

## Index for Appendix One: Technical information sheets for proposed MRLs

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## Proposed amendment to the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2007

### 1. Proposal to set a MRL for Abamectin

It is proposed that a MRL is set for Abamectin when used as an insecticide for tomatoes.

It is proposed that Schedule One of the NZ (MRL) Food Standards 2007 be amended by deleting the following MRL:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Abamectin	71751-41-2	Sum of : avermectin B1a avermectin B1b (Z)-8,9 avermectin B1a (Z)-8,9 avermectin B1b	Tomatoes	0.02(*)

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

As a replacement for the deleted MRL, it is proposed that Schedule One of the NZ (MRL) Food Standards 2007 be amended to include:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Abamectin	71751-41-2	Sum of : avermectin B1a avermectin B1b (Z)-8,9 avermectin B1a (Z)-8,9 avermectin B1b	Tomatoes	0.1

The final entry for Abamectin in Schedule One of the NZ (MRL) Food Standards 2007 will therefore read:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Abamectin	71751-41-2	Sum of : avermectin B1a avermectin B1b (Z)-8,9 avermectin B1a (Z)-8,9 avermectin B1b	Avocados Kiwifruit Liver Mammalian fats Meat Pome fruits Strawberries Tomatoes	0.02(*) 0.02(*) 0.015 0.02 0.01 0.02(*) 0.02(*) 0.1

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

### Chemical Information

Common name of compound	Abamectin
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<b>Use of compound</b>	Insecticide
<b>Chemical Abstract Services (CAS) Registry number</b>	71751-41-2
<b>Type of compound</b>	Avermectin
<b>Administration method</b>	Ground spray

### Good Agricultural Practice (GAP)

Abamectin is approved for use as an insecticide for tomatoes. Application may be up to 3 times per season as required, at 5.4-8.1gai/ha with a withholding period of 3 days.

### Residues Information

Abamectin currently has a MRL of 0.02mg/kg(\*) set for its use on tomatoes, however it has been determined this only represents its use on field tomatoes. When Abamectin is used to approved GAP on glasshouse tomatoes there is the potential for residues of up to 0.1mg/kg. A reassessed MRL of 0.1mg/kg is therefore proposed to support GAP.

### Dietary Risk Assessment

<b>Acceptable Daily Intake (ADI)</b>	0.002mg/kg bw/day
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The potential daily exposure via food ( $PDE_{(food)}$ ) is used for dietary intake calculations where a value has been set. An appropriate acceptable daily intake (ADI) is used in the absence of a  $PDE_{(food)}$ .

The chronic dietary exposure to Abamectin 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 Organisation, 1997].

The NEDI for Abamectin is equivalent to 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 Abamectin as an insecticide for use on tomatoes, according to the approved GAP, is very unlikely to pose any health risks from consumption of the harvested commodity.

### Other International MRLs

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

## Proposed amendment to the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2007

### 2. Proposal to set MRLs for Carprofen

It is proposed that MRLs are set for Carprofen when used as an anti-inflammatory drug for cattle and horses.

It is proposed that Schedule One of the NZ (MRL) Food Standards 2007 be amended to include the following; this will be the resulting entry for Carprofen in Schedule One of the NZ (MRL) Food Standards 2007:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Carprofen	53716-49-7	Carprofen	Cattle Fat	1
			Cattle Kidney	1
			Cattle Liver	1
			Cattle Meat	0.5
			Horse Fat	1
			Horse Kidney	1
			Horse Liver	1
			Horse Meat	0.5
			Milk	1

#### Chemical Information

Common name of compound	Carprofen
Use of compound	Anti-inflammatory
Chemical Abstract Services (CAS) Registry number	53716-49-7
Type of compound	Non-steroidal anti-inflammatory drug
Administration method	Intravenous and subcutaneous

#### Good Agricultural Practice (GAP)

Carprofen is proposed for use as an anti-inflammatory for cattle and horses. Application may be as necessary, at 1ml/35kg bw for cattle and 1ml/70kg bw for horses, with a withholding period of 21 days for cattle, 30 days for horses, and nil days for milk.

#### Residues Information

Residue data for cattle and horses support MRLs of 1mg/kg for liver, kidney and fat, and 0.5mg/kg for meat, at 30 days after the last treatment, and 1mg/kg for milk at 0 days after the last treatment. MRLs of 1mg/kg in liver, fat and kidneys of horse and cattle, and milk of cattle, and 0.5mg/kg in meat of horse and cattle are therefore proposed to support GAP.

