



Proposals to Amend the New Zealand
(Maximum Residue Limits of Agricultural
Compounds) Food Standards 2009

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New Zealand Food Safety Authority
P O Box 2835
WELLINGTON
Telephone: (04) 894-2500
Fax: (04) 894-2583

Website

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- Comments should be to the point and, where possible, reasons and data to support comment are requested.
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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 28 September 2009 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 2009.

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 2009 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.

The proposed MRLs have been thoroughly assessed in accordance with international methodologies such as those utilised by the expert committees advising the Codex Alimentarius Commission (Codex). Information on the technical assessment of each proposal is included in this document and covers the following:

- rationale
- chemical information
- good agricultural practice (GAP)
- residues information
- dietary risk assessment
- toxicological / public health assessment
- international MRLs.

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). PDE_{food} and ADI are described below.

A PDE_{food} or Potential Daily Exposure (food), is a value determined by a toxicological evaluation by Environmental Risk Management Authority New Zealand (ERMA NZ) as part of its responsibilities under the Hazardous Substances and New Organisms Act (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. NZFSA uses a PDE_{food} , rather than the internationally-determined ADI, where a PDE_{food} is available, due to the HSNO Act in New Zealand. The ADI and PDE_{food} are largely equivalent, as they are determined using the same set of toxicology data and in a very similar scientific process.

An ADI or Acceptable Daily Intake 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 (FAO) joint expert committees, made up of toxicologists and residue specialists. The ADI information from these joint committees also feeds into the Codex Alimentarius Commission (Codex), which sets international MRLs.

NZFA 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

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

- 0.05mg/kg for abamectin in sheep fat;
 - 0.025mg/kg for abamectin in sheep liver;
 - 0.02mg/kg for abamectin in sheep kidney and sheep meat;
 - 0.02mg/kg for abamectin in cattle fat as a replacement for 0.02mg/kg in mammalian fat
 - 0.015mg/kg for abamectin in cattle liver as a replacement for 0.015mg/kg in Liver
 - 0.01mg/kg for abamectin in cattle meat as a replacement for 0.01mg/kg in Meat
 - 0.5mg/kg for fluquinconazole in mammalian fat
 - 0.1mg/kg for fluquinconazole in mammalian kidney
 - 0.2mg/kg for fluquinconazole in mammalian liver
 - 0.02mg/kg* for fluquinconazole in mammalian meat
 - 0.01mg/kg* for fluquinconazole in wheat
 - 7mg/kg for monepantel in goat fat;
 - 5mg/kg for monepantel in goat liver;
 - 2mg/kg for monepantel in goat kidney;
 - 0.7mg/kg for monepantel in goat meat;
 - 0.4mg/kg for nitroxylnil in cattle meat and kidney;
 - 0.2mg/kg for nitroxylnil in cattle fat;
-

¹The purpose of the HSNO Act 1996 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”.

- 0.02mg/kg for nitroxylnil in cattle liver;
- 0.1mg/kg for spinosad in grapes

New MRL Exemptions

NZFA proposes to add the following MRL exemption to the Standards:

- Chlorine dioxide when used as a fungicide on fruit and vegetables;
- Ethyl formate when used as a post-harvest fumigant on cereal grains, fruit, oilseeds and vegetables

Next Steps

Following the closing date for submissions (5:00pm on Wednesday 28th September 2008), 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 Abamectin

It is proposed that MRLs are set for abamectin when used as an anthelmintic for cattle and sheep. It is proposed that Schedule One of the NZ (MRL) Food Standards 2009 be amended by deleting the following MRL:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Abamectin	71751-42-2	Sum of : avermectin B1a avermectin B1b (Z)-8,9 avermectin B1a (Z)-8,9 avermectin B1b	Liver Mammalian fats Meat	0.015 0.02 0.01

As a replacement for the deleted MRLs, it is proposed that Schedule One of the NZ (MRL) Food Standards 2009 be amended to include the following:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Abamectin	71751-42-2	Sum of : avermectin B1a avermectin B1b (Z)-8,9 avermectin B1a (Z)-8,9 avermectin B1b	Cattle fat Cattle liver Cattle meat Sheep fat Sheep kidney Sheep liver Sheep meat	0.02 0.015 0.01 0.05 0.02 0.025 0.02

The final entry for abamectin in Schedule One of the NZ (MRL) Food Standards 2009 will therefore read:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Abamectin	71751-42-2	Sum of : avermectin B1a avermectin B1b (Z)-8,9 avermectin B1a (Z)-8,9 avermectin B1b	Avocados Cattle fat Cattle liver Cattle meat Kiwifruit Pome fruits Sheep fat Sheep kidney Sheep liver Sheep meat Strawberries Tomatoes	0.02(*) 0.02 0.015 0.01 0.02(*) 0.02(*) 0.05 0.02 0.025 0.02 0.02(*) 0.1

Amendment Rationale

The proposed MRLs represent a reassessment of the residue data available for abamectin to allow harmonisation with current overseas MRLs for sheep, as the MRLs to be deleted to accommodate the change are for unspecified species. MRLs for cattle at the same levels are also to be included.

