Proposals to Amend the Maximum Residue Levels for Agricultural Compounds Food Notice 2016

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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 Levels for Agricultural Compounds) Food Notice.

For **each compound** you are commenting on, please clearly answer the following questions. Any additional comment is welcome, along with supporting discussion, 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 <u>at all</u> 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? If so, why do you disagree?

Submissions close at 5pm on **4 September 2016**. Your comments should be sent to:

MRL Amendments
ACVM Programmes and Appraisals
MPI Systems Audit, Assurance and Monitoring Directorate
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 of your submission may be made.

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 levels (MRLs) are the maximum legal levels 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 Levels for Agricultural Compounds) Food Notice. The MRL Food Notice is amended a number of times each year to reflect changes in the use of agricultural compounds in the production of food. The MRL Food Notice is 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 Food Notice, with the final decision on any changes to the Notice resting with the Director-General of MPI. The Food Notice is issued under sections 405 and 406(1) of the Food Act 2014. When setting or amending MRLs, the Director-General must take into account:

- 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; and
- such other matters as appropriate.

Once the amended MRL Food Notice is in place, official chemical residue monitoring programmes are reviewed and are 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. Where an internationally-determined ADI is not available, an ADI may be calculated by MPI to quantify the dietary exposure risk.

The chronic dietary exposure to a substance is estimated by the National Estimated Dietary Intake (NEDI) calculation, encompassing all registered uses of the chemical and food consumption data based upon the 1997 National Nutritional Survey for adults and the 1995 National Nutrition Survey of Australia, for children. The NEDI calculation is made in accordance with Guidelines for predicting dietary intake of pesticide residues (revised) [World Health Organization, 1997]. The NEDI calculation provides an estimation of the portion of the $PDE_{(food)}$ or ADI that can be expected from consumption of food containing residues complying with existing and proposed MRLs to determine whether the chronic dietary exposure risk is acceptable

Clause 144 of the Food Regulations 2015 states that imported food must contain residues of agricultural compounds no greater than the MRLs specified for that food in a notice set under the Food Act 2014 (section (1)(a)), the default MRL of 0.1 mg/kg (section (1)(c)), or the current editions of either the Maximum Residue Limits (MRLs) and Extraneous Maximum Residue Limits (EMRLs) for Pesticides (Codex Pesticides Residues in Food Online Database), or the Maximum Residue Limits for Veterinary Drugs in Food (Codex Veterinary Drug Residue in Food Online Database) (section (1)(d)).

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.

2.2 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 3) and covers:

- rationale;
- chemical information;
- good agricultural practice;
- residues information;
- dietary risk assessment;
- toxicological/public health assessment; and
- MRLs set by Codex and other countries.

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 or food safety concerns.

2.2.1 New and Amended MRLS

MPI proposes to add the following new MRLs to the MRL Notice and/or amend the existing entries for certain compounds:

- Abamectin: 0.01 (*) mg/kg when used on bulb onions, and 0.02 mg/kg when used on green onions.
- Aviglycine: 0.02 mg/kg when used on cherries.
- Bixafen: 0.05 mg/kg when used on barley.
- Cephapirin: 0.06 mg/kg in cattle milk.

- Cyproconazole: 0.05 mg/kg (*) when used on grapes; and 0.5 mg/kg in edible offal (mammals), 0.02 mg/kg in fat (mammalian), and 0.01 mg/kg in milk as a result of use in beets.
- Diclazuril: 1.0 mg/kg in cattle and sheep fat, 2.0 mg/kg in cattle and sheep kidney, 0.5 mg/kg in cattle and sheep muscle, and 3.0 mg/kg in cattle and sheep liver.
- Fenpyrazamine: 0.05 mg/kg when used on grapes.
- Fluopyram: 1.0 mg/kg when used on fruiting vegetables (except cucurbits).
- Fluxapyroxad: 0.02 mg/kg when used on pome fruits (apples and pears).
- Indoxacarb: 0.5 mg/kg when used on brassica vegetables (except cabbage); 3 mg/kg when used on cabbage; and 3 mg/kg when used on head lettuce.
- Meloxicam: 0.01 mg/kg in sheep fat and muscle, and 0.065 mg/kg in sheep liver and kidney.
- Metamitron: 0.01 mg/kg (*) when used on apples.
- Methoxyfenozide: 0.4 mg/kg when used on stone fruit.
- Prothioconazole: 0.1 mg/kg when used on barley.
- Spirotetramat: 0.2 mg/kg in apples.
- Thiamethoxam: 0.01 (*) mg/kg in bulb onions, and 0.2 mg/kg in green onions.
- Trifloxystrobin: 0.05 mg/kg in fat (mammalian), 0.04 mg/kg in kidney (mammalian), and 0.05 mg/kg in liver (mammalian) when used on sugar beets and fodder grown for animal feed.
- Trinexapac-ethyl: 0.05 mg/kg (*) of 4-(cyclopropyl-α-hydroxy-methylene)-3,5-dioxo-cyclohexanecarboxylic acid when used on cereal crops, and 0.2 mg/kg of trinexapac (acid) when used on cereal crops (except maize and sweet corns).
- Tulathromycin: 0.45 mg/kg in sheep muscle, 0.25 mg/kg in sheep fat, 5.4 mg/kg in sheep liver, and 1.8 mg/kg in sheep kidney.

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

2.2.2 New Exceptions from Maximum Residue Levels

MPI proposes to add the following exceptions from Maximum Residue Levels for Agricultural Chemicals (Schedule 2):

- Mixtures of chito-oligosaccharides and oligogalacturonans, for use on fruits and vegetables.
- Ozone, for use as an agricultural chemical.
- Polyoxin D zinc salt, for use as an agricultural chemical.
- Prohydrojasmon, when used as a colour enhancer on apples.

MPI proposes to amend the following exceptions from Maximum Residue Levels for Agricultural Chemicals (Schedule 2):

- Amend the entry for ‘Microbial Pesticide Organisms’ to change the classification of these substances to ‘Microbial Active Ingredients’.

MPI proposes to amend the following exceptions from Maximum Residue Levels for Veterinary Medicines (Schedule 3):

- Amend the entry for 'Bismuth and its salts' to include the use of intramammary teat sealants in cattle.

2.2.3 Other Amendments

MPI proposes to amend the residue definitions for the following compounds:

- Emamectin, to harmonise with overseas trading partners and Codex.
- Indoxacarb, to harmonise with the current definition set by Codex.
- Prothioconazole, to harmonise it with the current definition set by Codex in 2008.
- Trinexapac-ethyl, to correct errors in the current Notice entry.

3 Proposals

3.1 PROPOSAL TO SET MRLS FOR ABAMECTIN

It is proposed that MRLs are set for abamectin to support the good agricultural practice (GAP) use on bulb onions and green onions.

The current entry for abamectin in Schedule 1 of the MRL Notice is:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Abamectin	71751-42-2	*Sum of :* avermectin B1a avermectin B1b (Z)-8,9 avermectin B1a (Z)-8,9 avermectin B1b	Avocados Cattle fat Cattle liver Cattle meat Kiwifruit Pome fruits Sheep fat Sheep kidney Sheep liver Sheep meat Strawberries Tomatoes	0.02(*) 0.02 0.015 0.01 0.02(*) 0.02(*) 0.05 0.02 0.025 0.02 0.02(*) 0.1

The revised entry for abamectin in Schedule 1 of the MRL Notice will read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Abamectin	71751-42-2	*Sum of :* avermectin B1a avermectin B1b (Z)-8,9 avermectin B1a (Z)-8,9 avermectin B1b	Avocados Bulb onions Cattle fat Cattle liver Cattle meat Green onions Kiwifruit Pome fruits Sheep fat Sheep kidney Sheep liver Sheep meat Strawberries Tomatoes	0.02(*) 0.01 0.02 0.015 0.01 0.02 0.02(*) 0.02(*) 0.05 0.02 0.025 0.02 0.02(*) 0.1

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

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 abamectin as an insecticide on bulb onions and green onions, and in accordance with the application rates and withholding periods that are proposed as good agricultural practice GAP.

3.1.2 Chemical Information

Common name of compound	Abamectin
Use of compound	Insecticide
Chemical Abstract Services (CAS) Registry number	71751-42-2
Type of compound	Avermectin
Administration method	Spray

3.1.3 Good Agricultural Practice

Abamectin is proposed for use as an insecticide on bulb and green onions to be applied at a rate of 27gai/ha to treat infestation with thrips (*Thrips tabaci*), with the first application indicated by reaching the threshold level for the insect. Treatment is repeated at seven day intervals as a cluster of three or four sequential applications, with a maximum of four applications per year. The withholding period is 14 days.

3.1.4 Residue Information

The residue data for the crops support an MRL of 0.01 mg/kg in bulb onions and 0.02 mg/kg in green onions after treatment with abamectin. The MRLs are proposed to support GAP.

3.1.5 Dietary Risk Assessment

The $PDE_{(food)}$ of 0.002 mg/kg bw/d was considered appropriate for use in the assessment.