## Dietary Risk Assessment

<b>Acceptable Daily Intake (ADI)</b>	0.005mg/kg bw/day
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The potential daily exposure via food ( $PDE_{(food)}$ ) is used for dietary intake calculations where a value has been set. An appropriate acceptable daily intake (ADI) is used in the absence of a  $PDE_{(food)}$ .

The chronic dietary exposure to Carprofen 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 Organisation, 1997].

The NEDI for Carprofen is equivalent to 30% 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 Carprofen as a anti-inflammatory drug for use on cattle and horses, according to the GAP specified above, is very unlikely to pose any health risks from consumption of animal products from treated animals.

## Other International MRLs

European Union		
Compound	Food	Maximum Residue Limit (mg/kg)
Carprofen	Cattle Fat	1
	Cattle Kidney	1
	Cattle Liver	1
	Cattle Meat	0.5
	Horse Fat	1
	Horse Kidney	1
	Horse Liver	1
	Horse Meat	0.5
	Milk	Exempt

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

## Proposed amendment to the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2007

### 3. Proposal to set MRLs for Fenpropidin

It is proposed that MRLs are set for Fenpropidin in animal products as a result of its use as a fungicide on barley and wheat for animal feed.

It is proposed that Schedule One of the NZ (MRL) Food Standards 2007 be amended to include:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Fenpropidin	67306-00-7	Fenpropidin	Mammalian fat	0.01(*)
			Mammalian kidney	0.02
			Mammalian liver	0.03
			Mammalian muscle	0.01(*)
			Milk	0.005(*)

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

The final entry for Fenpropidin in Schedule One of the NZ (MRL) Food Standards 2007 will therefore read:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Fenpropidin	67306-00-7	Fenpropidin	Barley	0.02(*)
			Mammalian fat	0.01(*)
			Mammalian kidney	0.02
			Mammalian liver	0.03
			Mammalian muscle	0.01(*)
			Milk	0.005(*)
			Wheat	0.02(*)

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

#### Chemical Information

<b>Common name of compound</b>	Fenpropidin
<b>Use of compound</b>	Fungicide
<b>Chemical Abstract Services (CAS) Registry number</b>	67306-00-7
<b>Type of compound</b>	Piperidine
<b>Administration method</b>	Ground and Aerial spray

## Good Agricultural Practice (GAP)

Fenpropidin is proposed for use as a fungicide for wheat and barley. Application may be throughout plant growth stages 29-33 and 39-49, at 750gai/ha with a withholding period of 70 days.

## Residues Information

Residue data for barley and wheat grains support MRLs of 0.02mg/kg\* at 70 days after the last treatment. MRLs of 0.02mg/kg have been set to regulate the above GAP.

### **Animal Transfer**

The NZFSA residue assessor has determined that limit of quantification MRLs of 0.01mg/kg can be set for mammalian fat and muscle, 0.005mg/kg can be set for milk, 0.02mg/kg can be set for kidney and 0.03mg/kg can be set for liver.

## Dietary Risk Assessment

ERMA NZ PDE <sub>(food)</sub>	0.016mg/kg bw/day
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The potential daily exposure via food (PDE<sub>(food)</sub>) is used for dietary intake calculations. The PDE<sub>(food)</sub> is a value set by the Environmental Risk Management Authority, and represents the proportion of the acceptable daily exposure (ADE) to a substance via the food route as relevant to the New Zealand population. The methodology for calculation of these values is set out in the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001 and can be found at [www.legislation.govt.nz](http://www.legislation.govt.nz).

The chronic dietary exposure to Fenpropidin 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 Organisation, 1997].

The NEDI for Fenpropidin is equivalent to 0.5% of the PDE<sub>(food)</sub>. 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 Fenpropidin as a fungicide for use on barley and wheat, according to the GAP specified above, is very unlikely to pose any health risks from consumption of the harvested commodity and through transfer into the tissues of grazing mammalian species.

## Other International MRLs

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

## Proposed amendment to the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2007

### 4. Proposal to set MRLs for Fenpropimorph

It is proposed that MRLs are set for Fenpropimorph when used as a fungicide for wheat and barley, and in animal products as a result of its use as a fungicide on barley and wheat for animal feed.

