



Proposals to Amend the New Zealand  
(Maximum Residue Limits of Agricultural  
Compounds) Food Standards 2008

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## Submissions

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

- Wherever possible, comment should be specific to a particular section in the document. All major sections are numbered and these numbers should be used to link comments to the document.
- 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.
- As a number of copies may be made of your comments, please use good quality type, and make sure the comments are clearly hand-written in black or blue ink.

Please include the following information in your submission:

- The title of the discussion document;
- 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 30<sup>th</sup> July 2008 to:**

MRL Amendments, Policy Group, New Zealand Food Safety Authority

PO Box 2835, Wellington, fax: (04) 894 2583, or email: [policy@nzfsa.govt.nz](mailto: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 2008.

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 2008 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) ( $PDE_{\text{food}}$ ) or where there is no  $PDE_{\text{food}}$ , by comparing it with the Acceptable Daily Intake (ADI).  $PDE_{\text{food}}$  and ADI are described below.

A  $PDE_{\text{food}}$  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.<sup>1</sup> A  $PDE_{\text{food}}$  gives the potential daily exposure a person may be subject to from a substance, via food. NZFSA uses a  $PDE_{\text{food}}$ , rather than the internationally-determined ADI, where a  $PDE_{\text{food}}$  is available, due to the HSNO Act in New Zealand. The ADI and  $PDE_{\text{food}}$  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.

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:

- 0.0003mg/kg for chloramphenicol in any food
- 0.3mg/kg for chlorantraniliprole in brassica vegetables and pomefruit;
- 0.05mg/kg for cymoxanil in garlic, onions and potatoes;
- 1mg/kg for cyprodinil in strawberries;
- 1mg/kg for fludioxinil in strawberries;
- 0.2mg/kg for formetanate hydrochloride in onions;
- 0.15mg/kg for lincomycin in cattle milk;
- 0.02mg/kg for myclobutanil in cucurbits (inedible peel);
- 1.5mg/kg for neomycin in cattle milk as a replacement for 0.5mg/kg for neomycin in cattle milk; and
- 0.05mg/kg for spinosad in tomatoes as a replacement for 0.01mg/kg for spinosad in tomatoes.

### New MRL Exemptions

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

- Chlorhexidine and its digluconate salt when applied as a topical antiseptic to all food producing species except fish.

## Next Steps

Following the closing date for submissions (5:00pm on Wednesday 30<sup>th</sup> July 2008), all submissions will be considered and analysed before a recommendation is made to the Minister for Food Safety, the Hon Lianne Dalziel, 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 an MRL for Chloramphenicol

It is proposed that an MRL is set for chloramphenicol when occurring as a veterinary medicine in all food products. It is proposed that Schedule One of the NZ (MRL) Food Standards 2008 be amended to include the following; this will be the resulting entry for chloramphenicol in Schedule One of the NZ (MRL) Food Standards 2008:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Chloramphenicol	56-75-7	<i>Sum of:</i> chloramphenicol and chloramphenicol glucuronide <i>Expressed as:</i> chloramphenicol	Any food	0.0003*

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

## Amendment Rationale

The proposed MRL for chloramphenicol represents that it is unacceptable for chloramphenicol to be used in veterinary medicine in New Zealand or to be detectable in any food products. This MRL will apply to all food products imported into, or produced in, New Zealand.

## Chemical Information

<b>Common name of compound</b>	Chloramphenicol
<b>Use of compound</b>	Antibiotic
<b>Chemical Abstract Services (CAS) Registry number</b>	56-75-7
<b>Type of compound</b>	Phenicol
<b>Administration method</b>	n/a

## Good Agricultural Practice

Chloramphenicol is not registered for use or used in New Zealand and is widely banned or restricted overseas. Given this status it is unacceptable that it is used for any purpose leading to residues in food in New Zealand.

## Residues Information

The proposed MRL is at the limit of analytical quantification. Therefore, the MRL represents that no detectable residues of chloramphenicol should occur in any food products.

## Dietary Risk Assessment

As residues of chloramphenicol are proposed to be regulated to the limit of analytical quantification in all food products, the proposal is not expected to result in any dietary risk.

## Toxicological / Public Health Assessment

It has been determined that the use of chloramphenicol in the veterinary treatment of food producing animal species is unacceptable. Therefore, regulating that no detectable residues shall occur in food products will ensure that there is no risk to public health.

