Proposals to Amend the Maximum Residue Levels for Agricultural Compounds Food Notice 2017

MPI Discussion Paper No: 2017/34

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

ISBN No: 978-1-77665-737-7 (online)
ISSN No: 2253-3907 (online)

December 2017

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Requests for further copies should be directed to:

Publications Logistics Officer
Ministry for Primary Industries
PO Box 2526
WELLINGTON 6140

Email: brand@mpi.govt.nz
Telephone: 0800 00 83 33
Facsimile: 04-894 0300

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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 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? If so, why do you disagree?

Submissions close at 5pm on **29 January 2018**. 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. The New Zealand MRLs are established based on domestic use of a particular compound, and are used to monitor GAP in New Zealand. Because they are based on use patterns, conditions, and animal or plant management needs here in New Zealand, they may differ from MRLs established overseas for a similar use. As imported food commodities can comply with either a Codex MRL or a MRL established in the MRL Food Notice, New Zealand's obligations under the Agreement on the Application of Sanitary and Phytosanitary Measures are met.

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) Food Safety website at: http://mpi.govt.nz/document-vault/11329.

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 Health Based Guidance Value (HBGV). This may be either a Potential Daily Exposure (food) ($PDE_{(food)}$) or an Acceptable Daily Intake (ADI). 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. The HBGV is reported as milligrams of compound per kilogram bodyweight per day (mg/kg bw/d)

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.

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. An ADI may also occasionally be set in New Zealand by the EPA. Where an EPA-determined or an internationally-determined ADI is not available, an ADI may be calculated by MPI to quantify the dietary exposure risk.

As required by the HSNO Act in New Zealand, MPI uses the $PDE_{(food)}$ set by the EPA as the HBGV for the estimation of dietary intake when one is available. Where there is no $PDE_{(food)}$, the estimated dietary intake is compared with the ADI, set by the EPA, the WHO/FAO joint expert committees, the Australian Pesticides and Veterinary Medicines Authority (APVMA), or the European Food Safety Authority (EFSA). If none of these are available, the HBGV used will be the MPI-determined ADI.

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)).

The "other international MRLs" listed in each entry is a summary of the MRLs set by Codex and other internationally regulatory bodies. For animal commodities, MRLs set by our major trading partners (Australia, Canada, China, Codex, the European Union, Japan, and the United States) are reviewed and compared; for horticultural commodities, only MRLs set by Codex and Australia are reviewed and compared unless there is a particular trade reason to include other regions. Other international MRLs are reviewed and reported if there is a particular trade risk to be considered. Where a particular international body or regulator does not have MRLs set for the species or crop for which a New Zealand MRL is being proposed, that international body or regulator is omitted from the "other international MRLs" section of the entry.

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 AMENDMENTS

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 authorities.

Where an existing entry has been revised to propose new or amended MRLs, the changes can be identified in the proposed revised entries as highlighted in bold print.

MPI reviewed the estimated dietary exposure assessments for the application of the proposals in this discussion paper and compared them with the appropriate HBGV (the $PDE_{(food)}$ or an 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 Amendment to Part 1 of the Notice

MPI proposes to add a definition of 'active ingredient' to section 1.2 of Part 1: Requirements in the Notice.

2.2.2 Amendments to Schedule 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:

- Chlormequat: 1 mg/kg in barley.
- Fluopyram: 0.7 mg/kg in stonefruit.
- Fluralaner: 1.3 mg/kg in chicken eggs, 0.65 mg/kg in chicken fat/skin, 0.42 mg/kg in chicken kidney, 0.65 mg/kg in chicken liver, and 0.065 mg/kg in chicken meat.
- Fluxapyroxad: 0.01(*) mg/kg in stonefruit, and 0.01(*) mg/kg in winter squash.
- Halofuginone: 0.02 mg/kg in chicken fat/skin, 0.2 mg/kg in chicken kidney, 0.3 mg/kg in chicken liver, and 0.01 mg/kg in chicken meat.
- Lignocaine: 5 mg/kg in deer velvet.
- Oxathiapiprolin: 0.01(*) mg/kg in bulb onions.
- Trifloxystrobin: 0.03 mg/kg in stonefruit.

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

2.2.3 Amendments to Schedule 2: New and Amended Exceptions from Maximum Residue Levels for Agricultural Chemicals

MPI proposes to add an exception from Maximum Residue Levels for Agricultural Chemicals (Schedule 2) for active ingredients that are foods or food additives when used as an agricultural chemical.

