



Proposals to Amend the New Zealand
(Maximum Residue Limits of Agricultural
Compounds) Food Standards 2010

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NZFSA seeks submissions from all interested parties on any aspect of the document. The following points may be of assistance in preparing comments:

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- Omissions should be clearly and separately indicated.
- Comments should be to the point and, where possible, reasons and data to support comment are requested.
- The use of examples to illustrate particular points is encouraged.
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- Your name and title (if applicable);
- Your organisation's name (if applicable);
- Your address;
- The number(s) of the sections you are commenting on.

Please submit your response by 5:00pm on Wednesday 4th August 2010 to:

MRL Amendments, Policy Group, New Zealand Food Safety Authority

PO Box 2835, Wellington, fax: (04) 894 2583, or email: policy@nzfsa.govt.nz

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Introduction

The New Zealand Food Safety Authority (NZFSA) invites public comment on this discussion document which outlines proposals to amend the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2010.

Maximum residue limits (MRLs) are the maximum legal limits for residues of agricultural compounds and veterinary medicines in food for sale in New Zealand.

MRLs are primarily a tool for monitoring the use of agricultural compounds in accordance with good agricultural practice (GAP). GAP is not explicitly defined or regulated, but is the generally accepted means for producing safe primary produce in a particular location while taking account of climate, pests or diseases and other environmental factors.

MRLs are used to minimise risks to public health by ensuring that chemical residues in food are as low as practicable, without compromising the ability of the chemical to successfully do what is intended.

Background

MRLs are set out in the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards. The Standards are amended a number of times each year to reflect changes in the use of agricultural compounds in the production of food. The current MRL Food Standards 2010 are on the NZFSA website at: <http://www.nzfsa.govt.nz/policy-law/legislation/food-standards/index.htm>

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

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

There are two stages in determining an appropriate MRL. Firstly, GAP for the use of the particular agricultural compound in production of a particular food must be determined. Secondly, it must be demonstrated that the residues arising from the use of the agricultural compound in accordance with GAP are unlikely to pose any human health risks. MRL proposals are set at a level that supports GAP and allows for the monitoring of compliance with GAP.

The New Zealand Food Safety Authority (NZFSA) assesses MRL proposals in accordance with internationally accepted methodologies, such as those utilised by the expert committees advising the Codex Alimentarius Commission (Codex).

Possible implications for public health are considered during the toxicological and dietary risk assessments, by comparing the estimated dietary intake with a Potential Daily Exposure (food) (PDE_{food}) or, where there is no PDE_{food} , by comparing it with the Acceptable Daily Intake (ADI).

A PDE_{food} is a value determined by a toxicological evaluation by the Environmental Risk Management Authority New Zealand as part of its responsibilities under the Hazardous Substances and New Organisms Act 1996 (the HSNO Act), which has some responsibility for managing public health.¹ A PDE_{food} gives the potential daily exposure a person may be subject to from a substance, via food. The ADI and PDE_{food} are largely equivalent, as they are determined using the same set of toxicology data and in a very similar scientific process.

An ADI is defined by the World Health Organization (WHO) as: “The daily intake which, during an entire lifetime, appears to be without appreciable risk on the basis of all the known facts at the time”. “Without appreciable risk” has been further defined as: “the practical certainty that injury will not result even after a lifetime of exposure”. ADIs are established by the WHO and Food and Agriculture Organization of the United Nations joint expert committees, made up of toxicologists and residue specialists. The ADI information from these joint committees also feeds into Codex, which sets international MRLs.

Information on the technical assessment of each proposal is included in this document and covers (where relevant) the following:

- rationale
- chemical information
- good agricultural practice (GAP)
- residues information

¹The purpose of the HSNO Act is “to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms”.

- dietary risk assessment
- toxicological / public health assessment
- international MRLs.

NZFSA has reviewed the estimated dietary exposure assessments for the applications of these proposals and has determined that the residues associated with the proposed MRLs do not present any public health and safety concerns.

