



Proposals to Amend (No.2) the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2014

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1	Submissions	1
2	Introduction	2
2.1	Background	2
2.2	Summary of Proposed Amendment	3
3	Proposals	4
3.1	Proposal to set MRL for acibenzolar-s-methyl	4
3.2	Proposal to set MRL for clopyralid	5
3.3	Proposal to set MRLs for cyflufenamid	6
3.4	Proposal to set MRLs for decoquinate	8
3.5	Proposal to set MRL for fluthiacet-methyl	9
3.6	Proposal to set MRL for spinetoram	10
3.7	Proposal to set MRL for streptomycin	10
3.8	Proposal to set MRL for sulfloxaflor	14
3.9	Proposal to exempt <i>Banda de Lupinus albus doce</i> (BLad)	15
3.10	Proposal to extend exemption for plant extract (unrefined)	17
3.11	Proposal to exempt polysaccharides	18

1 Submissions

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.

For **each compound** you are commenting on, please clearly answer the following questions. Any additional comment is welcome, along with supporting reasons and data or examples to illustrate particular points.

On balance, do you oppose any of the commodity MRLs proposed for this compound?

Do you oppose an MRL being set at all for this compound for the commodity?

If an MRL is to be set for this compound for the commodity, do you disagree with the particular level proposed?

Submissions close at 5pm on **30 December 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.

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 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.

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 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.

Once the standard is in place, 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 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 and compared them with the appropriate reference health standard (the PDE (food) or the ADI). 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:

- 0.02(*) mg/kg for acibenzolar-s-methyl when used as an immune stimulant on kiwifruit
- 4 mg/kg for clopyralid when used as a herbicide on beetroot
- 0.05 mg/kg for cyflufenamid on grapes, 0.01(*) mg/kg on winter squash when used as a fungicide
- 0.2 mg/kg for decoquinate in poultry meat, 0.8 mg/kg in poultry offal and 0.4 mg/kg in poultry skin/fat when used as an anticoccidial in poultry
- 0.01(*) mg/kg for fluthiacet-methyl when used as a herbicide on maize
- 0.05 mg/kg for spinetoram when used as an insecticide on citrus
- 0.01(*) mg/kg for streptomycin when used as a bactericide on kiwifruit
- 0.01(*) mg/kg for sulfoxaflor when used as an insecticide on barley.

2.2.2 Exempt from MRLS

MPI proposes to exempt the following substances from MRLs:

- Extend the current exemption for the plant extracts (unrefined) to include *Camellia sinensis* and *Fallopia sachalinensis* to the list of plant species
- *Banda de Lupinus albus doce* (BLad) when used as a fungicide
- Polysaccharides when used as an agricultural chemical.

2.2.3 Other Amendments

There are no other amendments.

3 Proposals

3.1 PROPOSALS TO SET MRLS FOR ACIBENZOLAR-S-METHYL

It is proposed that an MRL is set for acibenzolar-s-methyl when used on kiwifruit. The final entry for acibenzolar-s-methyl 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)
Acibenzolar-s-methyl	135158-54-2	Sum of Acibenzolar-s-methyl and Acibenzolar acid (CGA210007) Expressed as: Acibenzolar-s-methyl	Kiwifruit	0.02(*)

(*) 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 use of a new active ingredient. The proposed MRL will manage the use of acibenzolar-s-methyl as an elicitor of the systemic activated resistance (SAR) response in kiwifruit 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	Acibenzolar-s-methyl
Use of compound	Elicitor/Fungicide
Chemical Abstract Services (CAS) Registry number	135158-54-2
Type of compound	Benzothiadiazole
Administration method	Spray

3.1.3 Good Agricultural Practice

Acibenzolar-s-methyl is proposed for use as an immune stimulant in kiwifruit. Application is at maximum rate of:

- Foliar - 100 gai/ha to be applied at a maximum of 4 sprays at 21 day intervals and not applied between flowering and harvest; and
- Soil - 0.25 gai/plant to be applied at a maximum of 4 sprays at 21 day intervals with 14 days withholding period.

3.1.4 Residue Information

The residue data for the crops supports an MRL of 0.02 mg/kg for acibenzolar-s-methyl in kiwifruit when the last treatment is 14 days prior to harvest. An MRL of 0.02 mg/kg in kiwifruit 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 0.0035 mg/kg bw/d was considered appropriate for use in the assessment. The proposed MRL is; kiwifruit – 0.02 mg/kg.