The new exception will make three of the current entries in Schedule 2 redundant, as they are classed as foods used as active ingredients. They are:

- Canola oil
- Fish oil (food grade)
- Soya bean oil

Discussion of the removal of these redundant entries is included in section 3.13 of this proposal document.

In addition to the new exceptions to this schedule, MPI proposes to amend the entries in Schedule 2 for microbial active ingredients, to better define these substances and their condition of exception, and for iron-EDTA complex and iron phosphate, to extend the scope of an exception to encompass elemental iron.

2.2.4 Amendments to Schedule 3: Exceptions from Maximum Residue Levels for Veterinary Medicines

There are no amendments proposed for Schedule 3 of the Notice.

3 Proposals

3.1 PROPOSAL TO ADD A DEFINITION FOR 'ACTIVE INGREDIENT' TO PART 1 OF THE NOTICE

It is proposed that a definition for 'active ingredient' is added to section 1.2 of the Food Notice.

The schedules for exceptions from maximum residue levels use the term 'active ingredient' in establishing the substance definition and/or the conditions of exception for certain entries. The current definitions section of the Notice (section 1.2) in the requirements states that all terms used in the Notice are defined in the Food Act 2014 or the Food Regulations 2015. It has been noted that 'active ingredient' is not defined in either of these references.

Section 1.2 currently states:

(1) All terms used in this Part of this Notice and that are defined in the Food Act 2014 (the Act) or the Food Regulations 2015, but not defined in this Part of this Notice, have the same meaning as in that Act or Regulations.

The revised section will read:

(1) All terms used in this Part of this Notice and that are defined in the Food Act 2014 (the Act) or the Food Regulations 2015, but not defined in this Part of this Notice, have the same meaning as in that Act or Regulations.

(2) In this Notice, **active ingredient** has the same meaning as defined in Regulation 3 of the Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011.

This will provide a definition of the term 'active ingredient' and align with one already present in a relevant piece of legislation.

3.2 PROPOSAL TO AMEND THE MRLS FOR CHLORMEQUAT

It is proposed that MRLs for chlormequat are amended to support the GAP use of the compound on barley.

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

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Chlormequat	7003-89-6	Chlormequat cation	Oats	5
			Wheat	1

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

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Chlormequat	999-81-5	Chlormequat cation	Oats	5
			Wheat	1
			Barley	**1**

3.2.1.1 Amendment Rationale

The MRL is being proposed to support a new use for chlormequat on barley in accordance with the application rates and withholding periods that are proposed as GAP in New Zealand.

This amendment will also include correction of the CAS number listed in the Notice.

3.2.2 Chemical Information

Common name of compound	Chlormequat
Use of compound	Plant Growth Regulator
Chemical Abstract Services (CAS) Registry number	999-81-5
Type of compound	Quaternary ammonium compounds
Administration method	Spray

3.2.2.1 Good Agricultural Practice

The proposed use of chlormequat is as a plant growth regulator, in combination with either a chlorethephon/mepiquat-chloride combination, or trinexapac-ethyl, to control height growth in barley. Chlormequat is to be applied in a single application with a maximum rate of 1.5 kg active ingredient (ai)/ha at Growth Stage BBCH 30-32 (the start of stem elongation). This use will attract a livestock withholding period of 42 days from the last application.

3.2.2.2 Residue Information

The residue data for the use of chlormequat in barley demonstrated that, when applied as per the proposed use pattern, chlormequat residues did not exceed 0.92 mg/kg in barley grain in any of the trial work conducted. The proposed MRL of 1 mg/kg is therefore sufficient to support GAP when used on barley.

Data was also reviewed to support this use with respect to animal grazing. The trial work conducted confirmed that residues remained below the limit of quantification (0.01 mg/kg) in all animal commodities when a 42-day livestock withholding period is observed. It has therefore been concluded that animal commodity MRLs are not required at this time to manage the potential for transfer residues. The default MRL of 0.1 mg/kg will apply to all animal commodities.

3.2.2.3 Dietary Risk Assessment

The HBGV of 0.07 mg/kg bw/d was considered appropriate for use in the assessment.

Based on the residues of chlormequat expected in food from crops treated according to existing and proposed GAP uses, the NEDI for chlormequat is equivalent to less than 10% of the HBGV.

