Ministry for Primary Industries
Manatū Ahu Matua

Proposals to Amend (No.1) the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2012

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

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Growing and Protecting New Zealand

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Submission

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

The following points may be of assistance in preparing comments:

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

Please include the following information in your submission:

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

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

MRL Amendments
MPI Food Policy
PO Box 2835
Wellington

Email: FoodPolicy@MPI.govt.nz
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1 Introduction

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

1.1 BACKGROUND

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

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

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

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

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

An ADI is defined by the World Health Organization (WHO) as: “the daily intake which, during an entire lifetime, appears to be without appreciable risk on the basis of all the known facts at the time”. “Without appreciable risk” has been further defined as: “the practical certainty that injury will not result even after a lifetime of exposure”. ADIs are established by

the WHO and Food and Agriculture Organization (FAO) of the United Nations joint expert committees, which are made up of toxicologists and residue specialists. The ADI information from these joint committees also feeds into the Codex Alimentarius Commission (Codex), which sets international MRLs.

1.2 SUMMARY OF PROPOSED AMENDMENT

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

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

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

New MRLS

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

- 0.01 mg/kg for ametoctradin when used as a fungicide on potatoes;
- 0.2 mg/kg for boscalid when used as a fungicide on onions and other bulb vegetables, the subsequent crops planted in rotation (root vegetables and tuber vegetables), and consequently the following animal commodities MRLs from the transfer of residues to animals: Mammalian fat – 0.3 mg/kg, Mammalian kidney – 0.3 mg/kg, Mammalian liver – 0.2 mg/kg, Milk – 0.1 mg/kg;
- 0.01 mg/kg for fluopyram when used as a fungicide on onions and consequently the following animal commodities MRLs from the transfer of residues to animals; Mammalian meat – 0.1 mg/kg, Mammalian offal – 0.7 mg/kg, Milk – 0.07 mg/kg;
- 0.1 mg/kg for isopyrazam when used as a fungicide on pome fruits;
- 0.01 mg/kg for saflufenacil when used as a herbicide on pome fruits and maize;
- 0.2 mg/kg for spinetoram when used as an insecticide on stone fruits and 0.15 mg/kg for spinetoram when used as an insecticide on vegetable brassicas.

MRL Amendments

MPI proposes to change the current MRL for the following substances in the MRL Standards:

- Deltamethrin in tamarillos from 0.02 mg/kg to 0.1 mg/kg; and
- Nicarbazin in poultry edible offal from 9 mg/kg to 15 mg/kg.

MRL Exemptions

MPI proposes to exempt the following substances from the MRL Standards:

- Methyl anthranilate when used as a bird repellent; and
- N6-Benzyladenine when used as a plant growth regulator in pome fruits and cherries.

2 Proposals

2.1 PROPOSAL TO SET AN MRL FOR AMETOCTRADIN

It is proposed that an MRL is set for ametoctradin when used on potatoes. It is proposed that Schedule One of the MRL Standards be amended to include the following, and that this will be the resulting entry for ametoctradin in Schedule One of the MRL Standards:

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(*)

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 registration in New Zealand for the active ingredient ametoctradin. The proposed MRL will manage the use of ametoctradin as a fungicide to control late blight in potatoes, and to the application rates and withholding periods that are proposed as good agricultural practice (GAP) in New Zealand.

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

Good Agricultural Practice

Ametoctradin is proposed for use as a fungicide in potatoes. Application is at a rate of 240gai/ha at 7 – 10 day intervals using the shorter 7 day interval when heavy infection pressure occurs.

Residues Information

The residue data for potatoes supports an MRL of 0.01mg/kg for ametoctradin when the last treatment is 14 days prior to harvest. An MRL of 0.01 mg/kg is proposed to support GAP.

Dietary Risk Assessment

The potential daily exposure via food (PDE (food)) is used for dietary intake calculation where a value has been set. An appropriate acceptable daily intake (ADI) is used in the absence of a PDE (food). There is no PDE (food) so the ADI of 10 mg/kg bw/d was considered appropriate for use in the assessment and is consistent with overseas regulatory bodies.

