

Table of Contents

1	Proposal to set MRLs for Amitraz.....	2
2	Proposal to set an MRL for Azinphos-methyl	4
3	Proposal to set an MRL for Doramectin	6
4	Proposal to set MRLs for Marbofloxacin.....	9
5	Proposal to set an MRL for Myclobutanil.....	11
6	Proposal to set an MRL for Pyraclostrobin	13
7	Proposal to set an MRL for Quinoxifen.....	16
8	Proposal to delete MRLs for Benalaxyl, Bromopropylate, sec-Butylamine, Methidathion, Methylene chloride, Naled, Nitrothal isopropyl and Phosmet	18
9	Proposal to exempt Ammonium thiosulphate	20
10	Proposal to exempt Extract of Azadirachta indica	22
11	Proposal to exempt 1, 4-dimethylnapthalene	24
12	Proposal to exempt Hydrogen peroxide	26
13	Proposal to exempt Peroxyacetic acid	28
14	Proposal to exempt Potassium bicarbonate	30
15	Proposal to delete the MRL exemption for Oestradiol 17 β and its esters and conjugates.....	32

1 Proposal to set MRLs for Amitraz

It is proposed that MRLs are set for amitraz when used as a miticide for use in beehives. 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 amitraz in Schedule One of the NZ (MRL) Food Standards 2007:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Amitraz	33089-61-1	Sum of: Amitraz and metabolites containing the 2,4-dimethylaniline moiety Expressed as: Amitraz	Honey Other Bee products	0.1 1

Amendment Rationale

The proposed MRLs represent a reassessment of a currently approved use pattern for amitraz control of varroa mite in beehives. The reassessed residue data indicates that MRLs for amitraz can be promulgated into the MRL Standards to support the good agricultural practice (GAP) of the currently approved use pattern. The proposed MRLs are for honey and for other bee products (including comb honey, royal jelly, pollen and propolis). The MRLs differ because of the higher fat content of other bee products allowing a greater absorption of residues.

Chemical Information

Common name of compound	Amitraz
Use of compound	Miticide
Chemical Abstract Services (CAS) Registry number	33089-61-1
Type of compound	Formamidine
Administration method	Impregnated strips

Good Agricultural Practice

Amitraz is used as a miticide for the treatment of varroa in beehives. Application may be for a 6 week period throughout spring before honey supers are added.

Residues Information

Residue data for honey supports an MRL of 0.1mg/kg when honey supers are not present during treatment. An MRL of 0.1mg/kg is therefore proposed to support GAP. Residue data for other bee products (comb honey, wax, propolis and pollen) supports an MRL of 1mg/kg. An MRL of 1mg/kg is therefore proposed to support GAP.

Dietary Risk Assessment

Acceptable Daily Intake (ADI)	0.01mg/kg bw/day
--------------------------------------	------------------

The potential daily exposure via food ($PDE_{(food)}$) is used for dietary intake calculation where a value has been set. An appropriate acceptable daily intake (ADI) is used in the absence of a $PDE_{(food)}$.

The chronic dietary exposure to amitraz 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 amitraz is equivalent to 6% 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 amitraz as a miticide for use in beehives, according to the GAP specified above, is very unlikely to pose any health risks from consumption of the harvested commodity.

International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
European Union		
Amitraz	Honey	0.2
USA		
Amitraz	Honey	1

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.

2 Proposal to set an MRL for Azinphos-methyl

It is proposed that an MRL is set for azinphos-methyl when used as an insecticide for potatoes. It is proposed that Schedule One of the NZ (MRL) Food Standards 2007 be amended by deleting the following entry:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Azinphos-methyl	85-50-0	Azinphos-methyl	Vegetables	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 the following entry:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Azinphos-methyl	85-50-0	Azinphos-methyl	Potatoes	0.05*

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

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

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Azinphos-methyl	85-50-0	Azinphos-methyl	Fruits (except kiwifruit)	2
			Kiwifruit	4
			Potatoes	0.05*

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

Amendment Rationale

The proposed MRL represents a reassessment of currently approved use patterns for azinphos-methyl. As use patterns have not been registered for use on vegetables other than potatoes for over five years it is considered that the MRLs supporting these uses can be removed from the standard. As azinphos-methyl is still registered for use on potatoes the deleted vegetable MRL will be replaced solely with an MRL for potatoes. This can be set at the limit of quantification because no residues are expected to be present in potatoes treated to good agricultural practice (GAP) (see below).