Summary of Proposed Amendment

New MRLs

NZFSA proposes to add the following new MRLs to the Standards:

- 0.1mg/kg for derquantel in sheep fat, muscle and offal
- 0.01mg/kg for foramsulfuron in maize
- 0.01mg/kg for iodosulfuron-methyl-sodium in cereals
- 15mg/kg for maleic hydrazide in bulb vegetables
- 0.01mg/kg for mesosulfuron-methyl in wheat
- 0.1mg/kg for methoxyfenozide in avocados
- 0.1mg/kg for spirotetramat in kiwifruit
- 10mg/kg for sulphur dioxide in blueberries, grapes and longans
- 0.5mg/kg for uniconazole-P in avocados.

MRL Exemptions

NZFSA proposes to exempt the following MRLs from the Standards

- MRLs for benzalkonium chloride when used on pome fruits
- MRLs for bromochlorodimethylhydantoin when used on fruits and vegetables
- MRLs for pine oil when used as a herbicide.

Next Steps

Following the closing date for submissions (5:00pm on Wednesday 4th August 2010), all submissions will be considered and analysed before a recommendation is made to the Minister for Food Safety, the Hon Kate Wilkinson, who makes the final decision on issuing any amendments to the Food Standards.

If an amendment is agreed upon, it will be signed by the Minister for Food Safety and will come into force 28 days after being published in the *New Zealand Gazette*.

1 Proposal to set MRLs for Derquantel

It is proposed that MRLs are set for derquantel when used as a veterinary medicine for sheep. It is proposed that Schedule One of the NZ (MRL) Food Standards 2010 be amended to include the following; and that this will be the resulting entry for derquantel in Schedule One of the NZ (MRL) Food Standards 2010:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Derquantel	187865-22-1	Derquantel	Sheep Fat	0.1
			Sheep Muscle	0.1
			Sheep Offal	0.1

Amendment Rationale

The proposed MRLs represent a new registration in New Zealand for the active ingredient derquantel. The proposed MRLs will manage the new uses of derquantel as an anthelmintic treatment for sheep, to the application rates and withholding periods that are approved GAP in New Zealand.

Chemical Information

Common name of compound	Derquantel
Use of compound	Anthelmintic
Chemical Abstract Services (CAS) Registry number	187865-22-1
Type of compound	Spiroindole
Administration method	Oral drench

Good Agricultural Practice

Derquantel is approved for use as an anthelmintic drench for sheep. Application is of 2mg of derquantel per kg of bodyweight, with a withholding period of 14 days being approved for its use in a registered product.

Residues Information

Residue data for derquantel supports an MRL of 0.1mg/kg for all tissues. An MRL of 0.1mg/kg is therefore proposed to support GAP.

Dietary Risk Assessment

Potential daily exposure via food ($PDE_{(food)}$)	0.005mg/kg bw/day
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The $PDE_{(food)}$ is a value set by the Environmental Risk Management Authority (ERMA), which 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 derquantel 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 derquantel is equivalent to less than 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 derquantel as an anthelmintic drench for sheep according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

Other International MRLs

Food imported to New Zealand must comply with either Codex Alimentarius Commission (Codex) MRLs, New Zealand's domestic MRL Standards, or, if no appropriate Codex or domestic MRL exists, the default MRL of 0.1mg/kg.

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 Foramsulfuron

It is proposed that an MRL is set for foramsulfuron when used as a herbicide for control of broad-leaved and grass weeds in maize. It is proposed that Schedule One of the NZ (MRL) Food Standards 2010 be amended to include the following; and that this will be the resulting entry for foramsulfuron in Schedule One of the NZ (MRL) Food Standards 2010:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Foramsulfuron	173159-57-4	Foramsulfuron	Maize	0.01(*)

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 registration in New Zealand for the active ingredient foramsulfuron. The proposed MRL will manage the new use of foramsulfuron when used as a herbicide for control of broad-leaf and grass weeds in maize, to the application rates and withholding periods that are approved GAP in New Zealand.

Chemical Information

Common name of compound	Foramsulfuron
Use of compound	Herbicide
Chemical Abstract Services (CAS) Registry number	173159-57-4
Type of compound	Sulfonylurea
Administration method	Spray

Good Agricultural Practice (GAP)

Foramsulfuron is approved as a herbicide for control of broad-leaf and grass weeds in maize. Application is made once before weeds reach the 5 leaf stage (broadleaf weeds) or before tillering (grass weeds) at a rate of 45gai/ha, with a withholding period of “do not apply after the 8 leaf stage”.