The chronic dietary exposure to ametoctradin is estimated by the National Estimated Dietary Intake (NEDI) calculation. 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 less than 0.1% 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 ametoctradin as a fungicide for potatoes according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
European Union	Potato	0.01(*)
USA	Potato	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 will be notified to the World Trade Organization. Any country may choose to comment if they believe the proposed MRL represents a barrier to their trade.

2.2 PROPOSAL TO SET AN MRL FOR BOSCALID

It is proposed that an MRL is set for boscalid when used on onions, the subsequent crops planted in rotation with onions (root vegetables and tuber vegetables), and in animal products (milk, and mammalian fat, kidney and liver). The current entry for boscalid in Schedule One of the MRL Standards is:

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

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

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Residue Limit (mg/kg)
Boscalid	188425-85-6	Boscalid	Bulb vegetables	0.2
			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	0.05(*)
			Tuber vegetables	0.5

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

Amendment Rationale

The proposed MRLs represent the expansion of use of a currently registered active ingredient. They will manage the use of boscalid as a fungicide to control white rot in bulb onions to the application rates and withholding periods that are proposed as good agricultural practice (GAP) in New Zealand, and the subsequent rotational crops like other bulb vegetables and root and tuber vegetables. Also the proposed MRLs will manage residues in animal products.

Chemical Information

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

Good Agricultural Practice

Boscalid is proposed for use as a fungicide in bulb onions at a rate of 400gai/ha, up to four times per season and with not more than 2 sequential applications, alternating with non-strobilurin/anilide fungicides as protectant foliar sprays.

Residues Information

The residue data for bulb onions supports an MRL of 0.2 mg/kg for boscalid when the last treatment is 56 days prior to harvest. The rotational crop data supports an MRL of 0.2 mg/kg for other bulb vegetables and 0.5 mg/kg for root and tuber vegetables. Also data for the potential transfer of residues to animal supports an MRL of 0.3 mg/kg for mammalian fat, 0.2 mg/kg for liver, 0.3 mg/kg for kidney and 0.1 mg/kg for milk.

Dietary Risk Assessment

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

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

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

Toxicological/Public Health Assessment

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

Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Australia	Onions, Bulb	T1.0
	Bulb Vegetables (excluding bulb onions)	T3
	Carrot	T1
	Potato	0.5
	Edible offal (Mammalian)	0.3
	Milk	0.1
'T' denotes that the MRL, residue definition or use is temporary to enable further experimental work to be carried out , and will be reconsidered at some future date		
Codex	Bulb vegetables	5
	Root and tuber vegetables	2
	Meat	0.7
	Edible offal	0.2
	Milk	0.1
European Union	Onions (Silverskin onions)	5
	Garlic	5
	Spring onions	6
	Other bulb vegetables	5
	Root and Tuber	2
	Mammalian fat	0.7
	Mammalian kidney	0.3
	Mammalian liver	0.2
	Milk	0.1
Japan	Potato	0.05
	Carrot	0.7
	Horseradish	0.7
	Onion	3.0
	Garlic	3.0
	Mammalian fat	0.3
	Mammalian liver	0.35
	Mammalian kidney	0.35
	Milk	0.1
USA	Bulb vegetable	3.0
	Garlic	3.0
	Carrot	1.0
	Potato	0.05
	Mammalian fat	0.3
	Milk	0.1

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

2.3 PROPOSAL TO SET AN MRL FOR FLUOPYRAM

It is proposed that an MRL is set for fluopyram when used on onions and in animal products from animals exposed to residues of fluopyram in feed. It is proposed that Schedule One of the MRL Standards be amended to include the following, and that this will be the resulting entry for fluopyram in Schedule One of the MRL Standards:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Fluopyram	658066-35-4	Plant commodities: Fluopyram Animal commodities: Sum of fluopyram and 2-(trifluoromethyl) benzamide, expressed as fluopyram	Bulb onions	0.01(*)
			Mammalian meat	0.1
			Mammalian offal	0.7
			Milk	0.07

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 registration in New Zealand for the active ingredient fluopyram. The proposed MRL will manage the use of fluopyram as a fungicide to control white rot in onions, to the application rates and withholding periods that are proposed as good agricultural practice (GAP) in New Zealand.