Chemical Information

Common name of compound	Azinphos-methyl
Use of compound	Insecticide
Chemical Abstract Services (CAS) Registry number	86-50-0

Type of compound	Organophosphate
Administration method	Foliar spray

Good Agricultural Practice

Azinphos-methyl has previously been registered for use on all vegetable crops. However, the use patterns have been withdrawn for all instances of use on vegetables except for potatoes. GAP for potatoes is currently approved at 560gai/ha with a withholding period of 14 days. The purpose of this change is to reflect that azinphos-methyl is no longer registered for use on all vegetables by restricting the MRL that reflects GAP solely to potatoes.

Residues Information

As azinphos-methyl is no longer approved for use on vegetable crops other than potatoes the MRLs for all vegetables have been withdrawn and replaced with a limit of quantification MRL of 0.05mg/kg for potatoes.

Dietary Risk Assessment

Acceptable Daily Intake (ADI)	0.005mg/kg bw/day
--------------------------------------	-------------------

The potential daily exposure via food ($PDE_{(food)}$) is used for dietary intake calculation where a value has been set. An appropriate acceptable daily intake (ADI) is used in the absence of a $PDE_{(food)}$.

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

The NEDI for azinphos-methyl is equivalent to 40% 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 restriction of the use of Azinphos-methyl as an insecticide for use on potatoes, according to 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.

3 Proposal to set an MRL for Doramectin

It is proposed that an MRL is set for doramectin when used as an anthelmintic for sheep. 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)
Doramectin	117704-25-3	Doramectin	Sheep meat	0.01

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

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Doramectin	117704-25-3	Doramectin	Sheep meat	0.02

The final entry for doramectin in Schedule One of the NZ (MRL) Food Standards 2007 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	0.02

Amendment Rationale

The proposed MRL represents a change in the use patterns of doramectin. The MRL will allow the use of doramectin as a subcutaneous injection to occur in sheep for the treatment of parasites. The increase in the MRL for sheep meat will harmonise New Zealand with MRLs currently in place in Australia and the European Union.

Chemical Information

Common name of compound	Doramectin
Use of compound	Anthelmintic
Chemical Abstract Services (CAS) Registry number	117704-25-3

Type of compound	Avermectin
Administration method	Subcutaneous injection

Good Agricultural Practice

The proposed use of doramectin as an anthelmintic for sheep by way of subcutaneous injection is good agricultural practice (GAP) and aligns with uses in cattle and swine. The application rate is proposed at 0.02mg/kg bw with a withholding period of 49 days.

Residues Information

Residue data for sheep meat supports an MRL of 0.02mg/kg at 49 days after the last treatment. An MRL of 0.02mg/kg is therefore proposed to support GAP.

Dietary Risk Assessment

Acceptable Daily Intake (ADI)	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. An appropriate acceptable daily intake (ADI) is used in the absence of a $PDE_{(food)}$.

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 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 doramectin is equivalent to 14% 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 doramectin as an anthelmintic for use in sheep, according to the GAP specified above, is very unlikely to pose any health risks from consumption of the harvested commodity.

International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
European Union		
Doramectin	Sheep meat	0.02
Australia		
Doramectin	Sheep meat	0.02

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.

4 Proposal to set MRLs for Marbofloxacin

It is proposed that MRLs be set for marbofloxacin in pig fat, meat and offal when used as an antibiotic for treatment of Mastitis Metritis Agalacticae syndrome. It is proposed that Schedule One of the NZ (MRL) Food Standards 2007 be amended to include the following entries:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Marbofloxacin	115550-35-1	Marbofloxacin	Pig fat	0.05
			Pig kidney	0.15
			Pig liver	0.15
			Pig meat	0.15

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

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Marbofloxacin	115550-35-1	Marbofloxacin	Cattle fat	0.05
			Cattle kidney	0.15
			Cattle liver	0.15
			Cattle meat	0.15
			Cattle milk	0.075
			Pig fat	0.05
			Pig kidney	0.15
			Pig liver	0.15
			Pig meat	0.15

Amendment Rationale

The proposed MRLs represent a reassessment of a currently approved use pattern for marbofloxacin in pigs. The assessed data indicates that MRLs of 0.05mg/kg in fat and 0.15mg/kg in other tissues are suitable to manage the good agricultural practice (GAP) (see below) of this compound.

