



Proposals to Amend (No.3) the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2013

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

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1 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.

Submissions close at 5pm on **25 July 2014**. Your comments should be sent to:

MRL Amendments
MPI Food Policy
PO Box 2526
Wellington 6140

Email: FoodPolicy@MPI.govt.nz

Please include your name and address on your submission. If you are making comments on behalf of an organisation, also include your title and the name of the organisation.

Please make sure your comments can be clearly read, as a number of copies may be made of your submission. Comments should be specific to a particular section in the document. All major sections are numbered; please state the number(s) of the section(s) beside each comment.

Please include reasons and data to support your comments, and examples to illustrate particular points where appropriate.

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.

2 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, 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.

2.1 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> .

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 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.

Once confirmed, the Chemical and Microbiological Assurances team within MPI will be advised so that official chemical residue monitoring programmes are reviewed and amended as necessary.

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.

2.2 SUMMARY OF PROPOSED AMENDMENTS

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:

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

2.2.1 New MRLs

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

- 0.5 mg/kg in bulb onions for ametoctradin when used as a fungicide;
- 0.01 mg/kg in cereal grain, 0.15 mg/kg in mammalian meat, 0.4 mg/kg in edible offal and 0.04 mg/kg in milk for bixafen when used as a fungicide in cereals;
- 1.5 mg/kg in citrus and beans for boscalid when used as a fungicide;
- 0.1 mg/kg in field tomatoes, 0.01 mg/kg(*) in potatoes and bulb onions, 0.01 mg/kg(*) in mammalian meat, fat and edible offal for cyantraniliprole when used as an insecticide in bulb onions, potatoes, field tomatoes and fodder brassicas;
- 0.1 mg/kg in pome fruit for etoxazole when used as a miticide;
- 0.1 mg/kg in wheat grain, 0.3 mg/kg in barley grain, 0.01 mg/kg in mammalian meat, 0.03 mg/kg in edible offal, 0.05 mg/kg in mammalian fat, 0.005 mg/kg in milk, 0.02 mg/kg in apple for fluxapyroxad when used as a fungicide in barley, wheat crops and apples;
- 0.2 mg/kg in grapes for imidacloprid when used as an insecticide;
- 0.01 mg/kg in winter squash and pumpkins for lambda-cyhalothrin when used as an insecticide;
- 0.01 mg/kg in potatoes for lufenuron when used as an insecticide;
- 0.4 mg/kg in beans, 0.7 mg/kg in citrus for pyraclostrobin when used as a fungicide;
- 0.7 mg/kg in blueberries for spirotetramat when used as an insecticide.

2.2.2 Exempt from MRLs

- Exempt pegbovigrastim from MRL when used as a veterinary medicine.

2.2.3 Other Amendments

There are no other amendments

3 Proposals

3.1 PROPOSALS TO SET MRL FOR AMETOCTRADIN

It is proposed that an MRL is set for ametoctradin when used on bulb onions. The current entry for ametoctradin 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)
Ametoctradin	865318-97-4	Ametoctradin	Potato	0.01(*)

The revised entry for ametoctradin 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)
Ametoctradin	865318-97-4	Ametoctradin	Bulb onions Potato	0.5 0.01(*)

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

3.1.1 Amendment Rationale

The proposed MRL represents the expansion of use of a currently registered active ingredient. The proposed MRL will manage the use of ametoctradin as a fungicide on bulb onions and in accordance with the application rates and withholding periods that are proposed as good agricultural practice (GAP) in New Zealand.

3.1.2 Chemical Information

Common name of compound	Ametoctradin
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	865318-97-4
Type of compound	Triazolopyrimidine
Administration method	Spray

3.1.3 Good Agricultural Practice

Ametoctradin is proposed for use as a fungicide in bulb onions. Application is at maximum rate of 240 gai/ha, to be applied to treat downy mildew at 7 - 10 day intervals with 14 days withholding period.

3.1.4 Residue Information

The residue data for the crops supports an MRL of 0.5 mg/kg for ametoctradin in bulb onions when the last treatment is 14 days prior to harvest. An MRL of 0.5 mg/kg in bulb onions is proposed to support GAP.

3.1.5 Dietary Risk Assessment

The potential daily exposure via food ($PDE_{(food)}$) is used for dietary intake calculation where a value has been set by EPA. An appropriate acceptable daily intake (ADI) is used in the absence of a $PDE_{(food)}$. The $PDE_{(food)}$ of 7 mg/kg bw/d was considered appropriate for use in the assessment. The proposed MRL is; bulb onions – 0.5 mg/kg.

The chronic dietary exposure to ametoctradin 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].

