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Proposed amendment to the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2006

1. Proposal to set MRLs for Closantel

It is proposed that MRLs are set for closantel when used as an anthelmintic for cattle.

It is proposed that Schedule One of the NZ (MRL) Food Standards 2006 be amended to include:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Closantel	57808-65-8	Closantel	Cattle fat	3
			Cattle kidney	3
			Cattle liver	1
			Cattle muscle	1

The resulting entry for closantel in Schedule One of the NZ (MRL) Food Standards 2006 will therefore read:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Closantel	57808-65-8	Closantel	Cattle fat	3
			Cattle kidney	3
			Cattle liver	1
			Cattle muscle	1
			Edible offal of sheep	5
			Sheep meat	2

Chemical Information

Common name of compound	Closantel
Use of compound	Anthelmintic
Chemical Abstract Services (CAS) Registry number	57808-65-8
Type of compound	Salicylanilide
Administration method	Subcutaneous Injection

Residues Information

The proposed closantel MRLs have been determined in order to manage residues resulting from good agricultural practice (GAP) as determined by Codex Alimentarius.

Dietary Risk Assessment

Acceptable Daily Intake (ADI)	0.03mg/kg bw/day
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For dietary intake calculations the potential daily exposure via food ($PDE_{(food)}$) is used if a value has been set by New Zealand's Environmental Risk Management Authority. In the absence of a $PDE_{(food)}$ an appropriate acceptable daily intake (ADI) is used instead. In the case of closantel, the ADI has been set by the Joint Expert Committee on Food Additives (JECFA).

The chronic dietary exposure to closantel 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 for closantel is equivalent to 10% of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Public Health Risk Assessment

It has been determined that the use of closantel as an injectable anthelmintic for cattle is very unlikely to pose any toxicological health risks from consumption of the processed cattle fat, kidney, liver or muscle.

Consideration of International MRLs

Codex MRLs

As specified in the NZ (MRL) Food Standards 2006 imported foods may contain agricultural compounds no greater than the level specified by Codex Alimentarius, thus for imported food containing this agricultural compound the following Codex Alimentarius MRLs are applicable:

Compound	Food	Maximum Residue Limit (mg/kg)
Closantel	Cattle fat	3
	Cattle kidney	3
	Cattle liver	1
	Cattle muscle	1

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 2006

2. Proposal to set a MRL for Doramectin

It is proposed that a MRL is set for doramectin when used as an anthelmintic for cattle.

It is proposed that Schedule One of the NZ (MRL) Food Standards 2006 be amended to include:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Doramectin	117704-25-3	Doramectin	Milk	0.015

The resulting entry for doramectin in Schedule One of the NZ (MRL) Food Standards 2006 will therefore read:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Doramectin	117704-25-3	Doramectin	Cattle fat	0.15
			Cattle kidney	0.03
			Cattle liver	0.1
			Cattle meat	0.01
			Milk	0.015
			Pig fat	0.15
			Pig kidney	0.03
			Pig liver	0.1
			Pig meat	0.01
			Sheep fat	0.15
			Sheep kidney	0.03
			Sheep liver	0.1
			Sheep meat	0.01

Chemical Information

Common name of compound	Doramectin
Use of compound	Veterinary anthelmintic
Chemical Abstract Services (CAS) Registry number	117704-25-3
Type of compound	Avermectin
Administration method	Topical

Residues Information

The proposed doramectin MRL has been determined in order to manage residue resulting from good agricultural practice (GAP) as determined by Codex Alimentarius

Dietary Risk Assessment

Acceptable Daily Intake (ADI)	0.001mg/kg bw/day
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For dietary intake calculations the potential daily exposure via food ($PDE_{(food)}$) is used if a value has been set by New Zealand's Environmental Risk Management Authority. In the absence of a $PDE_{(food)}$, an appropriate acceptable daily intake (ADI) is used instead. In the case of doramectin, the ADI has been set by the Joint Expert Committee on Food Additives (JECFA).

The chronic dietary exposure to doramectin is estimated by the National Estimated Dietary Intake (NEDI) calculation encompassing all registered uses of the chemical and food consumption data based upon the 2006 World Health Organisation's Global Environmental Monitoring System (Cluster Diet: M) and the 1995 National Nutrition Survey of Australia, for children.

The NEDI for doramectin is equivalent to approximately 60% of the ADI. It is therefore concluded that the chronic dietary exposure is tolerable and the risk posed is acceptable.

