



Proposals to Amend (No.1) the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2015

MPI Discussion Paper No: 2015/25

Prepared by the Systems Audit, Assurance and Monitoring
Directorate of the Ministry for Primary Industries

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1 Submissions

The Ministry for Primary Industries (MPI) invites public comment on this discussion document, which outlines proposals to amend the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2015.

For **each compound** you are commenting on, please clearly answer the following questions. Any additional comment is welcome, along with supporting reasons and data or examples to illustrate particular points.

On balance, do you oppose any of the commodity MRLs proposed for this compound?

Do you oppose an MRL being set at all for this compound for the commodity?

If an MRL is to be set for this compound for the commodity, do you disagree with the particular level proposed?

Submissions close at 5pm on **Wednesday 26 August 2015**. Your comments should be sent to:

MRL Amendments
ACVM Programmes and Appraisals
MPI Systems Audit, Assurance and Monitoring
PO Box 2526
Wellington 6140

Email: ACVM.Consultation@mpi.govt.nz

Please include your name and address on your submission. If you are making comments on behalf of an organisation, also include your title and the name of the organisation.

Please make sure your comments can be clearly read, as a number of copies may be made of your submission.

The Official Information Act

The Official Information Act 1982 (the OIA) states that information is to be made available unless there are grounds for withholding it. The grounds for withholding information are outlined in the OIA. Submitters may wish to indicate any grounds for withholding information contained in their submission. Reasons for withholding information could include that information is commercially sensitive or that the submitters wish personal information such as names or contact details to be withheld. MPI will take such indications into account when determining whether or not to release information. Any decision to withhold information requested under the OIA may be reviewed by the Ombudsman.

2 Introduction

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.

2.1 BACKGROUND

MRLs are set out in the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2015 (the MRL Standards). The MRL Standards are amended a number of times each year to reflect changes in the use of agricultural compounds in the production of food. The MRL Standards are available from the Ministry for Primary Industries (MPI) Foodsafety website at: <http://www.foodsafety.govt.nz/elibrary/industry/register-list-mrl-agricultural-compounds.htm> .

MPI administers the MRL Standards, but the final decision on any changes to the MRL Standards rests with the Minister for Food Safety. Under section 11E and 11L of the Food Act 1981, 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.

Once the standard is in place, official chemical residue monitoring programmes are reviewed and amended as necessary.

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)). Where there is no PDE (food), the estimated dietary intake is compared with the Acceptable Daily Intake (ADI). PDE (food) and ADI are described below.

A PDE (food) is a value determined by a toxicological evaluation by the Environmental Protection Authority (EPA) as part of its responsibility for managing public health under the Hazardous Substances and New Organisms Act 1996 (the HSNO Act). A PDE (food) gives the potential daily exposure a person may be subject to from a substance, via food. MPI uses a PDE (food) where it is available, rather than the internationally-determined ADI, as required by 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 through 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 (FAO) of the United Nations joint expert committees, which are 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.

2.2 SUMMARY OF PROPOSED AMENDMENT

The proposed MRLs have been thoroughly assessed in accordance with international methodologies such as those utilised by the expert committees advising Codex. Information on the technical assessment of each proposal is included in this document (refer section 2) and covers the following:

- rationale;
- chemical information;
- good agricultural practice;
- residues information;
- dietary risk assessment;
- toxicological/public health assessment; and
- international MRLs.

MPI reviewed the estimated dietary exposure assessments for the application of the proposals in this discussion paper and compared them with the appropriate reference health standard (the PDE (food) or the ADI). MPI has determined that the residues associated with the proposed MRLs do not present any public health and safety concerns.

2.2.1.1 New MRLS

MPI proposes to add the following new MRLs to the MRL Standards:

- 0.01 (*) mg/kg for cyazofamid when used as a fungicide on potatoes
- 0.6 mg/kg for cyprodinil when used as a fungicide on blackcurrants
- 0.8 mg/kg for fludioxonil when used as a fungicide on blackcurrants
- 0.05 mg/kg for fluopyram on grapes, and 0.01 (*) mg/kg on kiwifruit when used as a fungicide
- 0.15 mg/kg for kanamycin in milk when used as an antibiotic in dairy cows
- 0.02(*) mg/kg for spinetoram when used as an insecticide on assorted tropical and subtropical fruits - inedible peel (except kiwifruit)

2.2.1.1.1 Exempt from MRLs

MPI proposes to exempt the following substances from MRLs:

