# Proposals to Amend (No. 3) the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2014

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# 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 January 2015. 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: <a href="http://www.foodsafety.govt.nz/elibrary/industry/register-list-mrl-agricultural-compounds.htm">http://www.foodsafety.govt.nz/elibrary/industry/register-list-mrl-agricultural-compounds.htm</a> .

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

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

- 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:

- 0.5 mg/kg for cyprodinil when used as a fungicide on blueberries
- 0.5 mg/kg for fludioxonil when used as a fungicide on blueberries
- 0.01 (\*) mg/kg for lambda-cyhalothrin when used as an insecticide on kumara
- 0.6 mg/kg for saflufenacil in edible mammalian offal, 0.01 mg/kg in milk, mammalian meat and mammalian fat when used a herbicide in pasture.
- 0.05 mg/kg for sulfoxaflor on root and tuber vegetables, 0.1 mg/kg on cauliflower, 0.5 mg/kg on cucurbits (except pumpkins and winter squash), 1.0 mg/kg on fruiting vegetables (except sweetcorn and mushrooms), 1.0 mg/kg on head lettuce, 3.0 mg/kg on vegetable brassicas (except cauliflower), 5.0 mg/kg leafy vegetables (except head lettuce) when used as an insecticide.

#### 2.2.2 Other Amendments

There are no other amendments.

# 3 Proposals

# 3.1 PROPOSAL TO SET AN MRL FOR CYPRODINIL

It is proposed that an MRL is set for cyprodinil when used on blueberries. The current entry for cyprodinil 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)
Cyprodinil	121552-61-2	Cyprodinil	Bulb onions	0.01 (*)
			Grapes	1
			Pome fruits	0.01
			Stone fruits (except	0.02 (*)
			cherries	
			Strawberries	1

The revised entry for cyprodinil 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)
Cyprodinil	121552-61-2	Cyprodinil	Blueberries Bulb onions Grapes Pome fruits	0.5 0.01 (*) 1 0.01
			Stone fruits (except cherries Strawberries	0.02 (*)

<sup>(\*)</sup> indicates that the maximum residue limit has been set at or about the limit of analytical quantification.

#### 3.1.1 Amendment Rationale

The proposed MRL represents the expansion of use of a currently registered active ingredient. The proposed MRL will manage the use of cyprodinil as a fungicide when used on blueberries 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	Cyprodinil	
Use of compound	Fungicide	
Chemical Abstract Services (CAS) Registry number	121552-61-2	
Type of compound	Anilopyrimidine	
Administration method	Spray	

# 3.1.3 Good Agricultural Practice

Cyprodinil is proposed for use as a fungicide in blueberries to be applied at 300 gai/ha to treat Botrytis and Anthracnose, with the first application at full flowering and the second application no later than 14 days after the completion of flowering, with at least 28 days before harvest.

#### 3.1.4 Residue Information

The residue data for the crop supports an MRL of 0.5 mg/kg for cyprodinil in blueberries. The MRL is proposed to support GAP.

# 3.1.5 Dietary Risk Assessment

The potential daily exposure via food (PDE<sub>(food)</sub>) 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<sub>(food)</sub>. The PDE<sub>(food)</sub> of 0.0135 mg/kg bw/d was considered appropriate for use in the assessment. The proposed MRL is: blueberries – 0.5 mg/kg.

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

Based on the proposed MRLs, the NEDI for cyprodinil is equivalent to 9.3% of the PDE<sub>(food)</sub>. 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 cyprodinil on blueberries, according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

### 3.1.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Australia	Blueberries	3.0
Codex	Bush fruit	10.0
USA	Blueberries	5.0

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.

#### 3.2 PROPOSAL TO SET AN MRL FOR FLUDIOXONIL

It is proposed that an MRL is set for fludioxonil when used on blueberries. The current entry for fludioxonil 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)
Fludioxonil	131341-86-1	Fludioxonil	Bulb onions	0.01 (*)
			Grapes	1
			Strawberries	1

The revised entry for fludioxonil 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)
Fludioxonil	131341-86-1	Fludioxonil	Blueberries Bulb onions	0.5 0.01 (*)
			Duin utilutis	0.01()

Grapes	1
Strawberries	1

<sup>(\*)</sup> indicates that the maximum residue limit has been set at or about the limit of analytical quantification.