Based on the residues expected in food from crops treated according to existing and proposed GAP uses, the NEDI for abamectin is equivalent to less than 7.5% of the $PDE_{(food)}$. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

3.1.6 Toxicological/Public Health Assessment

It has been determined that the use of abamectin on bulb and green onions, according to the GAP specified above, is unlikely to pose any health risks from consumption of treated produce.

3.1.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Australia	Bulb vegetables	0.05
European Union	Onions	0.01
	Spring onions/green onions and Welsh onions	0.01
United States	Bulb onion	0.01
	Green onion	0.08

3.2 PROPOSAL TO SET AN MRL FOR AVIGLYCINE

It is proposed that an MRL is set for aviglycine to support the GAP use on cherries.

The current entry for aviglycine in Schedule 1 of the MRL Notice is:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Aviglycine	49669-74-1	Aviglycine	Pome fruits	0.1
			Stone fruits (except cherries)	0.1

The revised entry for aviglycine in Schedule 1 of the MRL Notice will read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Aviglycine	49669-74-1	Aviglycine	Pome fruits	0.1
			Stone fruits (except cherries)	0.1
			Cherries	0.02 (*)

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

3.2.1 Amendment Rationale

The proposed MRL represents the expansion of use of a currently registered active ingredient. The proposed MRL will manage the use of aviglycine on cherries as a plant growth regulator and in accordance with the application rates and withholding periods that are proposed as GAP in New Zealand.

3.2.2 Chemical Information

Common name of compound	Aviglycine
Use of compound	Plant growth regulator
Chemical Abstract Services (CAS) Registry number	49669-74-1
Type of compound	Aminoethoxyvinylglycine
Administration method	Spray

3.2.3 Good Agricultural Practice

Aviglycine is proposed for use as a plant growth regulator on cherries to be applied at 830gai/ha in 1000-1500L/ha to extend flower viability by delaying senescence. The active is to be applied at 30-60% flowering, and is to be used no later than full bloom.

3.2.4 Residue Information

The residue data for the crop supports an MRL of 0.02(*) mg/kg for use of aviglycine on cherries. The MRL is proposed to support GAP.

3.2.5 Dietary Risk Assessment

The ADI of 0.006 mg/kg bw/d was considered appropriate for use in the assessment and is consistent with overseas reputable regulatory bodies.

Based on the residues expected in food from crops treated according to existing and proposed GAP uses, the NEDI for aviglycine is equivalent to less than 3% of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

3.2.6 Toxicological/Public Health Assessment

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

3.2.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Australia	Cherries	0.05
Japan	Cherries	0.2

3.3 PROPOSAL TO SET AN MRL FOR BIXAFEN

It is proposed that an MRL is set for bixafen to support the GAP use on barley.

The current entry for bixafen in Schedule 1 of the MRL Notice is:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Bixafen	581809-46-3	Plant commodities: Bixafen Animal commodities: Bixafen plus its metabolite desmethyl bixafen expressed as bixafen	Cereal grains Mammalian fat Mammalian kidney Mammalian meat Mammalian liver Milk	0.01(*) 0.4 0.3 0.15 1.5 0.04

The revised entry for bixafen in Schedule 1 of the MRL Notice will read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Bixafen	581809-46-3	Plant commodities: Bixafen Animal commodities: Bixafen plus its metabolite desmethyl bixafen expressed as bixafen	Barley grain Cereal grains (except barley grain) Mammalian fat Mammalian kidney Mammalian meat Mammalian liver Milk	0.05 0.01(*) 0.4 0.3 0.15 1.5 0.04

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

3.3.1 Amendment Rationale

The proposed MRL has arisen from a review of the current MRL for cereal grain as it pertained to barley grain after an application was submitted to revise the approved withholding period in that crop. The proposed MRL will manage the use of bixafen on barley as a fungicide and in accordance with the application rates and approved withholding periods that are considered GAP in New Zealand.

3.3.2 Chemical Information

Common name of compound	Bixafen
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	581809-46-3
Type of compound	Pyrazole
Administration method	Spray

3.3.3 Good Agricultural Practice

Bixafen is used as a fungicide in barley and other cereal crops. On barley, it is used at an application rate of 700-1000 mL/ha at the first sign of disease, with a second application 3-4 weeks later if needed. Bixafen is used to treat scald, net blotch, ramularia leaf spot, and leaf rust in barley, and will attract a withholding period of 56 days when used on this commodity.

3.3.4 Residue Information

The residue data for the crop supports an MRL of 0.05 mg/kg for bixafen in barley. The MRL is proposed to support GAP.

3.3.5 Dietary Risk Assessment

The ADI of 0.02 mg/kg bw/d was considered appropriate for use in the assessment.

Based on the residues expected in food from crops treated according to existing and proposed GAP uses, the NEDI for bixafen is equivalent to less than 2% of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

3.3.6 Toxicological/Public Health Assessment

It has been determined that the use of bixafen on barley, in accordance with the GAP specified above, is unlikely to pose any health risks from consumption of treated produce with the proposed MRL in place.

3.3.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Australia	Barley	0.3
European Union	Barley	0.5

3.4 PROPOSAL TO AMEND AN MRL FOR CEPHAPIRIN

It is proposed that the existing MRL for cephapirin in cattle milk is amended to support GAP.

The current entry for cephapirin in Schedule 1 of the MRL Notice is:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Cephapirin	21593-23-7	*Sum of:* Cephapirin Des-acetylcephapirin *Expressed as:* Cephapirin	Cattle fat Cattle meat Cattle milk Edible offal of cattle	0.1 0.1 0.01 0.1

The revised entry for cephapirin in Schedule 1 of the MRL Notice will read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Cephapirin	21593-23-7	*Sum of:* Cephapirin Des-acetylcephapirin *Expressed as:* Cephapirin	Cattle fat Cattle meat Cattle milk Edible offal of cattle	0.1 0.1 0.06 0.1

3.4.1 Amendment Rationale

The proposed revision to the milk MRL will align the New Zealand limit with that used overseas. The proposed MRL will manage the use of cephapirin as an antibiotic in dairy cattle in accordance with the dose rates, use patterns, and withholding periods that are proposed as GAP in New Zealand.

3.4.2 Chemical Information

Common name of compound	Cephapirin
Use of compound	Antibiotic
Chemical Abstract Services (CAS) Registry number	21593-23-7
Type of compound	Cephalosporin
Administration method	Intramammary and intrauterine infusion

3.4.3 Good Agricultural Practice

Cephapirin is used as a dry cow therapy intramammary infusion for the treatment and prevention of mastitis in dairy cows, and as an intrauterine infusion for the treatment of endometritis in cows. For mastitis, treatment is administered by infusing 300 mg cephapirin per teat at the end of the final milking (at "drying off"); treatment is to be administered at least 28 days before calving, and if calving occurs within that 28 days, the full 28 days plus a further eight milkings must elapse before milk can enter the food chain. For endometritis, treatment is administered by a single dose of 500 mg cephapirin directly into the uterus; a nil milk withholding period currently applies for products approved to treat endometritis.

3.4.4 Residue Information

The residue data for the use of cephapirin as a mastitis treatment supports the revision of the milk MRL to 0.06 mg/kg. This MRL is proposed to support GAP.

3.4.5 Dietary Risk Assessment

The microbiological ADI of 0.00254 mg/kg bw/d was considered appropriate for use in the assessment.

Based on the residues expected in food from animals treated according to existing and proposed GAP uses, the NEDI for cephapirin is equivalent to less than 20 % of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

3.4.6 Toxicological/Public Health Assessment

For veterinary medicines intended for use in dairy animals, GAP is the shortest withholding period that will manage all associated risks; although the proposed MRL exceeds that set by Canada, Australia, and the United States, the proposed MRL of 0.06 mg/kg meets that set in the EU and can be considered acceptable from a dietary intake perspective. It is therefore considered representative of GAP.

It has been determined that the use of cephapirin in dairy cows when treated according to GAP, is unlikely to pose any health risks from consumption of treated produce.

3.4.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Australia	Cattle milk	0.01
Canada	Milk	0.02
European Union	Bovine milk	0.06
United States	Milk, Dairy cattle	0.02

3.5 PROPOSAL TO SET MRLS FOR CYPROCONAZOLE

It is proposed that MRLs are set for cyproconazole to support the GAP use on fodder and sugar beets, and grapes. This includes proposed MRLs for animal commodities resulting from use of cyproconazole on animal feeds.

The current entry for cyproconazole in Schedule 1 of the Food Notice is:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Cyproconazole	94361-06-5	Cyproconazole, sum of isomers	Bulb onions	0.01(*)
			Garlic	0.01(*)
			Peas	0.01(*)

The revised entry for cyproconazole in Schedule 1 of the Food Notice will read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Cyproconazole	94361-06-5	Cyproconazole, sum of isomers	Bulb onions	0.01 (*)
			Edible offal (mammalian)	0.5
			Fat (mammalian)	0.02
			Garlic	0.01 (*)
			Grapes	0.05 (*)
			Meat (mammalian)	0.02
			Milk	0.01
			Peas	0.01(*)

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

3.5.1.1 Amendment Rationale

The proposed MRL is required to support the additional use of a currently registered active ingredient on fodder and sugar beets. The proposed MRLs will manage the use of cyproconazole on fodder and sugar beets in accordance with the application rates and withholding periods that are proposed as GAP in New Zealand. This is because fodder and sugar beets are used only as animal feed in New Zealand, and therefore the proposed MRLs for commodities from animals that consume the crops will be reflective of GAP.