- Extracts of *Neotyphodium uncinatum strain AR1006* (containing the Loline alkaloids: N-acetyllooline, N-acetylnorloline, N-formyllooline) when used as an insecticide for food producing plant species
- Extend the exemption of plant extracts (unrefined) to include extracts from *Melaleuca alternifolia* (Tea Tree)

2.2.1.1.2 Other Amendments

- Proposal to delete the MRL for azinphos-methyl
- Amend a typographical error for the MRL of cyprodinil when used on strawberries
- Amend a typographical error in the spelling of fuberidazole
- Proposal to move Pegbovigrastim to Schedule 3
- Proposal to combine the entry for streptomycin with the entry for dihydrostreptomycin and streptomycin.

3 Proposals

3.1 PROPOSAL TO SET AN MRL FOR CYAZOFAMID

It is proposed that an MRL is set for cyazofamid when used on potatoes.

The final entry for cyazofamid in Schedule One of the MRL Standards will read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Cyazofamid	120116-88-3	<i>Cyazofamid</i>	Potatoes	0.01 (*)

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

3.1.1.1 Amendment Rationale

The proposed MRL represents a use of the new active ingredient. The proposed MRL will manage the use of cyazofamid, a fungicide, when used on potatoes and in accordance with the application rates and withholding periods that are proposed as good agricultural practice (GAP) in New Zealand.

3.1.1.2 Chemical Information

Common name of compound	Cyazofamid
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	120116-88-3
Type of compound	Sulfonamide/Imidazole
Administration method	Spray

3.1.1.3 Good Agricultural Practice

Cyazofamid is proposed for use as a fungicide on potatoes to be applied at 80 gai/ha to treat Late Blight, with a maximum of six applications 7-10 days apart, according to disease pressure, with a 7 day withholding period.

3.1.1.4 Residue Information

The residue data for the crop supports an MRL of 0.01 (*) mg/kg for cyazofamid in potatoes. The MRL is proposed to support GAP.

3.1.1.5 Dietary Risk Assessment

The potential daily exposure via food ($PDE_{(food)}$) is used for dietary intake calculation where a value has been set by EPA. An appropriate acceptable daily intake (ADI) is used in the absence of a $PDE_{(food)}$. The $PDE_{(food)}$ of 0.67 mg/kg bw/d was considered appropriate for use in the assessment. The proposed MRL is: potatoes – 0.01 (*) mg/kg.

The chronic dietary exposure to cyazofamid 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].

Based on the proposed MRLs, the NEDI for cyazofamid 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.

3.1.1.6 Toxicological/Public Health Assessment

It has been determined that the use of cyazofamid on potatoes, according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

3.1.1.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
USA	Potatoes	0.02

Under clause 6(3)(b) of the MRL Standards 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 *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.

3.2 PROPOSAL TO SET AN MRL FOR CYPRODINIL AND AMEND THE TYPOGRAPHICAL ERROR OF THE MRL SET FOR STRAWBERRIES

It is proposed that an MRL is set for cyprodinil when used on blackcurrants and the typographical error corrected for the MRL of strawberries.

The current entry for cyprodinil in Schedule One of the MRL Standards is:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Cyprodinil	121552-61-2	<i>Cyprodinil</i>	Blueberries	0.5
			Bulb onions	0.01 (*)
			Grapes	1
			Pome fruits	0.01
			Stone fruits (except cherries)	0.02 (*)
			Strawberries	10

The revised entry for cyprodinil in Schedule One of the MRL Standards will therefore read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Cyprodinil	121552-61-2	<i>Cyprodinil</i>	Blackcurrants	0.6
			Blueberries	0.5
			Bulb onions	0.01 (*)
			Grapes	1
			Pome fruits	0.01
			Stone fruits (except cherries)	0.02 (*)
			Strawberries	1

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

3.2.1.1 Amendment Rationale

The proposed MRL represents the expansion of use of a currently registered active ingredient. The proposed MRL will manage the use of cyprodinil as a fungicide when used on

blackcurrants and in accordance with the application rates and withholding periods that are proposed as good agricultural practice (GAP) in New Zealand.

The typographical error was introduced during the Proposals to Amend (No. 3) the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2014. This will be corrected back to 1 mg/kg for use on strawberries.