Based on the proposed MRLs, the NEDI for ametoctradin is equivalent to < 1% of the $PDE_{(food)}$. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

3.1.6 Toxicological/Public Health Assessment

It has been determined that the use of ametoctradin as a fungicide for bulb onions according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

3.1.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Codex	Bulb onion	1.5
European Union	Bulb onion	1.5
USA	Bulb onion	1.5

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 has been notified to the World Trade Organization. Any country may choose to comment if they believe the proposed MRL represents a barrier to their trade.

3.2 PROPOSALS TO SET MRLS FOR BIXAFEN

It is proposed that an MRL is set for bixafen when used in cereals. The final entry for bixafen in Schedule One of the MRL Standards will read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Bixafen	581809-46-3	Plant commodities:	Cereal grains	0.01(*)
		Bixafen	Mammalian fat	0.4
		Animal commodities:	Mammalian kidney	0.3
		Bixafen plus its	Mammalian meat	0.15
		metabolite desmethyl	Mammalian liver	1.5
		bixafen expressed as bixafen	Milk	0.04

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

3.2.1 Amendment Rationale

The proposed MRLs represents a use of the new active ingredient. The proposed MRLs will manage the use of bixafen as a fungicide in cereals in accordance with the application rates and withholding periods that are proposed as good agricultural practice (GAP) in New Zealand.

3.2.2 Chemical Information

Common name of compound	Bixafen
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	581809-46-3

3.2.3 Good Agricultural Practice

Bixafen is proposed for use as a fungicide in cereals. Application is at maximum rate of 75 gai/ha with a withholding period of 56 days for cereal grain and 42 days for forage.

3.2.4 Residue Information

The residue data for the crops and the animals supports an MRL of 0.01 mg/kg for bixafen in cereal grain and 0.4 mg/kg for mammalian fat; 1.5 mg/kg for mammalian liver, 0.15 mg/kg for mammalian meat, 0.3 mg/kg for mammalian kidney and 0.04 mg/kg for milk. These MRLs are proposed to support GAP.

3.2.5 Dietary Risk Assessment

The potential daily exposure via food ($PDE_{(food)}$) is used for dietary intake calculation where a value has been set by EPA. An appropriate acceptable daily intake (ADI) is used in the absence of a $PDE_{(food)}$. The $PDE_{(food)}$ of 0.014 mg/kg bw/d was considered appropriate for use in the assessment. The proposed MRLs are; MRL of 0.01 mg/kg for bixafen in cereal grain and 0.4 mg/kg for mammalian fat; 1.5 mg/kg for mammalian liver, 0.15 mg/kg for mammalian meat, 0.3 mg/kg for mammalian kidney and 0.04 mg/kg for milk.

The chronic dietary exposure to bixafen 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].

Based on the proposed MRLs, the NEDI for bixafen is equivalent to less than 1 % of the $PDE_{(food)}$. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

3.2.6 Toxicological/Public Health Assessment

It has been determined that the use of bixafen as a fungicide for cereals according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

3.2.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
European Union	Barley	0.5
	Fat	0.4
	Kidney	0.3
	Liver	1.5
	Milk	0.04
	Muscle	0.15
	Wheat	0.05
Japan	Barley	0.5
	Cattle fat	0.4
	Cattle meat	0.2
	Cattle kidney	0.3
	Cattle liver	2
	Milk	0.04
	Wheat	0.05

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 has been notified to the World Trade Organization. Any country may choose to comment if they believe the proposed MRL represents a barrier to their trade.

3.3 PROPOSALS TO SET MRLS FOR BOSCALID

It is proposed that an MRL is set for boscalid when used on beans and citrus. 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	Bulb vegetables	0.2
			Cherries	3
			Grapes	5
			Kiwifruit	0.1(*)
			Mammalian fat	0.3
			Mammalian kidney	0.3
			Mammalian liver	0.2
			Milk	0.1
			Pome fruits	0.05(*)
			Root vegetables	0.5
			Stone fruits (except cherries)	0.05(*)
			Tuber vegetables	0.5

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

The revised entry 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 Permitted Residue Level (mg/kg)
Boscalid	188425-85-6	Boscalid	Beans	1.5
			Bulb vegetables	0.2
			Cherries	3
			Citrus	1.5
			Grapes	5
			Kiwifruit	0.1(*)
			Mammalian fat	0.3
			Mammalian kidney	0.3
			Mammalian liver	0.2
			Milk	0.1
			Pome fruits	0.05(*)
			Root vegetables	0.5
			Stone fruits (except cherries)	0.05(*)
			Tuber vegetables	0.5

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

3.3.1 Amendment Rationale

The proposed MRLs represent the expansion of use of a currently registered active ingredient. The proposed MRLs will manage the use of boscalid as a fungicide on beans and citrus and in

accordance with the application rates and withholding periods that are proposed as good agricultural practice (GAP) in New Zealand.