Residues Information

Residue data for maize supports a limit of detection MRL of 0.01mg/kg for foramsulfuron when treatment is made before the 8 leaf stage. An MRL of 0.01mg/kg is therefore proposed to support GAP.

Dietary Risk Assessment

Potential daily exposure via food ($PDE_{(food)}$)	0.35mg/kg bw/day
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The $PDE_{(food)}$ is a value set by the Environmental Risk Management Authority (ERMA), which 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 foramsulfuron is estimated by the National Estimated Dietary Intake (NEDI) calculation encompassing all registered uses of the chemical and food consumption data based upon the 1997 National Nutritional Survey for adults and the 1995 National Nutrition Survey of Australia, for children. The NEDI calculation is made in accordance with *Guidelines for predicting dietary intake of pesticide residues (revised)* [World Health Organization, 1997].

The NEDI for foramsulfuron is less than 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 foramsulfuron as a herbicide for control of broad-leaf and grass weeds in maize according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

Other International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
European Commission		
Foramsulfuron	Maize	0.01*
Japan		
Foramsulfuron	Corn (maize, including pop corn and sweet corn)	0.01
US		
Foramsulfuron	Corn, field, grain/corn, field, forage/ corn, field, stover/corn, pop, grain/corn, pop, forage/corn, pop, stover; corn, sweet, forage; corn, sweet, kernel plus cob with husks removed; corn, sweet, stover	Exempt

Food imported to New Zealand must comply with either Codex Alimentarius Commission (Codex) MRLs, New Zealand's domestic MRL Standards, or, if no appropriate Codex or domestic MRL exists, the default MRL of 0.1mg/kg.

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 Iodosulfuron-methyl-sodium

It is proposed that an MRL is set for iodosulfuron-methyl-sodium when used as a herbicide for control weeds around cereals. It is proposed that Schedule One of the NZ (MRL) Food Standards 2010 be amended to include the following; and that this will be the resulting entry for iodosulfuron-methyl in Schedule One of the NZ (MRL) Food Standards 2010:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Iodosulfuron-methyl-sodium	144550-36-7	Iodosulfuron-methyl	Cereals	0.01(*)

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

Amendment Rationale

The proposed MRL represents the extension of uses for iodosulfuron-methyl-sodium to cover use on maize, as iodosulfuron-methyl-sodium has previously been approved for use on small grain cereals it is appropriate to promulgate a cereal crop grouping MRL. The proposed MRLs will manage all uses of iodosulfuron-methyl-sodium as a herbicide for control weeds around cereals, to the application rates and withholding periods that are approved GAP in New Zealand.

Chemical Information

Common name of compound	Iodosulfuron-methyl-sodium
Use of compound	Herbicide
Chemical Abstract Services (CAS) Registry number	144550-36-7
Type of compound	Triazinylsulfonyleurea
Administration method	Spray

Good Agricultural Practice

Iodosulfuron-methyl-sodium is approved as a herbicide for cereals. Application is once in the season during tillering or before the 8 leaf stage in maize, at rates of up to 7.5gai/ha.

Residues Information

Residue data for cereals supports a limit of quantification MRL of 0.01mg/kg for iodosulfuron-methyl-sodium when the last treatment is made prior to the end of tillering, or the 8 leaf stage for maize. An MRL of 0.01mg/kg is therefore proposed to support GAP.

Dietary Risk Assessment

Acceptable Daily Intake	0.03mg/kg bw/day
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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 iodosulfuron-methyl-sodium 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 iodosulfuron-methyl-sodium is equivalent to less than 1% 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 Iodosulfuron-methyl-sodium when used as a herbicide for control of weeds around cereals according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

Other International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
Australia		
Iodosulfuron-methyl	Wheat	0.01*
EU		
Iodosulfuron-methyl	Cereals	0.02*
Japan		
Iodosulfuron-methyl	Corn (maize, including pop corn and sweet corn)	0.03
	Wheat	0.01
USA		
Iodosulfuron-methyl-sodium	Corn, field, grain	0.03
	Wheat	0.02

Food imported to New Zealand must comply with either Codex Alimentarius Commission (Codex) MRLs, New Zealand's domestic MRL Standards, or, if no appropriate Codex or domestic MRL exists, the default MRL of 0.1mg/kg.