Chemical Information

Common name of compound	Fluopyram
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	658066-35-4
Type of compound	Benzamide, pyramide
Administration method	Spray

Good Agricultural Practice

Fluopyram is proposed for use as a fungicide in onions. Application is at a rate of 250gai/ha with two applications at monthly intervals starting at 4 – 6 weeks after planting.

Residues Information

The residue data for onions supports an MRL of 0.01mg/kg for fluopyram when the last treatment is 70 days prior to harvest. An MRL of 0.01 mg/kg is proposed to support GAP.

Residues in food crops grown subsequently to onions treated according to GAP are unlikely to be higher than the NZ default MRL, based on limited studies reviewed by Joint FAO/WHO Meeting on Pesticide Residues (JMPR). However, higher residues could occur in animal feed crops, with a conservative estimate that residues should be less than 0.5 mg/kg (dry matter).

An animal transfer assessment concluded that estimated residues (parent plus benzamide) will be up to 0.5 mg/kg in liver, up to 0.05 mg/kg in other tissues, and in milk 0.01-0.03mg/kg. To harmonise with Codex, the following MRLs are proposed:
0.1mg/kg for mammalian meat, 0.7 mg/kg for offal and 0.07mg/kg for milk.

Dietary Risk Assessment

The potential daily exposure via food (PDE (food)) is used for dietary intake calculation where a value has been set. An appropriate acceptable daily intake (ADI) is used in the absence of a PDE (food). The ADI of 0.01 mg/kg bw/d was considered appropriate for use in the assessment and is consistent with overseas reputable regulatory bodies.

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

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

Toxicological/Public Health Assessment

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

Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Codex	Edible offal (mammalian)	0.7
	Meat	0.1
European Union	Onion (silverskin onions)	0.1
	Mammalian meat	0.1
	Mammalian offal	0.7
	Milk	0.1

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

2.4 PROPOSAL TO SET AN MRL FOR ISOPYRAZAM

It is proposed that an MRL is set for isopyrazam when used on pome fruits. The current entry for isopyrazam 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)
Isopyrazam	881685-58-1	Isopyrazam, sum of isomers	Barley	0.5
			Wheat	0.2

The final entry for isopyrazam 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)
Isopyrazam	881685-58-1	Isopyrazam, sum of isomers	Barley	0.5
			Wheat	0.2
			Pome fruits	0.1

Amendment Rationale

The proposed MRLs represent the expansion of use of a currently registered active ingredient. They will manage the use of isopyrazam as a fungicide to control powdery mildew and blackspot in pome fruits to the application rates and withholding periods that are proposed as good agricultural practice (GAP) in New Zealand.

Chemical Information

Common name of compound	Isopyrazam
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	881685-58-1
Type of compound	Pyrazole
Administration method	Spray

Good Agricultural Practice

Isopyrazam is proposed for use as a fungicide in pome fruits at a rate of 150gai/ha over flowering, during infection, or during leaf extension.

Residues Information

The residue data for pome fruits supports an MRL of 0.1 mg/kg for isopyrazam when the last treatment is 35 days prior to harvest. An MRL of 0.1 mg/kg is proposed to support GAP.

Dietary Risk Assessment

The potential daily exposure via food (PDE (food)) is used for dietary intake calculation where a value has been set. An appropriate acceptable daily intake (ADI) is used in the absence of a PDE (food). The PDE (food) of 0.0385 mg/kg bw/d have been set by EPA and was considered appropriate for use in the assessment.

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

Based on the proposed MRLs, the NEDI for isopyrazam is equivalent to less than 2% 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 isopyrazam as a fungicide in pome fruits according to GAP (specified above), is very unlikely to pose any health risks from consumption of treated produce.

Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
European Union	Pome fruit	0.01(*)

NOTE: (*) 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 will be notified to the World Trade Organization. Any country may choose to comment if they believe the proposed MRL represents a barrier to their trade.