The chronic dietary exposure to acibenzolar-s-methyl 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 acibenzolar-s-methyl 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 acibenzolar-s-methyl as an elicitor of the systemic activated resistance (SAR) response for kiwifruit, 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

Currently, there are no other international MRLs for acibenzolar-s-methyl in kiwifruit.

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.

3.2 PROPOSALS TO SET MRLS FOR CLOPYRALID

It is proposed that an MRL is set for clopyralid when used on beetroot. The final entry for clopyralid 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)
Clopyralid	1702-17-6	Clopyralid	Beetroot	4

3.2.1 Amendment Rationale

The proposed MRL represents an additional use of clopyralid. The proposed MRL will manage the additional use of clopyralid as a herbicide on beetroots 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	Clopyralid
Use of compound	Herbicide
Chemical Abstract Services (CAS) Registry number	1702-17-6
Type of compound	Pyridine
Administration method	Spray

3.2.3 Good Agricultural Practice

Clopyralid is proposed for use as a herbicide in beetroots. Application will be the same as currently approved for the fodder beets which is at maximum rate of 300 gai/ha, application after 2 true leaf stage and before bulbous root formation.

3.2.4 Residue Information

The residue data for the crop supports an MRL of 4 mg/kg when the last treatment is before bulbous root formation. MRL of 4 mg/kg is 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 0.105 mg/kg bw/d was considered appropriate for use in the assessment. The proposed MRL is; beetroot – 4 mg/kg.

The chronic dietary exposure to clopyralid 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 clopyralid is equivalent to 1.1% 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 clopyralid as a herbicide for beetroots 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)
Canada	Beetroot	4
EU	Beetroot	1
USA	Beetroot	4

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.

3.3 PROPOSALS TO SET MRLS FOR CYFLUFENAMID

It is proposed that an MRL is set for cyflufenamid when used on grapes and winter squash. The final entry for cyflufenamid 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)
Cyflufenamid	180409-60-3	Cyflufenamid	Grapes	0.05
			Winter squash	0.01(*)

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

3.3.1 Amendment Rationale

The proposed MRL represents the use of a new active ingredient. The proposed MRL will manage the use of cyflufenamid as a fungicide on grapes and winter squash 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	Cyflufenamid
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	180409-60-3
Type of compound	Benzeneacetamide
Administration method	Spray

3.3.3 Good Agricultural Practice

Cyflufenamid is proposed for use as a fungicide in grapes and winter squash. Application is at maximum rate of:

- Grapes – 2.5 gai/100L to be applied at first sign of disease then again 10 – 21 days later up to pre-bunch closure; and
- Winter squash – 12.5 gai/ha to be applied before the first sign of disease and then again 10 – 14 days later up to 28 days before harvest.

3.3.4 Residue Information

The residue data for the crops supports MRLs of 0.05 mg/kg and 0.01 mg/kg for cyflufenamid in grapes and winter squash respectively when the last treatment is pre-bunch closure for grapes and 28 days before harvest for winter squash. MRLs of 0.05 mg/kg and 0.01 mg/kg in grapes and winter squash respectively 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 0.03 mg/kg bw/d was considered appropriate for use in the assessment. The proposed MRLs are; grapes - 0.05 mg/kg, winter squash – 0.01 mg/kg. The chronic dietary exposure to cyflufenamid 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 cyflufenamid is equivalent to < 1% of the $PDE_{(food)}$. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

3.3.6 Toxicological/Public Health Assessment

It has been determined that the use of cyflufenamid as a fungicide for grapes and winter squash according to the GAP specified above, 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)
Australia	Grapes	0.15
	Winter squash	0.1
EU	Grapes	0.15
	Winter squash	0.04
Japan	Grapes	0.5
	Winter squash	0.3
USA	Grapes	0.15
	Winter squash	0.07

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.