3.2.1.2 Chemical Information

Common name of compound	Cyprodinil
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	121552-61-2
Type of compound	Anilopyrimidine
Administration method	Spray

3.2.1.3 Good Agricultural Practice

Cyprodinil is proposed for use as a fungicide in blackcurrants to be applied at 300 gai/ha to treat Botrytis, with a maximum of two applications over flowering, according to disease pressure, with no applications made after the completion of flowering/petal fall.

3.2.1.4 Residue Information

The residue data for the crop supports an MRL of 0.6 mg/kg for cyprodinil in blackcurrants. The MRL is proposed to support GAP.

3.2.1.5 Dietary Risk Assessment

The potential daily exposure via food ($PDE_{(food)}$) is used for dietary intake calculation where a value has been set by EPA. An appropriate acceptable daily intake (ADI) is used in the absence of a $PDE_{(food)}$. The $PDE_{(food)}$ of 0.0135 mg/kg bw/d was considered appropriate for use in the assessment. The proposed MRL is: blackcurrants – 0.6 mg/kg.

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 Organization, 1997].

Based on the proposed MRLs, the NEDI for cyprodinil is equivalent to less than 10% of the $PDE_{(food)}$. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

3.2.1.6 Toxicological/Public Health Assessment

It has been determined that the use of cyprodinil on blackcurrants, according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

3.2.1.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Codex	Bush fruit	10.0
European Union	Bush fruit	5.0
USA	Currants	3.0

Under clause 6(3)(b) of the MRL Standards 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 *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.

3.3 PROPOSAL TO SET AN MRL FOR FLUDIOXONIL

It is proposed that an MRL is set for fludioxonil when used on blackcurrants.

The current entry for fludioxonil in Schedule One of the MRL Standards is:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Fludioxonil	131341-86-1	<i>Fludioxonil</i>	Blueberries	0.5
			Bulb onions	0.01 (*)
			Grapes	1
			Strawberries	1

The revised entry for fludioxonil in Schedule One of the MRL Standards will therefore read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Fludioxonil	131341-86-1	<i>Fludioxonil</i>	Blackcurrants	0.8
			Blueberries	0.5
			Bulb onions	0.01 (*)
			Grapes	1
			Strawberries	1

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

3.3.1.1 Amendment Rationale

The proposed MRL represents the expansion of use of a currently registered active ingredient. The proposed MRL will manage the use of fludioxonil as a fungicide when used on blackcurrants and in accordance with the application rates and withholding periods that are proposed as good agricultural practice (GAP) in New Zealand.

3.3.1.2 Chemical Information

Common name of compound	Fludioxonil
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	131341-86-1
Type of compound	Phenylpyrrole
Administration method	Spray

3.3.1.3 Good Agricultural Practice

Fludioxonil is proposed for use as a fungicide in blackcurrants to be applied at 200 gai/ha to treat Botrytis, with a maximum of two applications over flowering, according to disease pressure, with no applications made after the completion of flowering/petal fall.

3.3.1.4 Residue Information

The residue data for the crop supports an MRL of 0.8 mg/kg for fludioxonil in blackcurrants. The MRL is proposed to support GAP.

3.3.1.5 Dietary Risk Assessment

The potential daily exposure via food ($PDE_{(food)}$) is used for dietary intake calculation where a value has been set by EPA. An appropriate acceptable daily intake (ADI) is used in the absence of a $PDE_{(food)}$. The $PDE_{(food)}$ of 0.0165 mg/kg bw/d was considered appropriate for use in the assessment. The proposed MRL is: blackcurrants – 0.8 mg/kg.

The chronic dietary exposure to fludioxonil 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].

Based on the proposed MRLs, the NEDI for fludioxonil is equivalent to less than 10 % of the $PDE_{(food)}$. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

3.3.1.6 Toxicological/Public Health Assessment

It has been determined that the use of fludioxonil on blackcurrants, according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

3.3.1.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
European Union	Currants	2.0
USA	Bushberries	2.0

Under clause 6(3)(b) of the MRL Standards 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 *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.

3.4 PROPOSAL TO SET AN MRL FOR FLUOPYRAM

It is proposed that an MRL is set for fluopyram when used on grapes and kiwifruit.