The proposed MRL in grapes reflects a current use pattern which has not previously had a specific MRL set. The proposed MRL of 0.05 mg/kg (the limit of quantification when the data was generated) is in accordance with the application rates and withholding periods that are currently considered as good agricultural practice (GAP) in New Zealand.

3.5.2 Chemical Information

Common name of compound	Cyproconazole
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	94361-06-5
Type of compound	Triazole – Demethylation inhibitor (DMI)
Administration method	Spray

3.5.2.1 Good Agricultural Practice

The proposed use of cyproconazole is to control foliar fungal diseases in fodder and sugar beets using 2 foliar sprays of 56gai/ha, with a 42 day WHP, in combination with trifloxystrobin. In NZ, fodder and sugar beets are grown as animal feeds, for which MRLs are not required.

The current use in grapes is up to 4 applications of 1.5gai/100 litres of water, to control powdery mildew. The product is recommended in rotation with fungicides with alternative modes of action in order to manage resistance. A 28 day WHP has been proposed in accordance with Good Agricultural Practice.

3.5.2.2 Residue Information

The residue data for beets and sugar beets supports MRLs for cyproconazole in animal commodities of 0.5, 0.02, 0.02 and 0.01 mg/kg for edible offal (mammalian), fat

(mammalian), meat (mammalian), and milk, respectively. The MRLs are proposed to support GAP.

The residue data for grapes supports an MRL of 0.05 mg/kg in accordance with GAP.

3.5.2.3 Dietary Risk Assessment

The ADI of 0.02 mg/kg bw/d was considered appropriate for use in the assessment of dietary exposure for all crops, and is consistent with overseas reputable regulatory bodies.

Based on the residues expected in food from crops treated according to existing and proposed GAP uses, the NEDI for cyproconazole in animal commodities is equivalent to less than 7 % of the ADI. It is therefore concluded that the chronic dietary exposure from all sources is small and the risk is acceptable.

The NEDI for cyproconazole when used on grapes is equivalent to less than 6 % of the ADI.

3.5.2.4 Toxicological/Public Health Assessment

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

3.5.2.5 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Australia	Edible Offal (mammalian)	1
	Meat (mammalian)	0.03
	Milks	0.01
Codex	Edible offal (mammalian)	0.5
	Fat (mammalian)	0.02
	Meat (from mammals other than marine mammals)	0.02
	Milk	0.01
European Union	Grapes	0.20
	Muscle (all animal species)	0.05
	Edible offals (other than liver & kidney)	0.5
	Liver	0.5
	Kidney	0.5
	Fat tissue	0.05
	Milk	0.05
Japan	Grapes	0.20
United States	Cattle and sheep by-products	0.01
	Cattle and sheep fat	0.01
	Cattle and sheep kidney	0.01
	Cattle and sheep liver	0.5
	Milk	0.02

3.6 PROPOSAL TO SET MRLS FOR DICLAZURIL

It is proposed that MRLs are set for diclazuril when used in sheep and cattle (calves and lambs) to support GAP.

This compound currently has no entry in Schedule 1 of the MRL Notice.

The proposed entry for diclazuril in Schedule 1 of the MRL Notice will read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Diclazuril	1019831-37-2	Diclazuril	Cattle fat	1.0
			Cattle kidney	2.0
			Cattle muscle	0.5
			Cattle liver	3.0
			Sheep fat	1.0
			Sheep kidney	2.0
			Sheep muscle	0.5
			Sheep liver	3.0

3.6.1 Amendment Rationale

The proposed MRLs represent the registration of a new product for use in production animals. The proposed MRLs will manage the use of diclazuril as a treatment for coccidiosis in calves and lambs, with dose rates and withholding periods that are proposed as good agricultural practice (GAP) in New Zealand.

3.6.2 Chemical Information

Common name of compound	Diclazuril
Use of compound	Coccidiostat
Chemical Abstract Services (CAS) Registry number	1019831-37-2
Type of compound	Benzeneacetonitrile derivative
Administration method	Oral

3.6.3 Good Agricultural Practice

Diclazuril is proposed for use as an aid in the control of coccidiosis in lambs and calves at a proposed dose rate of 2.5 mg/kg body weight by a single oral dose.

3.6.4 Residue Information

The residue data for the target species supports MRLs of diclazuril of: 1.0 mg/kg in cattle and sheep fat; 2.0 mg/kg in cattle and sheep kidney; 0.5 mg/kg in cattle and sheep muscle; and 3.0 mg/kg in cattle and sheep liver. These MRLs are proposed to support GAP.

3.6.5 Dietary Risk Assessment

The ADI of 0.03 mg/kg bw/d was considered appropriate for use in the assessment and is consistent with overseas reputable regulatory bodies.

Based on the residues expected in food from animals treated according to proposed GAP uses, the NEDI for diclazuril 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.

3.6.6 Toxicological/Public Health Assessment

It has been determined that the use of diclazuril as a coccidiostat in the management of intestinal parasites in sheep and cattle, when administered in accordance with GAP, is very unlikely to pose any health risks from consumption of treated produce.

3.6.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Codex	Sheep Muscle	0.5
	Sheep Fat	1
	Sheep liver	3

3.7 PROPOSAL TO AMEND THE RESIDUE DEFINITION FOR EMAMECTIN BENZOATE

It is proposed that the residue definition for emamectin benzoate is amended.

The current entry for emamectin benzoate in Schedule 1 of the MRL Notice is:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Emamectin benzoate	155569-91-8	*Sum of:* emamectin B1a emamectin B1b (Z)-8,9 emamectin B1a (Z)-8,9 emamectin B1b *Expressed as:* emamectin	Avocados Grapes Kiwifruit Pome fruits	0.005 0.002(*) 0.002(*) 0.001(*)

The revised entry for emamectin benzoate in Schedule One of the MRL Notice will read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Emamectin benzoate	155569-91-8	*Sum of:* emamectin B1a emamectin B1b *Expressed as:* emamectin	Avocados Grapes Kiwifruit Pome fruits	0.005 0.002(*) 0.002(*) 0.001(*)

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

3.7.1 Amendment Rationale

In 2010, the residue definition for emamectin benzoate was amended in Australia to only the sum of emamectin B1a and B1b without the inclusion of the 8,9-Z isomers. This was based on a lack of significant residues of the 8,9-Z isomers, and the lack of any quantifiable residues of toxicological significance associated with these isomers. This approach has also been taken by Codex and the EU, who have determined residue definitions based on either emamectin B1a alone expressed as emamectin, or the sum of emamectin B1a and B1b (Australia).

In New Zealand, there is also a notable lack of detectable residues for the 8,9-Z isomers, and with no toxicologically significant residues associated with these isomers there is no need to continue to include them in the New Zealand residue definition.

3.7.2 Chemical Information

Common name of compound	Emamectin benzoate
Use of compound	Insecticide
Chemical Abstract Services (CAS) Registry number	155569-91-8
Type of compound	4'-deoxy-4'-epi-methylamino derivative of avermectin B1
Administration method	Spray

3.7.3 Good Agricultural Practice

Emamectin is used as an insecticide in apples, pears, avocados, grapes and kiwifruit. The current use patterns, withholding periods, and MRLs are still considered appropriate to support GAP and will not change.

3.7.4 Residue Information

The residue data for the approved crops support the current MRLs, and demonstrate consistently low levels of total emamectin residues and levels of the 8,9-Z isomers below the

limit of detection. It is therefore considered that the residue data supports the change in the residue definition.

3.7.5 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)	Residue Definition
Australia	Grapes	0.002	Sum of emamectin B1a and emamectin B1b
Codex	Grapes	0.03	Emamectin B1a benzoate
	Pome fruits	0.02	
European Union	Avocados	0.01	Emamectin benzoate B1a, expressed as emamectin
	Grapes (all types)	0.05	
	Kiwi fruits (green, red, yellow)	0.01	
	Pome fruits (all types)	0.02	
USA	Apples	0.025	Sum of emamectin (a mixture of a minimum of 90% 4'-epi-methylamino-4'-deoxyavermectin B1a and maximum of 10% 4'-epi-methylamino-4'-deoxyavermectin B1b) and its metabolites 8,9-isomer of the B 1a and B1b component of the parent (8,9-ZMA), or 4'-deoxy-4'-epi-amino-avermectin B1a and 4'-deoxy-4'-epi-amino-avermectin B1b; 4'-deoxy-4'-epi-amino avermectin B1a (AB 1a); 4'-deoxy-4'-epi-(N-formyl-N-methyl)amino-avermectin (MFB 1a); and 4'-deoxy-4'-epi-(N-formyl)amino-avermectin B 1a (FAB 1a), calculated as the stoichiometric equivalent of emamectin.
	Grapes, wine	0.03	
	Pears	0.025	

3.8 PROPOSAL TO SET AN MRL FOR FENPYRAZAMINE

It is proposed that an MRL is set for fenpyrazamine to support the GAP use on grapes.