3.2.2.4 Toxicological/Public Health Assessment

It has been determined that the use of chlormequat in barley, according to the GAP specified above, is unlikely to pose any health risks from authorised use.

3.2.2.5 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Australia	Wheat	5
	Barley	T2
Codex	Oats	10
	Wheat	3
	Barley	2

3.3 PROPOSAL TO AMEND THE MRLS FOR FLUOPYRAM

It is proposed that MRLs for fluopyram are amended to support the GAP use of the compound on stonefruit.

The current entry for fluopyram in Schedule 1 of the 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	0.01(*)
			Cereal grains	0.01(*)
			Carrots	0.2
			Eggs	0.3
			Fruiting vegetables (except cucurbits)	1
			Grapes	0.05
			Mammalian meat	0.5
			Mammalian fat	0.5
			Mammalian kidney	0.7
			Mammalian liver	3
			Milk	0.3

The revised entry for fluopyram in Schedule1 of the 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	0.01(*)
			Cereal grains	0.01(*)
			Carrots	0.2
			Eggs	0.3
			Fruiting vegetables (except cucurbits)	1
			Grapes	0.05
			Mammalian meat	0.5
			Mammalian fat	0.5
			Mammalian kidney	0.7
			Mammalian liver	3
			Milk	0.3
			Stonefruit	**0.7**

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

3.3.1.1 Amendment Rationale

The MRL is being proposed to support a new use for fluopyram on stonefruit in accordance with the application rates and withholding periods that are proposed as GAP in New Zealand.

3.3.2 Chemical Information

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

3.3.2.1 Good Agricultural Practice

The proposed use of fluopyram (concurrently with trifloxystrobin) is to control brown rot in stonefruit by applying 125 gai/ha over flowering or in the pre-harvest period. The use of this compound is limited to a maximum of two consecutive applications with a retreatment interval of 7 days, and a maximum of three applications per season. This use will attract a withholding period that limits application to no closer than one day before harvest.

3.3.2.2 Residue Information

The residue data for the use of fluopyram on stonefruit demonstrated that when applied as per the proposed use pattern and observing a withholding period of one day, residues of fluopyram in the treated fruit did not exceed 0.6 mg/kg. The proposed MRL of 0.7 mg/kg is therefore sufficient to support GAP when used on stonefruit.

Data was also reviewed to support this use with respect to orchard treatment and animal grazing. The existing MRLs, and the current controls on the use of fluopyram related to animal consumption (i.e. an established two-month clean feed period), are sufficient to manage the potential for animal transfer residues. The current MRLs in animal commodities will remain unchanged.

3.3.2.3 Dietary Risk Assessment

The HBGV of 0.0084 mg/kg bw/d was considered appropriate for use in the assessment.

Based on the residues of fluopyram expected in food from crops treated according to existing and proposed GAP uses, the NEDI for fluopyram is equivalent to less than 50% of the HBGV.

3.3.2.4 Toxicological/Public Health Assessment

It has been determined that the use of fluopyram in stonefruit, according to the GAP specified above, is unlikely to pose any health risks from authorised use.

3.3.2.5 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Australia	Cherries	3
	Stone fruits (except cherries)	2
Codex	Cherries (includes all commodities in this subgroup)	0.7
	Peaches (includes all commodities in this subgroup)	1
	Plums (including prunes) (includes all commodities in this subgroup)	0.5

3.4 PROPOSAL TO SET MRLS FOR FLURALANER

It is proposed that MRLs are set for fluralaner to support the GAP use of the compound in chickens.

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

The new entry for fluralaner in Schedule 1 of the Notice will read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Fluralaner	864731-61-3	Fluralaner	Chicken eggs	1
			Chicken fat/skin	0.6
			Chicken kidney	0.4
			Chicken liver	0.6
			Chicken meat	0.06

3.4.1 MRL Promulgation Rationale

The MRLs are being proposed to support a new use for fluralaner on chickens in accordance with use rates and withholding periods that are proposed as GAP in New Zealand.