3.3.2 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

3.3.3 Good Agricultural Practice

Boscalid is proposed for use as a fungicide on beans and citrus.

- Beans - Application is at maximum rate of 378 gai/ha to be applied to treat Botrytis, Sclerotinia white and mould prior to infection and continue at 7 to 14 day intervals with 7 days withholding period;
- Citrus - 12.6 gai/100L to be applied to treat Alternaria brown spot, Citrus scab and Melanose from flowering at 21 to 28 day intervals with 1 day withholding period.

3.3.4 Residue Information

The residue data for the crops and the animals supports an MRL of 1.5 mg/kg for boscalid in beans and citrus. These MRLs are proposed to support GAP.

3.3.5 Dietary Risk Assessment

The potential daily exposure via food ($PDE_{(food)}$) is used for dietary intake calculation where a value has been set by EPA. An appropriate acceptable daily intake (ADI) is used in the absence of a $PDE_{(food)}$. The $PDE_{(food)}$ of 0.028 mg/kg bw/d was considered appropriate for use in the assessment. The proposed MRLs are; beans and citrus – 1.5 mg/kg.

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].

Based on the proposed MRLs, the NEDI for boscalid is equivalent to < 16% of the $PDE_{(food)}$. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

3.3.6 Toxicological/Public Health Assessment

It has been determined that the use of boscalid as a fungicide for beans and citrus according to GAP, is very unlikely to pose any health risks from consumption of treated produce.

3.3.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Codex	Beans	3
	Citrus	2
European Union	Beans	3
	Citrus	2
Japan	Beans	2.5
	Citrus	10
USA	Beans	2.5
	Citrus	2

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 has been notified to the World Trade Organization. Any country may choose to comment if they believe the proposed MRL represents a barrier to their trade.

3.4 PROPOSALS TO SET MRLS FOR CYANTRANILIPROLE

It is proposed that an MRL is set for cyantraniliprole when used on bulb onions, potatoes, field tomatoes and fodder brassicas. The final entry for cyantraniliprole in Schedule One of the MRL Standards will read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Cyantraniliprole	736994-63-1	Cyantraniliprole	Bulb onions	0.01(*)
			Tomatoes	0.1
			Mammalian fat	0.01(*)
			Mammalian kidney	0.01(*)
			Mammalian meat	0.01(*)
			Mammalian liver	0.01(*)
			Milk	0.01(*)
			Potatoes	0.01(*)

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

3.4.1 Amendment Rationale

The proposed MRLs represent a use of the new active ingredient. The proposed MRLs will manage the use of cyantraniliprole as an insecticide in bulb onions, potatoes, field tomatoes and fodder brassicas in accordance with the application rates and withholding periods that are proposed as good agricultural practice (GAP) in New Zealand.

3.4.2 Chemical Information

Common name of compound	Cyantraniliprole
Use of compound	Insecticide
Chemical Abstract Services (CAS) Registry number	736994-63-1
Type of compound	Diamide
Administration method	Spray

3.4.3 Good Agricultural Practice

Cyantraniliprole is proposed for use as an insecticide in bulb onions, potatoes, field tomatoes and fodder brassicas.

- Potatoes, field tomatoes - Application is at a rate of 50 gai/ha to be applied to treat Tomato/potato psyllid, Potato tuber moth, Green peach aphid and Tomato fruit worm at 7 to 14 day intervals with 3 days withholding period for tomatoes and 14 days withholding period for potatoes;
- Bulb onions - Application is at a rate of 50 gai/ha to be applied to treat Thrips at 7 to 10 day intervals with 14 days withholding period;
- Fodder brassicas - Application is at a rate of 15 gai/ha to be applied to treat Caterpillars, Leaf miners, Aphids at 2 to 3 day week intervals with 14 days WITHHOLDING PERIOD to grazing or feeding to livestock.

3.4.4 Residue Information

The residue data for the crops supports an MRL of 0.01 mg/kg for cyantraniliprole in bulb onions, potatoes, field tomatoes and fodder brassicas. MRLs of 0.1 mg/kg in field tomatoes, 0.01 mg/kg(*) in potatoes, bulb onions, mammalian meat, fat, edible offal and milk are proposed to support GAP.

3.4.5 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 $PDE_{(food)}$ of 0.007 mg/kg bw/d was considered appropriate for use in the assessment and is consistent with overseas reputable regulatory bodies. The proposed MRLs are; 0.1 mg/kg in field tomatoes, 0.01 mg/kg(*) in potatoes, bulb onions, mammalian meat, fat, edible offal and milk

The chronic dietary exposure to cyantraniliprole 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].