It is proposed that Schedule One of the NZ (MRL) Food Standards 2007 be amended by deleting the following:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Fenpropimorph	67564-91-4	Fenpropimorph	Cereal grains	0.5

As a replacement for the deleted MRL and to include animal products MRLs it is proposed that Schedule One of the NZ (MRL) Food Standards 2007 be amended by including the following; this will be the resulting entry for Fenpropimorph in Schedule One of the NZ (MRL) Food Standards 2007:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Fenpropimorph	67564-91-4	<i>Plant products:</i> Fenpropimorph	Barley	0.5
		<i>Animal products:</i> Sum of: Fenpropimorph and Fenpropimorph carboxylic acid	Mammalian kidney Mammalian liver Milk Wheat	0.1 1 0.01 0.05(*)
		<i>Expressed as:</i> Fenpropimorph equivalents		

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

### Chemical Information

Common name of compound	Fenpropimorph
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	67564-91-4
Type of compound	Morpholine
Administration method	Spray

### Good Agricultural Practice (GAP)

Fenpropimorph is proposed for use as a fungicide for wheat and barley. Application may be up until the end of flowering, at 375gai/ha with a withholding period of 42 days.

### Residues Information

A MRL of 0.5mg/kg is currently in place for barley and wheat for human consumption (cereal grains), however it has been determined that levels in wheat will not exceed the limit of detection at 42 days from the last treatment. A reassessed MRL of 0.05mg/kg\* is therefore proposed for wheat to support GAP. The MRL for Barley will remain at 0.5mg/kg.

### Animal Transfer

It has been determined that levels of up to 2.5mg/kg dry matter may be present in wheat straw and stubble for grazing 42 days after the last treatment. MRLs of 1mg/kg in mammalian liver, 0.1mg/kg in mammalian kidney and 0.01mg/kg in milk are proposed to accommodate for potential transfer of residues in to animal tissues following grazing of treated stubble or straw.

### Dietary Risk Assessment

<b>Acceptable Daily Intake (ADI)</b>	0.003mg/kg bw/day
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The potential daily exposure via food ( $PDE_{(food)}$ ) is used for dietary intake calculations where a value has been set. An appropriate acceptable daily intake (ADI) is used in the absence of a  $PDE_{(food)}$ .

The chronic dietary exposure to Fenpropimorph 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 Organisation, 1997].

The NEDI for Fenpropimorph is equivalent to 7% 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 Fenpropimorph as a fungicide for use on wheat, according to the GAP specified above, is very unlikely to pose any health risks from consumption of the harvested commodity and the consumption of animal products from animals grazing treated wheat and barley stubble and straw.

### Other International MRLs

The Netherlands		
Compound	Food	Maximum Residue Limit (mg/kg)
Fenpropimorph	Mammalian kidney	0.1(P)
	Mammalian liver	1(P)
	Mammalian milk	0.01

NOTE: (P) indicates these are provisional MRLs

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

## Proposed amendment to the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2007

### 5. Proposal to set a MRL for Mandipropamid

It is proposed that a MRL is set for Mandipropamid when used as a fungicide for potatoes.

It is proposed that Schedule One of the NZ (MRL) Food Standards 2007 be amended to include the following; this will be the resulting entry for Mandipropamid in Schedule One of the NZ (MRL) Food Standards 2007:

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

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

#### Chemical Information

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

#### Good Agricultural Practice (GAP)

Mandipropamid is proposed for use as a fungicide for potatoes. Application may be throughout early-to-mid season, at 150gai/ha at 10-14 day intervals with a withholding period of 14 days.

#### Residues Information

Residue data for potatoes support a limit of quantification MRL of 0.01mg/kg at 14 days after the last treatment. A MRL of 0.01mg/kg is therefore proposed to support GAP.

#### Dietary Risk Assessment

ERMA NZ PDE <sub>(food)</sub>	0.1mg/kg bw/day
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The potential daily exposure via food (PDE<sub>(food)</sub>) is used for dietary intake calculations. The PDE<sub>(food)</sub> is a value set by the Environmental Risk Management Authority, and represents the proportion of the acceptable daily exposure (ADE) to a substance via the food route as relevant to the New Zealand population. The methodology for calculation of these values is set out in the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001 and can be found at [www.legislation.govt.nz](http://www.legislation.govt.nz).