Chemical Information

Common name of compound	Abamectin
Use of compound	Anthelmintic
Chemical Abstract Services (CAS) Registry number	71751-42-2
Type of compound	Avermectin
Administration method	Oral, topical and subcutaneous injection.

Good Agricultural Practice

Abamectin is currently approved in New Zealand as an anthelmintic treatment for gastro-intestinal round-worms and lungworms in cattle and sheep use may be through oral, injectable or topical administration. Dose rates and withholding periods vary dependant on the application method.

Residues Information

Current use patterns for abamectin manage residues to the unspecified animal tissue MRL presently in the standard. By adopting the MRLs approved in the EU for sheep tissues it is conceived that a decrease in the withholding period for abamectin products could occur, with the potential to allow greater flexibility in treatments. The proposed MRLs for cattle are identical to the current MRLs for unspecified animal tissues and represent only an alteration to represent the species more accurately.

Dietary Risk Assessment

Acceptable Daily Intake (ADI)	0.002mg/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 abamectin is estimated by the National Estimated Dietary Intake (NEDI) calculation encompassing all registered uses of the chemical and food consumption data based upon the 1997 National Nutritional Survey for adults and the 1995 National Nutrition Survey of Australia, for children. The NEDI calculation is made in accordance with *Guidelines for predicting dietary intake of pesticide residues (revised)* [World Health Organisation, 1997].

The NEDI for abamectin is equivalent to 10.3% of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Toxicological / Public Health Assessment

It has been determined that the use of abamectin as an anthelmintic for use on sheep and cattle according to the good agricultural practice specified above, remains very unlikely to pose any health risks from consumption animal products from treated animals.

Other International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
EU		
Abamectin	Ovine fat	0.05
	Ovine kidney	0.02
	Ovine liver	0.025
	Ovine meat	0.02

Under Provision (3)(b) of the NZ (MRL) Food Standards 2009 imported food may contain residues of agricultural compounds no greater than the MRLs specified for that food in the current editions or supplements of the FAO/WHO Codex Alimentarius Commission publications titled "Pesticide Residues in Food" or "Residues of Veterinary Drugs in Foods".

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

2 Proposal to set MRLs for Fluquinconazole

It is proposed that MRLs are set for fluquinconazole when used as a seed treatment fungicide for wheat and in animal products as a result of its use as a fungicide for wheat for animal feed. It is proposed that Schedule One of the NZ (MRL) Food Standards 2009 be amended to include the following, this will be the resulting entry for fluquinconazole in Schedule One:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Fluquinconazole	136426-54-5	Fluquinconazole	Mammalian fat	0.5
			Mammalian kidney	0.1
			Mammalian liver	0.2
			Mammalian meat	0.02*
			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 MRLs represent a new registration in New Zealand for the active ingredient fluquinconazole. The proposed MRL will manage the new use of fluquinconazole as a fungicide on wheat and in animal products as a result of residues in animal feed, to the application rates and withholding periods that are approved good agricultural practice in New Zealand.

Chemical Information

Common name of compound	Fluquinconazole
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	136426-54-5
Type of compound	Conazole
Administration method	Seed treatment

Good Agricultural Practice

Fluquinconazole is proposed for use as a fungicide for wheat. Application is to seed at a rate of 167gai/t with a withholding period of 42 days for grazing.

Residues Information

Residue data for wheat supports a limit of quantification MRL of 0.01mg/kg at harvest following application of fluquinconazole as a seed treatment. An MRL of 0.01mg/kg is therefore proposed to support GAP.

Animal Transfer

Wheat forage is a primary animal feed, residue data indicates residues of fluquinconazole may occur in wheat forage at 42 days after sowing, to accommodate for the potential of residues to transfer to animal tissues MRLs of 0.2mg/kg in mammalian liver, 0.1mg/kg in mammalian kidneys, 0.5mg/kg in mammalian fat, and 0.02mg/kg in mammalian meat, are proposed.