3.4.2 Chemical Information

Common name of compound	Fluralaner
Use of compound	Ectoparasiticide
Chemical Abstract Services (CAS) Registry number	864731-61-3
Type of compound	Isoxazoline
Administration method	Oral (in water)

3.4.2.1 Good Agricultural Practice

The proposed use of fluralaner is for the treatment and control of *Dermanyssus gallinae* (poultry red mite) in chickens. Use of this compound is limited to two doses of 0.5 mg fluralaner/kg bodyweight administered one week apart, in the drinking water of breeder and layer hens only (not broiler chickens). Use of the compound will attract a meat withholding period of 14 days; no egg withholding period is required.

3.4.2.2 Residue Information

The MRLs proposed for fluralaner in New Zealand align with those set for the compound in the EU. Residue data for the use of fluralaner in chickens demonstrated that when applied as per the proposed use pattern, residues were found to be less than the proposed MRLs in all tissues by 14 days: 0.06 mg/kg in muscle, 0.5 mg/kg in liver, 0.4 mg/kg in kidney, and 0.6 mg/kg in skin and fat. In addition, residues in eggs did not exceed 0.9 mg/kg at any point in the egg residue trials, confirming that the use pattern considered to be GAP in New Zealand will conform to the proposed MRL at all times without the need for an egg withholding period. The proposed MRLs are therefore sufficient to support GAP when used in chickens.

3.4.2.3 Dietary Risk Assessment

The HBGV of 0.01 mg/kg bw/d was considered appropriate for use in the assessment.

Based on the residues of fluralaner expected in edible tissues from chickens treated according to the proposed GAP uses, and the residues in eggs from treated chickens, the NEDI for fluralaner is equivalent to less than 7% of the HBGV.

3.4.2.4 Toxicological/Public Health Assessment

It has been determined that the use of fluralaner in layer chickens, according to the GAP specified above, is unlikely to pose any health risks from authorised use.

3.4.2.5 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
EU	Muscle	0.065
	Skin and fat in natural proportions	0.65
	Liver	0.65
	Kidney	0.42
	Eggs	1.3

3.5 PROPOSAL TO AMEND THE MRLS FOR FLUXAPYROXAD

It is proposed that MRLs for fluxapyroxad are amended to support the GAP use of the compound on stonefruit and winter squash.

The current entry for fluxapyroxad in Schedule 1 of the 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
			Bulb vegetables	0.2
			Edible offal	0.03
			Mammalian fat	0.05
			Mammalian meat	0.01(*)
			Milk	0.005
			Pears	0.02
			Wheat grain	0.1

The revised entry for fluxapyroxad in Schedule1 of the 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
			Bulb vegetables	0.2
			Edible offal	0.03
			Mammalian fat	0.05
			Mammalian meat	0.01(*)
			Milk	0.005
			Pears	0.02
			Stonefruit	**0.01(*)**
			Wheat grain	0.1
			Winter squash	**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 new MRLs are proposed to support new uses for fluxapyroxad on stonefruit and winter squash in accordance with application rates and withholding periods that are proposed as GAP for these crops in New Zealand.

3.5.2 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

3.5.2.1 Good Agricultural Practice

The proposed use of fluxapyroxad on stonefruit is for the control of fungal diseases at an application rate of 6.25 gai/100L (between 62.5 and 187.5 gai/ha, dependent on tree height) from early flowering to the onset of shuck fall. The compound is to be applied at an interval of 5-11 days when conditions favour disease, and not more than twice in succession or three sprays per season, with the last application no later than the onset of shuck fall (BBCH 72). Stock must not be allowed to graze treated orchards until after harvest, in lieu of withholding periods.

The proposed use of fluxapyroxad on winter squash is for the control of powdery mildew at an application rate of 60 gai/ha at the first sign of disease or when plants begin to run, with a maximum of 2 applications per season. Application is to occur alternatively with other fungicides. This use will attract a withholding period of 21 days from the last application.

3.5.2.2 Residue Information

The residue data for the use of fluxapyroxad on stonefruit demonstrated that when applied as per the proposed use pattern and all restrictions on timing and applications are observed, residues of fluxapyroxad in fruit at harvest were below 0.01 mg/kg. The proposed MRL of 0.01 mg/kg (at or about the limit of analytical quantification) is therefore sufficient to support GAP for fluxapyroxad on stonefruit.

The residue data for the use of fluxapyroxad on winter squash demonstrated that when applied according to the proposed GAP, residues of fluxapyroxad in the treated squash were less than 0.01 mg/kg. The proposed MRL of 0.01 mg/kg (at or about the limit of analytical quantification) is therefore sufficient to support GAP for fluxapyroxad on winter squash.