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

The NEDI for Mandipropamid is equivalent to 0.02% of the PDE<sub>(food)</sub>. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

### **Toxicological / Public Health Assessment**

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

### **Other International MRLs**

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

## Proposed amendment to the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2007

### 6. Proposal to set MRLs for Picoxystrobin

It is proposed that MRLs are set for Picoxystrobin when used as a fungicide for barley, and in animal products as a result of its use as a fungicide on barley and wheat for animal feed.

It is proposed that Schedule One of the NZ (MRL) Food Standards 2007 be amended by deleting the following MRL:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Picoxystrobin	117428-22-5	Picoxystrobin	Barley	0.01(*)

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

As a replacement for the deleted MRL and to promulgate animal products MRLs; it is proposed that Schedule One of the NZ (MRL) Food Standards 2007 be amended to include:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Picoxystrobin	117428-22-5	Picoxystrobin	Barley	0.2
			Mammalian fat	0.01(*)
			Mammalian meat	0.01(*)
			Mammalian offal	0.01(*)

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

The final entry for Picoxystrobin in Schedule One of the NZ (MRL) Food Standards 2007 will therefore read:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Picoxystrobin	117428-22-5	Picoxystrobin	Barley	0.2
			Mammalian fat	0.01(*)
			Mammalian meat	0.01(*)
			Mammalian offal	0.01(*)
			Wheat	0.01(*)

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

### Chemical Information

Common name of compound	Picoxystrobin
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	117428-22-5
Type of compound	Strobilurin

<b>Administration method</b>	Spray
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### Good Agricultural Practice (GAP)

Picoxystrobin is proposed for use as a fungicide for barley. Application may be once per growing season, at 190gai/ha with a withholding period of 35 days for cereal grains and 28 days for grazing of green feed or making of silage.

### Residues Information

The GAP for picoxystrobin use on barley has changed with a reduction in the withholding period from 70 days to 35 days, this allows treatment of fungal diseases later in the season, and consequently the expected concentration of residues in the harvested commodity has increased.

Residue data for barley support a MRL of 0.2mg/kg at 35 days after the last treatment. A MRL of 0.2mg/kg is therefore proposed to support GAP. The proposed MRL will replace a limit of quantification MRL of 0.01mg/kg for barley.

### Animal Transfer

As cereals are recognised as forage crops the residues in treated crops have been analysed for their transfer in to the tissues of grazing animals, and because no residues are expected to result in animal products following the grazing of crops treated to GAP, animal transfer MRLs of 0.01mg/kg for mammalian meat, fat and offal are proposed.

### Dietary Risk Assessment

<b>Acceptable Daily Intake (ADI)</b>	0.043mg/kg bw/day
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The potential daily exposure via food ( $PDE_{(food)}$ ) is used for dietary intake calculations where a value has been set. An appropriate acceptable daily intake (ADI) is used in the absence of a  $PDE_{(food)}$ .

The chronic dietary exposure to Picoxystrobin 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 Organisation, 1997].

The NEDI for Picoxystrobin is equivalent to 0.12% 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 Picoxystrobin as a fungicide for use on barley, according to the GAP specified above, is very unlikely to pose any health risks from consumption of the harvested commodity, and from consumption of animal products from animals grazing on treated commodities.

### Other International MRLs

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

## Proposed amendment to the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2007

### 7. Proposal to set a MRL for Pyrimethanil

It is proposed that a MRL is set for Pyrimethanil when used as a fungicide for apples.

It is proposed that Schedule One of the NZ (MRL) Food Standards 2007 be amended to include:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Pyrimethanil	53112-28-0	Pyrimethanil	Apples	0.05(*)

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

The final entry for Pyrimethanil in Schedule One of the NZ (MRL) Food Standards 2007 will therefore read:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Pyrimethanil	53112-28-0	Pyrimethanil	Apples Grapes	0.05(*) 5

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

#### Chemical Information

Common name of compound	Pyrimethanil
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	53112-28-0
Type of compound	Pyrimidine
Administration method	Spray

#### Good Agricultural Practice (GAP)

Pyrimethanil is proposed for use as a fungicide for apples. Application may be between tight cluster and 90% petal fall at 20gai/ha but must not be after 90% petal fall.

#### Residues Information

Residue data for apples support a limit of quantification MRL of 0.05mg/kg when the last treatment is before 90% petal fall. A MRL of 0.05mg/kg\* is therefore proposed to support GAP.