## Other International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
<b>Canada</b>		
Chloramphenicol	All foods	Banned
<b>European Union</b>		
Chloramphenicol	All foods	Banned

Note that in the European Community, a Minimum Required Performance Limit (MRPL) of 0.0003mg/kg is required for testing laboratories. This level is set at the content of an analyte which can be detected and confirmed by official laboratories in the European Union. The MRPL is set to ensure harmonised implementation of the controls to certify the absence of chloramphenicol in the consignments.

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 an MRL for Chlorantraniliprole

It is proposed that an MRL is set for chlorantraniliprole when used as an insecticide for brassica vegetables and pome fruits. It is proposed that Schedule One of the NZ (MRL) Food Standards 2008 be amended to include the following; this will be the resulting entry for chlorantraniliprole in Schedule One of the NZ (MRL) Food Standards 2008:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Chlorantraniliprole	500008-45-7	Chlorantraniliprole	Brassica vegetables	0.3
			Pome fruit	0.3

### Amendment Rationale

The proposed MRL for chlorantraniliprole represents the registration in New Zealand of a new active ingredient. The proposed MRL will manage the use of chlorantraniliprole as an insecticide on brassica vegetable and pome fruits to the application rates and withholding periods that are approved good agricultural practice (GAP) in New Zealand (see below).

### Chemical Information

<b>Common name of compound</b>	Chlorantraniliprole
<b>Use of compound</b>	Insecticide
<b>Chemical Abstract Services (CAS) Registry number</b>	500008-45-7
<b>Type of compound</b>	Diamide
<b>Administration method</b>	Spray

### Good Agricultural Practice

Chlorantraniliprole is proposed for use as an insecticide for brassica vegetables. Application may be 3 times per season as pests appear, at 20gai/ha with a withholding period of 7 days.

Chlorantraniliprole is also proposed for use as an insecticide for pome fruits. Application may be 3 times per season from petal fall, at 63gai/ha with a withholding period of 14 days.

### Residues Information

Residue data for chlorantraniliprole in brassica vegetables supports an MRL of 0.3mg/kg at 7 days after the last treatment. An MRL of 0.3mg/kg is therefore proposed to support GAP.

Residue data for chlorantraniliprole in pome fruits supports an MRL of 0.3mg/kg at 14 days after the last treatment. An MRL of 0.3mg/kg is therefore proposed to support GAP.

### *Animal Transfer*

Residue transfer to animals grazing treated orchards has not been assessed as it is not acceptable practice that treated orchards be grazed. Animals may consume treated brassica vegetables, however it is not expected that residues will result in any animal derived food products. Animal derived food product limits are therefore not proposed.

### **Dietary Risk Assessment**

<b>Acceptable Daily Intake (ADI)</b>	1.58mg/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 chlorantraniliprole 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 chlorantraniliprole is equivalent to 0.03% 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 chlorantraniliprole as an insecticide for use on brassica vegetables and pome fruits, according to GAP specified above, is very unlikely to pose any health risks from consumption of the harvested commodities.

### **Other International MRLs**

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

### 3 Proposal to set an MRL for Cymoxanil

It is proposed that an MRL is set for cymoxanil when used as a fungicide for garlic, onions and potatoes. It is proposed that Schedule One of the NZ (MRL) Food Standards 2008 be amended to include the following entries:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Cymoxanil	57966-95-7	Cymoxanil	Garlic	0.05*
			Onions	0.05*
			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 cymoxanil in Schedule One of the NZ (MRL) Food Standards 2008 will therefore read:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Cymoxanil	57966-95-7	Cymoxanil	Garlic	0.05*
			Onions	0.05*
			Peas	0.05*
			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 MRLs represent new use patterns in New Zealand of cymoxanil as a fungicide on garlic, onions and potatoes to the application rates and withholding periods that are approved good agricultural practice (GAP) in New Zealand (see below).

#### Chemical Information

<b>Common name of compound</b>	Cymoxanil
<b>Use of compound</b>	Fungicide
<b>Chemical Abstract Services (CAS) Registry number</b>	57966-95-7
<b>Type of compound</b>	Aliphatic nitrogen
<b>Administration method</b>	Spray

#### Good Agricultural Practice

Cymoxanil is proposed for use as a fungicide for garlic, potatoes and onions. Application may be throughout plant growth, at 0.09 - 0.165kgai/ha with a withholding period of 14 days.