Data were also reviewed to support this use with respect to orchard treatment and animal grazing. The existing MRLs, and the controls on the use of fluxapyroxad related to animal consumption (i.e. prohibition on animals grazing treated orchards until after harvest), are sufficient to manage the potential for animal transfer residues. The current MRLs in animal commodities will remain unchanged.

3.5.2.3 Dietary Risk Assessment

The HBGV of 0.014 mg/kg bw/d was considered appropriate for use in the assessment.

Based on the residues of fluxapyroxad expected in food from crops treated according to existing and proposed GAP uses, the NEDI for fluxapyroxad is equivalent to less than 5% of the HBGV.

3.5.2.4 Toxicological/Public Health Assessment

It has been determined that the use of fluxapyroxad in stonefruit and winter squash, according to the GAP specified above, is unlikely to pose any health risks from authorised use.

3.5.2.5 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Australia	All other foods [*specific MRLs are only set for animal products, wheat, barley, and barley bran*]	0.1
Codex	Cherries (includes all commodities in this subgroup)	3
	Fruiting vegetables, cucurbits	0.6
	Peaches (including nectarine and apricots) (includes all commodities in this subgroup)	1.5
	Plums (including prunes) (includes all commodities in this subgroup)	1.5

3.6 PROPOSAL TO AMEND THE MRLS FOR HALOFUGINONE

It is proposed that MRLs for halofuginone are amended to support the GAP use of the compound in chickens.

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

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Halofuginone	55837-20-2	Halofuginone	Cattle fat	0.02
			Cattle kidney	0.03
			Cattle liver	0.03
			Cattle meat	0.01

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

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Halofuginone	55837-20-2	Halofuginone	Cattle fat	0.02
			Cattle kidney	0.03
			Cattle liver	0.03
			Cattle meat	0.01
			Chicken fat/skin	**0.02**
			Chicken kidney	**0.2**
			Chicken liver	**0.3**
			Chicken meat	**0.01**

3.6.1.1 Amendment Rationale

The new MRLs are proposed to support a new use for halofuginone in chickens in accordance with the application rates and withholding periods that are proposed as GAP in New Zealand.

3.6.2 Chemical Information

Common name of compound	Halofuginone
Use of compound	Coccidiostat
Chemical Abstract Services (CAS) Registry number	55837-20-2
Type of compound	Quinazolinone alkaloid
Administration method	Oral

3.6.2.1 Good Agricultural Practice

The proposed use of halofuginone is to prevent and control coccidiosis in broiler chickens with an administration rate of 3g halofuginone/tonne of feed fed continuously. This use will attract a meat withholding period of two days from cessation of treatment.

An egg withholding period is not required for this product because the proposed use is restricted to broiler chickens only.

3.6.2.2 Residue Information

The residue data for the use of halofuginone in chickens demonstrated that when used as per the proposed use pattern and observing a withholding period of two days, residues were less than 0.23 mg/kg in liver, less than 0.15 mg/kg in kidney, less than 0.02 mg/kg in skin and fat, and less than 0.005 mg/kg in muscle. The MRLs are proposed to support GAP, and to help facilitate trade with most of our major trading partners.

No data was provided or evaluated for residues in eggs as the proposed use of halofuginone is restricted to broiler chickens only.

3.6.2.3 Dietary Risk Assessment

The HBGV of 0.0003 mg/kg bw/d was considered appropriate for use in the assessment.

Based on the residues of halofuginone expected in food from animals treated according to existing and proposed GAP uses, the NEDI for halofuginone is equivalent to less than 14% of the HBGV.

3.6.2.4 Toxicological/Public Health Assessment

It has been determined that the use of halofuginone in chickens, according to the GAP specified above, is unlikely to pose any health risks from authorised use.

3.6.2.5 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Australia	Edible offal of poultry	1
	Meat, poultry	0.05
Canada	Kidney, Chickens	0.02
	Liver, Chickens	0.06
	Muscle, Chickens	0.01
	Skin and fat, Chickens	0.02
China	Chicken/Turkey muscle	0.1
	Chicken/Turkey skin with fat	0.2
	Chicken/Turkey liver	0.13
Japan	Edible offal, chicken	1
	Fat, chicken	0.01
	Kidney, chicken	1
	Liver, chicken	0.4
	Muscle, chicken	0.01
United States	Liver, broilers	0.3
	Muscle, broilers	0.1
	Skin with fat, broilers	0.2
Taiwan	Chicken fat (skin)	0.2
	Liver, Chicken	0.3
	Muscle, Chicken	0.1

3.7 PROPOSAL TO AMEND THE MRLS FOR LIGNOCAINE

It is proposed that MRLs for lignocaine are amended to support the GAP use of the compound in velvet removal in deer.