Based on the proposed MRLs, the NEDI for cyantraniliprole is equivalent to less than 3 % of the $PDE_{(food)}$. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

3.4.6 Toxicological/Public Health Assessment

It has been determined that the use of cyantraniliprole as an insecticide for bulb onions, potatoes, field tomatoes and fodder brassicas according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

3.4.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Australia	Bulb onion	0.05
	Edible offal	0.01(*)
	Meat	0.01(*)
	Milk	0.01(*)
	Potato	0.05
	Tomato	0.05
USA	Bulb onion	0.04
	Mammalian fat	0.01(*)
	Edible offal	0.01(*)
	Meat	0.01(*)
	Milk	0.01(*)
	Potato	0.15
	Tomato	2

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

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 has been notified to the World Trade

Organization. Any country may choose to comment if they believe the proposed MRL represents a barrier to their trade.

3.5 PROPOSAL TO SET MRLS FOR ETOXAZOLE

It is proposed that an MRL is set for etoxazole when used on pome fruit. The current entry for etoxazole 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)
Etoxazole	153233-91-1	Etoxazole	Avocados	0.1

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

The revised entry for etoxazole 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)
Etoxazole	153233-91-1	Etoxazole	Avocados	0.1
			Pome fruit	0.1

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

3.5.1 Amendment Rationale

The proposed MRL represents the expansion of use of a currently registered active ingredient. The proposed MRL will manage the use of etoxazole as a miticide on pome fruits and in accordance with the application rates and withholding periods that are proposed as good agricultural practice (GAP) in New Zealand.

3.5.2 Chemical Information

Common name of compound	Etoxazole
Use of compound	Miticide
Chemical Abstract Services (CAS) Registry number	153233-91-1
Type of compound	Diphenyl oxazoline
Administration method	Spray

3.5.3 Good Agricultural Practice

Etoxazole is proposed for use as a miticide on pome fruits to be applied to treat European red mites and Two spotted mites with 14 days withholding period.

3.5.4 Residue Information

The residue data for the crops and the animals supports an MRL of 0.1 mg/kg for etoxazole in pome fruits. This MRL is proposed to support GAP.

3.5.5 Dietary Risk Assessment

The potential daily exposure via food ($PDE_{(food)}$) is used for dietary intake calculation where a value has been set by EPA. An appropriate acceptable daily intake (ADI) is used in the absence of a $PDE_{(food)}$. The $PDE_{(food)}$ of 0.105 mg/kg bw/d was considered appropriate for use in the assessment. The proposed MRL is; pome fruits – 0.1 mg/kg.

The chronic dietary exposure to etoxazole 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].

Based on the proposed MRLs, the NEDI for etoxazole is equivalent to < 1% of the PDE_(food). It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

3.5.6 Toxicological/Public Health Assessment

It has been determined that the use of etoxazole as a miticide for pome fruits according to GAP, is very unlikely to pose any health risks from consumption of treated produce.

3.5.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Australia	Pome fruits	0.2
Codex	Pome fruits	0.07
European Union	Pome fruits	0.07
Japan	Apple, Pear	0.5
USA	Pome fruit	0.2

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 has been notified to the World Trade Organization. Any country may choose to comment if they believe the proposed MRL represents a barrier to their trade.

3.6 PROPOSAL TO SET MRLS FOR FLUXAPYROXAD

It is proposed that an MRL is set for fluxapyroxad when used on barley, wheat crops and apples. The final entry for fluxapyroxad in Schedule One of the MRL Standards will read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Fluxapyroxad	907204-31-3	Fluxapyroxad	Apples	0.02
			Barley grain	0.3
			Mammalian fat	0.05
			Edible offal	0.03
			Mammalian meat	0.01(*)
			Milk	0.005
			Wheat grain	0.1

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

3.6.1 Amendment Rationale

The proposed MRLs represent a use of the new active ingredient. The proposed MRLs will manage the use of fluxapyroxad as a fungicide in barley, wheat crops and apples in accordance with the application rates and withholding periods that are proposed as good agricultural practice (GAP) in New Zealand.

3.6.2 Chemical Information

Common name of compound	Fluxapyroxad
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	907204-31-3
Type of compound	Pyrazole

3.6.3 Good Agricultural Practice

Fluxapyroxad is proposed for use as a fungicide on barley, wheat crops and apples to be applied to treat:

- Barley, wheat crops – Covered smut, Loose smut, Leaf stripe, Leaf rust, Net blotch, Scald, Powdery mildew, Ramularia leaf, Awn spot, Common bunt, Brown rust, Stem rust and Stripe rust with Do not graze or cut for feed period of 42 days;
- Apples – Blackspot and Powdery mildew at 7 – 10 days intervals from green tip up to 2nd cover (when fruitlets are less than 25mm in size and harvest is at least 12 weeks away).