#### Dietary Risk Assessment

Acceptable Daily Intake (ADI)	0.1mg/kg bw/day
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The potential daily exposure via food ( $PDE_{(food)}$ ) is used for dietary intake calculations where a value has been set. An appropriate acceptable daily intake (ADI) is used in the absence of a  $PDE_{(food)}$ .

The chronic dietary exposure to Pyrimethanil 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 Organisation, 1997].

The NEDI for Pyrimethanil is equivalent to 3% of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

### **Toxicological / Public Health Assessment**

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

### **Other International MRLs**

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

## Proposed amendment to the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2007

### 8. Proposal to set MRLs for Spinetoram

It is proposed that MRLs are set for Spinetoram when used as an insecticide for apples and pears.

It is proposed that Schedule One of the NZ (MRL) Food Standards 2007 be amended to include the following; this will be the resulting entry in Schedule One of the NZ (MRL) Food Standards 2007:

Compound	CAS#	Residue definition	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	0.05 0.05

#### Chemical Information

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

#### Good Agricultural Practice (GAP)

Spinetoram is proposed for use as an insecticide for apples and pears. Application may be throughout mid-to-late season at 2.5gai/100L with a withholding period of 7 days.

#### Residues Information

Residue data for apples and pears support MRLs of 0.05mg/kg at 7 days after the last treatment. MRLs of 0.05mg/kg are therefore proposed to support GAP.

#### Dietary Risk Assessment

Provisional ERMA NZ PDE <sub>(food)</sub>	0.024mg/kg bw/day
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The potential daily exposure via food (PDE<sub>(food)</sub>) is used for dietary intake calculations. The PDE<sub>(food)</sub> is a value set by the Environmental Risk Management Authority, and represents the proportion of the acceptable daily exposure (ADE) to a substance via the food route as relevant to the New Zealand population. The methodology for calculation of these values is set out in the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001 and can be found at [www.legislation.govt.nz](http://www.legislation.govt.nz).

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 Organisation, 1997].

The NEDI for Spinetoram is equivalent to 0.2% 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 Spinetoram as an insecticide for use on apples and pears, according to the GAP specified above, is very unlikely to pose any health risks from consumption of the harvested commodity.

### **Other International MRLs**

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

## Proposed amendment to the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2007

### 9. Proposal to set a MRL for Spinosad

It is proposed that a MRL is set for Spinosad when used as an insecticide for stonefruit.

It is proposed that Schedule One of the NZ (MRL) Food Standards 2007 be amended by deleting the following MRL:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Spinosad	168316-95-8 (131929-60-7 + 131929-63-0)	<i>Sum of:</i> spinosyn A spinosyn D <i>Expressed as:</i> Spinosad	Stone fruits	0.2

As a replacement for the deleted MRL, it is proposed that Schedule One of the NZ (MRL) Food Standards 2007 be amended to include:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Spinosad	168316-95-8 (131929-60-7 + 131929-63-0)	<i>Sum of:</i> spinosyn A spinosyn D <i>Expressed as:</i> Spinosad	Stone fruits	1

The final entry for Spinosad in Schedule One of the NZ (MRL) Food Standards 2007 will therefore read:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Spinosad	168316-95-8 (131929-60-7 + 131929-63-0)	<i>Sum of:</i> spinosyn A spinosyn D <i>Expressed as:</i> Spinosad	Citrus fruits Kiwifruit Potatoes Sheep fat Sheep kidney Sheep liver Sheep meat Stone fruits Tomatoes	0.05 0.2 0.01(*) 0.2 0.05 0.05 0.05 1 0.01(*)

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

### Chemical Information

Common name of compound	Spinosad
Use of compound	Insecticide
Chemical Abstract Services (CAS) Registry number	168316-95-8 (131929-60-7 + 131929-63-0)
Type of compound	Spinosyn
Administration method	Spray

## Good Agricultural Practice (GAP)

Spinosad is currently approved with a withholding period of 28 when used on stonefruits, however there has been a requirement for a shorter withholding period to control insect pests upto harvest. Spinosad is proposed for use as an insecticide for stonefruit. Application may be up until late season at an application rate of 4.8gai/100L with a withholding period of 1 day.

## Residues Information

Residue data for stonefruit support a MRL of 1mg/kg at 1 day after the last treatment. A MRL of 1mg/kg is therefore proposed to support GAP.

## Dietary Risk Assessment

Acceptable Daily Intake (ADI)	0.02mg/kg bw/day
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The potential daily exposure via food ( $PDE_{(food)}$ ) is used for dietary intake calculations where a value has been set. An appropriate acceptable daily intake (ADI) is used in the absence of a  $PDE_{(food)}$ .