2.5 PROPOSAL TO SET AN MRL FOR SAFLUFENACIL

It is proposed that an MRL is set for saflufenacil when used on pome fruits and maize. It is proposed that Schedule One of the MRL Standards be amended to include the following, and that this will be the resulting entry for saflufenacil in Schedule One of the MRL Standards:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Saflufenacil	372137-35-4	Saflufenacil	Pome fruits	0.01(*)
			Maize	0.01(*)

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 registration in New Zealand for the active ingredient saflufenacil. The proposed MRL will manage the use of saflufenacil as a herbicide in maize crops and pome fruits, to the application rates and withholding periods that are proposed as good agricultural practice (GAP) in New Zealand.

Chemical Information

Common name of compound	Saflufenacil
Use of compound	Herbicide
Chemical Abstract Services (CAS) Registry number	372137-35-4
Type of compound	Pyrimidinedione
Administration method	Spray

Good Agricultural Practice

Saflufenacil is proposed for use as a herbicide in pome fruits and maize. Application rates and timing are as follows:

- Pome fruits - 17.5 gai/ha for pome fruits. Apply 1 – 3 times per season under trees that have mature bark.
- 70 – 105 gai/ha for the maize crops. Apply once as a pre-emergence treatment as soon as practical after planting and before the crop or weeds emerges.

Residues Information

The residue data for pome fruits and maize supports an MRL of 0.01mg/kg for the two food crops. For pome fruits the last treatment must be 28 days prior to harvest. An MRL of 0.01 mg/kg is proposed to support GAP.

Dietary Risk Assessment

The potential daily exposure via food (PDE (food)) is used for dietary intake calculation where a value has been set. An appropriate acceptable daily intake (ADI) is used in the absence of a PDE (food). The PDE (food) of 0.014 mg/kg bw/d have been set by EPA and was considered appropriate for use in the assessment.

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

Based on the proposed MRLs, the NEDI for saflufenacil 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.

Toxicological/Public Health Assessment

It has been determined that the use of saflufenacil as a herbicide for pome fruits and maize according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Codex	Sweet corn	0.01
Australia	Cereal grain	0.03(*)
	Pome fruit	0.03(*)

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

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

2.6 PROPOSAL TO SET AN MRL FOR SPINETORAM

It is proposed that an MRL is set for spinetoram when used on stone fruits and vegetable brassicas. The current entry for spinetoram 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)
Spinetoram	187166-40-1 + 187166-15-0	*Sum of*: XDE-175-J XDE-175-L Expressed as: Spinetoram	Apples Pears Potatoes Tomatoes	0.05 0.05 0.02(*) 0.02(*)

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

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Residue Limit (mg/kg)
Spinetoram	187166-40-1 + 187166-15-0	*Sum of*: XDE-175-J XDE-175-L Expressed as: Spinetoram	Apples Pears Stone fruit Vegetable brassicas Potatoes Tomatoes	0.05 0.05 0.2 0.15 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 MRLs represent the expansion of use of a currently registered active ingredient. They will manage the use of spinetoram as an insecticide to control leafroller, oriental fruit moth and thrips in stonefruit and diamond back moth, white butterfly and looper caterpillars in vegetable brasiccas to the application rates and withholding period that is proposed as good agricultural practice (GAP) in New Zealand.

Chemical Information

Common name of compound	Spinetoram (XDE-175-J + XDE-175-L)
Use of compound	Insecticide
Chemical Abstract Services (CAS) Registry number	187166-40-1 + 187166-15-0
Type of compound	Spinosym
Administration method	Spray

Good Agricultural Practice

Spinetoram is proposed for use as an insecticide in stonefruit at a rate of 2.4-4.8gai/100L, apply in 2000 litres of water per hectare. Apply from petal fall at 10-14 day intervals with last applications 3 days before harvest. For vegetable brassicas, it will be applied at a rate of 24gai per hectare in at least 250L of water per hectare with a withholding period of 3 days.

Residues Information

The residue data for stonefruits supports an MRL of 0.2 mg/kg for spinetoram when the last treatment is 3 days prior to harvest. For vegetable brassicas, the residue data supports and MRL of 0.15 mg/kg when the last treatment is 3 days prior to harvest.