#### 3.2.1 Amendment Rationale

The proposed MRL represents the expansion of use of a currently registered active ingredient. The proposed MRL will manage the use of fludioxonil as a fungicide when used on blueberries and 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	Fludioxonil
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	131341-86-1
Type of compound	Phenylpyrrole
Administration method	Spray

# 3.2.3 Good Agricultural Practice

Fludioxonil is proposed for use as a fungicide in blueberries to be applied at 200 gai/ha to treat Botrytis and Anthracnose, with the first application at full flowering and the second application no later than 14 days after the completion of flowering, with at least 28 days before harvest.

#### 3.2.4 Residue Information

The residue data for the crop supports an MRL of 0.5 mg/kg for fludioxonil in blueberries. The MRL 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 0.0165 mg/kg bw/d was considered appropriate for use in the assessment. The proposed MRL is: blueberries – 0.5 mg/kg.

The chronic dietary exposure to fludioxonil 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 fludioxonil is equivalent to 8.8% 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 fludioxonil on blueberries, 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)
Australia	Blueberries	2.0
Codex	Blueberries	2.0
USA	Bush fruit	2.0

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.

# 3.3 PROPOSAL TO SET AN MRL FOR LAMBDA-CYHALOTHRIN

It is proposed that an MRL is set for lambda-cyhalothrin when used on kumara. The current entry for lambda-cyhalothrin in Schedule One of the MRL Standards is:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Lambda-cyhalothrin	91465-08-6	Lambda-cyhalothrin	Citrus fruits	0.01(*)
			Grapes	0.01(*)
			Maize	0.01(*)
			Onions	0.01(*)
			Potatoes	0.01(*)
			Pumpkins	0.01(*)
			Sweetcorn	0.01(*)
			Winter squash	0.01(*)

The revised entry for lambda-cyhalothrin in Schedule One of the MRL Standards will therefore read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Lambda-cyhalothrin	91465-08-6	Lambda-cyhalothrin	Citrus fruits	0.01(*)
			Grapes	0.01(*)
			Kumara	0.01(*)
			Maize	0.01(*)
			Onions	0.01(*)
			Potatoes	0.01(*)
			Pumpkins	0.01(*)
			Sweetcorn	0.01(*)
			Winter squash	0.01(*)

<sup>(\*)</sup> 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 expansion of use of a currently registered active ingredient. The proposed MRL will manage the use of lambda-cyhalothrin as an insecticide when used on kumara 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	Lambda-cyhalothrin	
Use of compound	Insecticide	
Chemical Abstract Services (CAS) Registry number	91465-08-6	
Type of compound	Pyrethroid	
Administration method	Spray	

# 3.3.3 Good Agricultural Practice

Lambda-cyhalothrin is proposed for use as an insecticide in kumara to be applied at 200 gai/ha at first sign of pests, then at 2 week intervals, with no more than 3 applications per season and a 14 day withholding period.

#### 3.3.4 Residue Information

The residue data for the crop supports an MRL of 0.01(\*) mg/kg for lambda-cyhalothrin in kumara. The MRL is proposed to support GAP.

# 3.3.5 Dietary Risk Assessment

The potential daily exposure via food (PDE<sub>(food)</sub>) 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<sub>(food)</sub>. The PDE<sub>(food)</sub> of 0.0004 mg/kg bw/d was considered appropriate for use in the assessment. The proposed MRL is: kumara -0.01(\*) mg/kg.

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

Based on the proposed MRLs, the NEDI for lambda-cyhalothrin is equivalent to 58.1% of the PDE<sub>(food)</sub>. 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 lambda-cyhalothrin on kumara, 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)
Codex	Root and Tuber Vegetables	0.01
EU	Root and Tuber Vegetables	0.02
USA	Sweet Potatoes	0.02

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.