The current entry for fluopyram in Schedule One of the MRL Standards is:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Fluopyram	658066-35-4	<i>Plant commodities:</i>	Bulb onions	0.01 (*)
		<i>Fluopyram</i>	Mammalian meat	0.1
		<i>Animal commodities: Sum</i>	Mammalian offal	0.7
		<i>of fluopyram and 2- (trifluoromethyl)benzamide, expressed as fluopyram</i>	Milk	0.07

The revised entry for fluopyram in Schedule One of the MRL Standards will therefore read:

Compound	CAS#	Residue to which the	Food	Maximum Permitted
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Common Name		maximum residue limit applies		Residue Level (mg/kg)
Fluopyram	658066-35-4	<i>Plant commodities:</i>	Bulb onions	0.01 (*)
		<i>Fluopyram</i>	Grapes	0.05
		<i>Animal commodities: Sum</i>	Kiwifruit	0.01 (*)
		<i>of fluopyram and 2-</i>	Mammalian meat	0.1
		<i>(trifluoromethyl)benzamide,</i>	Mammalian offal	0.7
		<i>expressed as fluopyram</i>	Milk	0.07

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

3.4.1.1 Amendment Rationale

The proposed MRL represents the expansion of use of a currently registered active ingredient. The proposed MRL will manage the use of fluopyram as a fungicide when used on grapes and kiwifruit in accordance with the application rates and withholding periods that are proposed as good agricultural practice (GAP) in New Zealand.

3.4.1.2 Chemical Information

Common name of compound	Fluopyram
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	658066-35-4
Type of compound	Pyridinyl ethylbenzimidides
Administration method	Spray

3.4.1.3 Good Agricultural Practice

Fluopyram is proposed for use as a fungicide in kiwifruit to be applied at 150 gai/ha to treat Sclerotinia, with a single application made 7 days prior to the start of flowering up to 80% flowering, and a withholding period of up to 80% flowering. Use on grapes is for 7.5 gai/100L applied, with up to 2 applications, from immediately before flowering through to 80% cap-fall, and a withholding period of up to 80% cap-fall.

3.4.1.4 Residue Information

The residue data for the crops supports an MRL of 0.01 (*) mg/kg for fluopyram in kiwifruit, and 0.05 mg/kg in grapes. The MRL are proposed to support GAP.

3.4.1.5 Dietary Risk Assessment

The potential daily exposure via food ($PDE_{(food)}$) is used for dietary intake calculation where a value has been set by EPA. An appropriate acceptable daily intake (ADI) is used in the absence of a $PDE_{(food)}$. The $PDE_{(food)}$ of 0.0084 mg/kg bw/d was considered appropriate for use in the assessment. The proposed MRLs are:

kiwifruit – 0.01 (*) mg/kg

grapes – 0.05 mg/kg

The chronic dietary exposure to fluopyram 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].

Based on the proposed MRLs, the NEDI for fluopyram is equivalent to less than 5 % of the $PDE_{(food)}$. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

3.4.1.6 Toxicological/Public Health Assessment

It has been determined that the use of fluopyram on kiwifruit and grapes, according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

3.4.1.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Codex	Grapes	2.0
European Union	Grapes	1.5
USA	Grapes	2.0

Under clause 6(3)(b) of the MRL Standards 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 *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.

3.5 PROPOSAL TO SET AN MRL FOR KANAMYCIN

It is proposed that an MRL is set for kanamycin when used on dairy cattle.

This will be the entry for kanamycin in Schedule One of the MRL Standards:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Kanamycin	59-01-8	<i>Kanamycin A</i>	Milk	0.15

3.5.1.1 Amendment Rationale

The proposed MRL represents the use pattern in New Zealand for a new active ingredient kanamycin. The proposed MRL will manage the use of kanamycin as an antibiotic for dairy cattle and the application rates and withholding periods that are proposed as GAP in New Zealand.

3.5.1.2 Chemical Information

Common name of compound	Kanamycin
Use of compound	Antibiotic
Chemical Abstract Services (CAS) Registry number	59-01-8
Type of compound	Aminoglycoside
Administration method	Injection

3.5.1.3 Good Agricultural Practice

Kanamycin is proposed for use as an antibiotic in dairy cattle. It is to be applied as an injection to the infected quarter twice, with an interval of 24 hours, at a dose rate of 100,000 IU with the following withholding periods:

- Cattle meat or offal – 14 days
- Milk – 84 hours

3.5.1.4 Residue Information

The residue data supports an MRL of 0.15 mg/kg for milk at the proposed withholding periods. The MRL is proposed to support GAP. With the proposal limited to intramammary use on dairy cattle and with a conservative withholding period for slaughter, residues are unlikely to result in any other animal products.