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 an MRL for Maleic Hydrazide

It is proposed that an MRL is set for maleic hydrazide when used as a plant growth regulator on bulb vegetables. It is proposed that Schedule One of the NZ (MRL) Food Standards 2010 be amended by deleting the following entry:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Maleic hydrazide	123-33-1	Sum of: Free maleic hydrazide Conjugated maleic hydrazide Expressed as: maleic hydrazide	Onions	15

As a replacement for the deleted entry, is proposed that Schedule One of the NZ (MRL) Food Standards 2010 be amended to include the following entry:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Maleic hydrazide	123-33-1	Sum of: Free maleic hydrazide Conjugated maleic hydrazide Expressed as: Maleic hydrazide	Bulb vegetables	15

The final entry for maleic hydrazide in Schedule One of the NZ (MRL) Food Standards 2010 will therefore read:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Maleic hydrazide	123-33-1	Sum of: Free maleic hydrazide Conjugated maleic hydrazide Expressed as: Maleic hydrazide	Bulb vegetables Potatoes	15 50

Amendment Rationale

The proposed MRL represents a correction in the crop grouping terminology for the current MRL to represent the applicability of the residue limit to apply to all bulb vegetable varieties. This is consistent with overseas approvals. The proposed MRL will manage the uses of maleic hydrazide as a plant

growth regulator on bulb vegetables, to the application rates and withholding periods that are proposed GAP in New Zealand.

Chemical Information

Common name of compound	Maleic hydrazide
Use of compound	Plant growth regulator
Chemical Abstract Services (CAS) Registry number	123-33-1
Type of compound	Pyridazine
Administration method	Spray

Good Agricultural Practice (GAP)

Maleic hydrazide is used as a plant growth regulator for bulb vegetables. Application is made to mature bulbs, at a rate of 2.4kgai/ha 10-14 days before harvest.

Residues Information

Residue data for bulb vegetables supports an MRL of 15mg/kg for maleic hydrazide when the last treatment is made 10-14 days before harvest. An MRL of 15mg/kg is therefore proposed to support GAP.

Dietary Risk Assessment

Acceptable Daily Intake	0.3mg/kg bw/day
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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 maleic hydrazide 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 maleic hydrazide is equivalent to less than 35% 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 maleic hydrazide as plant growth regulator for bulb vegetables, according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

Other International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
Australia		
Maleic hydrazide	Garlic	15
	Onions, bulb	15
Codex Alimentarius		
Maleic hydrazide	Garlic	15
	Onion, Bulb	15
	Shallots	15
European Commission		
Maleic hydrazide	Garlic	15
	Onions(Silverskin onions)	15
	Shallots	15
Japan		
Maleic hydrazide	Garlic	50
	Onions	20
United States		
Maleic hydrazide	Onions, bulb	15

Food imported to New Zealand must comply with either Codex Alimentarius Commission (Codex) MRLs, New Zealand's domestic MRL Standards, or, if no appropriate Codex or domestic MRL exists, the default MRL of 0.1mg/kg.

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.

5 Proposal to set an MRL for Mesosulfuron-methyl

It is proposed that an MRL is set for mesosulfuron-methyl when used as a herbicide around wheat. It is proposed that Schedule One of the NZ (MRL) Food Standards 2010 be amended to include the following; and that this will be the resulting entry for mesosulfuron-methyl in Schedule One of the NZ (MRL) Food Standards 2010:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Mesosulfuron-methyl	208465-21-8	Mesosulfuron-methyl	Wheat	0.01(*)

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

Amendment Rationale

The proposed MRL represents the approval of a new herbicide active ingredient in New Zealand for post-emergent control of weeds in wheat. The proposed MRL will manage the use of mesosulfuron-methyl to GAP in New Zealand.

