



Proposals to Amend (No. 2) the New
Zealand (Maximum Residue Limits of
Agricultural Compounds) Food Standards
2008

NZFSA Public Discussion Paper 06/08

August 2008

Online

ISBN number 978-0-478-32236-1

ISSN number 1177-7478

Print

ISBN number 978-0-478-32235-4

ISSN number 1174-961X

IMPORTANT DISCLAIMER

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

NZFSA 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.

Further copies

Requests for further copies should be directed to:

New Zealand Food Safety Authority
P O Box 2835
WELLINGTON
Telephone: (04) 894-2500
Fax: (04) 894-2583

Website

A copy of this document can be found at: <http://www.nzfsa.govt.nz/policy-law/consultation/index.htm>

Submissions

NZFSA seeks submissions from all interested parties on any aspect of the document. 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.
- Omissions should be clearly and separately indicated.
- Comments should be to the point and, where possible, reasons and data to support comment 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, and 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 Organization's name (if applicable);
- Your address;
- The number(s) of the sections you are commenting on.

Please submit your response by 5:00pm on 15 October 2008 to:

MRL Amendments, Policy Group, New Zealand Food Safety Authority

PO Box 2835, Wellington, fax: (04) 894 2583, or email: policy@nzfsa.govt.nz

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. NZFSA 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.

Table of Contents

Table of Contents	3
Introduction	4
Background	4
Summary of Proposed Amendment	6
Next Steps	6
1 Proposal to set MRLs for Boscalid	7
2 Proposal to set MRLs for Clomazone	9
3 Proposal to set an MRL for Cyprodinil	11
4 Proposal to set an MRL for Emamectin benzoate	13
5 Proposal to set MRLs for Fenbendazole	15
6 Proposal to set MRLs for Mandipropamid	18
7 Proposal to set MRLs for Monepantel	20
8 Proposal set an MRL for 1-Naphthylacetic acid	22
9 Proposal to set MRLs for Oxfendazole	24
10 Proposal to set an MRL for Pyraclostrobin	27

Introduction

The New Zealand Food Safety Authority (NZFSA) invites public comment on this discussion document which outlines proposals to amend the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2008.

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.

Background

MRLs are set out in the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards. The Standards are amended a number of times each year to reflect changes in the use of agricultural compounds in the production of food. The current MRL Food Standards 2008 are on the NZFSA website at: <http://www.nzfsa.govt.nz/policy-law/legislation/food-standards/index.htm>

NZFSA administers the MRL Standards, but the final decision on any changes to the Standards rests with the Minister for Food Safety. Under section 11E of the Food Act, 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.

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

- rationale
- chemical information
- good agricultural practice (GAP)
- residues information
- dietary risk assessment
- toxicological / public health assessment
- international MRLs.

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}) or where there is no PDE_{food} , by comparing it with the Acceptable Daily Intake (ADI). PDE_{food} and ADI are described below.

A PDE_{food} or Potential Daily Exposure (food), is a value determined by a toxicological evaluation by Environmental Risk Management Authority New Zealand (ERMA NZ) as part of its responsibilities under the Hazardous Substances and New Organisms Act (the HSNO Act), which has some responsibility for managing public health.¹ A PDE_{food} gives the potential daily exposure a person may be subject to from a substance, via food. NZFSA uses a PDE_{food} , rather than the internationally-determined ADI, where a PDE_{food} is available, due to 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 in a very similar scientific process.

An ADI or Acceptable Daily Intake 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 of the United Nations (FAO) joint expert committees, made up of toxicologists and residue specialists. The ADI information from these joint committees also feeds into Codex, which sets international MRLs.

¹The purpose of the HSNO Act 1996 is “to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms”. 5

Summary of Proposed Amendment

NZFSA has reviewed the estimated dietary exposure assessments for the applications of these proposals and has determined that the residues associated with the proposed MRLs do not present any public health and safety concerns.