There is currently no entry in Schedule 1 of the MRL Notice.

The proposed entry for fenpyrazamine in Schedule 1 of the MRL Notice will read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Fenpyrazamine	473798-59-3	Fenpyrazamine (parent only)	Grapes	0.05

3.8.1 Amendment Rationale

The proposed MRL represents the registration of a new active ingredient for use on grapes. The proposed MRL will manage the use of fenpyrazamine as a fungicide on grapes in accordance with the application rates and withholding periods that are proposed as GAP in New Zealand.

3.8.2 Chemical Information

Common name of compound	Fenpyrazamine
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	473798-59-3
Type of compound	Hydroxyanilide
Administration method	Spray

3.8.3 Good Agricultural Practice

Fenpyrazamine is proposed for use on wine grapes for the treatment of grey mould (*Botrytis cinerea*) at up to 2 foliar sprays of 40 gai/100L, applied to full coverage up to full bunch closure. This is considered GAP as part of a season-long control programme. The applicable withholding period is use up to pre-bunch closure but not less than 65 days before harvest.

3.8.4 Residue Information

The residue data for the crops supports an MRL for fenpyrazamine in grapes of 0.05 mg/kg. This MRL is proposed to support GAP.

3.8.5 Dietary Risk Assessment

The $PDE_{(food)}$ of 0.091 mg/kg bw/d was considered appropriate for use in the assessment and is consistent with overseas reputable regulatory bodies.

Based on the residues expected in food from crops treated according to the proposed GAP use, the NEDI for fenpyrazamine is equivalent to less than 0.2 % of the $PDE_{(food)}$. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

3.8.6 Toxicological/Public Health Assessment

It has been determined that the use of fenpyrazimine as a fungicide for use on wine grapes, when applied according to GAP, is very unlikely to pose any health risks from consumption of treated produce.

3.8.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Australia	Dried Grapes (currants, raisins, and sultanas)	10
	Table Grapes	2
	Wine Grapes	0.05
European Union	Table Grapes	3
	Wine Grapes	3
United States	Table grapes (no set MRL for wine grapes)	3

3.9 PROPOSAL TO SET AN MRL FOR FLUOPYRAM

It is proposed that an MRL is set for fluopyram to support the GAP use on fruiting vegetables (except cucurbits).

The current entry for fluopyram in Schedule 1 of the MRL Notice is:

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

The revised entry for fluopyram in Schedule 1 of the MRL Notice will read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Fluopyram	658066-35-4	Plant commodities: Fluopyram Animal commodities: Sum of fluopyram and 2-(trifluoromethyl) benzamide, expressed as fluopyram	Bulb onions Fruiting vegetables (except cucurbits) Grapes Mammalian meat Mammalian offal Milk	0.01(*) 1.0 0.05 0.1 0.7 0.07

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

3.9.1.1 Amendment Rationale

The proposed MRL represents an additional use of a currently registered active ingredient. The proposed MRL will manage the use of the fungicide fluopyram on greenhouse fruiting vegetables (except cucurbits) in accordance with the application rates and withholding periods that are proposed as GAP in New Zealand.

3.9.2 Chemical Information

Common name of compound	Fluopyram
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	65806-35-4
Type of compound	Succinate Dehydrogenase Inhibitor (SDHI)
Administration method	Spray

3.9.2.1 Good Agricultural Practice

The proposed use of fluopyram is to control *Botrytis* in greenhouse fruiting vegetables (except cucurbits) using up to 2 foliar sprays of 300gai/ha. The product is recommended in rotation with fungicides with alternative modes of action in order to manage resistance. A one day WHP has been proposed in accordance with common greenhouse practice for fruiting vegetables.

3.9.2.2 Residue Information

The residue data for the crop supports an MRL of 1.0 mg/kg for fluopyram on fruiting vegetables (except cucurbits). The MRL is proposed to support GAP.

3.9.2.3 Dietary Risk Assessment

The $PDE_{(food)}$ of 0.0084 mg/kg bw/d was considered appropriate for use in the assessment and is consistent with overseas reputable regulatory bodies.

Based on the residues expected in food from crops treated according to existing and proposed GAP uses, the NEDI for fluopyram is equivalent to less than 8 % of the $PDE_{(food)}$. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

3.9.2.4 Toxicological/Public Health Assessment

It has been determined that the use of fluopyram in greenhouse fruiting vegetables (except cucurbits), according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

3.9.2.5 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Australia	Tomatoes	0.90
Codex	Tomatoes	0.40
European Union	Eggplants	0.90
	Peppers (sweet)	0.90
	Tomatoes	0.80
China	Tomatoes	1.0
Japan	Tomatoes	0.40
United States	Eggplants	4.0
	Peppers (sweet)	1.0
	Tomatoes	4.0

3.10 PROPOSAL TO AMEND AN MRL FOR FLUXAPYROXAD

It is proposed that an MRL is set for fluxapyroxad to support the GAP use in pears.

The current entry for fluxapyroxad in Schedule 1 of the MRL Notice is:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Fluxapyroxad	907204-31-3	Fluxapyroxad	Apples	0.02
			Barley grain	0.3
			Mammalian fat	0.05
			Edible offal	0.03
			Mammalian meat	0.01(*)
			Milk	0.005
			Wheat grain	0.1

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

The revised entry for fluxapyroxad Schedule 1 of the MRL Notice will read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Fluxapyroxad	907204-31-3	Fluxapyroxad	Apples	0.02
			Barley grain	0.3
			Edible offal	0.03
			Mammalian fat	0.05
			Mammalian meat	0.01(*)
			Milk	0.005
			Pears	0.02
			Wheat grain	0.1

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

3.10.1 Amendment Rationale

The proposed MRL change represents the expansion of use of a currently registered active ingredient to include pears. The proposed MRLs will manage the use of fluxapyroxad as a fungicide on apples and pears in accordance with the application rates and withholding periods that are proposed as GAP in New Zealand.

3.10.2 Chemical Information

Common name of compound	Fluxapyroxad
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	907204-31-3
Type of compound	Pyrazole-carboxamide
Administration method	Spray

3.10.3 Good Agricultural Practice

Fluxapyroxad is proposed for use a fungicide for the treatment of black spot and powdery mildew on apples, and for black spot on pears. The fruit is treated at a rate of 6gai/100L of water at 7 to 10 day intervals from green tip to 21 days after petal fall. The withholding period applied to use of the product in apples and pears is that it must not be applied later than 21 days after petal fall or after fruitlets reach 25mm in diameter, whichever is sooner.

3.10.4 Residue Information

The residue data for the crops supports the extension of the MRL previously promulgated for apples at 0.02 mg/kg to all pome fruits. This MRL is proposed to support GAP.

3.10.5 Dietary Risk Assessment

The $PDE_{(food)}$ of 0.014 mg/kg bw/day was considered appropriate for use in the assessment and is consistent with overseas reputable regulatory bodies.

Based on the residues expected in food from crops treated according to existing and proposed GAP uses, the NEDI for fluxapyroxad is equivalent to less than I % of the $PDE_{(food)}$. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

3.10.6 Toxicological/Public Health Assessment

It has been determined that the use of fluxapyroxad as a fungicide in pome fruits, when treated according to GAP, is very unlikely to pose any health risks from consumption of treated produce.

3.10.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Australia	Pome fruits	0.8
Codex	Pome Fruits	0.9
European Union	Pome Fruits	0.9
United States	Apples	0.8
	Pears	0.8

3.11 PROPOSAL TO SET MRLS FOR INDOXACARB AND AMEND THE RESIDUE DEFINITION

It is proposed that the MRLs for indoxacarb are revised to set a separate MRL for cabbage (previously included as part of the brassica vegetables group), to amend the MRL set for head lettuce, and to amend the residue definition in light of new information.

The current entry for indoxacarb in Schedule 1 of the MRL Notice is:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Indoxacarb	173584-44-6	Indoxacarb, sum of isomers	Brassica vegetables	0.5
			Grapes	0.5
			Head lettuce	1
			Pome fruits	0.5

The revised entry for indoxacarb in Schedule One of the MRL Notice will read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Indoxacarb	173584-44-6	Sum of indoxacarb and its R enantiomer	Brassica vegetables (except cabbage)	0.5
			Cabbage	3
			Grapes	0.5
			Head lettuce	3
			Pome fruits	0.5

3.11.1 Amendment Rationale

The proposed MRLs are the result of new data and information indicating that the previous MRLs were no longer sufficient to manage GAP. The revisions in the MRLs for brassica vegetables and head lettuce, as well as the establishment of a separate MRL for cabbage, are the result of the assessment of that new information. The proposed MRLs will manage

the use of indoxacarb as an insecticide on brassicas and head lettuce in accordance with the application rates and withholding periods that are proposed as GAP in New Zealand.

The amendment of the residue definition is to allow for harmonisation with the residue definition established by Codex. The amended residue definition is in effect the same as is currently established, but expressed in a different way.