## Residues Information

Residue data for garlic, onions and potatoes support limit of quantification MRLs of 0.05mg/kg at 14 days after the last treatment. MRLs of 0.05mg/kg are therefore proposed to support GAP.

### *Animal Transfer*

Animals may be fed failed crops of onions and potatoes. Given that no residues are expected in treated crops, it is concluded that there is not likely to be any animal transfer of residues. Animal derived food product limits are therefore not proposed.

## Dietary Risk Assessment

<b>Acceptable Daily Intake (ADI)</b>	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 cymoxanil 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 cymoxanil 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 cymoxanil as a fungicide for use on garlic, onions and potatoes, according to the GAP specified above, is very unlikely to pose any health risks from consumption of the harvested commodities.

## Other International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
The Netherlands		
Cymoxanil	All foods	0.05*

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.

## 4 Proposal to set an MRL for Cyprodinil

It is proposed that an MRL is set for cyprodinil when used as a fungicide for strawberries. It is proposed that Schedule One of the NZ (MRL) Food Standards 2008 be amended to include the following entry:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Cyprodinil	121552-61-2	Cyprodinil	Strawberries	1

The final entry for cyprodinil in Schedule One of the NZ (MRL) Food Standards 2008 will therefore read:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Cyprodinil	121552-61-2	Cyprodinil	Grapes	0.2
			Nectarines	0.02
			Peaches	0.02
			Pome fruits	0.01
			Strawberries	1

### Amendment Rationale

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

### Chemical Information

<b>Common name of compound</b>	Cyprodinil
<b>Use of compound</b>	Fungicide
<b>Chemical Abstract Services (CAS) Registry number</b>	121552-61-2
<b>Type of compound</b>	Pyrimidine
<b>Administration method</b>	Spray

### Good Agricultural Practice

Cyprodinil is proposed for use as a fungicide for strawberries. Application may be 2-3 times at 7-14 day intervals after flowering, at 300gai/ha with a withholding period of 3 days.

### Residues Information

Residue data for strawberries support an MRL of 1mg/kg at 3 days after the last treatment. An MRL of 1mg/kg is therefore proposed to support GAP.

### Animal Transfer

Strawberries are not considered an animal feed commodity. Animal derived food product limits are therefore not proposed.

### Dietary Risk Assessment

<b>Acceptable Daily Intake (ADI)</b>	0.027mg/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 cyprodinil 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 cyprodinil is equivalent to 0.3% 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 cyprodinil as a fungicide for use on strawberries, according to the GAP specified above, is very unlikely to pose any health risks from consumption of the harvested commodity.

### Other International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
<b>The Netherlands</b>		
Cyprodinil	Strawberries	2

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 Fludioxinil

It is proposed that an MRL is set for fludioxinil when used as a fungicide for strawberries. It is proposed that Schedule One of the NZ (MRL) Food Standards 2008 be amended to include the following entry:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Fludioxinil	131341-86-1	Fludioxinil	Strawberries	1

The final entry for fludioxinil in Schedule One of the NZ (MRL) Food Standards 2008 will therefore read:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Fludioxinil	131341-86-1	Fludioxinil	Grapes Strawberries	0.05 1

### Amendment Rationale

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

### Chemical Information

<b>Common name of compound</b>	Fludioxinil
<b>Use of compound</b>	Fungicide
<b>Chemical Abstract Services (CAS) Registry number</b>	131341-86-1
<b>Type of compound</b>	Pyrimidine
<b>Administration method</b>	Spray

### Good Agricultural Practice

Fludioxinil is proposed for use as a fungicide for strawberries. Application may be 2-3 times at 7-14 day intervals after flowering, at 200gai/ha with a withholding period of 3 days.

### Residues Information

Residue data for strawberries support an MRL of 1mg/kg at 3 days after the last treatment. An MRL of 1mg/kg is therefore proposed to support GAP.

### Animal Transfer

Strawberries are not considered an animal feed commodity. Animal derived food product limits are therefore not proposed.

### Dietary Risk Assessment

<b>Acceptable Daily Intake (ADI)</b>	0.33mg/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 fludioxinil 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 fludioxinil is equivalent to 0.8% 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 fludioxinil as a fungicide for use on strawberries, according to the GAP specified above, is very unlikely to pose any health risks from consumption of the harvested commodity.