New MRLs

NZFSA proposes to add the following new MRLs to the Standards:

- Boscalid in grapes (3mg/kg) and in pome fruits (0.05mg/kg);
- Clomazone in brassica vegetables (0.01mg/kg) and in carrots (0.02mg/kg);
- Cyprodinil in stone fruit (except cherries) (0.02mg/kg);
- Emamectin benzoate in avocados (0.005mg/kg);
- Fenbendazole in mammalian fat (0.05mg/kg), mammalian kidney (0.05mg/kg), mammalian liver (0.5mg/kg), mammalian muscle (0.05mg/kg);
- Mandipropamid in bulb onions (0.01mg/kg) and in green onions (0.2mg/kg);
- Monepantel in sheep fat (7mg/kg), sheep liver (5mg/kg), sheep kidney (2mg/kg) and in sheep muscle (0.7mg/kg);
- 1-Naphthylacetic in mandarins (Satsuma and Encore) (0.01mg/kg);
- Oxfendazole in mammalian fat (0.05mg/kg), mammalian kidney (0.05mg/kg), mammalian liver (0.5mg/kg), mammalian muscle (0.05mg/kg);
- Pyraclostrobin in grapes (2mg/kg).

Next Steps

Following the closing date for submissions (5:00pm on Wednesday 30th July 2008), all submissions will be considered and analysed before a recommendation is made to the Minister for Food Safety, the Hon Lianne Dalziel, who makes the final decision on issuing any amendments to the Food Standards.

If an amendment is agreed upon, it will be signed by the Minister for Food Safety and will come into force 28 days after being published in the *New Zealand Gazette*.

1 Proposal to set MRLs for Boscalid

It is proposed that MRLs are set for boscalid when used as a fungicide for grapes and pome fruits. It is proposed that Schedule One of the NZ (MRL) Food Standards 2008 be amended to include the following; this will be the resulting entry for boscalid in Schedule One of the NZ (MRL) Food Standards 2008:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Boscalid	188425-85-6	Boscalid	Grapes Pome fruits	3 0.05*

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

Amendment Rationale

The proposed MRLs for boscalid represent the registration in New Zealand of a new active ingredient. The proposed MRLs will manage the new use of boscalid as a fungicide on pome fruits and grapes to the application rates and withholding periods that are approved good agricultural practice (GAP) in New Zealand (see below).

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 for grapes. Application may be throughout pre-flowering to pre-harvest, at rate of 378gai/ha with a withholding period of 28 days.

Boscalid is proposed for use as a fungicide for pome fruits. Application may be up to 2 times throughout early to mid growing season at 7-10 day intervals, at 12.6gai/ha with a withholding period of: do not apply after 90% petal fall.

Residues Information

Residue data for grapes supports an MRL of 3mg/kg at 28 days after the last treatment. An MRL of 3mg/kg is therefore proposed to support GAP.

Residue data for pome fruits supports a limit of quantification MRL of 0.05mg/kg when treatment is prior to 100% petal fall. An MRL of 0.05mg/kg is therefore proposed to support GAP.

Animal Transfer: Apple pomace, grape pomace and vineyard waste may be fed to animals, however given the expected consumption level of boscalid in these commodities it would not be expected that residues would be detectable in animal product commodities.

Dietary Risk Assessment

Acceptable Daily Exposure (ADE)	0.04mg/kg bw/day
ERMA NZ PDE_(food)	0.028mg/kg bw/day

The potential daily exposure via food (PDE_(food)) is used for dietary intake calculation where a value has been set. The potential daily exposure via food (PDE_(food)) is used for dietary intake calculation where a value has been set. The PDE_(food) is a value set by the Environmental Risk Management Authority (ERMA), and represents the proportion of the acceptable daily exposure to a substance via the food route as relevant to the New Zealand population. The methodology for calculation of these values is set out in the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001 which can be found at: www.legislation.govt.nz.

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 Nutritional Survey for adults and the 1995 National Nutrition Survey of Australia, for children. The NEDI calculation is made in accordance with *Guidelines for predicting dietary intake of pesticide residues (revised)* [World Health Organization, 1997].

The NEDI for boscalid is equivalent to 9% of the PDE_(food). It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Toxicological / Public Health Assessment

It has been determined that the use of boscalid as a fungicide for use on grapes and pome fruits, according to the GAP specified above, is very unlikely to pose any health risks from consumption of the harvested commodity.

Other International MRLs

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

2 Proposal to set MRLs for Clomazone

It is proposed that MRLs are set for Clomazone when used as a herbicide for brassica vegetables and carrots. It is proposed that Schedule One of the NZ (MRL) Food Standards 2008 be amended to include:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Clomazone	81777-89-1	Clomazone	Brassica vegetables	0.01*
			Carrots	0.02

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

Amendment Rationale

The proposed MRLs represent new use patterns in New Zealand for the active ingredient clomazone. The proposed MRLs will manage the new uses of clomazone as a herbicide on brassica vegetables and carrots to the application rates and withholding periods that are approved good agricultural practice (GAP) in New Zealand (see below).