Dietary Risk Assessment

The potential daily exposure via food (PDE (food)) is used for dietary intake calculation where a value has been set. An appropriate acceptable daily intake (ADI) is used in the

absence of a PDE (food). The PDE of 0.024 mg/kg bw/d has been set by EPA and is considered appropriate for use in the assessment of spinetoram.

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

Based on the proposed MRLs, the NEDI for spinetoram is equivalent to less than 1% of the PDE. 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 spinetoram as an insecticide in stonefruit according to GAP (specified above), is very unlikely to pose any health risks from consumption of treated produce.

Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Australia	Stone fruits	0.2
	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	0.2
CODEX	Apricots, Cherries, Peaches	0.2
	Plums	0.05(*)
Japan	Peaches	0.1
	Cabbage	0.5
	Other Fruits	0.2

NOTE: (*) 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 will be notified to the World Trade Organization. Any country may choose to comment if they believe the proposed MRL represents a barrier to their trade

2.7 PROPOSAL TO AMEND THE MRLS FOR DELTAMETHRIN

It is proposed that the current MRL of 0.02 mg/kg for deltamethrin on tamarillos is deleted and replaced with an MRL of 0.1 mg/kg. This will be the final entry for deltamethrin in Schedule One of the MRL Standards:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Deltamethrin	52918-63-5	Sum of:deltamethrin	Avocados	0.05(*)
		α–R-deltamethrin	Beans	0.05(*)
		trans-deltamethrin	Brassica vegetables	0.05(*)
		Expressed as:	Grapes	0.01(*)
		deltamethrin	Kiwifruit	0.01(*)
			Onions	0.01(*)
			Pome fruits	0.01(*)
			Potatoes	0.01(*)
			Stone fruits	0.02(*)
			Sweetcorn	0.01(*)
			Tamarillos	0.1
			Tomatoes	0.05(*)

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

Amendment Rationale

The proposed amendment is based on the information received by MPI which showed that residue levels of deltamethrin in tamarillos from various orchards around New Zealand were above the MRL of 0.02 mg/kg. It is noted that the current MRL is based on old residue data and is more likely the level does not reflect current good agricultural practice (GAP). Consequently, an MRL of 0.1 mg/kg is proposed as it is considered suitable to monitor the current GAP.

Chemical Information

Common name of compound	Deltamethrin
Use of compound	Insecticide
Chemical Abstract Services (CAS) Registry number	52918-63-5
Type of compound	Pyrethroid
Administration method	Spray

Good Agricultural Practice

Deltamethrin is currently approved for use as an insecticide in a broad range of fruit, vegetable crops and ornamentals. For tamarillos, the application rates are:

- 24.75 gai/100L – for the control of grass grub beetle pre-flowering. To be applied at dusk commencing when beetles first appear and at 6 – 8 day intervals over the beetle feeding period.
- 19.8 gai/100L – for the control of whitefly pre-flowering. To be applied immediately after pruning and repeat 7 – 10 days later.
- 12.4 gai/100L – for the control of whitefly post-flowering. To be applied at 10 – 14 day intervals.

Residues Information

Information received by MPI showed that residue levels of deltamethrin in tamarillos from various orchards around New Zealand were above the MRL of 0.02 mg/kg. It is noted that the current MRL is based on old residue data and is more likely the level does not reflect current GAP. An MRL of 0.1 mg/kg is therefore proposed to support GAP.

Dietary Risk Assessment

The PDE (food) is used for dietary intake calculation where a value has been set. An appropriate acceptable daily intake (ADI) is used in the absence of a PDE (food). The ADI of 0.01 mg/kg bw/d was considered appropriate for use in the assessment and is consistent with overseas reputable regulatory bodies.

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

Based on the proposed MRLs, the NEDI for deltamethrin is equivalent to less than 10% 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 deltamethrin as a insecticide for tamarillos according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
European Union	Tamarillos	0.3
Japan	Other fruits	0.5

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

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

2.8 PROPOSAL TO AMEND THE MRL FOR NICARBAZIN

It is proposed that the current MRL of 9 mg/kg for nicarbazin on edible offal is deleted and replaced with an MRL of 15 mg/kg. This will be the final entry for nicarbazin in Schedule One of the MRL Standards:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Nicarbazin	330-95-0	1,3-N,N'-bis (4 nitrophenyl) urea as nicarbazin	Poultry edible offal	15
			Poultry muscle	4
			Poultry skin/fat	4

Amendment Rationale

The proposed amendment is based on an MPI review which indicates that it will be prudent to base the edible offal MRL on the level of residues in the liver rather than the kidney. This is

because residue level in the liver is higher than in the kidney at the registered good agricultural practice (GAP).