3.6.4 Residue Information

The residue data for the crops and the animals supports an MRL of 0.1 mg/kg in wheat grain, 0.3 mg/kg in barley grain, 0.01 mg/kg in mammalian meat, 0.03 mg/kg in edible offal, 0.05 mg/kg in mammalian fat, 0.005 mg/kg in milk, 0.02 mg/kg in apple for fluxapyroxad. These MRLs are proposed to support GAP.

3.6.5 Dietary Risk Assessment

The potential daily exposure via food ($PDE_{(food)}$) is used for dietary intake calculation where a value has been set by EPA. An appropriate acceptable daily intake (ADI) is used in the absence of a $PDE_{(food)}$. The $PDE_{(food)}$ of 0.014 mg/kg bw/d was considered appropriate for use in the assessment. The proposed MRLs are; 0.1 mg/kg in wheat grain, 0.3 mg/kg in barley grain, 0.01 mg/kg in mammalian meat, 0.03 mg/kg in edible offal, 0.05 mg/kg in mammalian fat, 0.005 mg/kg in milk, 0.02 mg/kg in apple.

The chronic dietary exposure to fluxapyroxad 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].

Based on the proposed MRLs, the NEDI for fluxapyroxad is equivalent to < 1% of the $PDE_{(food)}$. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

3.6.6 Toxicological/Public Health Assessment

It has been determined that the use of fluxapyroxad as a fungicide for wheat, barley and apples according to GAP, is very unlikely to pose any health risks from consumption of treated produce.

3.6.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Australia	Apples	0.1
	Barley	0.2
	Edible offal	0.03
	Meat	0.05
	Milk	0.005
Codex	Barley	2
	Edible offal	0.1
	Meat	0.2
	Milk	0.02

European Union	Pome fruits	0.9
	Wheat	0.3
	Barley	2
	Fat	0.05
	Kidney	0.01(*)
	Liver	0.03
	Meat	0.01(*)
	Milk	0.005
	Pome fruits	0.7
	Wheat	0.4
USA	Barley grain	3
	Fat	0.05
	Kidney	0.03
	Liver	0.03
	Meat	0.01
	Milk	0.005
	Pome fruit	0.8
	Wheat grain	0.3

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

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 has been notified to the World Trade Organization. Any country may choose to comment if they believe the proposed MRL represents a barrier to their trade.

3.7 PROPOSAL TO SET MRLS FOR IMIDACLOPRID

It is proposed that an MRL is set for imidacloprid when used on grapes. The current entry for imidacloprid 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)
Imidacloprid	138261-41-3	Sum of:	Brassica vegetables	0.02(*)
		Imidacloprid and its	Citrus fruits	0.02(*)
		metabolites containing	Lettuce	1
		the 6-chloropyridinyl	Onions	0.02(*)
		moiety	Potatoes	0.02(*)
		Expressed as:	Sweetcorn	0.02(*)
		Imidacloprid		

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

The revised entry for imidacloprid 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)
Imidacloprid	138261-41-3	Sum of:	Brassica vegetables	0.02(*)
		Imidacloprid and its	Citrus fruits	0.02(*)
		metabolites containing	Grapes	0.2
		the 6-chloropyridinyl	Lettuce	1
		moiety	Onions	0.02(*)
		Expressed as:	Potatoes	0.02(*)
		Imidacloprid	Sweetcorn	0.02(*)

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

3.7.1 Amendment Rationale

The proposed MRL represents the expansion of use of a currently registered active ingredient. The proposed MRL will manage the use of imidacloprid as an insecticide on grapes and in accordance with the application rates and withholding periods that are proposed as good agricultural practice (GAP) in New Zealand.

3.7.2 Chemical Information

Common name of compound	Imidacloprid
Use of compound	Insecticide
Chemical Abstract Services (CAS) Registry number	138261-41-3
Type of compound	Neonicotinoid
Administration method	Spray

3.7.3 Good Agricultural Practice

Imidacloprid is proposed for use as an insecticide in non-bearing grapevines to bearing grapevines to be applied at 0.525 gai/vine to treat Mealy bugs with a Do no use after the second week of May withholding period.

3.7.4 Residue Information

The residue data for the crops and the animals supports an MRL of 0.2 mg/kg for imidacloprid in grapes. This MRL is proposed to support GAP.