Chemical Information

Common name of compound	Clomazone
Use of compound	Herbicide
Chemical Abstract Services (CAS) Registry number	81777-89-1
Type of compound	Isoxazolidinone
Administration method	Ground spray

Good Agricultural Practice

Clomazone is proposed for use as a herbicide for brassica vegetables and carrots. Application may be after sowing up to crop emergence, at 90-120gai/ha with a withholding period of 40 days for brassicas and 90 days for carrots.

Residues Information

Residue data for vegetable brassicas supports a limit of quantification MRL of 0.01mg/kg at 40 days after the last treatment. An MRL of 0.01mg/kg is therefore proposed to support GAP.

Residue data for carrots supports an MRL of 0.02mg/kg at 90 days after the last treatment. An MRL of 0.02mg/kg is therefore proposed to support GAP.

Animal Transfer: Brassica vegetables are considered a primary animal feed; however, given that no residues are expected in forage brassicas, residues will not be expected to accumulate in animal products. No animal commodity MRLs are therefore proposed at this time.

Dietary Risk Assessment

Acceptable Daily Intake (ADI)	0.03mg/kg bw/day
--------------------------------------	------------------

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 chronic dietary exposure to clomazone 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 Nutritional Survey for adults and the 1995 National Nutrition Survey of Australia, for children. The NEDI calculation is made in accordance with *Guidelines for predicting dietary intake of pesticide residues (revised)* [World Health Organization, 1997].

The NEDI for clomazone is equivalent to 0.8% of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Toxicological / Public Health Assessment

It has been determined that the use of clomazone as a herbicide for use on brassica vegetables and carrots, according to the GAP specified above, is very unlikely to pose any health risks from consumption of the harvested commodity.

Other International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
The Netherlands		
Clomazone	All food	0.01*

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

3 Proposal to set an MRL for Cyprodinil

It is proposed that an MRL is set for cyprodinil when used as a fungicide for stonefruit (except cherries). It is proposed that Schedule One of the NZ (MRL) Food Standards 2008 be amended by deleting the following entry:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Cyprodinil	121552-61-2	Cyprodinil	Nectarines	0.02
			Peaches	0.02

As a replacement for the deleted entry, it is proposed that Schedule One of the NZ (MRL) Food Standards 2008 be amended to include:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Cyprodinil	121552-61-2	Cyprodinil	Stonefruit (except cherries)	0.02*

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

The final entry for cyprodinil in Schedule One of the NZ (MRL) Food Standards 2008 will therefore read:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Cyprodinil	121552-61-2	Cyprodinil	Grapes	0.2
			Pome fruits	0.01
			Stonefruit (except cherries)	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 a new use pattern in New Zealand for the active ingredient cyprodinil. The proposed MRLs will manage the new uses of cyprodinil as a fungicide on stonefruit to the application rates and withholding periods that are approved good agricultural practice (GAP) in New Zealand (see below).

Chemical Information

Common name of compound	Cyprodinil
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	121552-61-2
Type of compound	Pyrimidine

Administration method	Spray
------------------------------	-------

Good Agricultural Practice

Cyprodinil is proposed for use as a fungicide for apricots. Application may be up to 4 times until 90% petal fall, at 15gai/100L with a withholding period of: do not apply after 90% petal fall.

Residues Information

Residue data for apricots supports an MRL of 0.02mg/kg at approximately 76 days after the last treatment. A limit of quantification MRL of 0.02mg/kg is therefore proposed to support GAP. The MRL is proposed to be combined with current MRLs for peaches and nectarines to establish a crop group MRL of 0.02mg/kg for stonefruit (except cherries).

Animal Transfer: Stonefruit are not primary animal feeds, therefore no animal commodity MRLs are proposed.

Dietary Risk Assessment

Acceptable Daily Intake (ADI)	0.027mg/kg bw/day
--------------------------------------	-------------------

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 chronic dietary exposure to cyprodinil 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 Nutritional Survey for adults and the 1995 National Nutrition Survey of Australia, for children. The NEDI calculation is made in accordance with *Guidelines for predicting dietary intake of pesticide residues (revised)* [World Health Organization, 1997].