### Other International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
<b>The Netherlands</b>		
Fludioxinil	Strawberries	2

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 Formetanate Hydrochloride

It is proposed that an MRL is set for formetanate hydrochloride when used as an insecticide for onions. It is proposed that Schedule One of the NZ (MRL) Food Standards 2008 be amended to include the following; this will be the resulting entry for formetanate hydrochloride in Schedule One of the NZ (MRL) Food Standards 2008:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Formetanate hydrochloride	23422-53-9	Formetanate free base	Onions	0.2

### Amendment Rationale

The proposed MRL for formetanate hydrochloride represents the registration in New Zealand of a new active ingredient. The proposed MRL will manage the new use of formetanate hydrochloride as an insecticide on onions to the application rates and withholding periods that are approved good agricultural practice (GAP) in New Zealand (see below).

### Chemical Information

<b>Common name of compound</b>	Formetanate hydrochloride
<b>Use of compound</b>	Insecticide
<b>Chemical Abstract Services (CAS) Registry number</b>	23422-53-9
<b>Type of compound</b>	N-methyl carbamate
<b>Administration method</b>	Spray

### Good Agricultural Practice

Formetanate hydrochloride is proposed for use as an insecticide for onions. Application may be on mature crops, at 0.75kgai/ha with a withholding period of 14 days.

### Residues Information

Residue data for onions support an MRL of 0.2mg/kg at 14 days after the last treatment. An MRL of 0.2mg/kg is therefore proposed to support GAP.

### Animal Transfer

Onions are not a primary animal feed crop. It is conceivable that failed crops may be fed to animals; however it is unlikely that detectable residues will arise in animal derived food products. Animal derived food product limits are therefore not proposed.

### Dietary Risk Assessment

<b>Acceptable Daily Intake (ADI)</b>	0.004mg/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 formetanate hydrochloride 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 formetanate hydrochloride is equivalent to 2% of the ADI/ $PDE_{(food)}$ . It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

### Toxicological / Public Health Assessment

It has been determined that the use of formetanate hydrochloride as an insecticide for use on onions, according to the GAP specified above, is very unlikely to pose any health risks from consumption of the harvested commodity.

### Other International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
<b>The Netherlands</b>		
Formetanate	All foods	0.05*

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

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 Lincomycin

It is proposed that an MRL is set for lincomycin when used as a veterinary medicine for cattle. It is proposed that Schedule One of the NZ (MRL) Food Standards 2008 be amended to include the following; this will be the resulting entry for lincomycin in Schedule One of the NZ (MRL) Food Standards 2008:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Lincomycin	154-21-2	Lincomycin	Cattle milk	0.15

### Amendment Rationale

The proposed MRL represents the setting of a New Zealand MRL for lincomycin in cattle milk that will be harmonised with MRLs set internationally by the European Union and by the Codex Alimentarius Commission.

It is intended that the increase in the MRL will allow the milking withholding period to be decreased allowing a greater flexibility in the use of lincomycin in the treatment of mastitis

### Chemical Information

Common name of compound	Lincomycin
Use of compound	Antibiotic
Chemical Abstract Services (CAS) Registry number	154-21-2
Type of compound	Lincosamide
Administration method	Intramammary

### Good Agricultural Practice

Lincomycin is currently approved in New Zealand as an antibiotic treatment for mastitis in cattle by way of intramammary, with a withholding period of 3 days for milk and 30 days for meat.

### Residues Information

The proposed MRL has been determined by Codex to represent a suitable international standard for residues.

### Dietary Risk Assessment

Acceptable Daily Intake (ADI)	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 lincomycin 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 lincomycin is equivalent to 3% of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

### Toxicological / Public Health Assessment

Promulgation of the proposed MRL for lincomycin as an antibiotic treatment for mastitis in cattle is very unlikely to pose any health risks from consumption of the milk from treated cattle.