3.5.1.5 Dietary Risk Assessment

The potential daily exposure via food ($PDE_{(food)}$) is used for dietary intake calculation where a value has been set by EPA. An appropriate acceptable daily intake (ADI) is used in the absence of a $PDE_{(food)}$. A microbiological ADI of 0.008 mg/kg bw/d was considered appropriate for use in the assessment. The potential for development of resistance is considered as part of the microbiological ADI, and was determined to be very low. The proposed MRL is:

0.15 mg/kg for milk

The chronic dietary exposure to kanamycin 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].

Based on the proposed MRLs, the NEDI for kanamycin is equivalent to less than 5 % of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

3.5.1.6 Toxicological/Public Health Assessment

It has been determined that the use of kanamycin as an antibiotic in dairy cattle, according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

3.5.1.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
European Union	Cattle fat	0.1
	Cattle kidney	2.5
	Cattle liver	0.6
	Cattle meat	0.1
	Milk	0.15
Japan	Cattle, muscle	0.04
	Cattle, fat	0.04
	Cattle, liver	0.04
	Cattle, kidney	0.04
	Milk	0.4

Under clause 6(3)(b) of the MRL Standards 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 *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.

3.6 PROPOSAL TO SET AN MRL FOR SPINETORAM

It is proposed that an MRL is set for spinetoram when used on assorted tropical and subtropical fruits – inedible peel (except kiwifruit).

The current entry for spinetoram in Schedule One of the MRL Standards is:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Spinetoram	187166-40-1 +	<i>Sum of: XDE-175-J XDE-175-L</i>	Apples	0.05
			Bulb onions	0.01(*)
	187166-15-0	<i>Expressed as: Spinetoram</i>	Citrus	0.05
			Mammalian fat	0.2
			Mammalian kidney	0.01(*)
			Mammalian liver	0.01(*)
			Mammalian meat	0.01(*)
			Pears	0.05
			Stone fruits	0.2
			Vegetable brassicas	0.15
			Potatoes	0.02(*)
			Tomatoes	0.02(*)

The revised entry for spinetoram in Schedule One of the MRL Standards will therefore read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Spinetoram	187166-40-1 +	<i>Sum of: XDE-175-J XDE-175-L</i>	Apples	0.05
			Bulb onions	0.01(*)
	187166-15-0	<i>Expressed as: Spinetoram</i>	Citrus	0.05
			Mammalian fat	0.2
			Mammalian kidney	0.01(*)
			Mammalian liver	0.01(*)
			Mammalian meat	0.01(*)
			Pears	0.05
			Potatoes	0.02(*)
			Stone fruits	0.2
			Assorted tropical and subtropical fruits – inedible peel (except kiwifruit)	0.02(*)
			Tomatoes	0.02(*)
			Vegetable brassicas	0.15

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

3.6.1.1 Amendment Rationale

The proposed MRL represents the expansion of use of a currently registered active ingredient. The proposed MRL will manage the use of spinetoram as an insecticide when used on assorted tropical and subtropical fruits – inedible peel (except kiwifruit) and in accordance with the application rates and withholding periods that are proposed as good agricultural practice (GAP) in New Zealand.

3.6.1.2 Chemical Information

Common name of compound	Spinetoram
Use of compound	Insecticide
Chemical Abstract Services (CAS) Registry number	187166-40-1 + 187166-15-0
Type of compound	Spinosoids
Administration method	Spray

3.6.1.3 Good Agricultural Practice

Spinetoram is proposed for use as an insecticide in assorted tropical and subtropical fruits – inedible peel (except kiwifruit) to be applied at 2.4 gai/100L to treat leafroller and 4.8 gai/100L to treat thrips, with a maximum application rate of 96 gai/ha and a maximum of four applications at 14 day intervals or according to pest pressure, with a 14 day withholding period.

3.6.1.4 Residue Information

The residue data for the crop supports an MRL of 0.02(*) mg/kg for spinetoram in assorted tropical and subtropical fruits – inedible peel (except kiwifruit). The MRL is proposed to support GAP.

3.6.1.5 Dietary Risk Assessment

The potential daily exposure via food ($PDE_{(food)}$) is used for dietary intake calculation where a value has been set by EPA. An appropriate acceptable daily intake (ADI) is used in the absence of a $PDE_{(food)}$. The $PDE_{(food)}$ of 0.017 mg/kg bw/d was considered appropriate for use in the assessment. The proposed MRL is:

Assorted tropical and subtropical fruits – inedible peel (except kiwifruit) – 0.02(*) mg/kg

The chronic dietary exposure to spinetoram 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].