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

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Lignocaine (lidocaine)	137-58-6	*Sum of:* Lignocaine and 2,6-dimethylaniline *Expressed as*: 2,6-dimethylaniline	Deer velvet	0.1

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

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Lignocaine (Lidocaine)	137-58-6	*Sum of:* Lignocaine and 2,6-dimethylaniline *Expressed as*: 2,6-dimethylaniline	Deer velvet	**5**

3.7.1.1 Amendment Rationale

The amended MRL is proposed after a review of new information on lignocaine. This review confirmed the existing MRL was not fit for purpose to manage lignocaine residues in deer velvet when the compound was used according to established GAP in New Zealand.

3.7.2 Chemical Information

Common name of compound	Lignocaine
Use of compound	Anaesthetic
Chemical Abstract Services (CAS) Registry number	137-58-6
Type of compound	Amide
Administration method	Injection as a local anaesthetic

3.7.2.1 Good Agricultural Practice

There is no change to GAP for lignocaine as previously established. Current GAP for the use of lignocaine in deer for the purposes of harvesting velvet requires the application of a tourniquet. This is followed by administering lignocaine as a local anaesthetic (ring block technique) at a rate of 20 mg lignocaine per centimetre of antler pedicle circumference, at the base of the antler between the top of the head and the tourniquet. This use does not attract the need for a withholding period for lignocaine in the harvested velvet.

3.7.2.2 Residue Information

New and existing residue data, as well as residue data obtained as part of the National Chemical Residues Programme (NCRP), were reviewed to determine if the existing MRL for lignocaine remained fit for purpose. It was determined that there was a degree of variability in velvet residues due to variations in tourniquet application and harvest techniques. This variability changed the residue profile for lignocaine even when GAP was adhered to. These variations were not represented in the original data set on which the current MRL was set, but has become apparent with the evaluation of a much larger data set.

When all data is taken into account, it was determined that when lignocaine is used as per established GAP, lignocaine residues were less than 4.5 mg/kg in 98% of velvet samples assayed. The revised MRL of 5 mg/kg is therefore proposed to support GAP for velvet harvesting while providing a more realistic representation of post-treatment residues.

It is noted that part of GAP for velvet harvest is the concurrent use of xylazine for sedation of the animal prior to administration of the local anaesthetic. Residues for xylazine, and the metabolite shared between both compounds 2,6-dimethylaniline, were also evaluated as part of the review. It was determined that the current xylazine MRL is still fit for purpose for managing the GAP use of that compound, and does not require amendment.

3.7.2.3 Dietary Risk Assessment

The HBGV of 0.021 mg/kg bw/d was considered appropriate for use in the assessment.

Based on the residues of lignocaine expected in food from animals treated according to existing and proposed GAP uses, the NEDI for lignocaine is equivalent to less than 35% of the HBGV, and the NEDI for total 2,6-dimethylaniline from both lignocaine and xylazine is equivalent to less than 40% of the HBGV.

3.7.2.4 Toxicological/Public Health Assessment

It has been determined that the use of lignocaine in the harvesting of velvet according to the GAP specified above, and accounting for the inherent variability associated with the procedure, is unlikely to pose any health risks from authorised use.

3.7.2.5 Other International MRLs

There are no international MRLs for lignocaine (or lidocaine) in deer velvet.

3.8 PROPOSAL TO SET MRLS FOR OXATHIAPIPROLIN

It is proposed that MRLs are set for oxathiapiprolin to support the GAP use of the compound on onions.

There is no current entry for oxathiapiprolin in Schedule 1 of the Notice.
The new entry for oxathiapiprolin in Schedule 1 of the Notice will read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Oxathiapiprolin	1003318-67-9	Oxathiapiprolin	Bulb onions	0.01(*)

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

3.8.1 MRL Promulgation Rationale

The proposed MRL is the result of the registration of a new product containing a new active ingredient for use as a fungicide on onions. It will manage the use of oxathiapiprolin in accordance with the application rates and withholding periods that are considered GAP in New Zealand.