The NEDI for cyprodinil is equivalent to 0.3% of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Toxicological / Public Health Assessment

It has been determined that the use of cyprodinil as a fungicide for use on stonefruit, according to the GAP specified above, is very unlikely to pose any health risks from consumption of the harvested commodity.

Other International MRLs

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.

4 Proposal to set an MRL for Emamectin benzoate

It is proposed that an MRL is set for emamectin benzoate when used as an insecticide for avocados. It is proposed that Schedule One of the NZ (MRL) Food Standards 2008 be amended to include:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Emamectin benzoate	155569-91-8	Sum of: emamectin B1a emamectin B1b (Z)-8,9 emamectin B1a (Z)-8,9 emamectin B1b Expressed as: emamectin	Avocados	0.005

The final entry for emamectin benzoate in Schedule One of the NZ (MRL) Food Standards 2008 will therefore read:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Emamectin benzoate	155569-91-8	Sum of: emamectin B1a emamectin B1b (Z)-8,9 emamectin B1a (Z)-8,9 emamectin B1b Expressed as: emamectin	Avocados Grapes Kiwifruit Pome fruits	0.005 0.002* 0.002* 0.001*

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

Amendment Rationale

The proposed MRL represents new use patterns in New Zealand for the active ingredient emamectin benzoate. The proposed MRLs will manage the new uses of emamectin benzoate as an insecticide on avocados to the application rates and withholding periods that are approved good agricultural practice (GAP) in New Zealand (see below).

Chemical Information

Common name of compound	Emamectin benzoate
Use of compound	Insecticide

Chemical Abstract Services (CAS) Registry number	155569-91-8
Type of compound	Avermectin
Administration method	Spray

Good Agricultural Practice

Emamectin benzoate is proposed for use as an insecticide for avocados. Application may be throughout plant growth, at a rate of 0.2gai/100L with a withholding period of 14 days.

Residues Information

Residue data for avocados support an MRL of 0.005mg/kg at 14 days after the last treatment. An MRL of 0.005mg/kg is therefore proposed to support GAP.

Animal Transfer: Avocados are not recognised as a significant animal feed crop, therefore no animal commodity MRLs are proposed.

Dietary Risk Assessment

Acceptable Daily Intake (ADI)	0.002mg/kg bw/day
--------------------------------------	-------------------

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 chronic dietary exposure to emamectin benzoate 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 Nutritional Survey for adults and the 1995 National Nutrition Survey of Australia, for children. The NEDI calculation is made in accordance with *Guidelines for predicting dietary intake of pesticide residues (revised)* [World Health Organization, 1997].

The NEDI for emamectin benzoate is equivalent to 0.08% of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Toxicological / Public Health Assessment

It has been determined that the use of emamectin benzoate as an insecticide for use on avocados, according to the GAP specified above, is very unlikely to pose any health risks from consumption of the harvested commodity.

Other International MRLs

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.

5 Proposal to set MRLs for Fenbendazole

It is proposed that MRLs are set for fenbendazole when used as a veterinary medicine for cattle, deer, goats, horses and sheep. It is proposed that Schedule One of the NZ (MRL) Food Standards 2008 be amended by deleting the following MRLs:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Fenbendazole	43210-67-9	<i>Sum of:</i> Fenbendazole Oxfendazole Fenbendazole sulphone <i>Expressed as:</i> Fenbendazole sulphone	Liver Meat	0.5 0.01

As a replacement for the deleted MRLs, it is proposed that Schedule One of the NZ (MRL) Food Standards 2008 be amended to include the following, this will be the resulting entry for fenbendazole in Schedule One of the NZ (MRL) Food Standards 2008:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Fenbendazole	43210-67-9	<i>Sum of:</i> Fenbendazole Oxfendazole Fenbendazole sulphone <i>Expressed as:</i> Fenbendazole sulphone	Mammalian fat	0.05
			Mammalian kidney	0.05
			Mammalian liver	0.5
			Mammalian muscle	0.05

Amendment Rationale

The proposed MRLs represent the expansion of the New Zealand MRLs for meat and edible offal to harmonise with MRLs set internationally and by the European Community. The proposal also seeks to refine the commodity names to better reflect the intent of the MRLs and correct an error in the residue definition.