Chemical Information

Common name of compound	Mesosulfuron-methyl
Use of compound	Herbicide
Chemical Abstract Services (CAS) Registry number	208465-21-8
Type of compound	Pyrimidinylsulfonyleurea
Administration method	Broadcast spray

Good Agricultural Practice

Mesosulfuron-methyl is proposed for use as a herbicide for control of weeds in wheat as a single application post emergence of 7.5gai/ha made approximately 85 days before harvest.

Residues Information

Residue data for wheat supports a limit of quantification MRL of 0.01mg/kg at harvest following application of mesosulfuron-methyl prior to growth stage 30. An MRL of 0.01mg/kg is therefore proposed to support GAP.

Dietary Risk Assessment

Potential daily exposure via food ($PDE_{(food)}$)	0.7mg/kg bw/day
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The PDE_(food) is a value set by the Environmental Risk Management Authority (ERMA), which 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 mesosulfuron-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 mesosulfuron-methyl is equivalent to less than 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 mesosulfuron-methyl as herbicide for control weeds in wheat, is very unlikely to pose any health risks from consumption of the harvested commodity.

Other International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
Australia		
Mesosulfuron-methyl	Wheat	0.01*
EU		
Mesosulfuron-methyl	Wheat (Spelt Triticale)	0.01*
Japan		
Mesosulfuron-methyl	Wheat	0.03
United States		
Mesosulfuron-methyl	Wheat	0.03

Food imported to New Zealand must comply with either Codex Alimentarius Commission (Codex) MRLs, New Zealand's domestic MRL Standards, or, if no appropriate Codex or domestic MRL exists, the default MRL of 0.1mg/kg.

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 Methoxyfenozide

It is proposed that an MRL is set for methoxyfenozide when used as an insecticide for avocados. It is proposed that Schedule One of the NZ (MRL) Food Standards 2010 be amended to include the following:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Methoxyfenozide	161050-58-4	Methoxyfenozide	Avocados	0.1

The final entry for methoxyfenozide in Schedule One of the NZ (MRL) Food Standards 2010 will therefore read:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Methoxyfenozide	161050-58-4	Methoxyfenozide	Avocados	0.1
			Kiwifruit	0.5
			Pome fruits	0.5

Amendment Rationale

The proposed MRL represents a new use pattern for the active ingredient methoxyfenozide. An MRL of 0.1mg/kg is deemed appropriate to manage the use of methoxyfenozide as an insecticide for control of leafrollers on avocados, to the application rates and withholding periods that have been approved as GAP in New Zealand.

Chemical Information

Common name of compound	Methoxyfenozide
Use of compound	Insecticide
Chemical Abstract Services (CAS) Registry number	161050-58-4
Type of compound	Diacylhydrazine
Administration method	Foliar spray

Good Agricultural Practice (GAP)

Methoxyfenozide is proposed as an insecticide on avocados. Application is as a full coverage spray made upto a maximum of four times a season with intervals of 3-4 weeks, at a rate of 6gai/100L, with a withholding period of 14 days.

Residues Information

The residue data for avocados support an MRL of 0.1mg/kg for methoxyfenozide when the last treatment is made 14 days before harvest. An MRL of 0.1mg/kg are therefore proposed to support GAP.

Dietary Risk Assessment

Potential daily exposure via food (PDE_(food))	0.08mg/kg bw/day
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The PDE_(food) is a value set by the Environmental Risk Management Authority (ERMA), which 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 methoxyfenozide 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 methoxyfenozide is equivalent to less than 1% 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 methoxyfenozide as an insecticide for use on avocados according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

Other International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
EU		
Methoxyfenozide	Avocados	0.02*
USA		
Methoxyfenozide	Avocados	0.6

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

Food imported to New Zealand must comply with either Codex Alimentarius Commission (Codex) MRLs, New Zealand's domestic MRL Standards, or, if no appropriate Codex or domestic MRL exists, the default MRL of 0.1mg/kg.

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.