3.11.2 Chemical Information

Common name of compound	Indoxacarb
Use of compound	Insecticide
Chemical Abstract Services (CAS) Registry number	173584-44-6
Type of compound	Oxadiazine
Administration method	Spray

3.11.3 Good Agricultural Practice

Indoxacarb is approved for use as an insecticide on head lettuce, cabbage, cauliflower, broccoli, and Brussels sprouts for the control of caterpillars of diamondback moth, cabbage white butterfly, and soybean looper. Crops are to be treated with a maximum of four applications at 7-14 day intervals from the first sign of insect presence at a dose rate of 75gai/ha. The withholding period applicable to all crops is to not apply within three days of harvest.

3.11.4 Residue Information

The new residue data support the amendment of indoxacarb MRL for head lettuce to 3mg/kg, and the setting of a cabbage-specific MRL of 3 mg/kg for cabbage. These amendments, resulting from review of the new data, also require the exclusion of cabbage from the brassica crop grouping. The new MRLs are proposed to support GAP.

3.11.5 Dietary Risk Assessment

The ADI of 0.01 mg/kg bw/d was considered appropriate for use in the assessment and is consistent with overseas reputable regulatory bodies.

Based on the residues expected in food from crops treated according to existing and proposed GAP uses, the NEDI for indoxacarb 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.

3.11.6 Toxicological/Public Health Assessment

It has been determined that the use of indoxacarb as an insecticide for brassica vegetables and head lettuce, when treated according to GAP, is very unlikely to pose any health risks from consumption of treated produce.

3.11.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)	Residue Definition
Australia	Brassica (cole or cabbage) vegetables, head cabbages and flowerhead brassicas	2.0	Sum of indoxacarb and its R-isomer
	Lettuce, head	3.0	
Codex	Broccoli	0.2	Sum of indoxacarb and its R enantiomer
	Cabbages, head	3.0	
	Cauliflower	0.2	
	Lettuce, head	7	
European Union	Broccoli	0.3	Sum of indoxacarb and its R enantiomer
	Cauliflowers	0.3	
	Other flowering brassica	0.3	
	Brussels sprouts	0.06	
	Head cabbages	0.2	
	Other head brassica	0.02	
	Chinese cabbage	3.0	
	Kales	0.4	
	Other leafy brassicas	0.4	
	Lettuces	3.0	
USA	Broccoli, all varieties	12	Indoxacarb, (S)-methyl 7-chloro-2,5-dihydro-2-[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl]amino]carbonyl]indeno[1,2-e][1,3,4][oxadiazine-4a(3H)-carboxylate, and its R-enantiomer, (R)-methyl 7-chloro-2,5-dihydro-2-[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl]amino]carbonyl]indeno[1,2-e][1,3,4][oxadiazine-4a(3H)-carboxylate
	Brussels Sprouts	12	
	Cabbage, all varieties	12	
	Cauliflower	12	
	Lettuce, head	14	

3.12 PROPOSAL TO SET MRLS FOR MELOXICAM

It is proposed that MRLs are set for meloxicam when used in sheep for the management of inflammation and pain to support the GAP.

The current entry for meloxicam in Schedule 1 of the MRL Notice is:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Meloxicam	71125-38-7	Meloxicam	Cattle kidney	0.035
			Cattle liver	0.05
			Cattle meat	0.025
			Milk	0.015
			Pig kidney	0.2
			Pig liver	0.1
			Pig meat	0.01

The revised entry for meloxicam in Schedule 1 of the MRL Notice will read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Meloxicam	71125-38-7	Meloxicam	Cattle kidney	0.035
			Cattle liver	0.05
			Cattle meat	0.025
			Milk	0.015
			Pig kidney	0.2
			Pig liver	0.1
			Pig meat	0.01
			Sheep fat	0.01
			Sheep kidney	0.065
			Sheep liver	0.065
			Sheep meat	0.01

3.12.1 Amendment Rationale

The proposed MRLs represent the expansion of use of a currently registered active ingredient. The proposed MRLs will manage the use of meloxicam when administered to sheep in the management of inflammation, fever and pain, in accordance with the dose rates and withholding periods that are proposed as GAP in New Zealand.

3.12.2 Chemical Information

Common name of compound	Meloxicam
Use of compound	Non-steroidal anti-inflammatory
Chemical Abstract Services (CAS) Registry number	71125-38-7
Type of compound	Oxicam (enolic acid)
Administration method	Injection

3.12.3 Good Agricultural Practice

Meloxicam is proposed for use in the treatment of pain and inflammation in sheep at a dose rate of 1 mg/kg bodyweight. The withholding period applicable to this species is 11 days from the last treatment.

3.12.4 Residue Information

The residue data for the target species support MRLs of 0.01 mg/kg in muscle and fat and 0.065 mg/kg in kidneys and liver from treated sheep. These MRLs are proposed to support GAP.

3.12.5 Dietary Risk Assessment

The ADI of 1.25 µg/kg bw/day or 75 µg/person/day was considered appropriate for use in the assessment and is consistent with overseas reputable regulatory bodies.

Based on the residues expected in food from animals treated according to existing and proposed GAP uses, the NEDI for meloxicam 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.

3.12.6 Toxicological/Public Health Assessment

It has been determined that the use of meloxicam as an anti-inflammatory, anti-pyretic, and analgesic in sheep, when treated according to GAP, is unlikely to pose any health risks from consumption of treated produce.

3.12.7 Other International MRLs

There are currently no international MRLs for use of meloxicam in sheep. It is noted however that the proposed MRLs were determined during a global joint review of the approval of the use of meloxicam in sheep, and the same MRLs that are proposed for promulgation in New Zealand will also be proposed for promulgation in Canada. Australia will be promulgating MRLs of 0.01 mg/kg for all sheep tissues.

3.13 PROPOSAL TO SET AN MRL FOR METAMITRON

It is proposed that an MRL is set for metamitron to support the GAP use on apples.

There is no current entry in Schedule 1 of the MRL Notice for metamitron.

The proposed entry for metamitron in Schedule 1 of the MRL Notice will read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Metamitron	41394-05-2	Metamitron	Apples	0.01 (*)

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

3.13.1 Amendment Rationale

The proposed MRL represents the expansion of use of a currently registered herbicide active ingredient. The proposed MRL will manage the use of metamitron as a plant growth regulator on apples in accordance with the application rates and withholding periods that are proposed as GAP in New Zealand.

3.13.2 Chemical Information

Common name of compound	Metamitron
Use of compound	Plant growth regulator
Chemical Abstract Services (CAS) Registry number	41394-05-2
Type of compound	Triazinones
Administration method	Spray

3.13.3 Good Agricultural Practice

Metamitron is proposed for use as a plant growth regulator on apples at a rate of 25-37 gai/100L of water with a minimum interval of five days between applications. The applicable withholding period for this use is application up to 30 days after full bloom.

3.13.4 Residue Information

The residue data for the crop proposed supports an MRL of 0.01 mg/kg in apples. This MRL is proposed to support GAP.

3.13.5 Dietary Risk Assessment

The ADI of 0.03 mg/kg bw/d was considered appropriate for use in the assessment and is consistent with overseas reputable regulatory bodies.

Based on the residues expected in food from crops treated according to the proposed GAP use, the NEDI for metamitron is equivalent to less than 0.05 % of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

3.13.6 Toxicological/Public Health Assessment

It has been determined that the use of metamitron as a plant growth regulator in apples, when used according to GAP is very unlikely to pose any health risks from consumption of treated produce.

3.13.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
European Union	Apples	0.1

3.14 PROPOSAL TO SET AN MRL FOR METHOXYFENOZIDE

It is proposed that an MRL is set for methoxyfenozide to support the GAP use on stone fruit.

The current entry for methoxyfenozide in Schedule 1 of the MRL Notice is:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Methoxyfenozide	161050-58-4	Methoxyfenozide	Avocados	0.1
			Blueberries	0.8
			Kiwifruit	0.5
			Nectarines	0.2
			Peaches	0.2
			Pome fruit	0.5

The revised entry for methoxyfenozide in Schedule 1 of the MRL Notice will read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Methoxyfenozide	161050-58-4	Methoxyfenozide	Avocados	0.1
			Blueberries	0.8
			Kiwifruit	0.5
			Pome fruit	0.5
			Stone fruit	0.4

3.14.1 Amendment Rationale

The proposed MRLs represent the expansion of use of a currently registered active ingredient from approval for the treatment of nectarines and peaches to all stone fruit. The proposed MRL will manage the use of methoxyfenozide as an insecticide on stone fruit in accordance with the application rates and withholding periods that are proposed as GAP in New Zealand.

3.14.2 Chemical Information

Common name of compound	Methoxyfenozide
Use of compound	Insecticide
Chemical Abstract Services (CAS) Registry number	161050-58-4
Type of compound	Dia-cylhydrazine
Administration method	Spray

3.14.3 Good Agricultural Practice

Methoxyfenozide is proposed for use as an insecticide on stone fruit at 6 gai/100L water at 2000L water/ha for a maximum of four applications per season at no less than 14 day intervals commencing at petal fall. This is the same use pattern currently approved for nectarines and peaches. A 14 day withholding period applies to this use.