3.7.5 Dietary Risk Assessment

The potential daily exposure via food ($PDE_{(food)}$) is used for dietary intake calculation where a value has been set by EPA. An appropriate acceptable daily intake (ADI) is used in the absence of a $PDE_{(food)}$. The $PDE_{(food)}$ of 0.03 mg/kg bw/d was considered appropriate for use in the assessment. The proposed MRL is; grapes – 0.2 mg/kg.

The chronic dietary exposure to imidacloprid 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].

Based on the proposed MRLs, the NEDI for imidacloprid is equivalent to < 3% of the $PDE_{(food)}$. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

3.7.6 Toxicological/Public Health Assessment

It has been determined that the use of imidacloprid as an insecticide for grapes according to GAP, is very unlikely to pose any health risks from consumption of treated produce.

3.7.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Codex	Grapes	1
European Union	Table Grapes, Wine grapes	1
Japan	Grapes	3
USA	Grapes	1

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 has been notified to the World Trade Organization. Any country may choose to comment if they believe the proposed MRL represents a barrier to their trade.

3.8 PROPOSAL TO SET MRLS FOR LAMBDA-CYHALOTHRIN

It is proposed that an MRL is set for lambda-cyhalothrin when used on winter squash and pumpkin seedlings. The current entry for lambda-cyhalothrin 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)
Lambda-cyhalothrin	91465-08-6	Lambda-cyhalothrin	Citrus fruits	0.01(*)
			Grapes	0.01(*)
			Maize	0.01(*)
			Onions	0.01(*)
			Potatoes	0.01(*)
			Sweetcorn	0.01(*)

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

The revised entry for lambda-cyhalothrin 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)
Lambda-cyhalothrin	91465-08-6	Lambda-cyhalothrin	Citrus fruits	0.01(*)
			Grapes	0.01(*)
			Maize	0.01(*)
			Onions	0.01(*)
			Potatoes	0.01(*)
			Pumpkins	0.01(*)
			Sweetcorn	0.01(*)
			Winter squash	0.01(*)

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

3.8.1 Amendment Rationale

The proposed MRLs represent the expansion of use of a currently registered active ingredient. The proposed MRLs will manage the use of lambda-cyhalothrin as an insecticide on winter squash and pumpkin seedlings in accordance with the application rates and withholding periods that are proposed as good agricultural practice (GAP) in New Zealand.

3.8.2 Chemical Information

Common name of compound	Lambda-cyhalothrin
Use of compound	Insecticide
Chemical Abstract Services (CAS) Registry number	91465-08-6
Type of compound	Pyrethroid
Administration method	Spray

3.8.3 Good Agricultural Practice

Lambda-cyhalothrin is proposed for use as an insecticide in winter squash and pumpkin seedlings to be applied at 10 gai/ha to treat cutworm.

3.8.4 Residue Information

The residue data for the crops and the animals supports an MRL of 0.01 mg/kg for lambda-cyhalothrin in winter squash and pumpkins. This MRL is proposed to support GAP.

3.8.5 Dietary Risk Assessment

The potential daily exposure via food ($PDE_{(food)}$) is used for dietary intake calculation where a value has been set by EPA. An appropriate acceptable daily intake (ADI) is used in the absence of a $PDE_{(food)}$. The $PDE_{(food)}$ of 0.0004 mg/kg bw/d was considered appropriate for use in the assessment. The proposed MRL is; winter squash, pumpkins – 0.01 mg/kg.

The chronic dietary exposure to lambda-cyhalothrin 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].

Based on the proposed MRLs, the NEDI for lambda-cyhalothrin is equivalent to < 60% of the $PDE_{(food)}$. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

3.8.6 Toxicological/Public Health Assessment

It has been determined that the use of lambda-cyhalothrin as an insecticide for winter squash and pumpkins according to GAP, is very unlikely to pose any health risks from consumption of treated produce.

3.8.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
EU	Pumpkins, Winter squash	0.05
Japan	Pumpkin (including squash)	0.5
USA	Vegetable cucurbit	0.05

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 has been notified to the World Trade Organization. Any country may choose to comment if they believe the proposed MRL represents a barrier to their trade.

3.9 PROPOSAL TO SET MRLS FOR LUFENURON

It is proposed that an MRL is set for lufenuron when used on potatoes. The current entry for lufenuron 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)
Lufenuron	103055-07-8	Lufenuron	Apples Pears	0.02(*) 0.05

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

The revised entry for lufenuron 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)
Lufenuron	103055-07-8	Lufenuron	Apples	0.02(*)
			Pears	0.05
			Potatoes	0.01(*)

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

3.9.1 Amendment Rationale

The proposed MRL represents the expansion of use of a currently registered active ingredient. The proposed MRL will manage the use of lufenuron as an insecticide on potatoes in accordance with the application rates and withholding periods that are proposed as good agricultural practice (GAP) in New Zealand.