Dietary Risk Assessment

Potential daily exposure via food ($PDE_{(food)}$)	0.00035mg/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 $PDE_{(food)}$ 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 fluquinconazole 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 fluquinconazole is equivalent to 74% of the $PDE_{(food)}$. It is therefore concluded that the chronic dietary exposure is acceptable.

Toxicological / Public Health Assessment

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

Other International MRLs

Under Provision (3)(b) of the NZ (MRL) Food Standards 2009, imported food may contain residues of agricultural compounds no greater than the MRLs specified for that food in the current editions or supplements of the FAO/WHO Codex Alimentarius Commission publications titled "Pesticide Residues in Food" or "Residues of Veterinary Drugs in Foods".

To meet New Zealand's obligations under the Agreement on the Application of Sanitary and Phytosanitary Measures the proposed 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.

3 Proposal to set MRLs for Monepantel

It is proposed that MRLs are set for monepantel as an anthelmintic for goats. It is proposed that Schedule One of the NZ (MRL) Food Standards 2009 be amended to include the following:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Monepantel	887148-69-8	Monepantel-sulphone	Goat fat	7
			Goat kidney	2
			Goat liver	5
			Goat meat	0.7

The final entry for monepantel in Schedule One of the NZ (MRL) Food Standards 2009 will therefore read:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Monepantel	887148-69-8	Monepantel-sulphone	Goat fat	7
			Goat kidney	2
			Goat liver	5
			Goat meat	0.7
			Sheep fat	7
			Sheep kidney	2
			Sheep liver	5
			Sheep meat	0.7

Amendment Rationale

The proposed MRLs represent the expansion of use of a currently registered active ingredient to support New Zealand trial work upon goats.

Chemical Information

Common name of compound	Monepantel
Use of compound	Anthelmintic
Chemical Abstract Services (CAS) Registry number	887148-69-8
Type of compound	Amino-Acetonitrile Derivative
Administration method	Oral drench

Good Agricultural Practice

Monepantel is currently approved in New Zealand for use as an anthelmintic for sheep; the proposed MRLs are to support the extension of use to goats for the purposes of conducting New Zealand trial work.

Residues Information

The proposed MRLs represent the extension of the current MRLs for sheep to cover potential residues from trial work on goats.

Dietary Risk Assessment

Potential daily exposure via food ($PDE_{(food)}$)	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 $PDE_{(food)}$ 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 monepantel 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 monepantel is equivalent to 3% of the $PDE_{(food)}$. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Toxicological / Public Health Assessment

The proposal for extension of MRLs to cover goats does not represent a public health risk given the low dietary burden of consumers and the small number of animals that are proposed to be treated under the trial conditions.

Other International MRLs

Under Provision (3)(b) of the NZ (MRL) Food Standards 2009 imported food may contain residues of agricultural compounds no greater than the MRLs specified for that food in the current editions or supplements of the FAO/WHO Codex Alimentarius Commission publications titled "Pesticide Residues in Food" or "Residues of Veterinary Drugs in Foods".

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

4 Proposal to set MRLs for Nitroxylin

It is proposed that MRLs are set for Nitroxylin when used as a fasciolicide for cattle. It is proposed that Schedule One of the NZ (MRL) Food Standards 2009 be amended by deleting the following MRL:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Nitroxylin	1689-89-0	Nitroxylin	Fats (except milk fats)	1

As a replacement for the deleted Fats MRL, it is proposed that Schedule One of the NZ (MRL) Food Standards 2009 be amended to include the following; this will be the resulting entry in Schedule One of the NZ (MRL) Food Standards 2009:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Nitroxylin	1689-89-0	Nitroxylin	Cattle meat	0.4
			Cattle kidney	0.4
			Cattle fat	0.2
			Cattle liver	0.02

Amendment Rationale

The proposed MRLs represent a reassessment of the current New Zealand MRL to derive more accurate levels representative of the tissue distribution of residues. The proposed MRLs will manage the use of nitroxylin as a fasciolicide on cattle.

Chemical Information

Common name of compound	Nitroxylin
Use of compound	Fasciolicide
Chemical Abstract Services (CAS) Registry number	1689-89-0
Type of compound	Unclassified
Administration method	Injection

Good Agricultural Practice

Nitroxylin is proposed for use as a fasciolicide (controlling liver fluke infestation) in cattle. The current MRL is inappropriate for representation of the distribution of nitroxylin residues in tissue. The proposed MRLs represent a reassessment of the tissue distribution of residues.