3.14.4 Residue Information

The residue data for the crops supports a methoxyfenozide MRL in stone fruit of 0.4 mg/kg. This MRL is proposed to support GAP.

3.14.5 Dietary Risk Assessment

The $PDE_{(food)}$ of 0.08 mg/kg bw/d was considered appropriate for use in the assessment and is consistent with overseas reputable regulatory bodies.

Based on the residues expected in food from crops treated according to existing and proposed GAP uses, the NEDI for Methoxyfenozide is equivalent to less than 1 % of the $PDE_{(food)}$. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

3.14.6 Toxicological/Public Health Assessment

It has been determined that the use of methoxyfenozide as an insecticide for stone fruit, when treated according to GAP, is very unlikely to pose any health risks from consumption of treated produce.

3.14.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Australia	Plums (including prunes)	0.3
	Stone fruits [except plums (including prunes)]	3
Codex	Stone fruits	2.0
European Union	Apricots	2.0
	Cherries (sweet)	2.0
	Peaches	2.0
	Plums	2.0
	Others	2.0
United States	Apricots	3.0
	Cherries, all varieties	3.0
	Mangoes	0.6
	Nectarines	3.0
	Peaches	3.0
	Plums, all varieties	3.0

3.15 PROPOSAL TO AMEND THE MRLS AND RESIDUE DEFINITION FOR PROTHIOCONAZOLE

It is proposed that an MRL is set for prothioconazole to support the GAP use on barley, that the current MRL for cereal grains is amended to exclude barley as a result, and that the residue definition for prothioconazole is amended to align with that set by Codex.

The current entry for prothioconazole in Schedule 1 of the MRL Notice is:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Prothioconazole	178928-70-6	*Sum of:* Prothioconazole Prothioconazole-desthio *Expressed as:* prothioconazole	Cereal grains	0.02 (*)

The revised entry for prothioconazole in Schedule 1 of the MRL Notice will read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Prothioconazole	178928-70-6	Prothioconazole-desthio	Barley grain	0.1
			Cereal grains (except barley grain)	0.01 (*)

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

3.15.1 Amendment Rationale

The proposed new MRL has arisen from a review of the current MRL for cereal grain as it pertained to barley grain after an application was submitted to revise the approved withholding period for barley. The proposed MRL will manage the use of prothioconazole on barley as a fungicide and in accordance with the application rates and approved withholding periods that are considered GAP in New Zealand.

In 2008, the JMPR adopted the residue definition 'prothioconazole-desthio' for both plant and animal products, and for dietary intake estimation. It is considered appropriate to amend the New Zealand residue definition to align with the JMPR definition given that the parent prothioconazole has not been detected in treated commodities, and both parent and metabolite are possibly present at or below the limit of quantification (LOQ) of 0.01mg/kg. The residue definitions for international MRLs are listed in section 3.15.7.

To reflect this change of the residue definition, it is also proposed that the MRL for cereal grains (except barley grain) is reduced to the LOQ of the new metabolite at 0.01 (*) mg/kg.

3.15.2 Chemical Information

Common name of compound	Prothioconazole
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	178928-70-6
Type of compound	Triazolinthione
Administration method	Spray

3.15.3 Good Agricultural Practice

Prothioconazole is used as a fungicide on barley and other small grain cereals excluding maize and sweetcorn. In barley, it is used at an application rate of 150 gai/ha for up to two applications at 3-4 week intervals. The withholding period is 56 days.

3.15.4 Residue Information

The residue data for the crop supports a prothioconazole MRL of 0.1 mg/kg on barley. This MRL is proposed to support GAP.

3.15.5 Dietary Risk Assessment

The ADI of 0.008 mg/kg bw/d was considered appropriate for use in the assessment and is consistent with overseas reputable regulatory bodies.

Based on the residues expected in food from crops treated according to existing and proposed GAP uses, the NEDI for prothioconazole is equivalent to less than 1% of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

3.15.6 Toxicological/Public Health Assessment

It has been determined that the use of prothioconazole as a fungicide on barley, when used according to GAP, is unlikely to pose any health risks from consumption of treated produce.

3.15.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)	Residue Definition
Australia	Cereal bran, unprocessed Cereal grains	0.5 0.3	Sum of prothioconazole and prothioconazole desthio (2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1H-1,2,4-triazol-1-yl)-propan-2-ol), expressed as prothioconazole
Codex	Barley	0.2	Prothioconazole-desthio
United States	Barley grain	0.35	Prothioconazole and its metabolite prothioconazole-desthio, or alpha-(1-chlorocyclopropyl)-alpha-[(2-chlorophenyl)methyl]-1H-1,2,4 triazole-1-ethanol, calculated as parent in or on the commodity.

3.16 PROPOSAL TO AMEND THE MRLS FOR SPIROTETRAMAT

It is proposed that an MRL is set for spirotetramat to support the GAP use on apples, and that the current MRL for pome fruits is amended to exclude apples as a result.

The current entry for spirotetramat in Schedule 1 of the MRL Notice is:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Spirotetramat	203313-25-1	*Sum of:* Spirotetramat and its enol metabolite *Expressed as:* Spirotetramat	Blueberries	0.7
			Citrus	1
			Grapes	0.02(*)
			Kiwifruit	0.1
			Pome fruits	0.02(*)
			Potatoes	0.5
			Tomatoes	0.3

The revised entry for spirotetramat in Schedule 1 of the MRL Notice will read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Spirotetramat	203313-25-1	*Sum of:* Spirotetramat and its enol metabolite *Expressed as:* Spirotetramat	Apples	0.2
			Blueberries	0.7
			Citrus	1
			Grapes	0.02(*)
			Kiwifruit	0.1
			Pome fruits (except apples)	0.02(*)
			Potatoes	0.5
			Tomatoes	0.3

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

3.16.1 Amendment Rationale

The proposed MRLs represent the expansion of use of a currently registered active ingredient. The proposed MRLs will manage the use of spirotetramat as an insecticide on apples at the application rates and withholding periods that are proposed as GAP in New Zealand.

3.16.2 Chemical Information

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

3.16.3 Good Agricultural Practice

Spirotetramat is proposed for use as an insecticide on apples for the control of apple leafcurling midge and armoured scales at a dose rate of 4.8 gai/100 litres of water and a minimum application rate of 960mL water/ha. Spirotetramat is applied to coincide with periods of peak midge egg laying, and at other points between mid-November and early February to control subsequent generations. Similar timing is used to control armoured scales. The withholding period for apples is 35 days.

3.16.4 Residue Information

The residue data for spirotetramat use on apples supports the MRL of 0.2 mg/kg. This MRL is proposed to support GAP.

3.16.5 Dietary Risk Assessment

The $PDE_{(food)}$ of 0.09 mg/kg bw/day was considered appropriate for use in the assessment and is consistent with overseas reputable regulatory bodies.

Based on the residues expected in food from crops treated according to existing and proposed GAP uses, the NEDI for spirotetramat 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.

3.16.6 Toxicological/Public Health Assessment

It has been determined that the use of spirotetramat as an insecticide on apples, when used according to GAP, is very unlikely to pose any health risks from consumption of treated produce.

3.16.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Australia	Pome fruits	0.5
Codex	Pome fruits	0.7
European Union	Apples	1.0
United States	Apples	0.7

3.17 PROPOSAL TO SET MRLS FOR THIAMETHOXAM

It is proposed that MRLs are set for thiamethoxam to support the GAP use on bulb onions and green onions.

The current entry for thiamethoxam in Schedule 1 of the MRL Notice is:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Thiamethoxam	153719-23-4	Thiamethoxam	Kiwifruit	1
			Leafy vegetables	5
			Maize	0.02(*)
			Pome fruits	0.1
			Potatoes	0.02(*)
			Sweetcorn	0.02(*)

The revised entry for thiamethoxam in Schedule 1 of the MRL Notice will read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Thiamethoxam	153719-23-4	Thiamethoxam	Bulb onions	0.01(*)
			Green onions	0.2
			Kiwifruit	1
			Leafy vegetables	5
			Maize	0.02(*)
			Pome fruits	0.1
			Potatoes	0.02(*)
			Sweetcorn	0.02(*)

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

3.17.1 Amendment Rationale

The proposed MRLs represent the expansion of use of a currently registered active ingredient. The proposed MRLs will manage the use of thiamethoxam as an insecticide on bulb and green onions in accordance with the application rates and withholding periods that are proposed as GAP in New Zealand.

3.17.2 Chemical Information

Common name of compound	Thiamethoxam
Use of compound	Insecticide
Chemical Abstract Services (CAS) Registry number	153719-23-4
Type of compound	Neonicotinoid
Administration method	Spray

3.17.3 Good Agricultural Practice

Thiamethoxam is proposed for use as an insecticide on bulb and green onions to be applied at a rate of 54gai/ha to treat infestation with thrips (*Thrips tabaci*), with the first application indicated by reaching the threshold level for the insect. Treatment is repeated at seven day intervals as a cluster of three or four sequential applications, with a maximum of four applications per year. The withholding period is 14 days.

3.17.4 Residue Information

The residue data for the crops supports thiamethoxam MRLs at 0.01(*) mg/kg for bulb onions and 0.2 mg/kg for green onions. These MRLs are proposed to support GAP.