3.9.2 Chemical Information

Common name of compound	Lufenuron
Use of compound	Insecticide
Chemical Abstract Services (CAS) Registry number	103055-07-8
Type of compound	Benzoylurea
Administration method	Spray

3.9.3 Good Agricultural Practice

Lufenuron is proposed for use as an insecticide in potatoes to be applied at 50 gai/ha to treat tomato/potato psyllid early in the season at 7 – 10 day intervals and 42 days withholding period.

3.9.4 Residue Information

The residue data for the crops supports an MRL of 0.01 mg/kg for lufenuron in potatoes. This MRL is proposed to support GAP.

3.9.5 Dietary Risk Assessment

The potential daily exposure via food ($PDE_{(food)}$) is used for dietary intake calculation where a value has been set by EPA. An appropriate acceptable daily intake (ADI) is used in the absence of a $PDE_{(food)}$. The $PDE_{(food)}$ of 0.005 mg/kg bw/d was considered appropriate for use in the assessment. The proposed MRL is; potatoes – 0.01 mg/kg.

The chronic dietary exposure to lufenuron 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].

Based on the proposed MRLs, the NEDI for lufenuron is equivalent to < 3% of the $PDE_{(food)}$. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

3.9.6 Toxicological/Public Health Assessment

It has been determined that the use of lufenuron as an insecticide for potatoes according to GAP, is very unlikely to pose any health risks from consumption of treated produce.

3.9.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
European Union	Potatoes	0.05

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 has been notified to the World Trade Organization. Any country may choose to comment if they believe the proposed MRL represents a barrier to their trade.

3.10 PROPOSAL TO SET MRLS FOR PYRACLOSTROBIN

It is proposed that an MRL is set for pyraclostrobin when used on beans and citrus. 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(*)
			Cherries	1
			Grapes	3
			Kiwifruit	0.02(*)
			Mammalian fat	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(*)

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

The revised 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(*)
			Beans	0.4
			Cherries	1
			Citrus	0.7
			Grapes	3
			Kiwifruit	0.02(*)
			Mammalian fat	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(*)

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

3.10.1 Amendment Rationale

The proposed MRLs represent the expansion of use of a currently registered active ingredient. The proposed MRLs will manage the use of pyraclostrobin as a fungicide on beans and citrus

in accordance with the application rates and withholding periods that are proposed as good agricultural practice (GAP) in New Zealand.

3.10.2 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

3.10.3 Good Agricultural Practice

Pyraclostrobin is proposed for use as a fungicide in beans and citrus.

- Beans - to be applied at 192 gai/ha to treat Botrytis, Sclerotinia white and mould at 7 – 10 day intervals and 7 days withholding period.
- Citrus - to be applied at 6.4 gai/100L water to treat Alternaria brown spot, Citrus scab and Melanose at 21 – 28 day intervals and 1 day withholding period.

3.10.4 Residue Information

The residue data for the crops supports an MRL of 0.4 mg/kg and 0.7 mg/kg for pyraclostrobin in beans and citrus respectively. These MRLs are proposed to support GAP.

3.10.5 Dietary Risk Assessment

The potential daily exposure via food ($PDE_{(food)}$) is used for dietary intake calculation where a value has been set by EPA. An appropriate acceptable daily intake (ADI) is used in the absence of a $PDE_{(food)}$. The $PDE_{(food)}$ of 0.015 mg/kg bw/d was considered appropriate for use in the assessment. The proposed MRLs are; beans – 0.4 mg/kg, citrus – 0.7 mg/kg.

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].

Based on the proposed MRLs, the NEDI for pyraclostrobin is equivalent to < 3% of the $PDE_{(food)}$. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

3.10.6 Toxicological/Public Health Assessment

It has been determined that the use of pyraclostrobin as a fungicide for beans and citrus according to GAP, is very unlikely to pose any health risks from consumption of treated produce.

3.10.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Codex	Beans (dry)	0.2
	Citrus	2
European Union	Beans	0.02(*)
	Citrus (except orange)	1
	Orange	2
Japan	Beans	0.5
	Citrus	2
USA	Bean	0.5
	Citrus	2

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

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 has been notified to the World Trade Organization. Any country may choose to comment if they believe the proposed MRL represents a barrier to their trade.