Based on the proposed MRLs, the NEDI for spinetoram is equivalent to 1 % of the $PDE_{(food)}$. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

3.6.1.6 Toxicological/Public Health Assessment

It has been determined that the use of spinetoram on assorted tropical and subtropical fruits – inedible peel (except kiwifruit), according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

3.6.1.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
European Union	Avocados	0.05
	Feijoas	0.05
	Kiwifruit	0.05
	Passionfruit	0.05
	Tamarillos	0.50
USA	Avocados	0.30
	Feijoas	0.30
	Passionfruit	0.30
Australia	Assorted tropical and sub-tropical fruits – inedible peel	0.30

Under clause 6(3)(b) of the MRL Standards 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 *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.

3.7 PROPOSAL TO EXEMPT EXTRACTS OF *NEOTYPHODIUM UNCINATUM* STRAIN AR1006

It is proposed that an MRL exemption is set for *Neotyphodium uncinatum* strain AR1006 when used as an insecticide on food producing plant species, and the primary mode of action derives from the presence of Loline alkaloids.

It is proposed that Schedule Two of the MRL Standards be amended by adding the following:

Substance	CAS#	Condition
<i>Neotyphodium uncinatum</i> strain AR1006 (containing the Loline alkaloids: N-acetyllooline, N-acetylnorlooline, N-formyllooline)	None (Lolines: 4914-36-7, 38964-35-1, 38964-33-9)	Where the primary mode of action derives from the presence of Loline alkaloids, and; When used as an insecticide for food producing plant species

3.7.1.1 Amendment Rationale

The proposed MRL exemption represents the use pattern in New Zealand for the new active ingredient *Neotyphodium uncinatum* strain AR1006 (containing the Loline alkaloids: N-acetyllooline, N-acetylnorlooline, N-formyllooline). This is a novel active ingredient, a naturally occurring bioactive compound product by *Neotyphodium* fungal endophytes. Available data indicate *Neotyphodium uncinatum* strain AR1006 (containing the Loline alkaloids: N-acetyllooline, N-acetylnorlooline, N-formyllooline) has a low toxicity and natural occurrence in certain field crops. The compositional nature of the Loline content is not fixed, and therefore the total Loline content and isomer ratios can differ, which means setting a residue limit is difficult.

3.7.1.2 Chemical Information

Common name of compound	<i>Neotyphodium uncinatum</i> strain AR1006 (containing the Loline alkaloids: N-acetyllooline, N-acetylnorlooline, N-formyllooline)
Use of compound	Insecticide
Chemical Abstract Services (CAS) Registry number	None (Lolines: 4914-36-7, 38964-35-1, 38964-33-9)
Type of compound	Alkaloid
Administration method	Spray

3.7.1.3 Good Agricultural Practice

Neotyphodium uncinatum strain AR1006 (containing the Loline alkaloids: N-acetyllooline, N-acetylnorlooline, N-formyllooline) is proposed for use as an insecticide on a wide range of crops, with application rates ranging from 125 mL in 100L water/ha - 2.5L in 1000L water/ha, with 14 day intervals, and a nil withholding period.

3.7.1.4 Residue Information

Neotyphodium uncinatum strain AR1006 (containing the Loline alkaloids: N-acetyllooline, N-acetylnorloline, N-formylloline) is a naturally occurring bioactive compound product by *Neotyphodium* fungal endophytes, available data indicate *Neotyphodium uncinatum strain AR1006* (containing the Loline alkaloids: N-acetyllooline, N-acetylnorloline, N-formylloline) has a low toxicity and natural occurrence in certain field crops. The compositional nature of the Loline content is not fixed, and therefore the total Loline content and isomer ratios can differ, which means setting a residue limit is difficult. It is therefore proposed that *Neotyphodium uncinatum strain AR1006* (containing the Loline alkaloids: N-acetyllooline, N-acetylnorloline, N-formylloline) is exempted from an MRL.

3.7.1.5 Dietary Risk Assessment

No ADI has been set for *Neotyphodium uncinatum strain AR1006* (containing the Loline alkaloids: N-acetyllooline, N-acetylnorloline, N-formylloline). Levels of *Neotyphodium uncinatum strain AR1006* (containing the Loline alkaloids: N-acetyllooline, N-acetylnorloline, N-formylloline) vary in harvested crops through the natural presence in the plant and the environment, and the data provided shows that the residues are of low toxicity. Therefore the use of *Neotyphodium uncinatum strain AR1006* (containing the Loline alkaloids: N-acetyllooline, N-acetylnorloline, N-formylloline) as an insecticide presents no dietary risk.