7 Proposal to set an MRL for Spirotetramat

It is proposed that an MRL is set for spirotetramat when used as an insecticide for control of armoured scales on kiwifruit. It is proposed that Schedule One of the NZ (MRL) Food Standards 2010 be amended to include the following:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Spirotetramat	203313-25-1	<i>Sum of:</i> Spirotetramat and its enol metabolite <i>Expressed as:</i> Spirotetramat	Kiwifruit	0.1

The final entry for spirotetramat in Schedule One of the NZ (MRL) Food Standards 2010 will therefore read:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Spirotetramat	203313-25-1	<i>Sum of:</i> Spirotetramat and its enol metabolite <i>Expressed as:</i> Spirotetramat	Kiwifruit Potatoes	0.1 0.5

Amendment Rationale

The proposed MRL represents a new use pattern in New Zealand for the active ingredient spirotetramat. The proposed MRLs will manage the use of spirotetramat as an insecticide for control of armoured scale on kiwifruit, to the application rates and withholding periods that are approved GAP in New Zealand.

Chemical Information

Common name of compound	Spirotetramat
Use of compound	Insecticide
Chemical Abstract Services (CAS) Registry number	203313-25-1
Type of compound	Tetramic acid
Administration method	Spray

Good Agricultural Practice (GAP)

Spirotetramat is approved as an insecticide on kiwifruit. Application is as a foliar treatment made up to a maximum of two times a season, at a rate of 96gai/ha, with a withholding period of not applying after fruit set.

Residues Information

The residue data for kiwifruit support an MRL of 0.1mg/kg for spirotetramat when the last treatment is made at fruit set. An MRL of 0.1mg/kg is therefore proposed to support GAP.

Dietary Risk Assessment

Potential daily exposure via food (PDE_(food))	0.09mg/kg bw/day
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The PDE_(food) is a value set by the Environmental Risk Management Authority (ERMA), which 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 spirotetramat 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 spirotetramat is equivalent to 1% 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 spirotetramat as an insecticide for use on kiwifruit according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

Other International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
EU		
Spirotetramat	Kiwi	0.1*

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

Food imported to New Zealand must comply with either Codex Alimentarius Commission (Codex) MRLs, New Zealand's domestic MRL Standards, or, if no appropriate Codex or domestic MRL exists, the default MRL of 0.1mg/kg.

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 set MRLs for Sulphur Dioxide

It is proposed that MRLs are set for sulphur dioxide when used on blueberries, grapes and longans. It is proposed that Schedule One of the NZ (MRL) Food Standards 2010 be amended to include the following; and that this will be the resulting entry for sulphur dioxide in Schedule One of the NZ (MRL) Food Standards 2010:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Sulphur dioxide and sodium and potassium sulphites	7446-09-5	Sum of sulphites including bisulphites and metabisulphites calculated as sulphur dioxide	Blueberries	10
			Grapes	10
			Longans	10

Amendment Rationale

The proposed MRLs are to be set to address the relocation of maximum permissible limits for sulphur dioxide for blueberries, grapes and longans from Standard 1.3.1 (Food Additives) of the Australia New Zealand Food Standards Code (the Code) to Standard 1.4.2 (Australia only MRLs). As the relocation has the potential to impact on food imported into New Zealand MRLs have been proposed to continue to allow these residues to be acceptable.

Chemical Information

Common name of compound	Sulphur dioxide
Use of compound	Preservative
Chemical Abstract Services (CAS) Registry number	7446-09-5
Administration method	Vapour

Good Agricultural Practice (GAP)

New Zealand GAP for this ingredient has not been defined.

Residues Information

It is proposed that the current maximum limit values of 10mg/kg for blueberries, grapes and longans soon to be relocated within the Code be incorporated into the MRL Standards.

Dietary Risk Assessment

Levels of sulphur dioxide present in food are not changing from those previously demonstrated to be safe, thus no dietary risk is presented by the proposed MRLs.

Toxicological / Public Health Assessment

As levels of sulphur dioxide in blueberries, grapes and longans are not proposed to change, the proposed MRLs are very unlikely to pose any health risks from consumption of treated produce.

Other International MRLs

Food imported to New Zealand must comply with either Codex Alimentarius Commission (Codex) MRLs, New Zealand's domestic MRL Standards, or, if no appropriate Codex or domestic MRL exists, the default MRL of 0.1mg/kg.

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.