Chemical Information

Common name of compound	Marbofloxacin
Use of compound	Antibiotic
Chemical Abstract Services (CAS) Registry number	115550-35-1
Type of compound	Fluoroquinolone
Administration method	Intramuscular injection

Good Agricultural Practice

Marbofloxacin is approved for use as an injectable antibiotic for pigs. Treatment is over 3 days, at 0.2mgai /kg bw with a withholding period after treatment of 4 days.

Residues Information

Residue data for pigs support MRLs of 0.15 mg/kg for meat, kidney and liver, and 0.05mg/kg for fat at 4 days after the last treatment. MRLs of 0.15mg/kg for meat, kidney and liver, and 0.05mg/kg for fat are therefore proposed to support GAP.

Dietary Risk Assessment

Acceptable Daily Intake (ADI)	0.0045mg/kg bw/day
--------------------------------------	--------------------

The potential daily exposure via food ($PDE_{(food)}$) is used for dietary intake calculation where a value has been set. An appropriate acceptable daily intake (ADI) is used in the absence of a $PDE_{(food)}$.

The chronic dietary exposure to marbofloxacin 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 marbofloxacin is equivalent to 13.2% 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 Marbofloxacin as an antibiotic for use in pigs, according to the GAP specified above, is very unlikely to pose any health risks from consumption of the harvested commodity.

International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
European Union		
Marbofloxacin	Pig fat	0.05
	Pig kidney	0.15
	Pig liver	0.15
	Pig meat	0.15

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.

5 Proposal to set an MRL for Myclobutanil

It is proposed that an MRL is set for myclobutanil when used as a fungicide for pomefruit. 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)
Myclobutanil	88671-89-0	Myclobutanil	Pome fruits	0.1

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

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Myclobutanil	88671-89-0	Myclobutanil	Grapes Pome fruits	0.2 0.1

Amendment Rationale

The proposed MRL represents a new use pattern in New Zealand for the active ingredient myclobutanil. The proposed MRL will manage the new use of myclobutanil as a fungicide for pome fruits to the application rates and withholding periods that are approved as good agricultural practice (GAP) (see below) in New Zealand.

Chemical Information

Common name of compound	Myclobutanil
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	88671-89-0
Type of compound	Conazole
Administration method	Spray

Good Agricultural Practice

Myclobutanil is used as a fungicide for pome fruit. Application may be up to 4 times at 7 day intervals from pink through to second cover, at 4.8gai/100L with a withholding period of 35 days.

Residues Information

Residue data for pome fruit support an MRL of 0.1mg/kg at 35 days after the last treatment. An MRL of 0.1mg/kg is therefore proposed to support GAP.

Dietary Risk Assessment

Acceptable Daily Intake (ADI)	0.03mg/kg bw/day
--------------------------------------	------------------

The potential daily exposure via food ($PDE_{(food)}$) is used for dietary intake calculation where a value has been set. An appropriate acceptable daily intake (ADI) is used in the absence of a $PDE_{(food)}$.

The chronic dietary exposure to myclobutanil 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 myclobutanil is equivalent to 0.5% of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Toxicological / Public Health Assessment

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

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.

6 Proposal to set an MRL for Pyraclostrobin

It is proposed that MRLs are set for pyraclostrobin when used as a fungicide for apples, pears, barley and wheat, and in animal products as a result of its use as a fungicide on barley, ryegrass and wheat for animal feed. 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 pyraclostrobin in Schedule One of the NZ (MRL) Food Standards 2007:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Pyraclostrobin	175013-18-0	<i>Plant commodities:</i> <i>Sum of:</i> Pyraclostrobin and its desmethoxy metabolite <i>Expressed as:</i> Pyraclostrobin <i>Animal commodities:</i> <i>Sum of:</i> Pyraclostrobin and metabolites hydrolysed to: 1-(4-chloro-phenyl)-1H-pyrazol-3-ol <i>Expressed as:</i> pyraclostrobin	Apples Barley Mammalian fat Mammalian kidney Mammalian liver Mammalian meat Milk Pears Wheat	0.02* 0.02* 0.02* 0.02* 0.02* 0.02* 0.02* 0.02*

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

Amendment Rationale

The proposed MRLs represent a range of new use patterns in New Zealand for the active ingredient pyraclostrobin. The proposed MRLs will manage the new use of pyraclostrobin as a fungicide on apples, pears, barley and wheat to the application rates and withholding periods that are approved good agricultural practice (GAP) in New Zealand. The MRLs are proposed at the limit of quantification to represent that no residues are expected in harvested commodities and in animal products, through treatment of feed, when this active is applied and used correctly.

