, which are made up of toxicologists and residue specialists. The ADI information from these joint committees also feeds into the Codex Alimentarius Commission (Codex), which sets international MRLs.

1.2 SUMMARY OF PROPOSED AMENDMENT

The proposed MRLs have been thoroughly assessed in accordance with international methodologies such as those utilised by the expert committees advising Codex. Information on the technical assessment of each proposal is included in this document (refer section 2) and covers the following:

- rationale;
- chemical information;
- good agricultural practice;
- residues information;
- dietary risk assessment;
- toxicological/public health assessment; and
- international MRLs.

MPI reviewed the estimated dietary exposure assessments for the application of the proposals in this discussion paper. MPI has determined that the residues associated with the proposed MRLs do not present any public health and safety concerns.

New MRLS

MPI proposes to add the following new MRLs to the MRL Standards:

- 3 mg/kg for boscalid when used as a fungicide on cherries; and
- 1 mg/kg for pyraclostrobin when used as a fungicide on cherries.

Note that there is also public consultation underway on amendments to MRLs for boscalid for bulb vegetables, mammalian fat, mammalian kidney, mammalian liver, milk, root vegetables and tuber vegetables. The discussion document, *Proposals to Amend (No.1) the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2012*, can be found at http://www.foodsafety.govt.nz/elibrary/industry/proposals-amend-nz-mrl-discussion-2012/index.htm. Consultation on these amendments closes at the same time as consultation on the current amendments (26 October 2012).

2 Proposals

2.1 PROPOSAL TO SET AN MRL FOR BOSCALID

It is proposed that an MRL is set so that boscalid can be used on cherries late in the season up to harvest. The current entry for boscalid in Schedule One of the MRL Standards is:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Boscalid	188425-85-6	Boscalid	Grapes	5
			Kiwifruit	0.1(*)
			Pome fruits	0.05(*)
			Stone fruits	0.05(*)

The final entry[1] for boscalid in Schedule One of the MRL Standards will therefore read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Residue Limit (mg/kg)
			Cherries	3
			Grapes	5
			Kiwifruit	0.1(*)
			Pome fruits	0.05(*)
			Stone fruits (except cherries)	0.05(*)

NOTE: (*) indicates that the maximum residue limit has been set at or about the limit of analytical quantification.

Amendment Rationale

The proposed MRL represents a change in the spray timing of a currently registered trade name product in cherries from a final spray at end of flowering to a final spray at harvest resulting in detectable residues of boscalid at harvest. The proposed MRL will manage the use of boscalid as a fungicide to control botrytis fruit rot in cherries up to harvest. The proposed change is considered good agricultural practice (GAP) in New Zealand.

Chemical Information

Common name of compound	Boscalid
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	188425-85-6
Type of compound	Carboxamide
Administration method	Spray

Good Agricultural Practice

Boscalid is proposed for use as a fungicide in cherries at a maximum rate of 252 gai/ha, at 5-14 day intervals with no more than 3 sprays per season.

Residues Information

The residue data for cherries supports an MRL of 3 mg/kg for boscalid with the last application up to harvest. An MRL of 3 mg/kg is proposed to support GAP

[1] There is also consultation underway that began on Monday 27 August 2012 on proposed amendments to the boscalid entry for bulb vegetables, mammalian fat, mammalian kidney, mammalian liver, milk, root vegetables and tuber vegetables. The discussion document for these amendments can be found at http://www.foodsafety.govt.nz/elibrary/industry/proposals-amend-nz-mrl-discussion-2012/index.htm. If these proposed amendments are made, they will also be included in the final entry. Consultation on these amendments also closes on 26 October 2012.

Dietary Risk Assessment

The potential daily exposure via food (PDE (food)) is used for dietary intake calculation where a value has been set. An appropriate acceptable daily intake (ADI) is used in the absence of a PDE (food). The PDE of 0.028 mg/kg bw/d has been set by EPA and is considered appropriate for use in the assessment of boscalid.

The chronic dietary exposure to boscalid is estimated by the National Estimated Dietary Intake (NEDI) calculation, encompassing all registered uses of the chemical and food consumption data based upon the 1997 National Nutrition Survey for adults (New Zealand) and the 1995 National Nutrition Survey (Australia), for children. The NEDI calculation is made in accordance with *Guidelines for predicting dietary intake of pesticide residues (revised)* [World Health Organization, 1997].

Based on the proposed MRLs, the NEDI for boscalid is equivalent to less than 20% of the PDE. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Toxicological/Public Health Assessment

Therefore, MPI has determined that the use of boscalid as a fungicide in cherries is very unlikely to pose any health risks from consumption of treated produce.

Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Codex	Stone fruits	3
European Union	Cherries	4
Japan	Cherries	3
USA	Stone fruits	3.5

Under clause 6(3)(b) of the MRL Standards imported food may contain residues of agricultural compounds no greater than the MRLs specified for that food in the current editions or supplements of the FAO/WHO Codex Alimentarius Commission publications *Pesticide Residues in Food or Residues of Veterinary Drugs in Foods*.

To meet New Zealand's obligations under the Agreement on the Application of Sanitary and Phytosanitary Measures the proposed MRL will be notified to the World Trade Organization. Any country may choose to comment if they believe the proposed MRL represents a barrier to their trade.

2.2 PROPOSAL TO SET AN MRL FOR PYRACLOSTROBIN

It is proposed that an MRL is set so that pyraclostrobin can be used on cherries late in the season up to harvest. The current entry for pyraclostrobin in Schedule One of the MRL Standards is:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Pyraclostrobin	175013-18-0	Pyraclostrobin	Apples	0.02(*)
			Barley	0.02(*)
			Grapes	3
			Kiwifruit	0.02(*)
			Mammalian fat	0.02(*)
			Mammalian kidney	0.02(*)
			Mammalian liver	0.02(*)
			Mammalian meat	0.02(*)
			Milk	0.02(*)
			Pears	0.02(*)
			Stone fruits	0.02(*)
			Wheat	0.02(*)

The final entry for pyraclostrobin in Schedule One of the MRL Standards will therefore read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Pyraclostrobin	175013-18-0	Pyraclostrobin	Apples	0.02(*)
			Barley	0.02(*)
			Cherries	1
			Grapes	3
			Kiwifruit	0.02(*)
			Mammalian fat	0.02(*)
			Mammalian kidney	0.02(*)
			Mammalian liver	0.02(*)
			Mammalian meat	0.02(*)
			Milk	0.02(*)
			Pears	0.02(*)
			Stone fruits (except cherries)	0.02(*)
			Wheat	0.02(*)

NOTE: (*) indicates that the maximum residue limit has been set at or about the limit of analytical quantification.

Amendment Rationale

The proposed MRL represents the change in the spray timing of a currently registered trade name product in cherries from a final spray at end of flowering to a final spray at harvest resulting in detectable residues of pyraclostrobin at harvest. The proposed MRL will manage the use of pyraclostrobin as a fungicide to control botrytis fruit rot in cherries up to harvest. The proposal is considered good agricultural practice (GAP) in New Zealand.

Chemical Information

Common name of compound	Pyraclostrobin
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	175013-18-0
Type of compound	Strobilurin
Administration method	Spray

Good Agricultural Practice

Pyraclostrobin is proposed for use as a fungicide in cherries. Application is at a maximum rate of 128gai/ha at 5-14 day intervals with no more than 3 sprays per season.

Residues Information

The residue data for cherries supports an MRL of 1mg/kg for pyraclostrobin with the last application up to harvest. An MRL of 1 mg/kg is proposed to support GAP.

Dietary Risk Assessment

The potential daily exposure via food (PDE (food)) is used for dietary intake calculation where a value has been set. An appropriate acceptable daily intake (ADI) is used in the absence of a PDE (food). The ADI of 0.03 mg/kg bw/d was considered appropriate for use in the assessment and is consistent with overseas reputable regulatory bodies.

The chronic dietary exposure to pyraclostrobin is estimated by the National Estimated Dietary Intake (NEDI) calculation encompassing all registered uses of the chemical and food consumption data based upon the 1997 National Nutrition Survey for adults (New Zealand) and the 1995 National Nutrition Survey (Australia), for children. The NEDI calculation is made in accordance with *Guidelines for predicting dietary intake of pesticide residues (revised)* [World Health Organization, 1997].

Based on the proposed MRLs, the NEDI for pyraclostrobin is equivalent to less than 5% of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Toxicological/Public Health Assessment

Therefore, MPI has determined that the use of pyraclostrobin as a fungicide for cherries is very unlikely to pose any health risks from consumption of treated produce.

Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Codex	Stone fruits	1
European Union	Cherries	2
Japan	Cherries	2
USA	Stone fruits	2.5

Under clause 6(3)(b) of the MRL Standards imported food may contain residues of agricultural compounds no greater than the MRLs specified for that food in the current editions or supplements of the FAO/WHO Codex Alimentarius Commission publications *Pesticide Residues in Food or Residues of Veterinary Drugs in Foods*.

To meet New Zealand's obligations under the Agreement on the Application of Sanitary and Phytosanitary Measures the proposed MRL will be notified to the World Trade Organization. Any country may choose to comment if they believe the proposed MRL represents a barrier to their trade.