Chemical Information

Common name of compound	Fenbendazole
Use of compound	Anthelmintic
Chemical Abstract Services (CAS) Registry number	43210-67-9
Type of compound	Benzimidazole
Administration method	Oral and topical

Good Agricultural Practice

Fenbendazole is currently approved in New Zealand as an anthelmintic treatment for gastro-intestinal round-worms, lungworms and tapeworms in cattle, deer, goats, horses and sheep use may be through oral or topical administration.

Dietary Risk Assessment

Acceptable Daily Intake (ADI)	0.007mg/kg bw/day
--------------------------------------	-------------------

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 chronic dietary exposure to fenbendazole 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 Nutritional Survey for adults and the 1995 National Nutrition Survey of Australia, for children. The NEDI calculation is made in accordance with *Guidelines for predicting dietary intake of pesticide residues (revised)* [World Health Organization, 1997].

The current NEDI for fenbendazole is equivalent to 0.7% of the ADI, with accommodation of the proposed MRLs the NEDI increases to 2.5% of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Toxicological / Public Health Assessment

It has been determined that the increase of the fenbendazole MRLs for mammalian fat, muscle and kidney to 0.05mg/kg is very unlikely to pose any health risks from consumption of the animal product commodities.

Other International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
Australia		
Fenbendazole	Cattle, edible offal of	0.1
	Cattle meat	0.1
	Goat, edible offal of	0.5
	Goat meat	0.5
	Sheep, edible offal of	0.5
	Sheep meat	0.5
Codex		
Fenbendazole	Cattle Muscle	0.1
	Cattle Fat	0.1
	Cattle Liver	0.5
	Cattle Kidney	0.1
	Pig Muscle	0.1
	Pig Fat	0.1

	Pig Liver	0.5
	Pig Kidney	0.1
	Sheep Muscle	0.1
	Sheep Fat	0.1
	Sheep Liver	0.5
	Sheep Kidney	0.1
	Goat Muscle	0.1
	Goat Fat	0.1
	Goat Liver	0.5
	Goat Kidney	0.1
	Horse Muscle	0.1
	Horse Fat	0.1
	Horse Liver	0.5
	Horse Kidney	0.1
EU		
Fenbendazole	Ruminant Muscle	0.05
	Ruminant Fat	0.05
	Ruminant Liver	0.5
	Ruminant Kidney	0.05
Japan		
Fenbendazole	Cattle Muscle	0.1
	Cattle Fat	0.1
	Cattle Liver	0.5
	Cattle Kidney	0.1
	Pig Muscle	0.1
	Pig Fat	0.1
	Pig Liver	0.5
	Pig Kidney	0.1
	Other terrestrial mammals, muscle	0.1
	Other terrestrial mammals, fat	0.1
	Other terrestrial mammals, liver	0.5
	Other terrestrial mammals, kidney	0.1

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

6 Proposal to set MRLs for Mandipropamid

It is proposed that MRLs are set for mandipropamid when used as a fungicide for bulb and green onions. It is proposed that Schedule One of the NZ (MRL) Food Standards 2008 be amended to include:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Mandipropamid	374726-62-2	Mandipropamid	Bulb onions Green onions	0.01* 0.2

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

The final entry for mandipropamid in Schedule One of the NZ (MRL) Food Standards 2008 will therefore read:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Mandipropamid	374726-62-2	Mandipropamid	Bulb onions Green onions Potatoes	0.01* 0.2 0.01*

Amendment Rationale

The proposed MRLs represent new use patterns in New Zealand for the active ingredient mandipropamid. The proposed MRLs will manage the new uses of mandipropamid as a fungicide on bulb and green onions to the application rates and withholding periods that are approved good agricultural practice (GAP) in New Zealand (see below).

Chemical Information

Common name of compound	Mandipropamid
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	374726-62-2
Type of compound	Carboxylic acid amide
Administration method	Spray

Good Agricultural Practice

Bulb Onions: Mandipropamid is proposed for use as a fungicide for bulb onions. Application may be throughout active growth at 100-150gai/ha with a withholding period of 7 days.

Green Onions: Mandipropamid is proposed for use as a fungicide for green onions. Application may be throughout active growth at 100-150gai/ha with a withholding period of 14 days.

Residues Information

Residue data for bulb onions support a limit of quantification MRL of 0.0 mg/kg at 7 days after the last treatment. An MRL of 0.01mg/kg is therefore proposed to support GAP. Residue data for green onions support an MRL of 0.2mg/kg at 14 days after the last treatment. An MRL of 0.2mg/kg is therefore proposed to support GAP.