9 Proposal to set an MRL for Uniconazole-P

It is proposed that an MRL is set for uniconazole-P when used as a plant growth regulator for avocados. It is proposed that Schedule One of the NZ (MRL) Food Standards 2010 be amended to include the following; and that this will be the resulting entry for uniconazole-P in Schedule One of the NZ (MRL) Food Standards 2010:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Uniconazole-P	83657-17-4	Uniconazole-P - sum of isomers, expressed as Uniconazole-P	Avocados	0.5

Amendment Rationale

The proposed MRL represents a new registration in New Zealand for the active ingredient uniconazole-P. The proposed MRL will manage the use of uniconazole-P as a plant growth regulator on avocados, to the application rates and withholding periods that are approved GAP in New Zealand.

Chemical Information

Common name of compound	Uniconazole-P
Use of compound	Plant growth regulator
Chemical Abstract Services (CAS) Registry number	83657-17-4
Type of compound	Triazole
Administration method	Spray

Good Agricultural Practice

Uniconazole-P is proposed for use as a plant growth regulator for avocados. Application is made once at 50% flowering (mid-bloom) at a rate of up to 50gai/100L water, with a withholding period of 14 days.

Residues Information

Residue data for avocados supports an MRL of 0.5 mg/kg for uniconazole-P when the last treatment is made 14 days before harvest. An MRL of 0.5mg/kg is therefore proposed to support GAP.

Dietary Risk Assessment

Acceptable Daily Intake	0.02mg/kg bw/day
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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 uniconazole-P 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 uniconazole-P is equivalent to less than 0.1% 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 uniconazole-P as a plant growth regulator on avocados according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

Other International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
Australia		
Uniconazole-P	Avocados	0.5
Japan		
Uniconazole-P	Avocados	0.5

Food imported to New Zealand must comply with either Codex Alimentarius Commission (Codex) MRLs, New Zealand's domestic MRL Standards, or, if no appropriate Codex or domestic MRL exists, the default MRL of 0.1mg/kg.

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.

10 Proposal to exempt Benzalkonium Chloride from an MRL

It is proposed that the current MRL exemption for benzalkonium chloride be extended for use as a fungicide on pome fruits.

It is proposed that Schedule Two of the NZ (MRL) Food Standards 2010 be amended by deleting the following entry:

Compound	CAS#	Condition
Benzalkonium chloride	8001-54-4	When applied as a fungicide prior to the end of flowering on kiwifruit and olives

It is proposed that Schedule Two of the NZ (MRL) Food Standards 2010 be amended to include the following; and that this will be the resulting entry for benzalkonium chloride in Schedule Two of the NZ (MRL) Food Standards 2010:

Compound	CAS#	Condition
Benzalkonium chloride	8001-54-4	When applied as a fungicide prior to the end of flowering on kiwifruit, olives and as a fungicide applied prior to the end of December on pome fruits

Amendment Rationale

The proposed MRL exemption represents an extension of the current use patterns for benzalkonium chloride to include treatment of pome fruits.

Chemical Information

Common name of compound	Benzalkonium chloride
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	8001-54-4
Type of compound	Quaternary ammonium
Administration method	Spray

Good Agricultural Practice

Benzalkonium chloride is proposed for use as a fungicide for pome fruit. Application may be at a 23gai/ha up until the end of December.

Dietary Risk Assessment

No acceptable daily intake (ADI) has been set for benzalkonium chloride however it is used safely in many cleaning products and medicinal products such as eye drops and mouth washes. Trace amounts of benzalkonium may be consumed with no incident through accidental contamination of food and water with surface cleaners and dishwashing liquids. No dietary risk is expected through the use of benzalkonium on apples.

Toxicological / Public Health Assessment

The exemption of benzalkonium chloride from an MRL to the conditions specified above is very unlikely to pose any health risks from consumption of the harvested commodity.

11 Proposal to exempt

Bromochlorodimethylhydantoin from an MRL

It is proposed that a MRL exemption be set for bromochlorodimethylhydantoin (BCDHM) when used as a biocide on fruit and vegetables.