The chronic dietary exposure to Spinosad 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 Organisation, 1997].

The NEDI for Spinosad is equivalent to 2% 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 Spinosad as an insecticide for use on stonefruit, according to the good agricultural practice specified above, is very unlikely to pose any health risks from consumption of the harvested commodity.

## Other International MRLs

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

## Proposed amendment to the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2007

### 10. Proposal to exempt 2-Propenoic acid, polymer with 2-propenal from the MRL Standards

It is proposed that a MRL exemption is set for 2-Propenoic acid, polymer with 2-propenal when used for broilers and swine.

It is proposed that Schedule Three of the NZ (MRL) Food Standards 2007 be amended to include the following; this will be the resulting entry for 2-Propenoic acid, polymer with 2-propenal in Schedule Three of the NZ (MRL) Food Standards 2007:

Compound	CAS#	Condition
2-Propenoic acid, polymer with 2-propenal	28349-72-6	When used for the management of intestinal health in broiler chickens and swine

#### Chemical Information

Common name of compound	2-Propenoic acid, polymer with 2-propenal
Use of compound	Anti-microbial
Chemical Abstract Services (CAS) Registry number	28349-72-6
Type of compound	Not classified
Administration method	Oral, within the drinking water

#### Good Agricultural Practice (GAP)

2-Propenoic acid, polymer with 2-propenal is proposed for use in the management of gastro-intestinal health in broiler chickens and swine. Application may be throughout animal growth, at 3mg a.i./kg bw/day until slaughter.

#### Residues Information

2-Propenoic acid, polymer with 2-propenal does not have a consistent residue definition. Given how the polymer is synthesised, the structure of the parent compound can vary. Its metabolism in animal tissues is considerably varied with the formation of many different metabolites, most of which are undetectable without radiolabels. It is therefore considerably difficult to accurately measure a residue in animal tissues resulting from the use of this product. This is the primary reason for recommending the exemption of 2-Propenoic acid, polymer with 2-propenal from a MRL. The recommended exemption is also supported by its very low toxicity and bioavailability in consumed tissues.

#### Dietary Risk Assessment

Acceptable Daily Intake (ADI)	0.5mg/kg bw/day
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Given the low bioavailability of 2-Propenoic acid, polymer with 2-propenal, coupled with its low toxicity, it is estimated that the dietary burden resulting from consumption of tissues of treated animals will be below 0.01% of the ADI.

### **Toxicological / Public Health Assessment**

It has been determined that the use of 2-Propenoic acid, polymer with 2-propenal as an anti-microbial for use in broilers and swine, according to the GAP specified above, is very unlikely to pose any health risks from consumption of the tissues of treated animals.

### **Other International MRLs**

<b>European Union</b>			
<b>Compound</b>	<b>Residue definition</b>	<b>Food</b>	<b>MRL (mg/kg)</b>
2-Propenoic acid, polymer with 2-propenal	Not specified	All foods	Exempt

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

## Proposed amendment to the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2007

### 11. Proposal to exempt Microbial Pesticide Organisms from the MRL Standards

It is proposed that microbial pesticide organisms be exempt from the NZ (Maximum Residue Limits of Agricultural Compounds and Veterinary Medicines) Food Standards 2007.

It is proposed that Schedule Two of the NZ (MRL) Food Standards 2007 be amended by deleting the following MRL exemptions:

Compound	CAS#	Condition
<i>Agrobacterium radiobacter</i> strain: K84 K1026	n/a	Used as a beneficial bacterium in the treatment and prevention of crown gall infections on food producing plant species
<i>Bacillus subtilis</i> strain: QST713	n/a	Used as a fungicide or bactericide on food producing plant species
<i>Beauveria bassiana</i> strains: Those indigenous to New Zealand	63428-82-0	Used as a biological insecticide for the control of aphids, thrips and whitefly on food producing plant species
<i>Cydia pomonella granulosis virus</i> strain: Mexican	n/a	Used to control codling moth larvae on food producing plant species

As a replacement for the deleted MRL exemptions it is proposed that Schedule Two of the NZ (MRL) Food Standards 2007 be amended to include the following exemption; this will be the resulting entry in Schedule Two of the NZ (MRL) Food Standards 2007.