# 3.4 PROPOSAL TO SET MRLS FOR SAFLUFENACIL

It is proposed that MRLs are set for saflufenacil when used on pasture. The current entry for saflufenacil 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)
Saflufenacil	372137-35-4	Saflufenacil	Pome fruits	0.01(*)
			Maize	0.01(*)

<sup>(\*)</sup> indicates that the maximum residue limit has been set at or about the limit of analytical quantification.

The revised entry for saflufenacil 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)
Saflufenacil	372137-35-4	Saflufenacil	Edible Mammalian Offal	0.6
			Maize	0.01(*)
			Mammalian Fat	0.01
			Mammalian Meat	0.01
			Milk	0.01
			Pome fruits	0.01(*)

<sup>(\*)</sup> indicates that the maximum residue limit has been set at or about the limit of analytical quantification.

#### 3.4.1 Amendment Rationale

The proposed MRLs represent the expansion of use of a currently registered active ingredient. The proposed MRLs will manage the use of saflufenacil as a herbicide when used on pasture and 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	Saflufenacil
Use of compound	Herbicide
Chemical Abstract Services (CAS) Registry number	372137-35-4
Type of compound	Pyrimidinedione
Administration method	Spray

# 3.4.3 Good Agricultural Practice

Saflufenacil is proposed for use as a herbicide on pasture to be applied at 17.5 gai/ha prior to oversowing pasture, with no more than 2 applications, at least 21 days between applications and a 2 day grazing livestock withholding period and a 14 day slaughter withholding period.

#### 3.4.4 Residue Information

The residue data for the crops supports MRLs for saflufenacil of:

0.01 mg/kg in milk; 0.01 mg/kg mammalian meat; 0.01 mg/kg mammalian fat and 0.6 edible mammalian offal. 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 PDE $_{(food)}$  of 0.014 mg/kg bw/d was considered appropriate for use in the assessment. The proposed MRLs are:

- 0.01 mg/kg in milk
- 0.01 mg/kg in mammalian meat
- 0.01 mg/kg in mammalian fat
- 0.6 mg/kg in edible mammalian offal

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

# 3.4.6 Toxicological/Public Health Assessment

It has been determined that the use of saflufenacil as a herbicide in pasture treated according to GAP, 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)
Codex	Mammalian Liver	0.3
EU	Mammalian Liver	0.6
Japan	Mammalian Liver	0.8
USA	Mammalian Liver	50

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 PROPOSAL TO SET MRLS FOR SULFOXAFLOR

It is proposed that an MRL is set for sulfoxaflor when used on root and tuber vegetables, cucurbits (outdoor only) (except pumpkins and winter squash), fruiting vegetables (except sweetcorn and mushrooms), leafy vegetables and vegetable brassicas. The current entry for sulfoxaflor in Schedule One of the MRL Standards is <sup>1</sup>:

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	0.05
			offal	
			Mammalian fat	0.01(*)
			Milk	0.01(*)
			Mammalian muscle	0.01(*)
			Wheat grain	0.01(*)[

<sup>(\*)</sup> 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:

<sup>&</sup>lt;sup>1</sup> An MRL for barley grain of 0.01(\*) is included in the proposed Amendment (2) to the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2014. Consultation on that proposal closes on 30 December 2014.

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Sulfoxaflor	946578-00-3	Sulfoxaflor	Cauliflower	0.1
			Cucurbits (except pumpkins and winter	0.5
			squash) Edible mammalian	0.05
			offal	
			Head lettuce	1.0
			Fruiting vegetables	1.0
			(except sweetcorn	
			and mushrooms)	
			Leafy vegetables	5.0
			(except head lettuce)	
			Mammalian fat	0.01(*)
			Milk	0.01(*)
			Mammalian muscle	0.01(*)
			Root and Tuber	0.05
			vegetables	
			Vegetable brassicas	3.0
			(except cauliflower)	
			Wheat grain	0.01(*)

<sup>(\*)</sup> indicates that the maximum residue limit has been set at or about the limit of analytical quantification.