3.4 PROPOSALS TO SET MRLS FOR DECOQUINATE

It is proposed that an MRL is set for decoquinatone when used in poultry. The final entry for decoquinatone 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)
Decoquinatone	18507-89-6	Decoquinatone	Poultry meat	0.2
			Poultry offal	0.8
			Poultry skin/fat	0.4

3.4.1 Amendment Rationale

The proposed MRLs represent the use of a new active ingredient. The proposed MRLs will manage the use of decoquinatone as an anticoccidial for poultry 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	Decoquinatone
Use of compound	Anticoccidial
Chemical Abstract Services (CAS) Registry number	18507-89-6
Type of compound	Quinoline
Administration method	Feed

3.4.3 Good Agricultural Practice

Decoquinatone is proposed for use as a anticoccidial for poultry. Application is at maximum dose of 1 mg/kg bodyweight with a nil withholding period.

3.4.4 Residue Information

The residue data for the animals supports MRLs of 0.2 mg/kg for decoquinatone in poultry meat, 0.8 mg/kg in poultry offal and 0.4 mg/kg in poultry skin/fat. These MRLs 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 by EPA. An appropriate acceptable daily intake (ADI) is used in the absence of a $PDE_{(food)}$. The ADI of 0.0375 mg/kg bw/d was considered appropriate for use in the assessment. The proposed MRLs are; 0.2 mg/kg for in poultry meat, 0.8 mg/kg in poultry offal and 0.4 mg/kg in poultry skin/fat.

The chronic dietary exposure to decoquinatone 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 decoquinatone is equivalent to less than 2 % of the ADI. 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 decoquinatone as an anticoccidial for poultry, 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)
Japan	Edible offal, Chicken	0.1
	Fat, Chicken	2
	Kidney, Chicken	0.1
	Liver, Chicken	0.1
	Muscle, Chicken	0.1
USA	Chicken skeletal muscle	1
	Other tissues, Chicken	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.

3.5 PROPOSALS TO SET MRLS FOR FLUTHIACET-METHYL

It is proposed that an MRL is set for fluthiacet-methyl when used on maize. The final entry for fluthiacet-methyl 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)
Fluthiacet-methyl	117337-19-6	Fluthiacet-methyl	Maize	0.01(*)

(*) 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 use of a new active ingredient. The proposed MRL will manage the use of fluthiacet-methyl as a herbicide on maize 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	Fluthiacet-methyl
Use of compound	Herbicide
Chemical Abstract Services (CAS) Registry number	117337-19-6
Type of compound	Imine
Administration method	Spray

3.5.3 Good Agricultural Practice

Fluthiacet-methyl is proposed for use as a herbicide on maize. Application is at maximum rate of 3 gai/ha to be applied ideally within 2 – 4 weeks after emergence up to the maize 6 leaf stage.

3.5.4 Residue Information

The residue data for the crops supports a MRL of 0.01 mg/kg for fluthiacet-methyl in maize when the last treatment is the maize 6 leaf stage. MRL of 0.01 mg/kg 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 $PDE_{(food)}$ is still to be set by EPA so the ADI is used. The ADI of 0.001 mg/kg bw/d was considered appropriate for use in the assessment. The proposed MRL is; maize - 0.01 mg/kg.

The chronic dietary exposure to fluthiacet-methyl 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 MRL, the NEDI for fluthiacet-methyl is equivalent to < 1% of the ADI. 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 fluthiacet-methyl as a herbicide for maize according to the GAP specified above, 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)
Japan	Corn (maize, including popcorn and sweetcorn)	0.1
USA	Corn	0.01

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.

3.6 PROPOSALS TO SET MRLS FOR SPINETORAM

It is proposed that an MRL is set for spinetoram when used on bulb onions and citrus. 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	<i>Sum of:</i>	Apples	0.05
		XDE-175-J	Mammalian fat	0.2
		XDE-175-L	Mammalian kidney	0.01(*)
		<i>Expressed as:</i>	Mammalian liver	0.01(*)
		Spinetoram	Mammalian meat	0.01(*)
			Pears	0.05
			Stone fruit	0.2
			Vegetable brassicas	0.15
			Potatoes	0.02(*)
			Tomatoes	0.02(*)

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

The revised 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 Permitted Residue Level (mg/kg)
Spinetoram	187166-40-1 + 18716-15-0	<i>Sum of:</i>	Apples	0.05
		XDE-175-J	Bulb onions	0.01(*)
		XDE-175-L	Citrus	0.05
		<i>Expressed as:</i>	Mammalian fat	0.2
		Spinetoram	Mammalian kidney	0.01(*)
			Mammalian liver	0.01(*)
			Mammalian meat	0.01(*)
			Pears	0.05
			Stone fruits	0.2
			Vegetable brassicas	0.15
			Potatoes	0.02(*)
			Tomatoes	0.02(*)