Chemical Information

Common name of compound	Pyraclostrobin
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	175013-18-0
Type of compound	Strobilurin
Administration method	Spray

Good Agricultural Practice

Pyraclostrobin is proposed for use as a fungicide for apples, pears, wheat and barley.

Apples

Application may be up to 4 times throughout early-to-mid growing season at 7-10 day intervals at 6.3gai/ha. Application must not be after 100% petal fall.

Pears

Application may be up to 4 times throughout early to mid growing season at 7-10 day intervals at 6.3gai/ha. Application must not be after 50% petal fall.

Barley and Wheat

Application may be 2 times during mid-tillering up to the ear emergence with a 3-5 week interval at 250gai/ha with a withholding period of 56 days.

Residues Information

Residue data for apples and pears support a limit of quantification MRL of 0.02mg/kg when the last treatment is prior to 100% petal fall (apples) or 50% petal fall (pears). MRLs of 0.02mg/kg are therefore proposed to support GAP. Residue data for barley and wheat support a limit of quantification MRL of 0.02mg/kg when the last treatment is 56 days before harvest. MRLs of 0.02mg/kg are therefore proposed to support GAP.

Animal Transfer

Transfer of residues to animals following grazing of orchards has not been considered. It is acceptable that orchards treated to GAP should not be grazed. Transfer of residues to animals following grazing of barley, ryegrass and wheat feed, fodder and straw, has been assessed 42 days after treatment and it has been determined that no residues will be detectable in animal tissues and milk following grazing.

Dietary Risk Assessment

Acceptable Daily Intake (ADI)	0.03 mg/kg bw/day
--------------------------------------	-------------------

The potential daily exposure via food ($PDE_{(food)}$) is used for dietary intake calculation where a value has been set. An appropriate acceptable daily intake (ADI) is used in the absence of a $PDE_{(food)}$.

The chronic dietary exposure to pyraclostrobin 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 pyraclostrobin is equivalent to 0.7% 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 pyraclostrobin as a fungicide for use on apples, pears, barley and wheat, according to the GAP specified above, is very unlikely to pose any health risks from consumption of the harvested commodity and animal commodities from animals consuming treated barley, ryegrass and wheat.

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.

7 Proposal to set an MRL for Quinoxifen

It is proposed that an MRL be set for quinoxifen when used as a fungicide for cucurbits. 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)
Quinoxifen	124495-18-7	Quinoxifen	Cucurbits (inedible peel)	0.01*

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

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

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Quinoxifen	124495-18-7	Quinoxifen	Cucurbits (inedible peel) Grapes	0.01* 0.3

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

Amendment Rationale

The proposed MRL represents a new use pattern in New Zealand for the active ingredient quinoxifen. The proposed MRL will manage the new use of quinoxifen as a fungicide on cucurbits to the application rates and withholding periods that are approved good agricultural practice (GAP) in New Zealand. The MRL is set at the limit of quantification to represent that no residues are expected to occur in harvested cucurbits when the active ingredient is applied and used correctly.

Chemical Information

Common name of compound	Quinoxifen
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	124495-18-7
Type of compound	Quinoline
Administration method	Spray

Good Agricultural Practice

Quinoxifen is proposed for use as a fungicide for cucurbits (inedible peel). Application may be up to 3 times at 14 day intervals after flowering at 50gai/ha with a withholding period of 14 days.

Residues Information

Residue data for cucurbits (inedible peel) support a limit of quantification MRL of 0.01mg/kg at 14 days after the last treatment. An MRL of 0.01mg/kg is therefore proposed to support GAP.

Dietary Risk Assessment

ERMA NZ PDE _(food)	0.16mg/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 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 quinoxyfen 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 quinoxyfen is equivalent to 0.01% 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 quinoxyfen as a fungicide for use on cucurbits (inedible peel), according to the GAP specified above, is very unlikely to pose any health risks from consumption of the harvested commodity.

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.