Public Health Risk Assessment

It has been determined that the use of doramectin as a topical anthelmintic on cattle is very unlikely to pose any toxicological health risks from consumption of milk.

Consideration of International MRLs

Codex MRLs

As specified in the NZ (MRL) Food Standards 2006 imported foods may contain agricultural compounds no greater than the level specified by Codex Alimentarius, thus for imported food containing this agricultural compound the following Codex Alimentarius MRLs are applicable:

Compound	Food	Maximum Residue Limit (mg/kg)
Doramectin	Milk	0.015

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 2006

3. Proposal to set MRLs for Fenpropidin

It is proposed that MRLs are set for fenpropidin when used as a fungicide for barley and wheat.

It is proposed that Schedule One of the NZ (MRL) Food Standards 2006 be amended to include the following, this will be the resulting entry for fenpropidin in Schedule One of the NZ (MRL) Food Standards 2006:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Fenpropidin	67306-00-7	Fenpropidin	Barley Wheat	0.02(*) 0.02(*)

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

Chemical Information

Common name of compound	Fenpropidin
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	67306-00-7
Type of compound	Piperidine
Administration method	Foliar 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 from trials reflecting the above GAP indicate that no measurable residues should be present in grain at harvest 70 days after the last treatment. An MRL of 0.02mg/kg* is therefore proposed to support GAP.

Dietary Risk Assessment

ERMA NZ PDE_(food)	0.016mg/kg bw/day
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The potential daily exposure via food (PDE_(food)) is used for dietary intake calculations. The PDE_(food) 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.

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 4% of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Public Health Assessment

It has been determined that the use of fenpropidin as a fungicide for use on barley and wheat, according to the good agricultural practice specified above, is very unlikely to pose any toxicological health risks from consumption of the harvested commodity.

Consideration of International MRLs

Codex MRLs

As specified in the NZ (MRL) Food Standards 2006 imported foods may contain agricultural compounds no greater than the level specified by Codex Alimentarius, currently no Codex Alimentarius MRLs have been determined for this agricultural compound.

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 2006

4. Proposal to set a MRL for Mesotrione

It is proposed that a MRL is set for mesotrione when used as a herbicide for maize.

It is proposed that Schedule One of the NZ (MRL) Food Standards 2006 be amended to include the following, this will be the resulting entry for mesotrione in Schedule One of the NZ (MRL) Food Standards 2006:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Mesotrione	104206-82-8	Mesotrione	Maize	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	Mesotrione
Use of compound	Herbicide
Chemical Abstract Services (CAS) Registry number	104206-82-8
Type of compound	Benzoylcyclohexanedione
Administration method	Boom spraying

Good Agricultural Practice (GAP)

Mesotrione is proposed for use as a broadleaf herbicide for maize. Application may be as a pre-emergent treatment at 168-216 gai/ha, or a post-emergent treatment before crops reach the second leaf stage or 75cm in height at 72-96 gai/ha.

Residues Information

Residue data from trials reflecting the above GAP indicate that measurable residues should not occur in grain from maize treated according to the above GAP. An MRL of 0.01 mg/kg* is therefore proposed to support GAP.

Dietary Risk Assessment

Acceptable Daily Intake (ADI)	0.01mg/kg bw/day
Acceptable Daily Exposure (ADE)	0.01mg/kg bw/day
ERMA NZ PDE_(food)	0.006mg/kg bw/day

The potential daily exposure via food ($PDE_{(food)}$) is used for dietary intake calculations. The $PDE_{(food)}$ 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.

The chronic dietary exposure to mesotrione 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 mesotrione is equivalent to 4% of the $PDE_{(food)}$. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Public Health Assessment

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

Consideration of International MRLs

Codex MRLs

As specified in the NZ (MRL) Food Standards 2006 imported foods may contain agricultural compounds no greater than the level specified by Codex Alimentarius, currently no Codex Alimentarius MRLs have been determined for this agricultural compound.

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 2006

5. Proposal to set a MRL for Pinoxaden

It is proposed that a MRL is set for Pinoxaden when used as a herbicide for cereal grains.