Animal Transfer: Residues are unlikely in animals consuming treated onions, therefore no animal commodity MRLs are proposed.

Dietary Risk Assessment

Acceptable Daily Exposure (ADE)	0.15mg/kg bw/day
ERMA NZ PDE_(food)	0.1mg/kg bw/day

The potential daily exposure via food (PDE_(food)) is used for dietary intake calculation where a value has been set. The potential daily exposure via food (PDE_(food)) is used for dietary intake calculation where a value has been set. The PDE_(food) is a value set by the Environmental Risk Management Authority (ERMA), and represents the proportion of the acceptable daily exposure to a substance via the food route as relevant to the New Zealand population. The methodology for calculation of these values is set out in the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001 which can be found at: www.legislation.govt.nz.

The chronic dietary exposure to mandipropamid 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 Nutritional Survey for adults and the 1995 National Nutrition Survey of Australia, for children. The NEDI calculation is made in accordance with *Guidelines for predicting dietary intake of pesticide residues (revised)* [World Health Organization, 1997].

The NEDI for mandipropamid is equivalent to 0.02% of the PDE_(food). It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Toxicological / Public Health Assessment

It has been determined that the use of mandipropamid as a fungicide for use on onions, according to the GAP specified above, is very unlikely to pose any health risks from consumption of the harvested commodity.

Other International MRLs

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.

7 Proposal to set MRLs for Monepantel

It is proposed that MRLs are set for monepantel when used as an anthelmintic for sheep. It is proposed that Schedule One of the NZ (MRL) Food Standards 2008 be amended to include the following; this will be the resulting entry for monepantel in Schedule One of the NZ (MRL) Food Standards 2008:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Monepantel	887148-69-8	Monepantel-sulphone	Sheep fat	7
			Sheep liver	5
			Sheep kidney	2
			Sheep muscle	0.7

Amendment Rationale

The proposed MRLs for monepantel represent a new veterinary medicine active ingredient that is proposed for registration in New Zealand. The proposed MRLs will allow the use of this product for the treatment of gastro-intestinal parasites in sheep according to the following good agricultural practice (GAP).

Chemical Information

Common name of compound	Monepantel
Use of compound	Anthelmintic
Chemical Abstract Services (CAS) Registry number	887148-69-8
Type of compound	Amino-Acetonitrile Derivative
Administration method	Oral

Good Agricultural Practice

Monepantel is a novel veterinary medicine active in New Zealand. The proposed GAP is the application of 2.5mg monepantel/ kg liveweight and a withholding period of 7 days.

Residues Information

Residues of monepantel, determined as the metabolite monepantel-sulphone, at 7 days after treatment are not expected to exceed 7mg/kg in sheep fat, 5mg/kg in sheep liver, 2mg/kg in sheep kidney and 0.7mg/kg in sheep muscle.

Dietary Risk Assessment

Acceptable Daily Intake (ADI)	0.09mg/kg bw/day
--------------------------------------	------------------

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 chronic dietary exposure to monepantel 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 Nutritional Survey for adults and the 1995 National Nutrition Survey of Australia, for children. The NEDI calculation is made in accordance with *Guidelines for predicting dietary intake of pesticide residues (revised)* [World Health Organization, 1997].

The NEDI for monepantel is equivalent to 1% of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Toxicological / Public Health Assessment

It has been determined that the use of monepantel as a veterinary medicine for use on sheep, according to the GAP specified above, is very unlikely to pose any health risks from consumption of animal product commodities.

Other International MRLs

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

8 Proposal set an MRL for 1-Naphthylacetic acid

It is proposed that an MRL is set for 1-naphthylacetic acid when used as a plant growth regulator for Satsuma and encore mandarin varieties. It is proposed that Schedule One of the NZ (MRL) Food Standards 2008 be amended to include the following, this will be the resulting entry for 1-naphthylacetic acid in Schedule One of the NZ (MRL) Food Standards 2008:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
1-Naphthylacetic acid	86-87-3	1-Naphthylacetic acid	Mandarins (Satsuma and Encore)	0.01*

Amendment Rationale

The proposed MRL represents a new use pattern in New Zealand for the active ingredient 1-naphthylacetic acid. The proposed MRL will manage the new uses of 1-naphthylacetic acid as a plant growth regulator on Satsuma and Encore mandarin varieties to the application rates and withholding periods that are approved good agricultural practice (GAP) in New Zealand (see below).