3.8.2 Chemical Information

Common name of compound	Oxathiapiprolin
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	1003318-67-9
Type of compound	Piperidinyl thiazole isoxazoline
Administration method	Spray

3.8.3 Good Agricultural Practice

Oxathiapiprolin is used as a preventative fungicide in bulb onions for the control of downy mildew. The first treatment is applied at a rate of 35gai/ha before infection is evident, then again 10 days later. Use of oxathiapiprolin attracts a withholding period of 14 days.

3.8.4 Residue Information

The residue data for the use of oxathiapiprolin on onions as per the residue definition demonstrated that when applied as per the proposed use pattern and observing the 14-day withholding period, residues of oxathiapiprolin in the onions at harvest were below the limit of quantification (0.01 mg/kg). The MRL is therefore proposed to be set at 0.01 mg/kg to support GAP in New Zealand.

An animal transfer residue assessment was not required in this case due to the inclusion of a label statement preventing the grazing or feeding of livestock after application of the compound. The default MRL of 0.1 mg/kg will apply to all animal commodities.

3.8.5 Dietary Risk Assessment

The HBGV of 0.7 mg/kg bw/d was considered appropriate for use in the assessment.

Based on the residues of oxathiapiprolin expected in food from crops treated according to proposed GAP uses, the NEDI for oxathiapiprolin is equivalent to less than 1% of the HBGV.

3.8.6 Toxicological/Public Health Assessment

It has been determined that the use of oxathiapiprolin on bulb onions, in accordance with the GAP specified above, is unlikely to pose any health risks from authorised use.

3.8.7 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Australia	Onion, Bulb	0.02
Codex	Onion, Bulb	0.04

3.9 PROPOSAL TO AMEND THE MRLS FOR TRIFLOXYSTROBIN

It is proposed that MRLs are amended for trifloxystrobin to support the GAP use of the compound on stonefruit.

The current entry for trifloxystrobin in Schedule 1 of the 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(*)
			Mammalian fat	0.05
			Mammalian kidney	0.04
			Mammalian liver	0.05
			Mammalian meat	0.05
			Mandarins (Clementine and Satsuma)	0.02(*)
			Pome fruits	0.02(*)
			Stone fruits (except cherries)	0.02(*)

The proposed entry for trifloxystrobin in Schedule 1 of the 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(*)
			Grapes	0.02(*)
			Kiwifruit	0.02(*)
			Mammalian fat	0.05
			Mammalian kidney	0.04
			Mammalian liver	0.05
			Mammalian meat	0.05
			Mandarins (Clementine and Satsuma)	0.02(*)
			Pome fruits	0.02(*)
			Stone fruits	**0.3**

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

3.9.1 Amendment Rationale

The new MRL is proposed to support a new use for trifloxystrobin on stonefruit in accordance with the application rates and withholding periods that are proposed as GAP in New Zealand.

When considering the revised MRL for stone fruits, it was determined that it was also appropriate to apply the proposed MRL to cherries. The current exclusion of cherries from the stone fruits is no longer required, and will be removed.

3.9.2 Chemical Information

Common name of compound	Trifloxystrobin
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	14151721-7
Type of compound	Strobilurin
Administration method	Spray

3.9.2.1 Good Agricultural Practice

The proposed use of trifloxystrobin (co-formulated with fluopyram) is to control brown rot in stonefruit by applying 125 gai/ha over flowering or pre-harvest. The use of this compound is limited to a minimum of seven days between applications, a maximum of two consecutive applications, and a maximum of three applications per season. This use will attract a withholding period that limits application to no later than one day before harvest.

3.9.2.2 Residue Information

The residue data for the use of trifloxystrobin on stonefruit as per the residue definition demonstrated that when applied as per the proposed use pattern and observing a withholding period of one day, residues in the treated fruit at harvest did not exceed 0.2 mg/kg. The MRL of 0.3 mg/kg is therefore proposed to support GAP.

Data was also reviewed to support this use with respect to orchard treatment and animal grazing. The existing MRLs, and the current controls on the use of trifloxystrobin related to animal consumption (i.e. an established two-month clean feed period), are sufficient to manage the potential for animal transfer residues. The current MRLs in animal commodities will remain unchanged.