3.11 PROPOSAL TO SET MRLS FOR SPIROTETRAMAT

It is proposed that an MRL is set for spirotetramat when used on blueberries. The current entry for spirotetramat 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)
Spirotetramat	203313-25-1	Spirotetramat	Kiwifruit	0.1
			Potatoes	0.5
			Tomatoes	0.3
			Grapes	0.02(*)

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

The revised entry for spirotetramat 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)
Spirotetramat	203313-25-1	Spirotetramat	Blueberries	0.7
			Kiwifruit	0.1
			Potatoes	0.5
			Tomatoes	0.3
			Grapes	0.02(*)

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

3.11.1 Amendment Rationale

The proposed MRL represents the expansion of use of a currently registered active ingredient. The proposed MRL will manage the use of spirotetramat as an insecticide on blueberries in accordance with the application rates and withholding periods that are proposed as good agricultural practice (GAP) in New Zealand.

3.11.2 Chemical Information

Common name of compound	Spirotetramat
Use of compound	Insecticide
Chemical Abstract Services (CAS) Registry number	203313-25-1
Type of compound	Tetramic acid
Administration method	Spray

3.11.3 Good Agricultural Practice

Spirotetramat is proposed for use as an insecticide in blueberries to be applied at 75 gai/ha to treat thrips and mealy bugs at 14 – 21 day intervals, up to 3 times per season and 7 days withholding period.

3.11.4 Residue Information

The residue data for the crop supports an MRL of 0.7 mg/kg for spirotetramat in blueberries. This MRL is proposed to support GAP.

3.11.5 Dietary Risk Assessment

The potential daily exposure via food ($PDE_{(food)}$) is used for dietary intake calculation where a value has been set by EPA. An appropriate acceptable daily intake (ADI) is used in the absence of a $PDE_{(food)}$. The $PDE_{(food)}$ of 0.004 mg/kg bw/d was considered appropriate for use in the assessment. The proposed MRL is; blueberries – 0.7 mg/kg.

The chronic dietary exposure to spirotetramat 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].

Based on the proposed MRLs, the NEDI for spirotetramat is equivalent to < 45% of the $PDE_{(food)}$. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

3.11.6 Toxicological/Public Health Assessment

It has been determined that the use of spirotetramat as an insecticide for blueberries according to GAP, is very unlikely to pose any health risks from consumption of treated produce.

3.11.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
European Union	Blueberries	0.1(*)
USA	Blueberries	3

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

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 has been notified to the World Trade Organization. Any country may choose to comment if they believe the proposed MRL represents a barrier to their trade.

3.12 PROPOSAL TO EXEMPT PEGBOVIGRASTIM FROM MRL

It is proposed that an MRL exemption is set for pegbovigrastim when used as a veterinary medicine.

It is proposed that Schedule Two of the MRL Standards be amended by adding the following:

Compound	CAS#	Condition
Pegbovigrastim	1363409-60-2	Used in ruminants

3.12.1 Amendment Rationale

The proposed MRL exemption represents a new use pattern in New Zealand for pegbovigrastim. Pegbovigrastim is a Granulocyte Colony Stimulating Factor and is a

naturally occurring immunomodulating cytokine and therefore will be completely metabolised. It is a constituent of the normal diet for people who consume meat or milk from cattle. It is a protein so is not expected to bind to other proteins. It also has negligible oral bioavailability so there is no need to establish an ADI or MRL as the use of this veterinary drug will not lead to any increase food safety risk.

3.12.2 Chemical Information

Common name of compound	Pegbovigrastim
Use of compound	Veterinary medicine
Chemical Abstract Services (CAS) Registry number	1363409-60-2
Type of compound	Protein
Administration method	Injectable

3.12.3 Good Veterinary Practice

Pegbovigrastim is a protein proposed for use as a veterinary medicine for restoration of suppressed immune cell function around the time of calving in cattle.

3.12.4 Residue Information

Pegbovigrastim is a Granulocyte Colony Stimulating Factor and is a naturally occurring immunomodulating cytokine and therefore will be completely metabolised. It's a constituent of the normal human diet of those that consume meat or milk from cattle. It's a protein so is not expected to bind to proteins. It has negligible oral bioavailability and there is no need to establish an ADI or MRL.

3.12.5 Dietary Risk Assessment

Pegbovigrastim is a constituent of the normal diet for people who consume meat or milk from cattle. Bioavailability studies in rodents show that it is completely degraded within minutes of exposure in the stomach. As there is no bioavailability, no ADI has been set and the use of pegbovigrastim as a veterinary medicine presents no dietary risk.

3.12.6 Toxicological/Public Health Assessment

It has been determined that the use of pegbovigrastim as a veterinary medicine, as specified above, is very unlikely to pose any health risks from consumption of commodities from treated animals.

3.12.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
European Union	Bovine	No MRL Required

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 has been notified to the World Trade Organization. Any country may choose to comment if they believe the proposed MRL represents a barrier to their trade.