Chemical Information

Common name of compound	Nicarbazin (a complex of two compounds, 4,4'-dinitrocarbanilide (DNC) and 4,6-dimethyl-2-pyrimidinol (HDP). DNC is the active component
Use of compound	Coccidiostat
Chemical Abstract Services (CAS) Registry number	330-95-0
Type of compound	Nitrophenylurea with pyrimidin
Administration method	Feed

Good Agricultural Practice

Nicarbazin is used as an anticoccidial agent for broiler chickens. It is to be applied as a feed with 40–50g of nicarbazin per tonne of complete feed and to be fed continuously to broiler chickens as the only ration for at least 14–28 days.

Residues Information

Residue data for broiler chickens supports MRLs of 15mg/kg (poultry offal) for nicarbazin in animals slaughtered immediately after the conclusion of treatment. MRL of 15mg/kg (poultry offal) is therefore proposed to support GAP.

Dietary Risk Assessment

The potential daily exposure via food (PDE (food)) is used for dietary intake calculation where a value has been set. An appropriate acceptable daily intake (ADI) is used in the absence of a PDE (food). MPI considered the ADI of 0.77 mg/kg bw/d was appropriate for use in the assessment and is consistent with overseas reputable regulatory bodies.

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

Based on the proposed MRLs, the NEDI for nicarbazin is equivalent to less than 10% of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Toxicological/Public Health Assessment

MPI has determined that the use of nicarbazin as a anticoccidial agent for broiler chickens, according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Australia	Chicken kidney	20
	Chicken liver	35
	Chicken muscle	5
	Chicken skin/fat	10
Codex	Chicken kidney	0.2
	Chicken liver	0.2
	Chicken muscle	0.2
	Chicken skin/fat	0.2
European Union	Chicken kidney	6
	Chicken liver	15
	Chicken muscle	4
	Chicken skin/fat	4
United State of America	Chicken kidney	4
	Chicken liver	4
	Chicken muscle	4
	Chicken skin/fat	4
Japan	Chicken kidney	0.2
	Chicken liver	0.2
	Chicken muscle	0.2
	Chicken skin/fat	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 will be notified to the World Trade Organization. Any country may choose to comment if they believe the proposed MRL represents a barrier to their trade.

2.9 PROPOSAL TO EXEMPT METHYL ANTHRANILATE FROM AN MRL

It is proposed that an MRL exemption is set for methyl anthranilate when used as an agricultural compound. It is proposed that Schedule Two of the MRL Standards be amended by adding the following:

Substance	CAS#	Condition
Methyl anthranilate	134-20-3	Used as a bird repellent

Amendment Rationale

The proposed MRL exemption represents a new use pattern in New Zealand for methyl anthranilate. The rapid decomposition of this compound into non-toxic substances, its presence in certain food crops naturally and in other foods as a flavour additive and its low toxicity mean it is not suitable to be managed against a chemical concentration limit.

Chemical Information

Common name of compound	Methyl anthranilate
Use of compound	Bird repellant
Chemical Abstract Services (CAS) Registry number	134-20-3
Type of compound	Ester of anthranilic acid
Administration method	Not known

Good Agricultural Practice

Methyl anthranilate is proposed for use as a bird repellent in vineyards and this use is exempt from Agricultural Compounds and Veterinary Medicines registration provided the residues are managed.

Residues Information

Methyl anthranilate is used in processed foods as a flavouring agent, and is naturally present in certain crop plants. Residues resulting from the use of methyl anthranilate as an agricultural compound may also degrade rapidly. Given residue of methyl anthranilate occurring in the plant as a result of agricultural compound use would be indistinguishable from background levels or levels added as a flavouring agent and the fact that it degrades rapidly in the environment, it is not appropriate to be regulated against an MRL.