Residues Information

Residue data for nitroxylnil indicates the current MRL for fats of unspecified species is inappropriate for the distribution of residues in tissues. To address this, more accurate MRLs to represent tissue distribution of nitroxylnil are proposed. As the current proposal for use is only for treatment of liver fluke in cattle, it is proposed the MRLs be limited to edible tissues of cattle.

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 nitroxylnil 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 nitroxylnil is equivalent to 1.5% 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 nitroxylnil as a fasciolicide for use on cattle, is very unlikely to pose any health risks from consumption of the harvested commodity.

Other International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
EU		
Nitroxylnil	Bovine muscle	0.4
	Bovine kidney	0.4
	Bovine fat	0.2
	Bovine liver	0.02

Under Provision (3)(b) of the NZ (MRL) Food Standards 2009 imported food may contain residues of agricultural compounds no greater than the MRLs specified for that food in the current editions or supplements of the FAO/WHO Codex Alimentarius Commission publications titled "Pesticide Residues in Food" or "Residues of Veterinary Drugs in Foods".

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

5 Proposal to set MRLs for Spinosad

It is proposed that MRLs are set for spinosad when used as an insecticide for grapes. It is proposed that Schedule One of the NZ (MRL) Food Standards 2009 be amended to include the following:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Spinosad	168316-95-8 (131929-60-7 + 131929-63-0)	<i>Sum of:</i> spinosyn A spinosyn D <i>Expressed as:</i> Spinosad	Grapes	0.1

The final entry for spinosad in Schedule One of the NZ (MRL) Food Standards 2009 will therefore read:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Spinosad	168316-95-8 (131929-60-7 + 131929-63-0)	<i>Sum of:</i> spinosyn A spinosyn D <i>Expressed as:</i> Spinosad	Citrus fruits Grapes Kiwifruit Potatoes Sheep fat Sheep kidney Sheep liver Sheep meat Stone fruits Tomatoes	0.05 0.1 0.2 0.01(*) 2 0.5 0.5 0.05 1 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 the setting of reassessment of the New Zealand MRL for spinosad in grapes. Currently the residues resulting from this use pattern are managed against the New Zealand default MRL (0.1mg/kg). It is proposed to replace this with a stated MRL of 0.1mg/kg.

Chemical Information

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

Good Agricultural Practice

Spinosad is currently approved for use as an insecticide on grapes, for control of leaf roller at a rate of 4.8gai/100L applied at capfall and bunch closure with a withholding period of 42 days. No change to the current good agricultural practice is proposed.

Residues Information

Residue data for grapes supports an MRL of 0.1 mg/kg when the last treatment is made 42 days before harvest. An MRL of 0.1mg/kg is therefore proposed to support GAP.

Dietary Risk Assessment

Acceptable Daily Exposure (ADI)	0.02mg/kg bw/day
ERMA NZ PDE_(food)	0.028mg/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 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 spinosad is estimated by the National Estimated Dietary Intake (NEDI) calculation encompassing all registered uses of the chemical and food consumption data based upon the 1997 National Nutritional Survey for adults and the 1995 National Nutrition Survey of Australia, for children. The NEDI calculation is made in accordance with *Guidelines for predicting dietary intake of pesticide residues (revised)* [World Health Organisation, 1997].

The NEDI for spinosad is equivalent to 3.8% of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Toxicological / Public Health Assessment

It has been determined that the use of spinosad as an insecticide for use on grapes 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		
Spinosad	Grape	0.5

Under Provision (3)(b) of the NZ (MRL) Food Standards 2009, imported food may contain residues of agricultural compounds no greater than the MRLs specified for that food in the current editions or supplements of the FAO/WHO Codex Alimentarius Commission publications titled “Pesticide Residues in Food” or “Residues of Veterinary Drugs in Foods”.

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

6 Proposal to exempt Chlorine dioxide from an MRL

It is proposed that an MRL exemption is set for chlorine dioxide when used as a fungicide for fruit and vegetables. It is proposed that Schedule Two of the NZ (MRL) Food Standards 2009 be amended to include the following, this will be the resulting entry for chlorine dioxide in Schedule Two of the NZ (MRL) Food Standards 2009.

Compound	CAS#	Condition
Chlorine dioxide	10049-04-4	When applied as a fungicide to fruit and vegetables at a concentration not exceeding 10ppm.