It is proposed that Schedule Two of the NZ (MRL) Food Standards 2010 be amended to include the following entry; and that this will be the resulting entry for bromochlorodimethylhydantoin in Schedule Two of the NZ (MRL) Food Standards 2010:

Compound	CAS#	Condition
Bromochlorodimethylhydantoin	16079-88-2	When applied as a biocide to fruits and vegetables

Amendment Rationale

The proposed MRL exemption represents a reassessment of the current use patterns for BCDMH. BCDMH is an approved sanitising agent under the New Zealand (Australia New Zealand Food Standards Code) Food Standards Code 2002. BCDMH residues resulting from its use as an agricultural compound are unlikely to exceed those acceptable from its use as a processing aid in the Food Standards Code. It is considered that setting an MRL is therefore not appropriate.

Nothing in the proposed exemption affects the requirement for compliance with the maximum permissible limit for the use of BCDMH as a processing aid under the Food Standards Code.

Chemical Information

Common name of compound	Bromochlorodimethylhydantoin (BCDMH)
Use of compound	Biocide
Chemical Abstract Services (CAS) Registry number	16079-88-2
Type of compound	Halogenated hydantoin
Administration method	Spray or post harvest dip

Good Agricultural Practice

Bromochlorodimethylhydantoin may be used as a pre harvest spray or as a post harvest dip or spray to fruit and vegetable crops. Application rate is variable with uses and acceptable contact time. No withholding period is necessary.

Dietary Risk Assessment

An acceptable daily intake (ADI) of 0.025mg/kg bw.day has been specified for the dimethylhydantoin component of BCDMH. A Food Standards Australia New Zealand dietary review² of BCDMH levels remaining in food from its use as a processing aid has identified that there is no dietary risk associated with this use. As the pre-harvest and post-harvest use of BCDMH as an agricultural compound are unlikely to leave residues in excess of those acceptable from the use of BCDMH as a processing aid it is considered that the dietary risks from the use of BCDMH are acceptable.

Toxicological / Public Health Assessment

The exemption of BCDMH from an MRL to the conditions specified above is very unlikely to pose any health risks from consumption of the treated commodity.

Other International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
Australia		
Bromo, chloro-dimethylhydantoin	Fruit, Vegetables and Ornamentals	Exempt

² <http://www.foodstandards.gov.au/foodstandards/applications/applicationa393bromo934.cfm>

12 Proposal to exempt Pine Oil from an MRL

It is proposed that an MRL exemption be set for pine oil when used as a herbicide.

It is proposed that Schedule Two of the NZ (MRL) Food Standards 2010 be amended to include the following; and that this will be the resulting entry for pine oil in Schedule Two of the NZ (MRL) Food Standards 2010:

Compound	CAS#	Condition
Pine oil	8002-09-3	When used as a herbicide

Amendment Rationale

The proposed MRL exemption represents a reassessment of the use pattern for pine oil, the use of this compound is as a herbicide for direct application to weeds. Due to the non-crop application and the difficulty of determining any residues, pine oil is suitable to be exempted from the requirement of an MRL.

Chemical Information

Common name of compound	Pine oil
Use of compound	Herbicide
Chemical Abstract Services (CAS) Registry number	8002-09-3
Type of compound	Essential oil
Administration method	Spot spray

Good Agricultural Practice

Pine oil is applied in the form of a spray directly to target weeds. Only indirect contact with food producing crops is likely; as such no specific GAP is required.

Residues Information

The composition of pine oil is of various terpene alcohols and other terpene derivatives, the composition can vary between sources of pine oil and methods of manufacture. Due to the large number of compounds that may be contained in the oil it is difficult to determine an appropriate marker residue that would be consistent for all sources of the oil. As such, analysis of residues in food resulting from the use of pine oil is of poor accuracy. On this basis setting an MRL is not appropriate.

Dietary Risk Assessment

Residues of pine oil are unlikely in food crops as direct application to the crop will cause phytotoxicity. There is therefore limited potential for dietary consumption.

Pine oil is present in home surface disinfectants. The potential exposure through this route is likely to be greater than any residues present in food.

Toxicological / Public Health Assessment

Pine oil was listed with a dietary reference dose of 0.05mg/kg bw/day for acute and chronic exposure by the United States Environmental Protection Agency. Given that no residues are expected from the agricultural uses of pine oil it is highly unlikely that these values will be exceeded.

Other International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
Australia		
Pine oil	All foods	Exempt