Chemical Information

Common name of compound	1-Naphthylacetic acid
Use of compound	Plant growth regulator (fruit thinning)
Chemical Abstract Services (CAS) Registry number	86-87-3
Type of compound	Synthetic auxin
Administration method	Spray

Good Agricultural Practice

1-naphthylacetic acid is proposed for use as a fruit thinning agent for the Satsuma and Encore mandarin varieties. Application may be when fruitlets are between 10-12mm diameter, at a rate of 30gai/ha with a withholding period of: do not apply after fruitlets exceed 12mm diameter.

Residues Information

Residue data for Satsuma and Encore mandarin support a limit of quantification MRL of 0.01mg/kg at 130 days after the last treatment. An MRL of 0.01mg/kg is therefore proposed to support GAP.

Dietary Risk Assessment

Acceptable Daily Intake (ADI)	0.15mg/kg bw/day
--------------------------------------	------------------

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 chronic dietary exposure to 1-naphthylacetic acid 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 Nutritional Survey for adults and the 1995 National Nutrition Survey of Australia, for children. The NEDI calculation is made in accordance with *Guidelines for predicting dietary intake of pesticide residues (revised)* [World Health Organization, 1997].

The NEDI for 1-naphthylacetic acid is equivalent to 0.09% of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Toxicological / Public Health Assessment

It has been determined that the use of 1-naphthylacetic acid as a plant growth regulator for use on Satsuma and Encore mandarins, according to the GAP specified above, is very unlikely to pose any health risks from consumption of the harvested commodity.

Other International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
The Netherlands		
1-Naphthyl-acetic acid	All food	0.05

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.

9 Proposal to set MRLs for Oxfendazole

It is proposed that MRLs are set for oxfendazole when used as a veterinary medicine for cattle, deer, goats, horses and sheep. It is proposed that Schedule One of the NZ (MRL) Food Standards 2008 be amended by deleting the following MRLs:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Oxfendazole	53716-50-0	<i>Sum of:</i> Fenbenzole Oxfendazole Fenbendazole sulphone <i>Expressed as:</i> Fenbendazole sulphone	Edible offal (except liver) Liver Meat	0.01 0.5 0.01

As a replacement for the deleted MRLs, it is proposed that Schedule One of the NZ (MRL) Food Standards 2008 be amended to include the following, this will be the resulting entry for oxfendazole in Schedule One of the NZ (MRL) Food Standards 2008:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Oxfendazole	53716-50-0	<i>Sum of:</i> Fenbendazole Oxfendazole Fenbendazole sulphone <i>Expressed as:</i> Fenbendazole sulphone	Mammalian fat Mammalian kidney Mammalian liver Mammalian muscle	0.05 0.05 0.5 0.05

Amendment Rationale

The proposed MRLs represent the expansion of the New Zealand MRLs for meat and edible offal to harmonise with MRLs set internationally by the European Community. The proposal also seeks to refine the commodity names to better reflect the intent of the MRLs and correct an error in the residue definition.

Chemical Information

Common name of compound	Oxfendazole
Use of compound	Anthelmintic
Chemical Abstract Services (CAS) Registry number	53716-50-0
Type of compound	Benzimidazole
Administration method	Oral and topical

Good Agricultural Practice

Oxfendazole is currently approved in New Zealand as an anthelmintic treatment for gastro-intestinal round-worms, lungworms and tapeworms in cattle, deer, goats, horses and sheep use may be through oral or topical administration.

Dietary Risk Assessment

Acceptable Daily Intake (ADI)	0.007mg/kg bw/day
--------------------------------------	-------------------

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 chronic dietary exposure to oxfendazole 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 Nutritional Survey for adults and the 1995 National Nutrition Survey of Australia, for children. The NEDI calculation is made in accordance with *Guidelines for predicting dietary intake of pesticide residues (revised)* [World Health Organization, 1997].

The current NEDI for oxfendazole is equivalent to 0.5% of the ADI, with accommodation of the proposed MRLs the NEDI increases to 2.5% of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Toxicological / Public Health Assessment

It has been determined that the increase of the oxfendazole MRLs for mammalian fat, muscle and kidney to 0.05mg/kg is very unlikely to pose any health risks from consumption of the animal product commodities.