3.17.5 Dietary Risk Assessment

The $PDE_{(food)}$ of 0.016 mg/kg bw/d was considered appropriate for use in the assessment and is consistent with overseas reputable regulatory bodies.

Based on the residues expected in food from crops treated according to existing and proposed GAP uses, the NEDI for thiamethoxam is equivalent to less than 2.1% of the

$PDE_{(food)}$. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

3.17.6 Toxicological/Public Health Assessment

It has been determined that the use of thiamethoxam as an insecticide for onions, when treated according to GAP, is very unlikely to pose any health risks from consumption of treated produce.

3.17.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
European Union	Onions	0.1
	Spring onions/green onions and Welsh onions	0.05
United States	Onion, bulb	0.03

3.18 PROPOSAL TO SET MRLS FOR TRIFLOXYSTROBIN

It is proposed that MRLs are set for residues in animal commodities when trifloxystrobin is used on fodder beets (including sugar beets) to support the GAP.

The current entry for trifloxystrobin in Schedule 1 of the Food Notice is:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Trifloxystrobin	141517-21-7	*Sum of:* trifloxystrobin and its free acid metabolite. *Expressed as:* trifloxystrobin equivalents	Cereal grains	0.05(*)
			Citrus fruits (except Clementine and Satsuma mandarins)	0.3
			Cucurbits (inedible peel)	0.02(*)
			Grapes	0.02(*)
			Kiwifruit	0.02(*)
			Mandarins (Clementine and Satsuma)	0.02(*)
			Pome fruits	0.02(*)
			Stone fruits (except cherries)	0.02(*)

The revised entry for trifloxystrobin in Schedule1 of the MRL Notice will read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Trifloxystrobin	141517-21-7	*Sum of:* trifloxystrobin and its free acid metabolite. *Expressed as:* trifloxystrobin equivalents	Cereal grains	0.05(*)
			Citrus fruits (except Clementine and Satsuma mandarins)	0.3
			Cucurbits (inedible peel)	0.02(*)
			Fat (mammalian)	0.05
			Grapes	0.02(*)
			Kidney (mammalian)	0.04
			Kiwifruit	0.02(*)
			Liver (mammalian)	0.05
			Meat (mammalian)	0.05
			Mandarins (Clementine and Satsuma)	0.02(*)
			Pome fruits	0.02(*)
			Stone fruits (except cherries)	0.02(*)

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

3.18.1.1 Amendment Rationale

The proposed MRL is required to support the additional use of a currently registered active ingredient on fodder and sugar beets. The proposed MRL will manage the use of trifloxystrobin on fodder and sugar beets in accordance with the application rates and withholding periods that are proposed as GAP in New Zealand. This is because fodder and sugar beets are used only as animal feed in New Zealand, and therefore the proposed MRLs for commodities from animals that consume the crops will be reflective of GAP.

3.18.2 Chemical Information

Common name of compound	trifloxystrobin
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	141517-21-7
Type of compound	Oximino acetate - Quinone outside Inhibitor
Administration method	Spray

3.18.2.1 Good Agricultural Practice

The proposed use of trifloxystrobin is to control is to control foliar fungal diseases in fodder and sugar beets using 2 foliar sprays of 131gai/ha, with a 42 day WHP, in combination with cyproconazole. In New Zealand, fodder and sugar beets are grown as animal feeds, for which MRLs are not required.

3.18.2.2 Residue Information

The residue data for beets and sugar beets supports trifloxystrobin MRLs in animal commodities at 0.05 mg/kg in fat (mammalian), 0.04 mg/kg in kidney (mammalian), 0.05 mg/kg in liver, and 0.05 mg/kg in meat (mammalian). These MRLs are proposed to support GAP.

3.18.2.3 Dietary Risk Assessment

The ADI of 0.04 mg/kg bw/d was considered appropriate for use in the assessment and is consistent with overseas reputable regulatory bodies.

Based on the residues expected in food from crops treated according to existing and proposed GAP uses, the NEDI for trifloxystrobin is equivalent to less than 4 % of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

3.18.2.4 Toxicological/Public Health Assessment

It has been determined that the use of trifloxystrobin in fodder and sugar beets, according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

3.18.2.5 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Australia	Edible offal (mammalian)	0.05
	Meat (mammalian)	0.05
	Milks	0.02
Codex	Kidney of cattle, goats, pigs and sheep	0.04
	Liver of cattle, goats, pigs, and sheep	0.05
	Meat (from mammals other than marine mammals)	0.05
	Milks	0.02
European Union	Swine (all tissues)	0.04
	Muscle (except swine)	0.04
	Fat (except swine)	0.06
	Liver (except swine)	0.07
	Kidney (except swine)	0.04
	Edible offals other than liver and kidney (except swine)	0.07
	Other tissues (except swine)	0.02
	Milks	0.02
United States	By products (except swine)	0.1
	Fat (except swine)	0.1
	Kidney (except swine)	0.1
	Liver (except swine)	0.1
	Meat (except swine)	0.1
	Swine (all tissues)	0.05

3.19 PROPOSAL TO SET MRLS FOR TRINEXAPAC-ETHYL AND CORRECT ERRORS IN ITS NOTICE ENTRY

It is proposed that an amended MRL is set for trinexapac-ethyl to support the GAP use on certain small grain cereal crops, and errors in the chemical name and CAS number be corrected.

The current entry for trinexapac-ethyl in Schedule 1 of the Food Notice is:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Trinexpac-ethyl	104273-73-6	4-(cyclopropyl-α-hydroxy-methylene)-3,5-dioxo-cyclohexanecarboxylic acid	Cereal grains	0.05(*)

The revised entry for trinexapac-ethyl in Schedule 1 of the Food Notice will read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Trinexapac-ethyl	95266-40-3	Trinexapac (acid)	Cereal grains, except maize and sweet corns	0.2

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

3.19.1.1 Amendment Rationale

The proposed MRL represents the extension of existing uses of a currently registered active ingredient to a new formulation type. The proposed MRL will manage the use of the plant growth regulator trinexapac-ethyl on cereals, in accordance with the application rates and

withholding periods that are proposed as GAP in New Zealand. The typographical errors to be corrected are the spelling of the common name and the CAS number of the compound.

3.19.1.2 Chemical Information

Common name of compound	Trinexapac-ethyl
Use of compound	Plant growth regulator
Chemical Abstract Services (CAS) Registry number	95266-40-3
Type of compound	Cyclohexanecarboxylate derivative (or 'unclassified')
Administration method	Spray

3.19.1.3 Good Agricultural Practice

Trinexapac-ethyl is currently used as a plant growth regulator on certain small grain cereals at 100 gai/ha to prevent lodging, with a single application at BBCH 31 (1st node visible). Use of trinexapac-ethyl attracts a 42 day withholding period for forage. The use pattern will remain the same, but information supplied in support of a new formulation type (dispersible concentrate) supports a higher MRL than the current MRL of 0.05 mg/kg.

3.19.1.4 Residue Information

The residue data for the crop supports an MRL of 0.2 mg/kg for trinexapac-ethyl in cereal grains (except maize and sweet corns). The MRL is proposed to support GAP.

3.19.1.5 Dietary Risk Assessment

The ADI of 0.3 mg/kg bw/d was considered appropriate for use in the assessment and is consistent with overseas reputable regulatory bodies.

Based on the residues expected in food from crops treated according to existing and proposed GAP uses, the NEDI for trinexapac-ethyl 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.

3.19.1.6 Toxicological/Public Health Assessment

It has been determined that the use of trinexapac-ethyl in cereal and ryegrass, according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

3.19.1.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Australia	Cereal grains	0.20
Codex	Barley grain	3.00
	Oat grain	3.00
	Wheat grain	3.00
European Union	Barley grain	3.00
	Corn grain	0.02
	Oat grain	3.00
	Rye grain	0.50
	Wheat grain	3.00
China	Wheat grain	0.05 proposed
Japan	Barley grain	0.60
	Oat grain	0.60
	Rye grain	0.60
	Wheat grain	0.60
United States	Barley grain	2.00
	Oat grain	4.00
	Rye grain	4.00
	Wheat grain	4.00

3.20 PROPOSAL TO SET MRLS FOR TULATHROMYCIN

It is proposed that an MRL is set for tulathromycin when used in sheep to support the GAP.