### Other International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
<b>Codex</b>		
Lincomycin	Cattle Milk	0.15
<b>European Union</b>		
Lincomycin	Milk	0.15
<b>Japan</b>		
Lincomycin	Milk	0.15 (Provisional)

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 set an MRL for Myclobutanil

It is proposed that an MRL is set for myclobutanil when used as a fungicide for cucurbits. It is proposed that Schedule One of the NZ (MRL) Food Standards 2008 be amended to include the following entry:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Myclobutanil	88671-89-0	Myclobutanil	Cucurbits (inedible peel)	0.02

The final entry for myclobutanil in Schedule One of the NZ (MRL) Food Standards 2008 will therefore read:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Myclobutanil	88671-89-0	Myclobutanil	Cucurbits (inedible peel)	0.02
			Grapes	0.2
			Pome fruits	0.1

### Amendment Rationale

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

### Chemical Information

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

### Good Agricultural Practice

Myclobutanil is proposed for use as a fungicide for cucurbits (inedible peel). Application may be up to 2 times at 10-14 day intervals, at 75gai/ha with a withholding period of 7 days.

## Residues Information

Residue data for cucurbits (inedible peel) support an MRL of 0.02mg/kg at 7 days after the last treatment. An MRL of 0.02mg/kg is therefore proposed to support GAP.

### *Animal Transfer*

It is not expected that residues will result in any animal derived food products. Animal derived food product limits are therefore not proposed.

## Dietary Risk Assessment

<b>Acceptable Daily Intake (ADI)</b>	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 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 0.77% 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 cucurbits (inedible peel), according to the GAP specified above, is very unlikely to pose any health risks from consumption of the harvested commodity.

## Other International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
<b>The Netherlands</b>		
Myclobutanil	Pumpkin	0.2

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 Neomycin

It is proposed that an MRL is set for neomycin when used as a veterinary medicine for cattle. It is proposed that Schedule One of the NZ (MRL) Food Standards 2008 be amended by deleting the following entry:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Neomycin	1404-04-2	Neomycin	Cattle milk	0.5

As a replacement for the deleted entry, it is proposed that Schedule One of the NZ (MRL) Food Standards 2008 be amended to include the following entry:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Neomycin	1404-04-2	Neomycin	Cattle milk	1.5

The final entry for Neomycin in Schedule One of the NZ (MRL) Food Standards 2008 will therefore read:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Neomycin	1404-04-2	Neomycin	Cattle milk	1.5
			Mammalian fat	0.5
			Mammalian kidney	5
			Mammalian liver	0.5
			Mammalian meat	0.5
			Poultry eggs	0.5
			Poultry fat	0.5
			Poultry liver	0.5
			Poultry meat	0.5

### Amendment Rationale

The proposed MRL represents the setting of a New Zealand MRL for neomycin in cattle milk that will be harmonised with MRLs set internationally by Australia, the European Union and by the Codex Alimentarius Commission.

It is intended that the increase in the MRL will allow the milking withholding period to be decreased allowing a greater flexibility in the use of neomycin in the treatment of bacterial infections and mastitis

## Chemical Information

<b>Common name of compound</b>	Neomycin
<b>Use of compound</b>	Antibiotic
<b>Chemical Abstract Services (CAS) Registry number</b>	1404-04-2
<b>Type of compound</b>	Aminoglycoside
<b>Administration method</b>	Intramammary or injection

## Good Agricultural Practice

Neomycin is currently approved in New Zealand as an antibiotic treatment for bacterial infections and mastitis in cattle way of intramammary or injection, with withholding periods ranging from 3-5days for milk and 30-35 days for meat.

## Residues Information

The proposed MRL has been determined by Codex to represent a suitable international standard for residues.

## Dietary Risk Assessment

<b>Acceptable Daily Intake (ADI)</b>	0.06mg/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 neomycin 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 neomycin is equivalent to 15% of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

## Toxicological / Public Health Assessment

Promulgation of the proposed MRL for neomycin as an antibiotic treatment for bacterial infections and mastitis in cattle is very unlikely to pose any health risks from consumption of milk from treated cattle.

### Other International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
<b>Codex</b>		
Neomycin	Cattle Milk	1.5
<b>European Union</b>		
Neomycin	Milk	1.5
<b>Australia</b>		
Neomycin	Milk	1.5 (Temporary)

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 set an MRL for Spinosad

It is proposed that an MRL is set for spinosad when used as an insecticide for Tomatoes. It is proposed that Schedule One of the NZ (MRL) Food Standards 2008 be amended by deleting the following entry:

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	Tomatoes	0.01*

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

As a replacement for the deleted entry, it is proposed that Schedule One of the NZ (MRL) Food Standards 2008 be amended to include the following entry:

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	Tomatoes	0.05

The final entry for spinosad in Schedule One of the NZ (MRL) Food Standards 2008 will therefore read:

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

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 change in good agricultural practice (GAP) for the active ingredient spinosad.