Other International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
Australia		
Oxfendazole	Edible offal (mammalian)	3
	Meat [Mammalian]	0.1
Codex		
Oxfendazole	Cattle Muscle	0.1
	Cattle Fat	0.1
	Cattle Liver	0.5
	Cattle Kidney	0.1
	Pig Muscle	0.1
	Pig Fat	0.1
	Pig Liver	0.5
	Pig Kidney	0.1
	Sheep Muscle	0.1
	Sheep Fat	0.1

	Sheep Liver	0.5
	Sheep Kidney	0.1
	Goat Muscle	0.1
	Goat Fat	0.1
	Goat Liver	0.5
	Goat Kidney	0.1
	Horse Muscle	0.1
	Horse Fat	0.1
	Horse Liver	0.5
	Horse Kidney	0.1
EU		
Oxfendazole	Ruminant Muscle	0.05
	Ruminant Fat	0.05
	Ruminant Liver	0.5
	Ruminant Kidney	0.05
Japan		
Oxfendazole	Cattle Muscle	0.1
	Cattle Fat	0.1
	Cattle Liver	0.5
	Cattle Kidney	0.1
	Pig Muscle	0.1
	Pig Fat	0.1
	Pig Liver	0.5
	Pig Kidney	0.1
	Other terrestrial mammals, muscle	0.1
	Other terrestrial mammals, fat	0.1
	Other terrestrial mammals, liver	0.5
	Other terrestrial mammals, kidney	0.1

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

10 Proposal to set an MRL for Pyraclostrobin

It is proposed that an MRL is set for pyraclostrobin when used as a fungicide for grapes. It is proposed that Schedule One of the NZ (MRL) Food Standards 2008 be amended to include:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Pyraclostrobin	175013-18-0	<i>Plant commodities:</i> Sum of: Pyraclostrobin and its desmethoxy metabolite <i>Expressed as:</i> Pyraclostrobin <i>Animal commodities:</i> Sum of: Pyraclostrobin and metabolites hydrolysed to: 1-(4-chloro-phenyl)-1H-pyrazol-3-ol <i>Expressed as:</i> Pyraclostrobin	Grapes	2

The final entry for pyraclostrobin in Schedule One of the NZ (MRL) Food Standards 2008 will therefore read:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Pyraclostrobin	175013-18-0	<i>Plant commodities:</i> Sum of: Pyraclostrobin and its desmethoxy metabolite <i>Expressed as:</i> Pyraclostrobin <i>Animal commodities:</i> Sum of: Pyraclostrobin and metabolites hydrolysed to: 1-(4-chloro-phenyl)-1H-pyrazol-3-ol <i>Expressed as:</i> Pyraclostrobin	Apples Barley Grapes Mammalian fat Mammalian kidney Mammalian liver Mammalian meat Milk Pears Wheat	0.02(*) 0.02(*) 2 0.02(*) 0.02(*) 0.02(*) 0.02(*) 0.02(*) 0.02(*) 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 a new use pattern in New Zealand for the active ingredient pyraclostrobin. The proposed MRL will manage the new uses of pyraclostrobin as a fungicide on grapes to the application rates and withholding periods that are approved good agricultural practice (GAP) in New Zealand (see below).

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 for grapes. Application may be throughout pre-flowering to pre-harvest, at rate of 192gai/ha with a withholding period of 28 days.

Residues Information

Residue data for grapes supports an MRL of 2 mg/kg at 28 days after the last treatment. An MRL of 2mg/kg is therefore proposed to support GAP.

Animal Transfer: Grape pomace and vineyard waste may be fed to animals, however given the expected consumption level of pyraclostrobin in these commodities it would not be expected that residues would exceed the current animal commodity MRLs.

Dietary Risk Assessment

Acceptable Daily Intake (ADI)	0.03 mg/kg bw/day
--------------------------------------	-------------------

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 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 Nutritional Survey for adults and the 1995 National Nutrition Survey of Australia, for children. The NEDI calculation is made in accordance with *Guidelines for predicting dietary intake of pesticide residues (revised)* [World Health Organization, 1997].

The NEDI for pyraclostrobin is equivalent to 1% of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Toxicological / Public Health Assessment

It has been determined that the use of pyraclostrobin as a fungicide for use on grapes, according to the GAP specified above, is very unlikely to pose any health risks from consumption of the harvested commodity.

Other International MRLs

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.