It is proposed that Table One of the NZ (MRL) Food Standards 2006 be amended to include the following, this will be the resulting entry for pinoxaden in Schedule One of the NZ (MRL) Food Standards 2006:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Pinoxaden	243973-20-8	Sum of: Pinoxaden and its M2 metabolite: (8-(2,6-diethyl-4-methyl-phenyl)-tetrahydro-9H-pyrazolo[1,2-d][1,4,5]oxadiazepine-7,9-dione <i>expressed as:</i> Pinoxaden	Cereal grains	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	Pinoxaden
Use of compound	Herbicide
Chemical Abstract Services (CAS) Registry number	243973-20-8
Type of compound	Phenylpyrazolin herbicide
Administration method	Boom spray

Good Agricultural Practice (GAP)

Pinoxaden is proposed for use as a herbicide for wheat and barley. GAP is for use as a boom spray (25-30 g ai/ha) when grass weeds are between the third leaf stage and the first node formation, with a withholding period of 70 days.

Residues Information

Residue data from trials reflecting the above GAP on wheat and barley indicate that measurable residues should not occur in grain at harvest, 70 days after treatment. The residue assessment has also indicated that this conclusion can be extended to include all cereals. An MRL of 0.01mg/kg* for cereal grains is therefore proposed to support GAP.

Dietary Risk Assessment

ERMA NZ Acceptable Daily Exposure (ADE)	0.1 mg/kg bw/day
ERMA NZ PDE_(food)	0.06 mg/kg bw/day

The potential daily exposure via food (PDE_(food)) is used for dietary intake calculations. The PDE_(food) 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.

The chronic dietary exposure to Pinoxaden 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 Pinoxaden is equivalent to 0.02% of the PDE_(food). It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Public Health Assessment

It has been determined that the use of Pinoxaden as a herbicide for use on wheat and barley, according to the GAP specified above, is very unlikely to pose any toxicological health risks from consumption of the harvested commodity.

Consideration of International MRLs**Codex MRLs**

As specified in the NZ (MRL) Food Standards 2006 imported foods may contain agricultural compounds no greater than the level specified by Codex Alimentarius, currently no Codex Alimentarius MRLs have been determined for this agricultural compound.

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 2006

6. Proposal to set MRLs for Ractopamine

It is proposed that MRLs are set for ractopamine when used as a growth stimulant for pigs.

It is proposed that Schedule One of the NZ (MRL) Food Standards 2006 be amended to include the following, this will be the resulting entry for ractopamine in Schedule One of the NZ (MRL) Food Standards 2006:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Ractopamine	97825-25-7	Ractopamine	Pig fat Pig kidney Pig liver Pig muscle	0.01 0.09 0.04 0.01

Chemical Information

Common name of compound	Ractopamine
Use of compound	Growth stimulant
Chemical Abstract Services (CAS) Registry number	97825-25-7
Type of compound	Adrenergic beta-agonist
Administration method	Orally in animal feed

Residues Information

Residue data for pigs supports MRLs of 0.01mg/kg for fat and muscle, 0.04mg/kg for liver and 0.09mg/kg for kidney at 12 hours after the last treatment.

Dietary Risk Assessment

Acceptable Daily Intake (ADI)	0.001mg/kg bw/day
Acceptable Daily Exposure (ADE)	0.001mg/kg bw/day
ERMA NZ PDE_(food)	0.001mg/kg bw/day

The potential daily exposure via food (PDE_(food)) is used for dietary intake calculation where a value has been set. The PDE_(food) 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.

The chronic dietary exposure to ractopamine 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 for ractopamine is equivalent to 2% of the ADI/PDE_(food). It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Public Health Assessment

It has been determined that the use of ractopamine as a growth stimulant for use on pigs, according to GAP, is very unlikely to pose any toxicological health risks from consumption of the processed pig fat, liver, kidney and muscle.

Consideration of International MRLs

Codex MRLs

As specified in the NZ (MRL) Food Standards 2006 imported foods may contain agricultural compounds no greater than the level specified by Codex Alimentarius, currently no Codex Alimentarius MRLs have been determined for this agricultural compound.

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 2006

7. Proposal to set MRLs for Trifloxystrobin

It is proposed that MRLs are set for trifloxystrobin when used as a fungicide for citrus fruits, grapes and stone fruits.