(*) 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 the expansion of use of a currently registered active ingredient. The proposed MRLs will manage the use of spinetoram as an insecticide on bulb onions and citrus and 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	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	Spinosyn
Administration method	Spray

3.6.3 Good Agricultural Practice

Spinetoram is proposed for use as an insecticide on:

- bulb onions at maximum rate of 60 gai/ha to treat Thrips with 4 applications at 7 days intervals with 3 days withholding period.
- citrus at maximum rate of 96 gai/ha to be applied to treat Thrips at 14 days intervals with 14 days withholding period.

3.6.4 Residue Information

The residue data for the crop supports an MRL of 0.01 mg/kg and 0.05 mg/kg for spinetoram in bulb onions and citrus respectively. 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 0.017 mg/kg bw/d was considered appropriate for use in the assessment. The proposed MRLs are bulb onions – 0.01 mg/kg, citrus – 0.05 mg/kg. 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 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 spinetoram is equivalent to < 2% 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 spinetoram as an insecticide for bulb onions and citrus 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	Citrus	3
Codex	Oranges	0.07
European Union	Onion	0.05(*)
	Citrus	0.2
Japan	Citrus	0.7
USA	Citrus	0.3

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.

3.7 PROPOSALS TO SET MRLS FOR STREPTOMYCIN

It is proposed that an MRL is set for streptomycin when used on kiwifruit. The current entry for streptomycin 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)
Streptomycin	57-92-1	Streptomycin	Pome fruits	0.1(*)
			Stone fruits	0.1(*)

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

The revised entry for streptomycin 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)
Streptomycin	57-92-1	Streptomycin	Kiwifruit	0.01(*)
			Pome fruits	0.1(*)
			Stone fruits	0.1(*)

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

3.7.1 Amendment Rationale

The proposed MRLs represent the use of a new active ingredient. The proposed MRLs will manage the use of streptomycin as a bactericide in kiwifruit 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	Streptomycin
Use of compound	Bactericide
Chemical Abstract Services (CAS) Registry number	57-92-1
Type of compound	Aminoglycoside
Administration method	Spray

3.7.3 Good Agricultural Practice

Streptomycin is proposed for use as a bactericide in kiwifruit at a rate of 10 gai/100L to be applied to treat Psa-V with a maximum of four applications and not to be applied between the start of flowering and harvest.

3.7.4 Residue Information

The residue data for the crops supports an MRL of 0.01 mg/kg for streptomycin in kiwifruit.

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. An appropriate acceptable daily intake (ADI) is used in the absence of a $PDE_{(food)}$. The $PDE_{(food)}$ of 0.025 mg/kg bw/d was considered appropriate for use in the assessment and is consistent with overseas reputable regulatory bodies. The proposed MRL is 0.01(*) in kiwifruit.

The chronic dietary exposure to streptomycin 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 streptomycin is equivalent to less than 13 % 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 streptomycin as a bactericide for kiwifruit according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

3.7.7 Other International MRLs

There are no overseas MRLs.

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.

3.8 PROPOSAL TO SET MRLS FOR SULFOXAFLOL

It is proposed that an MRL is set for sulfoxaflor when used on barley. The current entry for sulfoxaflor 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)
Sulfoxaflor	946578-00-3	Sulfoxaflor	Edible mammalian offal	0.05
			Mammalian fat	0.01(*)
			Milk	0.01(*)
			Mammalian muscle	0.01(*)
			Wheat grain	0.01(*)

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

The revised entry for sulfoxaflor 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)
Sulfoxaflor	946578-00-3	Sulfoxaflor	Barley grain	0.01(*)
			Edible mammalian offal	0.05
			Mammalian fat	0.01(*)
			Milk	0.01(*)
			Mammalian muscle	0.01(*)
			Wheat grain	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 MRL represents the expansion of use of a currently registered active ingredient. The proposed MRL will manage the use of sulfoxaflor as an insecticide on barley and 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	Sulfoxaflor
Use of compound	Insecticide
Chemical Abstract Services (CAS) Registry number	946578-00-3
Type of compound	Sulfoximine
Administration method	Spray

3.8.3 Good Agricultural Practice

Sulfoxaflor is proposed for use as an insecticide for barley to be applied to treat aphids at a maximum application rate of 50gai/ha with a withholding period of:

- *Barley fodder or green feed* - Do not graze or cut for feed for 28 days after the last application
- *Barley grain and straw* – No WHP is required when the product is used as directed.