8 Proposal to delete MRLs for Benalaxyl, Bromopropylate, sec-Butylamine, Methidathion, Methylene chloride, Naled, Nitrothal isopropyl and Phosmet

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

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Benalaxyl	71626-11-4	Benalaxyl	Grapes Tomatoes	0.5 0.5
Bromopropylate	18181-80-1	Bromopropylate	Citrus fruits	3
sec-Butylamine	13952-84-6	Sum of : Butylamine salts and base Expressed as: Butylamine	Citrus fruits	30
Methidathion	950-37-8	Methidathion	Citrus fruits	2
Methylene chloride	75-09-2	Methylene chloride	Spices	30
Naled	300-76-5	Naled, expressed as dichlorvos	Berries and other small fruits Vegetables	2 2
Nitrothal-isopropyl	10552-74-6	Nitrothal-isopropyl	Pome fruits	0.2
Phosmet	732-11-6	Phosmet	Kiwifruit Other fruit	15 10

The final entries for benalaxyl and bromopropylate in Schedule One of the NZ (MRL) Food Standards 2007 will therefore read:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Benalaxyl	71626-11-4	Benalaxyl	Potatoes	0.02(*)
Bromopropylate	18181-80-1	Bromopropylate	Berries and other small fruits (except grapes) Pome fruits Stone fruits	3 3 3

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

Amendment Rationale

No remaining entries for sec-butylamine, methidathion, methylene chloride, naled, nitrothal isopropyl and phosmet will be present in Schedule One of the NZ (MRL) Food Standards 2007. The above MRLs in the first table are proposed to be deleted as the use patterns for each active ingredient are no longer considered to be in-use within New Zealand. This has been determined to be the situation, given that no agricultural compound trade name products have been registered under the Agricultural Compounds and Veterinary Medicines Act 1997 with the above label use patterns over the last five years. The remaining MRLs listed in the second table represent the use patterns that still remain approved in New Zealand.

International MRLs

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

9 Proposal to exempt Ammonium thiosulphate

It is proposed that an MRL exemption is set for ammonium thiosulphate when used as a plant growth regulator for pomefruit and stonefruits. It is proposed that Schedule Two of the NZ (MRL) Food Standards 2007 be amended to include the following; this will be the resulting entry for ammonium thiosulphate in Schedule Two of the NZ (MRL) Food Standards 2007:

Compound	CAS#	Condition
Ammonium thiosulphate	7783-18-8	Applied during flowering for fruit reduction in pomefruit and stonefruit

Amendment Rationale

The proposed MRL exemption represents a reassessment of a currently approved use pattern for ammonium thiosulphate. The rapid chemical breakdown of this compound means it is not suitable to be managed against a concentration limit, and therefore it can be exempted from requiring an MRL.

Chemical Information

Common name of compound	Ammonium thiosulphate
Use of compound	Thinning agent/ fruit reduction agent
Chemical Abstract Services (CAS) Registry number	7783-18-8
Administration method	Ground spray

Good Agricultural Practice

Ammonium thiosulphate is used as a blossom thinner/fruit reducer for pome and stone fruits. Application may be throughout plant flowering period, at 0.8-1.2kgai/100L.

Residues Information

Ammonium thiosulphate rapidly ionises with water to form ammonium ions and thiosulphate ions. The thiosulphate is then further oxidised to sulphate, these breakdown products are all absorbed by the crop. Distinguishing between naturally occurring sulphate and ammonium within the crop and that occurring as a result of ammonium thiosulphate treatment is virtually impossible. Levels of sulphate and ammonium ions will be within natural ranges when the fruit is harvested. It is not possible to determine residues resulting from the use of ammonium thiosulphate as an agricultural compound. Therefore an MRL exemption is proposed for ammonium thiosulphate.

Dietary Risk Assessment

No acceptable daily intake (ADI) has been specified for ammonium thiosulphate. However, it is indicated to be of low oral toxicity on the basis of high LD₅₀ values of 1-2g/kg (LD₅₀ values = median

lethal dose, the dose required to kill 50% of a population of laboratory animals - usually rodents). Residues of sulphate ions and ammonium ions will be within the natural background range for fruit from treated orchards at the time of consumption. Because no detectable ammonium thiosulphate will be present on treated crops there is no dietary risk to consider.

Toxicological / Public Health Assessment

It has been determined that the use of ammonium thiosulphate as a blossom thinner/fruit reducer for use on pomefruit and stonefruit, according to the good agricultural practice specified above, is very unlikely to pose any health risks from consumption of the harvested commodity.

International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
United States		
Ammonium thiosulphate	Apples	Exempt
Australia		
Ammonium thiosulphate	Pomefruit Stonefruit	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.

10 Proposal to exempt Extract of *Azadirachta indica*

It is proposed that an MRL exemption be set for extract of *azadirachta indica* when used as an insecticide for food producing plant species. It is proposed that Schedule Two of the NZ (MRL) Food Standards 2007 be amended to include the following; this will be the resulting entry for extract of *azadirachta indica* in Schedule Two of the NZ (MRL) Food Standards 2007:

Compound	CAS#	Condition
Extract of <i>Azadirachta indica</i> (Neem) (containing azadirachtin)	None (Azadirachtin: 11141-17-6)	Where the primary mode of action derives from the presence of azadirachtin, and When used as an insecticide for food producing plant species.