Compound	CAS#	Condition
<i>Microbial Pesticide Organisms (consisting of either; whole organism, organism organelles, organism spores or occlusion bodies and genetically modified serotypes and strains)</i>	n/a	Except where otherwise stated in the NZ (MRL) Food Standards 2007: Where organism is registered under the Agricultural Compounds and Veterinary Medicines Act 1997 and intended for use as a plant compound, and; Where organism leaves no quantifiable residue of toxins or metabolites exceeding that of expected background levels, and; Where organism has been determined to be non-pathogenic or non-toxic to humans.

#### Purpose

Microbial pesticide organisms have become an important part of New Zealand agriculture. In the majority they are seen to represent a safer and more sustainable option of pest control and improvement of crop growing conditions.

## Chemical Information

<b>Name of Organism:</b>	<i>Microbial Pesticide Organism (consisting of either; whole organism, organism organelles, organism spores or occlusion bodies and genetically modified serotypes and strains)</i>
<b>Genus:</b>	All genus of protozoal, prokaryotic, viral and nematode organisms meeting exemption conditions
<b>Strains:</b>	All strains of the above genus (including genetically modified) that meet the exemption conditions
<b>Use of compound:</b>	Plant compound (Insecticide, Bactericide, Fungicide, Herbicide, Plant Growth Regulator and Nematicide)

## Residues Information

It is proposed that microbial pesticide organisms be included in the MRL standard as an exemption when used as a plant compound for any crops to relevant specified good agricultural practice.

The format for measuring residues of microbial pesticide organisms differs significantly from chemical pesticides, as levels are determined in colony forming units or similar microbiological terminology. Levels of the organism do not spread consistently throughout plant tissues and are not distributed evenly through the field as they are dependant on environmental factors. The majority of registered microbial pesticide organisms are also naturally present in the environment.

This exemption is proposed to cover registered microbial pesticides where the whole organism or organism structure is the active ingredient and the source of the residue. Organisms that act through production of a chemical toxin or bio-pesticides consisting of the produced toxin are not intended to be covered by this exemption.

## Breakdown Products / metabolites /significant microbial toxins

Organisms expressing detectable chemical breakdown products or toxins that exceed expected background environmental levels are not encompassed by this exemption.

## Dietary Risk Assessment

This exemption is intended as a generic exemption for registered microbial pesticide organisms that either through their natural presence in the diet or through no human pathogenicity, represent no additional dietary risk to New Zealand consumers.

## Current MRLs

Compound	CAS#	Condition
<i>Agrobacterium radiobacter</i> strains: K84 K1026	n/a	Used as a beneficial bacterium in the treatment and prevention of crown gall infections on food producing plant species
<i>Bacillus subtilis</i> strain: QST713	n/a	Used as a fungicide or bactericide on food producing plant species
<i>Bacillus thuringiensis</i>	68038-71-1	Used as an insecticide
<i>Beauveria bassiana</i> strains: Those indigenous to New Zealand	63428-82-0	Used as a biological insecticide for the control of aphids, thrips and whitefly on food producing plant species
<i>Cydia pomonella granulosis</i> Virus strain: Mexican	n/a	Used to control codling moth larvae on food producing plant species