It is proposed that Table One of the NZ (MRL) Food Standards 2006 be amended to include:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Trifloxystrobin	141517-21-7	<i>Sum of:</i> trifloxystrobin and its free acid metabolite. <i>expressed as:</i> trifloxystrobin equivalents	Citrus (except Clementine and Satsuma mandarins)	0.3
			Grapes	0.02(*)
			Mandarins (Clementine/ Satsuma)	0.02(*)
			Stone fruits (except cherries)	0.02(*)

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

The resulting entry for trifloxystrobin in Schedule One of the NZ (MRL) Food Standards 2006 will therefore read:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Trifloxystrobin	141517-21-7	<i>Sum of:</i> trifloxystrobin and its free acid metabolite. <i>expressed as:</i> trifloxystrobin equivalents	Cereal grains	0.05(*)
			Citrus (except Clementine and Satsuma mandarins)	0.3
			Cucurbits (inedible peel)	0.02(*)
			Grapes	0.02(*)
			Kiwifruit	0.02(*)
			Mandarins (Clementine/ Satsuma)	0.02(*)

			Pome fruits	0.02(*)
			Stone fruits (except cherries)	0.02(*)

Chemical Information

Common name of compound	Trifloxystrobin
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	141517-21-7
Type of compound	Strobilurin derivative
Administration method	Foliar spray

Good Agricultural Practice (GAP)

Citrus fruits: Trifloxystrobin is proposed for use as a fungicide on citrus. GAP is for foliar spray application over the flowering/fruit set period at a rate of 5gai/100 litres of water, with a repeat application up to one month after fruit set. Withholding periods of 120 days for mandarins (Clementine/Satsuma), and 28 days for other citrus fruit are consistent with this GAP.

Grapes: Trifloxystrobin is proposed for use as a fungicide on grapes. GAP is for foliar spray applications over flowering and up to bunch-closure at 14 day intervals at a rate of 6.25 gai/100 litres. A withholding period of 56 days is consistent with this GAP.

Stone fruits (except cherries): Trifloxystrobin is proposed for use as a fungicide on stone fruits (except cherries). GAP is for foliar spray applications (6.25 gai/100 litres) over flowering, up to petal-fall.

Residues Information

Citrus fruits: Residue data from trials reflecting the above GAP on Clementine and Satsuma mandarins indicate that measurable residues should not occur in fruit at harvest, 120 days after treatment. This supports an MRL at the limit of analytical quantification of 0.02 mg/kg at 120 days after the last treatment. Residue data from trials reflecting the above GAP on other citrus fruits indicate residues of trifloxystrobin and its free acid metabolite should not exceed 0.22 mg/kg at harvest, 28 days after treatment. MRLs of 0.02mg/kg* for mandarins (Clementine and Satsuma), and 0.3 mg/kg for other citrus are therefore proposed to support the above GAP.

Grapes: Residue data from trials reflecting the above GAP on grapes indicate that measurable residues should not occur in fruit at harvest, 56 days after treatment. A MRL of 0.02mg/kg is therefore proposed to support the above GAP.

Stone fruits (except cherries): Residue data from trials reflecting the above GAP on stone fruits (except cherries) indicate that measurable residues should not occur in fruit at harvest, following treatments up to petal-fall. A MRL of 0.02mg/kg is therefore proposed for stone fruit (except cherries) to support the above GAP.

Dietary Risk Assessment

Acceptable Daily Intake (ADI)	0.04mg/kg bw/day
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For dietary intake calculations the potential daily exposure via food ($PDE_{(food)}$) is used if a value has been set by New Zealand's Environmental Risk Management Authority. In the absence of a $PDE_{(food)}$, an appropriate acceptable daily intake (ADI) is used instead. In the case of trifloxystrobin, the ADI has been set by the Joint Expert Committee on Food Additives (JECFA).

The chronic dietary exposure to trifloxystrobin 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 trifloxystrobin is equivalent to 1% of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Public Health Assessment

It has been determined that the use of trifloxystrobin as a fungicide for use on citrus fruits and stone fruits (except cherries), according to the good agricultural practice specified above in addition to currently registered uses of trifloxystrobin in New Zealand, is very unlikely to pose any toxicological health risks from consumption of the harvested commodity.

Consideration of International MRLs

Codex MRLs

As specified in the NZ (MRL) Food Standards 2006 imported foods may contain agricultural compounds no greater than the level specified by Codex Alimentarius, thus for imported food containing this agricultural compound the following Codex Alimentarius MRLs are applicable:

Compound	Food	Maximum Residue Limit (mg/kg)
Trifloxystrobin	Pome fruits	0.7

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.