The MRL proposed for spinosad in tomatoes will allow the compound to be used closer to harvest in accordance with the specified GAP in New Zealand (see below) based on a new application method and formulation type. As spinosad is considered to be of very low toxicity, there is no risk to public health associated with consumption of tomatoes containing spinosad residues within the MRL.

Spinosad is used internationally and is considered as a 'risk reducing' compound relative to older chemistries. Spinosad has been specifically attributed 'risk reducing' status in Canada and the United States. As spinosad is naturally derived from bacteria, it has been permitted for use in organic production by the United States Department of Agriculture.

### Chemical Information

<b>Common name of compound</b>	Spinosad
<b>Use of compound</b>	Insecticide
<b>Chemical Abstract Services (CAS) Registry number</b>	500008-45-7
<b>Type of compound</b>	Spinosyn
<b>Administration method</b>	Ground spray and dustable powder

### Good Agricultural Practice

Spinosad is proposed for use as an insecticide for tomatoes. Application may be up to 7 times throughout plant growth at a rate of 10-20g per mature plant with a withholding period of 3 days.

### Residues Information

Residue data for tomatoes support an MRL of 0.05mg/kg at 3 days after the last treatment. An MRL of 0.05mg/kg is therefore proposed to support GAP.

### Dietary Risk Assessment

<b>Acceptable Daily Intake (ADI)</b>	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 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 3.5% 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 spinosad as an insecticide for use on tomatoes, according to the GAP specified above, is very unlikely to pose any health risks from consumption of the harvested commodity.

### **Other International MRLs**

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

# 11 Proposal to exempt Chlorhexidine

It is proposed that an MRL exemption is set for chlorhexidine when used as a topical antiseptic for all food producing species except fish. It is proposed that Schedule Three of the NZ (MRL) Food Standards 2008 be amended to include the following; this will be the resulting entry for chlorhexidine in Schedule Three of the NZ (MRL) Food Standards 2008:

Compound	CAS#	Condition
Chlorhexidine and its digluconate salt	55-56-1	All food producing species except fish; for topical use only

## Amendment Rationale

The proposed MRL exemption represents a reassessment of a currently approved use patterns for chlorhexidine, which has a very low toxicity. Chlorhexidine is commonly used in human medicine, and following the treatment of food producing species with chlorhexidine, any levels of residues likely to exist are insignificant. For these reasons chlorhexidine residues do not require a regulatory limit. Chlorhexidine can therefore be exempted from the requirement of a New Zealand MRL.

## Chemical Information

<b>Common name of compound</b>	Chlorhexidine
<b>Use of compound</b>	Topical antiseptic and disinfectant
<b>Chemical Abstract Services (CAS) Registry number</b>	55-56-1
<b>Type of compound</b>	Bis-biguanide
<b>Administration method</b>	Topical

## Good Agricultural Practice

Chlorhexidine and chlorhexidine digluconate are used as general disinfectants for cleansing wounds, skin, instruments and equipment. They are also used as teat dips and sprays for an aid in the control of mastitis in dairy cattle.

## Residues Information

Chlorhexidine is poorly absorbed after topical application. Following use as an antiseptic treatment of wounds or skin, residues in tissue would be expected to be insignificant. The use of chlorhexidine as a teat dip or spray in dairy animals usually occurs following milking; residues are unlikely to occur in milk from the following milking.

## Dietary Risk Assessment

<b>Acceptable Daily Intake (ADI)</b>	0.05mg/kg bw/day
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Residues of chlorhexidine are unlikely to occur in consumed milk or animal products. In addition chlorhexidine is poorly absorbed orally through the gastrointestinal tract with the majority of residues passing unchanged into the faeces. Given the low reported toxicity of chlorhexidine it would not be expected to result in any dietary risk.

## Toxicological / Public Health Assessment

Chlorhexidine has a long recorded history of safe use in human medicine for topical antiseptic and disinfectant use and within oral preparations such as lozenges and dental gels. Human volunteers have been reported to easily tolerate levels of 2000mg orally administered chlorhexidine per day for 7 days. Given that residues are unlikely to occur following the use of chlorhexidine as a veterinary medicine there is no risk to the public through the proposed MRL exemption.

## Other International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
<b>European Union</b>		
Chlorhexidine	All food producing species	Exempt for topical use only

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.