Amendment Rationale

The proposed MRL exemption represents a reassessment of the currently approved use patterns for extracts of *azadirachta indica* (Neem). Neem has a very low toxicity and represents a risk reducing insecticide. Neem's broadly defined good agricultural practice (GAP) means it is not required to be managed against a chemical concentration limit. It therefore does not require an MRL to regulate GAP.

Chemical Information

Common name of compound	Neem, Extract of <i>azadirachta indica</i>
Use of compound	Insecticide
Chemical Abstract Services (CAS) Registry number	None (Azadirachtin: 11141-17-6)
Type of compound	Tetranortriterpenoid , Plant derived insecticide
Administration method	Spray

Residues Information

Insecticide products containing neem have been available in New Zealand for many years. Neem is derived from the oil of the neem tree berries. The action of the insecticide is primarily derived from the presence of azadirachtin in the oil, although other components of the oil may cause synergistic or insecticidal effects.

Dietary Risk Assessment

Neem has been determined to be of very low toxicity. Extracts of neem have been used historically in parts of Asia for skin and dental treatments for what has claimed to be over 2000 years. Parts of the neem tree are consumed in certain Indian and Southeast Asian dishes. Neem is used in human medicine for skin and acne treatment and for the control of scabies and head lice. The active component azadirachtin has also been demonstrated to be of very low toxicity. Neem and azadirachtin do not represent a dietary intake risk from consumption of residues on treated food commodities.

Toxicological / Public Health Assessment

It has been determined that the use of neem as an insecticide for use on all food producing plant species is very unlikely to pose any health risks from consumption of the harvested commodity.

International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
United States		
Azadirachtin	Exemption	When used as a pesticide at 20 grams or less per acre on all raw agricultural commodities.

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.

11 Proposal to exempt 1, 4-dimethylnaphthalene

It is proposed that an MRL exemption be set for 1, 4-dimethylnaphthalene when used as a sprout inhibitor for potatoes. It is proposed that Schedule Two of the NZ (MRL) Food Standards 2007 be amended to include the following; this will be the resulting entry for 1, 4-dimethylnaphthalene in Schedule Two of the NZ (MRL) Food Standards 2007:

Compound	CAS#	Condition
1, 4-dimethylnaphthalene	571-58-4	When used for maintenance of sprout inhibition in stored potatoes

Amendment Rationale

The proposed MRL exemption represents a reassessment of a currently approved use pattern for 1, 4-dimethylnaphthalene. As residues in potatoes can't be distinguished from natural background levels the compound is not suitable to be managed against a concentration limit, and therefore it can be exempted from the requirement of a New Zealand MRL.

Chemical Information

Common name of compound	1,4-dimethylnaphthalene
Use of compound	Aromatic hydrocarbon
Chemical Abstract Services (CAS) Registry number	571-58-4
Type of compound	Potato sprout inhibitor
Administration method	Post harvest spray

Good Agricultural Practice

1, 4-dimethylnaphthalene is used as a sprout inhibitor for stored potatoes. Application may be throughout potato storage.

Residues Information

1, 4-dimethylnaphthalene (DMN) occurs naturally in potatoes in a role of inhibiting sprout development. Natural levels of DMN are in the order of 1-10mg/kg in pre-sprouting tubers. Prior to sprouting occurs, DMN is metabolised by the tuber to levels below 0.7mg/kg, therefore allowing sprout development. DMN is used as an agricultural compound to maintain the levels of DMN in the stored tubers so sprouting can be inhibiting for longer periods, allowing a greater shelf-life of stored potatoes. Application of DMN is intended to maintain the potato DMN level at a similar range to natural levels. Determining natural residues of DMN from those resulting from the application of DMN as an agricultural compound is impossible. Therefore it is proposed the 1, 4-dimethylnaphthalene be made exempt from the requirement of an MRL.