Amendment Rationale

The proposed MRL exemption represents a new registration in New Zealand for the active ingredient chlorine dioxide, the low application rate and 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. Nothing in the proposed exemption effects the requirement for compliance with the maximum permissible limit for the use of chlorine dioxide as a processing aid under the New Zealand (Australia New Zealand Food Standards Code) Food Standards Code 2002.

Chemical Information

Common name of compound	Chlorine dioxide
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	10049-04-4
Type of compound	Halogen oxide
Administration method	Spray

Good Agricultural Practice

Chlorine dioxide is proposed for use as a fungicide for control of fungi for fruit and vegetables. Application may be at a concentration of up to 10ppm chlorine dioxide.

Residues Information

Chlorine dioxide is rapidly decomposed in environmental media, breaking down to chloride ions and oxidised products of organic media. Given the low rate of application and the rapid decomposition it would not be expected that residues will remain on food at the time of consumption. Chlorine dioxide is also used in a range of processing aid roles and in some drinking water treatment.

Dietary Risk Assessment

No ADI has been set for chlorine dioxide however it was assessed by the Environmental Risk Management Authority to represent a negligible risk to human health, given it is used already for treatment of drinking water and as a processing aid it is unlikely to represent a dietary risk.

Toxicological / Public Health Assessment

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

Other International MRLs

Under Provision (3)(b) of the NZ (MRL) Food Standards 2009 imported food may contain residues of agricultural compounds no greater than the MRLs specified for that food in the current editions or supplements of the FAO/WHO Codex Alimentarius Commission publications titled "Pesticide Residues in Food" or "Residues of Veterinary Drugs in Foods".

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

7 Proposal to exempt Ethyl formate from an MRL

It is proposed that an MRL exemption is set for ethyl formate when used as a post harvest fumigant. It is proposed that Schedule Two of the NZ (MRL) Food Standards 2009 be amended by deleting the following:

Compound	CAS#	Condition
Ethyl formate	109-94-4	Used as a post-harvest fumigant on cereal grains, oilseeds and bananas

As a replacement for the deleted entry it is proposed the Schedule Two of the NZ (MRL) Food Standards 2009 be amended to include the following; this will be the resulting entry for ethyl formate in Schedule Two of the NZ (MRL) Food Standards 2009:

Compound	CAS#	Condition
Ethyl formate	109-94-4	Used as a post-harvest fumigant on cereal grains, fruit, oilseeds and vegetables

Amendment Rationale

The proposed MRL exemption represents an extension in use patterns in New Zealand for the active ingredient ethyl formate. The rapid decomposition of this compound in the environment, its presence in certain food crops naturally and in final foods as a flavour additive and its low toxicity mean it is not suitable to be managed against a chemical concentration limit.

Chemical Information

Common name of compound	Ethyl formate
Use of compound	Fumigant
Chemical Abstract Services (CAS) Registry number	109-94-4
Type of compound	Ester
Administration method	Vapour

Good Agricultural Practice

Ethyl formate is proposed for use as a post harvest fumigant for fruit and vegetables, rates differ dependant on the fumigation needs. No further GAP is required.

Residues Information

Ethyl formate is naturally present at significant levels in certain crop plants and at high levels in processed foods as a flavouring agent, any residues resulting from its use as an agricultural compound may also degrade rapidly. Given residue of ethyl formate occurring in the plant as a result of agricultural compound use would be indistinguishable from background levels or levels added as a flavouring agent it is not appropriate to be regulated against an MRL.

Dietary Risk Assessment

Ethyl formate is a naturally occurring component of the diet and is present in significant levels in certain crops such as berry fruit. Ethyl formate may also be used as a flavouring agent in certain processed foods. Ethyl formate is considered as generally recognised as safe by a number of overseas countries, thus levels occurring as a result of its agricultural uses will not represent a dietary risk.

Toxicological / Public Health Assessment

Ethyl formate occurs in the diet and may also be present in processed foods as a flavouring agent. It is considered generally recognised as safe, thus the proposed MRL exemption for ethyl formate represents no public health risk.

Other International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
Australia		
Ethyl formate	Post harvest fumigation of fruit and vegetables	Exempt

Under Provision (3)(b) of the NZ (MRL) Food Standards 2009 imported food may contain residues of agricultural compounds no greater than the MRLs specified for that food in the current editions or supplements of the FAO/WHO Codex Alimentarius Commission publications titled "Pesticide Residues in Food" or "Residues of Veterinary Drugs in Foods".

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