3.7.1.6 Toxicological/Public Health Assessment

It has been determined that the use of *Neotyphodium uncinatum strain AR1006* (containing the Loline alkaloids: N-acetyllooline, N-acetylnorloline, N-formylloline) as an insecticide, is very unlikely to pose any health risks from consumption of treated produce.

3.7.1.7 Other International MRLs

There are no other international MRLs for *Neotyphodium uncinatum strain AR1006* (containing the Loline alkaloids: N-acetyllooline, N-acetylnorloline, N-formylloline).

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.

3.8 PROPOSAL TO EXTEND THE EXEMPTION OF PLANT EXTRACTS (UNREFINED) TO INCLUDE MELALEUCA ALTERNIFOLIA

It is proposed that the current list of plant species in the plant extract (unrefined) exemption be amended to include *Melaleuca alternifolia* (Tea Tree).

It is proposed that the entry for Plant extracts (unrefined) in Schedule Two of the MRL Standards be amended to the following:

Substance	CAS#	Condition
Plant extracts (unrefined)	n/a	Except where otherwise stated in this standard: Where the extract is registered under the Agricultural Compounds and Veterinary Medicines Act 1997 and intended for use as an agricultural chemical, and; Where the extract is derived from plants of the following species: <i>Camellia sinesis</i> (Tea)

Fallopia sachalinensis (Giant knotweed),
Melaleuca alternifolia (Tea Tree)
Opuntia linheimeri (Texas prickly pear),
Quercus falcata (Southern red oak),
Rhus aromatica (Fragrant surmac),
Rhizophora mangle (Red mangrove)

3.8.1.1 Amendment Rationale

The proposed expansion of the MRL exemption for plant extracts represents the proposed new use of *Melaleuca alternifolia* (Tea tree) as an agricultural chemical. This is a novel active ingredient, although tea tree oil, a noted *Melaleuca alternifolia* extract has a long history of use in food and cosmetics. Available data indicate the primary chemicals present in *Melaleuca alternifolia* extracts have low toxicity and naturally occur in food crops, as well as have flavouring and cosmetic uses. The compositional nature of *Melaleuca alternifolia* extracts are not fixed, and therefore the ratios of primary chemical components can vary, which means setting a residue limit is difficult.

3.8.1.2 Chemical Information

Common name of compound	<i>Melaleuca alternifolia</i> (Tea tree)
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	None (Tea tree oil: 68647-73-4)
Type of compound	Plant extract
Administration method	Spray

3.8.1.3 Good Agricultural Practice

Melaleuca alternifolia extracts are proposed for use as a fungicide on a wide range of fruit and vegetable crops, with a nil withholding period.

3.8.1.4 Residue Information

Melaleuca alternifolia (extracts are complex mixture of various chemicals, predominantly terpenes). Many terpenes occur naturally at considerable levels as a volatile component of plants, including food plants, released as herbivore deterrents or predator/parasite chemoattractors. Due to their production under stress levels can vary significantly between plants depending on environmental conditions and pest pressures. The terpenes in tea tree oil are also reported to occur in many food plants, they may also be added to food as a single component or part of a mixture for flavouring purposes. Due to the volatile nature of terpenes their residences time on plant surfaces is low and as such persistent residues are not expected.

3.8.1.5 Dietary Risk Assessment

The toxicity of *Melaleuca alternifolia* extracts are low, with a long and safe history of use in health care, cosmetics and for many of its primary components in food. Although consuming neat extract may be hazardous, concentrations at this level would not be expected in food following their use of *Melaleuca alternifolia* extracts as agricultural chemical. The use of *Melaleuca alternifolia* extracts as agricultural compounds presents no dietary risk.

3.8.1.6 Toxicological/Public Health Assessment

It has been determined that the use of *Melaleuca alternifolia* extracts as agricultural chemicals is very unlikely to pose any health risks from consumption of treated produce.

3.8.1.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
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European Union	All foods	No MRL required
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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.

3.9 PROPOSAL TO DELETE THE MRLS FOR AZINPHOS-METHYL FROM THE MRL STANDARDS 2015

It is proposed that the following entries are deleted from the Schedule 1 of the MRL Standards 2015:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Azinphos-methyl	85-50-0	<i>Azinphos-methyl</i>	Stonefruit	2
			Strawberries	2
			Potatoes	0.05 (*)

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

3.9.1.1 Amendment Rationale

The use of azinphos-methyl in New Zealand is no longer approved by the Environment Protection Authority.