Dietary Risk Assessment

Methyl anthranilate is present in certain crops such as concord grapes. It may also be used as a flavouring agent in certain processed foods. The substance is volatile and degrades when exposed to ultraviolet light and elevated temperatures to non-toxic substances. It has a low toxicity and is rapidly metabolized in human intestine and liver. Therefore, any residues occurring as a result of its agricultural uses will not represent a dietary risk.

Toxicological/Public Health Assessment

Methyl anthranilate has a low toxicity profile: it is of low acute toxicity and is not a skin or eye irritant. It does not trigger any of the chronic toxicity endpoints. Therefore, the exemption of methyl anthranilate from an MRL to the conditions specified above is very unlikely to pose any health risks from consumption of the harvested commodity.

Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
USA	All food	Exempt

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

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

3.0 PROPOSAL TO EXEMPT N6-BENZYLADENINE FROM AN MRL

It is proposed that an MRL exemption is set for n6-benzyladenine when used as an agricultural compound. It is proposed that the entry for n6-benzyladenine in Schedule One of the MRL Standards be deleted:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
N6-Benzyladenine	1214-39-7	N6-Benzyladenine	Apples	0.01(*)
			Cherries	0.01(*)

Consequently, Schedule Two of the MRL Standards be amended to include the following; this will be the resulting entry for n6-benzyladenine in Schedule Two of the MRL Standards:

Substance	CAS#	Condition
N6-Benzyladenine	1214-39-7	Used as a plant growth regulator in pome fruits and cherries

Amendment Rationale

The proposed MRL exemption represents an amendment to the approved use pattern in New Zealand for n6-benzyladenine. While assessing the residue data, it was considered prudent to have an MRL exemption for n6-benzyladenine when used as a plant growth regulator based on the following rationales:

- Residue analysis of benzyladenine has indicated that it is rapidly depleted from treated plants with residue being undetectable in fruit within a few days, as its use as a plant growth regulator requires it to be applied much earlier in the season to have an effect.
- If there are any detectable residues, it is not considered to be of any risk to the consumer. This is because the substance is of low acute toxicity after oral, dermal and inhalation exposure: it is neither a skin or eye irritant nor a skin sensitizer and does not trigger any of the chronic toxicity endpoint. Also it is extensively and rapidly absorbed and excreted after oral administration.

Chemical Information

Common name of compound	N6-Benzyladenine
Use of compound	Plant Growth Regulator
Chemical Abstract Services (CAS) Registry number	1214-39-7
Type of compound	Cytokinin
Administration method	Spray

Good Agricultural Practice

N6-benzyladenine is proposed for use as a plant growth regulator with the following application rates:

- Apples (fruitlet thinner) – 1800 gai/ha
- Cherries (feathering) – 95 gai/1.5L of latex or acrylic acid.

Residues Information

Residue analysis of benzyladenine has indicated that it is rapidly depleted from treated plants with residue being undetectable in fruit within a few days. This is because its use as a plant growth regulator requires it to be applied much earlier in the season to have an effect. Therefore, it is not appropriate to be regulated against a. concentration level.

Dietary Risk Assessment

N6-benzyladenine is of low acute toxicity after oral, dermal and inhalation exposure: it is neither a skin or eye irritant nor a skin sensitizer and does not trigger any of the chronic toxicity endpoint. Also it is extensively and rapidly absorbed and excreted after oral administration. Therefore, any residues occurring as a result of its agricultural uses will not represent a dietary risk.

Toxicological/Public Health Assessment

N6-benzyladenine is of low acute toxicity after oral, dermal and inhalation exposure: it is neither a skin or eye irritant nor a skin sensitizer and does not trigger any of the chronic toxicity endpoint. Therefore, the exemption of methyl anthranilate from an MRL to the

conditions specified above is very unlikely to pose any health risks from consumption of the harvested commodity.

Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
USA	Apple and Pear	Exempt when applied at a rate of ≤182 grams of active ingredient per acre per season
Australia	Apple	0.2
	Pear	T0.2
'T' denotes that the MRL, residue definition or use is temporary to enable further experimental work to be carried out , and will be reconsidered at some future date		

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

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