#### 3.5.1 Amendment Rationale

The proposed MRLs represent the expansion of use of a currently registered active ingredient. The proposed MRLs will manage the use of sulfoxaflor as an insecticide when used on root and tuber vegetables, cucurbits (except pumpkins and winter squash), fruiting vegetables (except sweetcorn and mushrooms), leafy vegetables and vegetable brassicas 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	Sulfoxaflor
Use of compound	Insecticide
Chemical Abstract Services (CAS) Registry number	946578-00-3
Type of compound	Sulfoximine
Administration method	Spray

# 3.5.3 Good Agricultural Practice

Sulfoxaflor is proposed for use as an insecticide on:

- Root and tuber vegetables at a maximum rate of 72 gai/ha to treat aphids with a maximum of 4 applications, with at least 14 day intervals and a 7 day withholding period.
- Cucurbits (except pumpkins and winter squash) at a maximum rate of 96 gai/ha to treat aphids and Greenhouse whitefly with a maximum of 4 applications, with at least 14 day intervals and a 1 day withholding period
- Fruiting vegetables (except sweetcorn and mushrooms) at a maximum rate of 96 gai/ha to treat aphids and Greenhouse whitefly with a maximum of 4 applications, with at least 14 day intervals and a 1 day withholding period
- Leafy vegetables at a maximum rate of 96 gai/ha to treat aphids and Greenhouse whitefly with a maximum of 4 applications, with at least 14 day intervals and a 3 day withholding period

 Vegetable brassicas at a maximum rate of 96 gai/ha to treat aphids and Greenhouse whitefly with a maximum of 4 applications, with at least 14 day intervals and a 3 day withholding period

#### 3.5.4 Residue Information

The residue data for the crops supports MRLs of sulfoxaflor of:

0.05 mg/kg in root and tuber vegetables; 0.1 mg/kg in cauliflower; 0.5 mg/kg in cucurbits (except pumpkins and winter squash); 1.0 mg/kg in head lettuce; 1.0 mg/kg in fruiting vegetables (except sweetcorn and mushrooms); 5.0 mg/kg in leafy vegetables (except head lettuce); 3.0 mg/kg vegetable brassicas (except cauliflower). These MRLs are proposed to support GAP.

# 3.5.5 Dietary Risk Assessment

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

0.05 mg/kg in root and tuber vegetables

- 0.1 mg/kg in cauliflower
- 0.5 mg/kg in cucurbits (except pumpkins and winter squash)
- 1.0 mg/kg in head lettuce
- 1.0 mg/kg in fruiting vegetables (except sweetcorn and mushrooms)
- 5.0 mg/kg in leafy vegetables (except head lettuce)
- 3.0 mg/kg vegetable brassicas (except cauliflower)

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 9% of the  $PDE_{(food)}$ . It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

# 3.5.6 Toxicological/Public Health Assessment

It has been determined that the use of sulfoxaflor as an insecticide for root and tuber vegetables, cucurbits (except pumpkins and winter squash), fruiting vegetables (except sweetcorn and mushrooms), leafy vegetables and vegetable brassicas treated according to GAP, is very unlikely to pose any health risks from consumption of treated produce.

#### 3.5.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Australia	Broccoli	3.0
	Brussel Sprouts	3.0
	Cabbages (Head)	3.0
	Cauliflower	0.1
	Cucurbits	0.5
	Fruiting Vegetables	1.0
	Lettuce (Head)	1.0
	Lettuce (Leafy)	5.0
	Carrot	0.05
	Potato	0.01
	Sweet Potato	0.05
Codex	Broccoli	3.0

	Cabbage (Head)	0.4
	Cauliflowers	0.04
	Cucurbits	0.5
	Fruiting Vegetables	1.5
	Leafy Vegetables	6.0
	Carrot	0.05
	Potato	0.03
	Sweet Potato	0.03
USA	Broccoli	2.0
	Brussel Sprouts	2.0
	Cabbages (Head)	2.0
	Cauliflower	0.8
	Cucurbits	0.4
	Fruiting Vegetables	0.7
	Leafy Vegetables	6.0
	Root and Tuber Vegetables	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.