Dietary Risk Assessment

No chronic toxicity studies are available. Studies (acute) indicate the compound is of low oral toxicity with an LD₅₀ value of 2g/kg (LD₅₀ values = median lethal dose, the dose required to kill 50% of a population of laboratory animals - usually rodents). Additionally, the substance has been demonstrated as negative for mutagenicity in several invitro studies. Levels of 1, 4-dimethylnaphthalene are unlikely to exceed naturally occurring levels in potato tubers at the time of consumption. The toxicity data available for 1, 4-dimethylnaphthalene indicates it is of relatively low toxicity. Given its natural occurrence in the diet, without any recorded adverse effects it is considered that exempting 1, 4-dimethylnaphthalene from an MRL for its use as a sprout inhibitor will not result in any increase in dietary risk.

Toxicological / Public Health Assessment

It has been determined that the use of 1, 4-dimethylnaphthalene as a sprout inhibitor for use on potatoes, according to the good agricultural practice specified above, is very unlikely to pose any health risks from consumption of the harvested commodity.

International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
United States		
1, 4-dimethylnaphthalene	Post harvest potatoes	Exempt when applied in accordance with good agricultural practice

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.

12 Proposal to exempt Hydrogen peroxide

It is proposed that an MRL exemption be set for hydrogen peroxide when used as a fungicide and bactericide treatment for fruit. It is proposed that Schedule Two of the NZ (MRL) Food Standards 2007 be amended to include the following; this will be the resulting entry for hydrogen peroxide in Schedule Two of the NZ (MRL) Food Standards 2007:

Compound	CAS#	Condition
Hydrogen peroxide	7722-84-1	When used as a spray-on fungicide and bactericide treatment for fruit

Amendment Rationale

The proposed MRL exemption represents a new use pattern for hydrogen peroxide, the rapid chemical breakdown of this compound means it is not suitable to be managed against a concentration limit, and therefore it can be exempted from the requirement of an MRL.

Chemical Information

Common name of compound	Hydrogen peroxide
Use of compound	Disinfectant (fungicide / bactericide)
Chemical Abstract Services (CAS) Registry number	7722-84-1
Type of compound	Oxidizing agent/ Reactive oxygen species
Administration method	Spray

Good Agricultural Practice

Hydrogen peroxide is proposed for use as a fungicide and bactericide for fruit crops. Application may be throughout plant growth at rates up to 700gai/ha with a withholding period of 1 day.

Residues Information

The activity of hydrogen peroxide derives from the peroxy (O-O) bond. This bond is inherently unstable which makes it very reactive. It is through oxidation that this bond can rapidly destroy the cell walls of micro organisms. Given the reactivity of the bond it can be broken through reaction with environmental molecules or natural soil organisms. UV light may also breakdown the bond. Given that the instability of the active molecule residues occurring on the surface of treated fruit would be rapidly diminished, they are very unlikely to be detectable by the time of harvest. The breakdown product of hydrogen peroxide is water. Hydrogen peroxide is approved as a processing aid for food under the Australia New Zealand Food Standards Code which regulates residue levels resulting from this use at the limit of 5mg/kg in the final processed food.

Dietary Risk Assessment

Whilst hydrogen peroxide may be a moderately acute toxin, given the body's defence to prevent and control reactive oxygen species forming, it is of low toxicity in small amounts over an extended period. As residues of hydrogen peroxide are not expected on harvested fruits there is no risk of any chronic health effects from its use as an agricultural compound to good agricultural practice.

Toxicological / Public Health Assessment

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

International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
United States		
Hydrogen peroxide	All food commodities	Exempt when applied at $\geq 1\%$
Australia		
Hydrogen peroxide	Fruit and vegetables	Exempt as a disinfectant and fungicide

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.

13 Proposal to exempt Peroxyacetic acid

It is proposed that an MRL exemption is set for peroxyacetic acid when used as a fungicide and bactericide treatment for fruit. It is proposed that Schedule Two of the NZ (MRL) Food Standards 2007 be amended to include the following; this will be the resulting entry for peroxyacetic acid in Schedule Two of the NZ (MRL) Food Standards 2007:

Compound	CAS#	Condition
Peroxyacetic acid	79-21-0	When used as a spray-on fungicide and bactericide treatment for fruit

Amendment rationale

The proposed MRL exemption represents a new use pattern for peroxyacetic acid, the rapid chemical breakdown of this compound means it is not suitable to be managed against a concentration limit, and therefore it can be exempted from the requirement of an MRL.

Chemical Information

Common name of compound	Peroxyacetic acid
Use of compound	Disinfectant (fungicide / bactericide)
Chemical Abstract Services (CAS) Registry number	79-21-0
Type of compound	Oxidizing agent/ Reactive oxygen species
Administration method	Spray

Good Agricultural Practice

Peroxyacetic acid is proposed for use as a fungicide and bactericide for fruit crops. Application may be throughout plant growth at rates up to 700gai/ha with a withholding period of 1 day.