3.9.1.2 International MRLs

Under clause 6(3)(b) of the MRL Standards 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 *Pesticide Residues in Food or Residues of Veterinary Drugs in Foods*. Codex has set a number of MRLs for the use of azinphos-methyl. It is anticipated that the Codex MRLs for azinphos-methyl will be sufficient to regulate imports of any commodity containing azinphos-methyl residues.

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.

3.10 PROPOSAL TO AMEND THE TYPOGRAPHICAL ERROR OF THE SPELLING OF FUBERIDAZOLE

It is proposed to correct the typographical error for the spelling of Fuberidazole in Column 3. The current entry for fuberidazole in Schedule One of the MRL Standards is:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Fuberidazole	3878-19-1	<i>Fubaridazole</i>	Barley	0.05 (*)
			Oats	0.05 (*)
			Wheat	0.05 (*)

The revised entry for fuberidazole in Schedule One of the MRL Standards will therefore read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Fuberidazole	3878-19-1	Fuberidazole	Barley	0.05 (*)
			Oats	0.05 (*)
			Wheat	0.05 (*)

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

3.10.1.1 Amendment Rationale

The typographical error was introduced during a Proposals to Amend the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards

3.11 PROPOSAL TO MOVE PEGBOVIGRASTIM FROM SCHEDULE 2 TO SCHEDULE 3.

It is proposed to correct the Schedule the exemption of pegbovigrastim appears in. The current entry for pegbovigrastim in Schedule Two of the MRL Standards is:

Substance	CAS#	Condition
<i>Pegbovigrastim</i>	1363409-60-2	Used in ruminants

The revised entry for pegbovigrastim in Schedule Three of the MRL Standards will therefore read:

Substance	CAS#	Condition
<i>Pegbovigrastim</i>	1363409-60-2	Used in ruminants

3.12 PROPOSAL TO MOVE THE ENTRY FOR STREPTOMYCIN INTO THE ENTRY FOR DIHYDROSTREPTOMYCIN AND STREPTOMYCIN IN SCHEDULE 1.

It is proposed to correct the entry for streptomycin by combining it with the entry for dihydrostreptomycin and streptomycin in Schedule 1. The entry for streptomycin will be amended to read “See Dihydrostreptomycin”.

There are currently two separate entries for streptomycin in Schedule One of the MRL Standards:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Streptomycin	57-92-1	Streptomycin	Kiwifruit	0.01(*)
			Pome fruits	0.1(*)
			Stone fruits	0.1(*)

And:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Dihydrostreptomycin and streptomycin	128-46-1	Streptomycin or dihydrostreptomycin (MRLs cover streptomycin and dihydrostreptomycin)	Cattle fat	0.5
	and		Cattle kidney	1
	57-92-1		Cattle liver	0.5
			Cattle meat	0.5
			Cattle milk	0.2

singly or in combination)	Pig fat	0.5
	Pig kidney	1
	Pig liver	0.5
	Pig meat	0.5
	Poultry fat	0.5
	Poultry kidney	1
	Poultry liver	0.5
	Poultry meat	0.5
	Sheep fat	0.5
	Sheep kidney	1
	Sheep liver	0.5
	Sheep meat	0.5

The revised entries for ‘streptomycin’ and ‘dihydrostreptomycin and streptomycin’ in Schedule One of the MRL Standards will therefore read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Streptomycin (see Dihydrostreptomycin)	57-92-1			

And:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Dihydrostreptomycin and streptomycin	128-46-1 and 57-92-1	Streptomycin or dihydrostreptomycin (MRLs cover streptomycin and dihydrostreptomycin singly or in combination)	Cattle fat	0.5
			Cattle kidney	1
			Cattle liver	0.5
			Cattle meat	0.5
			Cattle milk	0.2
			Kiwifruit	0.01(*)
			Pig fat	0.5
			Pig kidney	1
			Pig liver	0.5
			Pig meat	0.5
			Pome fruits	0.1(*)
			Poultry fat	0.5
			Poultry kidney	1
			Poultry liver	0.5
			Poultry meat	0.5
			Sheep fat	0.5
			Sheep kidney	1
			Sheep liver	0.5
			Sheep meat	0.5
			Stone fruits	0.1(*)