3.8.4 Residue Information

The residue data for the crops supports an MRL of 0.01 mg/kg for sulfoxaflor in barley. This MRL is proposed to support GAP. No additional residue data for potential residue to grazing

animal was required as the current data used in the assessment of wheat was considered sufficient and that there will no amendments to the current MRL in animal commodities.

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 0.028 mg/kg bw/d was considered appropriate for use in the assessment. The proposed MRL is; barley grain – 0.01 mg/kg.

The chronic dietary exposure to sulfoxaflor 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 sulfoxaflor is equivalent to < 1% of the $PDE_{(food)}$. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

3.8.6 Toxicological/Public Health Assessment

It has been determined that the use of sulfoxaflor as an insecticide for barley 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)
Australia	Cereal grain	0.01
Codex	Barley	0.6
USA	Barley, grain	0.4

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.

3.9 PROPOSAL TO EXEMPT *BANDA DE LUPINUS ALBUS DOCE* (BLAD)

It is proposed that an MRL is set for *Banda de Lupinus albus doce* when used as fungicide.

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

Substance	CAS#	Condition
<i>Banda de Lupinus albus doce</i>	n/a	Used as fungicide

3.9.1 Amendment Rationale

The proposed MRL exemption represents the use pattern in New Zealand for the new active ingredient *Banda de Lupinus albus doce*. This is a novel active ingredient, a naturally occurring seed storage protein in white lupin. It is a 20kDa polypeptide of β -conglutin. It is formed during days 4 to 12 of the germination process of the flowering plant, sweet lupines.

Available data do indicate that BLAD has a non-toxic mode of action in that it binds to chitin, a major component of the fungal cell wall thereby inhibiting any fungal growth. No toxicity endpoints were identified. BLAD is also used in human and animal nutrition as food and feed. Therefore, it would be impossible to determine if a residue was from the use of the fungicidal product or not and exempting it from requiring a MRL is appropriate.

3.9.2 Chemical Information

Common name of compound	<i>Banda de Lupinus albus doce</i>
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	n/a
Type of compound	Polypeptide
Administration method	Spray

3.9.3 Good Agricultural Practice

Banda de Lupinus albus doce is proposed for use as a fungicide on a wide range of crops initially to investigate efficacy and plant safety on fungal diseases with up to 6 applications at the proposed application rates of 0.375 – 1kg/ha.

3.9.4 Residue Information

Banda de Lupinus albus doce is a naturally occurring seed storage protein in white lupin. It is a 20kDa polypeptide of β -conglutin. It is formed during days 4 to 12 of the germination process of the flowering plant, sweet lupines. Available data do indicate that BLAD has a no toxic mode of action in that it binds to chitin, a major component of the fungal cell wall thereby inhibiting any fungal growth. No toxicity endpoints were identified. BLAD is also used in human and animal nutrition and a food and feed item. It is not expected that levels of *Banda de Lupinus albus doce* resulting from treatment of a wide range of crops will be distinguishable from the naturally occurring levels in the plant or environment. It is therefore proposed that BLAD be exempted from an MRL.

3.9.5 Dietary Risk Assessment

No ADI has been set for *Banda de Lupinus albus doce*. Levels of *Banda de Lupinus albus doce* in harvested crops will not exceed levels present in its use as a food and feed item and through the natural presence in the plant and the environment. Therefore the use of *Banda de Lupinus albus doce* as a fungicide presents no dietary risk.

3.9.6 Toxicological/Public Health Assessment

It has been determined that the use of *Banda de Lupinus albus doce* as a fungicide, is very unlikely to pose any health risks from consumption of treated produce.

3.9.7 Other International MRLs

Country	Food	Condition)
USA	All food	Exempt when applied as a fungicide

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.