## International MRLs

Country and substance	Type of MRL	Condition
<b>US</b>		
<i>Bacillus subtilis</i> strain QST 713	Exemption	When used according to label directions
<i>Beauveria bassiana</i>	Exemption	When applied or used as ground and aerial foliar sprays for use only on terrestrial crops.
<i>Beauveria bassiana</i> strain: GHA	Exemption	When applied to growing crops according to good agricultural practices.
Occlusion bodies of the <i>granulosis virus</i> of <i>cydia pomonella</i>	Exemption	No condition of use applies
<i>Streptomyces lydicus</i> strain WYEC 108	Exemption	When used in or on all agricultural commodities when applied/used in accordance with label directions.
<b>Australia</b>		
<i>Agrobacterium radiobacter</i> strains: K84, K1026	Exemption	For the control of crown gall
<i>Bacillus licheniformis</i>	Exemption	When used to control Fusarium wilt in cotton
<i>Bacillus subtilis</i>	Exemption	When used to control Fusarium wilt in cotton
<i>Bacillus thuringiensis</i> Berliner subsp <i>aizawai</i>	Exemption	For use as an insecticide on food and non-food producing crops and ornamentals
<i>Bacillus thuringiensis kurstaki</i> delta endotoxin encapsulated in killed <i>Pseudomonas fluorescens</i>	Exemption	As an insecticide for cotton, pome fruits, stone fruits, grapes and vegetables
<i>Bacillus thuringiensis kurstaki</i> delta endotoxin protein	Exemption	Insecticide expressed in recombinant cotton
<i>Bacillus thuringiensis</i> Berliner subsp <i>kurstaki</i>	Exemption	For use as an insecticide on food and non-food producing crops, ornamentals, amenity plantings and in forestry
<i>Metarhizium anisopliae</i>	Exemption	Soil treatment for the control of the Red Headed Cockchafer (Pasture scarab), as a soil treatment for the control of Greyback Canegrub in bananas, papaya (paw paw), pineapple, sugarcane and taro, for the control of the Australian Plague Locust (adult and nymphs), Wingless Grasshopper, Spur Throated Locust and Migratory Locust {T} External treatment for the control of cattle tick ( <i>boophilus microplus</i> ) on beef cattle {T}, for the control of whitefly ( <i>Bemesia tabaci</i> ) on flowers and vegetables
<i>Neoplectana bibionis</i>	Exemption	Biological control of currant borer
Nuclear Polyhedrosis Virus <i>Heliothis</i>	Exemption	Insecticide
<i>Pseudomonas fluorescens</i>	Exemption	Control of bacterial blotch in cultivated mushrooms
<i>Trichoderma harzianum</i>	Exemption	Fungicide on grapevines
<i>Xenorhabdus nematophilus</i>	Exemption	Biological control of currant borer

## Explanatory note

The purpose of the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standard (MRL standard) is to define the maximum levels of agricultural compounds in food commodities for the purposes of providing regulation for the good agricultural practice of agricultural compounds. The MRL standard functions through defining a maximum concentration for a single or combination of chemical residues that is expected to occur from the use of an agricultural compound product. However as this function relies solely on the ability to detect and distinguish a significant chemical residue it cannot be applied universally to all agricultural compounds. To allow for this, the Standard also contains Schedule 2 and 3 which detail cases where certain compounds or organisms have been determined to not fit the criteria of a MRL and thus have been exempted from the requirement of having a MRL defined.

This proposal details the requested amendment to the MRL standard to include a generic exemption for microbial pesticides into Schedule 2 (exemptions for plant compounds). The rationale for the proposal is to legally promulgate the current NZFSA policy position that microbial pesticides do not fit the criteria for having a MRL defined in the MRL standard. The primary rationale for this determination is that as organisms, the majority of microbial pesticides do not leave a typical chemical residue. Therefore to regulate their use through setting a defined residue limit is unfeasible. As many of the currently used microbial pesticides are also indigenous to the environment, the determination of a residue figure becomes complicated by variation in background levels.

There are exceptions to this determination in that certain microbial pesticides act through the production of microbial toxins to produce the desired pesticidal effect. The proposed exemption contains a clause to omit these organisms from the generic exemption. This situation will be the case for bacillus thuringiensis, which acts as an insecticide through the formation of delta-endotoxins. These may leave a detectable chemical residue in certain cases. Bacillus thuringiensis will remain as a separate MRL exemption in Schedule 2 when the proposed generic microbial pesticide exemption comes into effect.

Whilst this proposed MRL exemption will allow applicable microbial pesticides to be waived from the requirement of complying with the New Zealand MRL Standard, it will not affect the requirements that organisms and products containing these organisms have under the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act). The exemption contains a clause to detail that the applicable microbial pesticides still have a requirement to have been assessed and registered as agricultural compounds under the ACVM Act. In undertaking registration the applicants for applicable microbial pesticide products are still required to identify that the use of their product represents good agricultural practice and that there is no risk to public health from the consumption of treated food commodities. This later risk assessment is reinforced by the provision of a condition to prevent organisms, pathogenic or toxic to humans, to be included within the MRL exemption. In addition as stipulated in Section 21(5) of the ACVM Act, the product prior to registration must have been demonstrated to have been assessed for approval under the Hazardous Substances and New Organisms Act 1996.

Finally, there may be situations other than those specified in the exemptions conditions where NZFSA may determine an organism not suitable to be encompassed by the generic exemption. The exemptions conditions manage this through the clause: "Except where otherwise stated in the NZ (MRL) Food Standards 2007." This gives NZFSA the ability to determine a specific MRL or separate exemption where necessary in the best interests of managing the use or residues of the organism.