The current entry for tulathromycin in Schedule 1 of the MRL Notice is:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Tulathromycin	217500-96-4	(2R,3S,4R,5R,8R,10R,11R,12S, 13S,14R)-2-ethyl-3,4,10,13-tetrahydroxy-3,5,8,10,12,14-hexamethyl-11-[[3,4,6trideoxy-3(dimethylamino)-β-Dxylo-hexopyranosyl]oxy]-1-oxa- 6-azacyclopentadecan-15-one expressed as tulathromycin equivalents	Cattle meat Cattle fat Cattle kidney Cattle liver Pig meat Pig fat/skin Pig kidney Pig liver	0.1 0.1 3 3 0.5 0.3 3 2

The revised entry for tulathromycin in Schedule 1 of the Food Notice will read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Tulathromycin	217500-96-4	(2R,3S,4R,5R,8R,10R,11R,12S, 13S,14R)-2-ethyl-3,4,10,13-tetrahydroxy-3,5,8,10,12,14-hexamethyl-11-[[3,4,6trideoxy-3(dimethylamino)-β-Dxylo-hexopyranosyl]oxy]-1-oxa- 6-azacyclopentadecan-15-one expressed as tulathromycin equivalents	Cattle meat Cattle fat Cattle kidney Cattle liver Pig meat Pig fat/skin Pig kidney Pig liver Sheep meat Sheep fat Sheep liver Sheep kidney	0.1 0.1 3 3 0.5 0.3 3 2 0.45 0.25 5.4 1.8

3.20.1 Amendment Rationale

The proposed MRLs represent the expansion of use of a currently registered active ingredient. The proposed MRLs will manage the use of the antibiotic tulathromycin in sheep when administered in accordance with the dose rates and withholding periods that are proposed as GAP in New Zealand.

3.20.2 Chemical Information

Common name of compound	Tulathromycin
Use of compound	Antibiotic
Chemical Abstract Services (CAS) Registry number	217500-96-4
Type of compound	Macrolide antimicrobial
Administration method	Injection

3.20.3 Good Agricultural Practice

Tulathromycin is proposed for use in sheep for the treatment of footrot at a dose rate of 2.5 mg/kg by a single intramuscular injection. Use of tulathromycin in sheep will attract a withholding period of 21 days.

3.20.4 Residue Information

The residue data for the target species sheep supports tulathromycin MRLs of 0.45 mg/kg for sheep meat, 0.25 mg/kg for sheep fat, 5.4 mg/kg for sheep liver, and 1.8 mg/kg for sheep kidney. These MRLs are proposed to support GAP.

3.20.5 Dietary Risk Assessment

The ADI of 0.011 mg/kg bw/d was considered appropriate for use in the assessment and is consistent with overseas reputable regulatory bodies.

Based on the residues expected in food from animals treated according to existing and proposed GAP uses, the NEDI for tulathromycin is equivalent to less than 2 % of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

3.20.6 Toxicological/Public Health Assessment

It has been determined that the administration of tulathromycin to sheep for the treatment of footrot, when used according to GAP, is unlikely to pose health risks from consumption of treated produce.

3.20.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
European Union	Sheep muscle	0.45
	Sheep fat	0.25
	Sheep liver	5.4
	Sheep kidney	1.8

3.21 PROPOSAL TO EXCEPT MIXTURES OF CHITO-OLIGOSACCHARIDES AND OLIGOGALACTURONANS FROM COMPLIANCE WITH AN MRL

It is proposed that an exception from compliance with an MRL is established for the use of mixtures of chito-oligosaccharides and oligogalacturonans when used in horticulture. Chito-oligosaccharides and oligogalacturonans are derived from chitosan and pectin, and depolymerise in the environment to glucosamine and galacturonic acid monomers. The monomers will further mineralise into C02, CH4, and H2, with no detectable residues of toxicological concern. In addition, chitosan is already listed in Schedule 2 with no condition of use.

There is currently no entry in Schedule 2 for mixtures of chito-oligosaccharides and oligogalacturonans.

The proposed entry in Schedule 2 will read:

Substance	CAS#	Condition
Mixtures of chito-oligosaccharides and oligogalacturonans	n/a	No condition of use applies

3.22 PROPOSAL TO EXCEPT OZONE FROM COMPLIANCE WITH AN MRL

It is proposed that an exception from compliance with an MRL is established for the use of ozone in kiwifruit when used as a biocide and fungicide. The use of ozone in this manner does not result in detectable residues in treated produce, and degradation products consist of oxygen and water.

In addition, FSANZ Standard 1.3.3 – Processing Aids allows for the direct contact of ozone with food, further supporting the lack of any residue or food safety risks associated with its use.

There is currently no entry in Schedule 2 for ozone.

The proposed entry in Schedule 2 will read:

Substance	CAS#	Condition
Ozone	10028-15-6	When used as an agricultural chemical

3.23 PROPOSAL TO EXCEPT POLYOXIN D ZINC SALT FROM COMPLIANCE WITH AN MRL

It is proposed that an exception from compliance with an MRL is established for the use of polyoxin D zinc salt when used as a fungicide on apples and grapes. Polyoxin D zinc salt is highly water soluble, resulting in low plant surface residence time and rapid degradation once washed off crop surfaces. The toxicity of the compound has also been determined to be negligible, and there are no dietary intake concerns.

In addition, polyoxin D zinc salt has been exempted from compliance with an MRL in the United States.

There is currently no entry in Schedule 2 for polyoxin D zinc salt.

The proposed entry in Schedule 2 will read:

Substance	CAS#	Condition
Polyoxin D zinc salt	10028-15-6	When used as an agricultural chemical

3.24 PROPOSAL TO EXCEPT PROHYDROJASMON FROM COMPLIANCE WITH AN MRL

It is proposed that an exception from compliance with an MRL is established for the use of prohydrojasmon when used as a pre-harvest colour enhancer for red varieties of apples. Prohydrojasmon is a natural derivative of jasmonic acid, and has been demonstrated to have low toxicity and to be of no significant dietary intake concern. Environmental degradation is rapid, with the compound being hydrolysed and then decomposed to CO_2.

The default MRL of 0.01 mg/kg applies to prohydrojasmon in the European Union, and a Japanese MRL of 0.05 mg/kg applies for its use in apples and grapes. It is considered that, due to the use pattern proposed as GAP, the lack of any toxicity concerns for this use, and the degradation profile of the compound, exception from an MRL will not preclude compliance to overseas limits.

There is currently no entry in Schedule 2 for prohydrojasmon.

The proposed entry in Schedule 2 will read:

Substance	CAS#	Condition
Prohydrojasmon	158474-72-7	When used as a colour enhancer in apples

3.25 PROPOSAL TO AMEND THE SCHEDULE 2 SUBSTANCE DESCRIPTION FOR ‘MICROBIAL PESTICIDE ORGANISMS’

It is proposed that the substance description for the exception for ‘Microbial Pesticide Organisms’ is amended to align with revised terminology associated with this type of substance.

As part of the drafting of the information requirements document *Microbial Agricultural Chemicals Information Requirements for Registration of Microbial Organisms used as Agricultural Chemicals*, the term 'Microbial Active Ingredients' was developed to be more in line with the industry understanding of these substances and was better representative of their status under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997. The change to the exception is proposed to ensure all references to these substances use the same terminology.

The current entry in Schedule 2 of the MRL Notice is:

Substance	CAS#	Condition
Microbial Pesticide Organisms (consisting of either: whole organism, organism organelles, organism spores or occlusion bodies and genetically modified serotypes and strains)	n/a	Except where otherwise stated in this standard Where an organism is registered under the Agricultural Compounds and Veterinary Medicines Act 1997 and intended for use as a plant compound, and; Where organism leaves no quantifiable residue of toxins or metabolites exceeding that of expected background levels, and; Where organism has been determined to be non-pathogenic or non-toxic to humans

The revised entry in Schedule 2 of the MRL Notice will read:

Substance	CAS#	Condition
Microbial Active Ingredients (any organism classified as a microorganism including but not limited to bacteria, protozoa, fungi and viruses, or the genetically modified or naturally occurring mutants of any of these microorganisms. This includes whole organisms (either viable or non-viable), organism organelles, organism metabolites, organism spores, or occlusion bodies.)	n/a	Except where otherwise stated in this Notice:: Where a Microbial Active Ingredient is in a product registered under the Agricultural Compounds and Veterinary Medicines Act 1997 and is intended for use as an agricultural chemical, and; Where a Microbial Active Ingredient leaves no quantifiable residue of toxins or metabolites exceeding that of expected background levels, and; Where a Microbial Active Ingredient has been determined to be non-pathogenic or non-toxic to humans; But does not include metabolites produced by a microorganism that have been isolated as an independent active ingredient.

3.26 PROPOSAL TO AMEND THE EXCEPTION FOR 'BISMUTH AND ITS SALTS' TO INCLUDE USE AS AN INTRAMAMMARY TEAT SEALANT

It is proposed that the current exception from compliance with an MRL for 'bismuth and its salts' is extended to include the use of bismuth salts (bismuth subnitrate) as a teat sealant in dairy cattle. The presence of bismuth in milk, colostrum, and dairy products is not a concern for food safety as the oral bioavailability and absorption of bismuth is negligible. Trade risks posed by its presence, specifically related to dairy and dairy product quality, are outside the scope of GAP and can be sufficiently managed by other controls under the Animal Products Act. In addition, the use of bismuth subnitrate as a teat sealant has been exempted from compliance to an MRL in Australia, the European Union, and China.

The current entry in Schedule 3 of the MRL Notice is:

Substance	CAS#	Condition
Bismuth and its salts	7440-69-9	Oral use as a gastrointestinal antacid agent

The revised entry in Schedule 3 of the MRL Notice will read:

Substance	CAS#	Condition
Bismuth and its salts	7440-69-9	Used as an oral gastrointestinal antacid agent or as an intramammary teat sealant