3.10 PROPOSAL TO EXTEND EXEMPTION FOR PLANT EXTRACT (UNREFINED)

It is proposed that the current list of plant species in the plant extract (unrefined) exemption to be amended to include *Camellia sinesis* and *Fallopia sachalinensis*.

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

Substance	CAS#	Condition
<i>Plant extracts (unrefined)</i>	n/a	Except where otherwise stated in this standard Where the extract is registered under the Agricultural Compounds and Veterinary Medicines Act 1997 and intended for use as an agricultural chemical, and Where the extract is derived from plants of the following species: <i>Camellia sinesis</i> (Tea) <i>Optunia linheimeri</i> (Texas prickly pear), <i>Quercus falcate</i> (Southern red oak), <i>Fallopia sachalinensis</i> (Giant knotweed) <i>Rhus aromatica</i> (Fragrant sumac), <i>Rhizophora mangle</i> (Red mangrove)¶

3.10.1 Amendment Rationale

The proposed MRL exemption represents the use pattern in New Zealand for the new active ingredients; the *extract of Camellia sinesis* and *Fallopia sachalinensis*. These extracts have low toxicity and are naturally present in food. Therefore, it would be impossible to determine if a residue was from the use of the fungicidal product or not and exempting it from requiring a MRL is appropriate.

3.10.2 Good Agricultural Practice

The extracts are proposed for use as a fungicide on a wide range of crops.

3.10.3 Residue Information

Extracts of *Camellia sinesis* and *Fallopia sachalinensis* have no identified toxicity and are naturally present in food. Therefore it would be impossible to determine if a residue was from the use of the product or not and exempting it from requiring a MRL is appropriate.

3.10.4 Dietary Risk Assessment

No ADI is necessary for the extracts as they have no identified toxicity. Therefore the use of the extracts as a fungicide presents no dietary risk.

3.10.5 Toxicological/Public Health Assessment

It has been determined that the use of the extracts as a fungicide, is very unlikely to pose any health risks from consumption of treated produce.

3.10.6 Other International MRLs

Fallopia sachalinensis

Country	Food	Condition
Canada	All food	Exempted from MRLs
USA	All food	Exempted from MRLs

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.

3.11 PROPOSAL TO EXEMPT POLYSACCHARIDES FROM MRL

It is proposed that an MRL is set for *polysaccharides* when used as an agricultural chemical.

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

Substance	CAS#	Condition
Polysaccharides	n/a	Used as an agricultural chemical

3.11.1 Amendment Rationale

The proposed MRL exemption represents the use pattern in New Zealand for the new active ingredient *polysaccharides*. They contain simple sugars, the monosaccharides and are naturally found in the body and food crop. When sprayed onto plants, they quickly depolymerise into glucosamine and galacturonic acid. These monomers are then metabolised into carbon dioxide, methane gas and hydrogen gas. Therefore, it would be impossible to determine if a residue was from the use of the product or not and exempting it from requiring a MRL is appropriate.

3.11.2 Chemical Information

Common name of compound	<i>Polysaccharides</i>
Use of compound	Not specified
Chemical Abstract Services (CAS) Registry number	n/a
Type of compound	Saccharide
Administration method	Spray

3.11.3 Good Agricultural Practice

Saccharide polymers are proposed for use on a wide range of crops initially to carry out trial work in order to obtain further information on efficacy.

3.11.4 Residue Information

Saccharide polymers and are naturally found in the body and food crop. They are quickly depolymerised in the environment into glucosamine and galacturonic acid monomers. The monomers are subsequently metabolised into CO₂, CH₄ and H₂. Therefore no residues of toxicological concern will be found. It is therefore proposed that *polysaccharides* be exempted from an MRL.

3.11.5 Dietary Risk Assessment

No ADI has been set for saccharide polymer. They are naturally found in the body and food crop. They are quickly depolymerised in the environment into glucosamine and galacturonic acid monomers. The monomers are subsequently metabolised into CO₂, CH₄ and H₂. Therefore no residues of toxicological concern will be found. Therefore the use of saccharide polymer as an agricultural chemical presents no dietary risk.

3.11.6 Toxicological/Public Health Assessment

It has been determined that the use of *polysaccharides*, are very unlikely to pose any health risks from consumption of treated produce.

3.11.7 Other International MRLS

Currently, there are no other international MRL exemptions for *polysaccharides*.

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.