Residues Information

The activity of peroxyacetic acid derives from the peroxy (O-O) bond. This bond is inherently unstable which makes it very reactive. It is through oxidation that it can rapidly destroy the cell walls of micro organisms. Given the reactivity of the bond it can be broken through reaction with environmental molecules or natural soil organisms. UV light may also breakdown the bond. Given that the instability of the active molecule residues occurring on the surface of treated fruit would be rapidly diminished, they are very unlikely to be detectable by the time of harvest. The breakdown products of

peroxyacetic acid are acetic acid and oxygen. Peroxyacetic acid is approved as a processing aid for food under the Australia New Zealand Food Standards Code.

Dietary Risk Assessment

Whilst peroxyacetic acid may be a moderately acute toxin, given the body's defence to prevent and control reactive oxygen species forming it is of low toxicity in small amounts over an extended period. As residues of peroxyacetic acid are not expected on harvested fruits there is no risk of any chronic health effects from its use as an agricultural compound to good agricultural practice. Peroxyacetic acid is approved for use as a processing aid and has been assessed to be safe in food.

Toxicological / Public Health Assessment

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

International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
United States		
Peroxyacetic acid	All food commodities	Exempt when applied at up to 100ppm
Australia		
Peroxyacetic acid	Fruit and vegetables	Exempt as a disinfectant or fungicide

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.

14 Proposal to exempt Potassium bicarbonate

It is proposed that an MRL exemption is set for potassium bicarbonate when used as a fungicide for fruit and cucurbits. It is proposed that Schedule Two of the NZ (MRL) Food Standards 2007 be amended to include the following; this will be the resulting entry for potassium bicarbonate in Schedule Two of the NZ (MRL) Food Standards 2007:

Compound	CAS#	Condition
Potassium bicarbonate	298-14-6	When used as a fungicide for fruit and cucurbits

Amendment Rationale

The proposed MRL exemption represents a new use pattern for potassium bicarbonate. The background levels of this active ingredient, its very low toxicity and its addition to food during processing as a food additive mean it is not required to be managed against a chemical concentration limit. Therefore it can be exempted from the requirement of an MRL.

Chemical Information

Common name of compound	Potassium bicarbonate
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	298-14-6
Type of compound	Bicarbonate salt
Administration method	Spray

Good Agricultural Practice

Potassium bicarbonate may be used as a contact fungicide for a variety of fruits and cucurbits. It is assigned a withholding period of 7 days.

Residues Information

Potassium bicarbonate rapidly decomposes after use to form potassium carbonate, water and carbon dioxide. These are all naturally occurring in the environment. It is not expected that levels of potassium bicarbonate resulting from treatment of fruit and cucurbits will be distinguishable from the naturally occurring levels of potassium and bicarbonate ions in the plant or environment. It is therefore proposed that potassium bicarbonate be exempted from an MRL.

Dietary Risk Assessment

Potassium bicarbonate is an approved food additive; it is recorded as very low acute toxicity. Given its natural presence in food, no average daily intake (ADI) has been assigned. Levels of potassium bicarbonate in harvested fruit and cucurbits will not exceed levels of potassium bicarbonate present in food from its use as a food additive and through the natural presence of potassium and bicarbonate ions. Therefore the use of potassium bicarbonate as a fungicide presents no dietary risk.

Toxicological / Public Health Assessment

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

International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
United States		
Potassium bicarbonate	All foods	Exempt when applied as a fungicide or post-harvest fungicide in accordance with good agricultural practices
Australia		
Potassium bicarbonate	All foods	Exempt when used as a fungicide
Canada		
Potassium bicarbonate	Food and feed crops	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.

15 Proposal to delete the MRL exemption for Oestradiol 17 β and its esters and conjugates

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

Compound	CAS#	Condition
Oestradiol-17 beta and its esters or conjugates	50-28-2	Used for treatment of suboestrus, dystocia, metritis, pyometra, retained placenta, anoestrus in mares or growth promotion in cattle

Amendment Rationale

Inline with a reassessment of products containing oestradiol-17 beta under the Agricultural Compounds and Veterinary Medicines Act 1997, the MRL exemption for oestradiol-17 beta is proposed to be withdrawn from the MRL Standards. Residues of oestradiol-17 beta in food producing animal species will be managed under the provisions of the Animal Products (Residue Specifications) Notice, issued under the Animal Products Act 1999.