3.9.2.3 Dietary Risk Assessment

The HBGV of 0.04 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, the NEDI for trifloxystrobin is equivalent to less than 10% of the HBGV.

3.9.2.4 Toxicological/Public Health Assessment

It has been determined that the use of trifloxystrobin in stone fruit, according to the GAP specified above, is unlikely to pose any health risks from authorised use.

3.9.2.5 Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Australia	Stone fruits	5
Codex	Stone fruits	3

3.10 PROPOSAL TO EXCEPT ACTIVE INGREDIENTS THAT ARE FOODS OR FOOD ADDITIVES FROM COMPLIANCE WITH A MRL

It is proposed that an exception from compliance with an MRL is established for all active ingredients that are foods or food additives when used as an agricultural compound. The residues risk associated with these kinds of compounds is negligible when the proposed condition is met because as a food, as defined under the Food Act, the residue risk in the commodities from which the food is derived has already been mitigated by compliance with the Act.

There is currently no entry in Schedule 2 for active ingredients that are foods or food additives as a group.

The proposed entry in Schedule 2 will read:

Substance	CAS#	Condition
Active ingredients that are foods or permitted food additives when the treated commodity at sale will be compliant with the Australia New Zealand Food Standards Code. Except where: The food is deemed a novel food as defined in section 1.1.2 of the Australia New Zealand Food Standards Code; And/or; The composition of the active ingredient deviates from the physicochemical range, or has undergone refining to a level exceeding that, accepted as common for the food.	n/a	Used as an agricultural compound.

Promulgation of this exception will result in the revocation of the following exceptions, as they will now fall under the overarching exception for foods and food additives used as active ingredients:

Substance	CAS#	Condition
Canola oil	120962-03-0	Used as an insecticide
Fish oil (food grade)	n/a	Used on food producing plant species
Soya bean oil	8001-22-7	Used as a fungicide

These exceptions will be removed from Schedule 2 when the new exception is promulgated.

3.11 PROPOSAL TO AMEND THE EXCEPTION FOR IRON-EDTA COMPLEX AND IRON PHOSPHATE

It is proposed that the exceptions from compliance with an MRL for iron-EDTA complex and iron phosphate are removed and replaced with a new exception for elemental iron, iron complexes, and iron salts.

The current entries in Schedule 2 of the Notice are:

Substance	CAS#	Condition
Iron-EDTA Complex	15275-07-7	When used in pellet form as a molluscicide

and

Substance	CAS#	Condition
Iron phosphate	10045-86-0	When used in pellet form as a molluscicide

The proposed entry in Schedule 2 will read:

Substance	CAS#	Condition
Elemental iron, iron complexes, and iron salts	n/a	When used in pellet form as a molluscicide

On review of the previously promulgated exceptions, it was determined that the scope of the exceptions were too narrow relative to the risk profile of elemental iron and other iron salts used as molluscicide. It has been determined that removal of these entries and the promulgation of a new exception is more appropriate to allow for other forms of iron to be used as molluscicides. Although the scope of the substance has changed, it is considered that the condition specifying its use pattern is sufficient to manage the associated risks; residues associated with iron-containing compounds used in any other form than in a pellet, or for any other reason other than as a molluscicide, will be subject to the applicable MRL or default MRL.

3.12 PROPOSAL TO AMEND THE EXCEPTION FOR MICROBIAL ACTIVE INGREDIENTS

It is proposed that the exception from compliance with an MRL for microbial active ingredients is revised to better define substances to and conditions under which this exception applies.

The current entry in Schedule 2 of the Notice is:

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.) Does not include metabolites produced by a microorganism that have been isolated as an independent active ingredient. .	n/a	Except where otherwise stated in this Notice: • where the Microbial Active Ingredient is the active ingredient in an agricultural compound registered under the Agricultural Compounds and Veterinary Medicines Act 1997 and intended for use as an agricultural chemical; and • where the Microbial Active Ingredient leaves no quantifiable residue of toxins or metabolites exceeding that of expected background levels; and • where the Microbial Active Ingredient has been determined to be non-pathogenic or non-toxic to humans.

The proposed entry in Schedule 2 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.) This exception applies when the Microbial Active Ingredient: • leaves no quantifiable residue of toxins or metabolites exceeding that of expected background levels; and • is non-pathogenic or non-toxic to humans. This exception does not include metabolites produced by a microorganism that have been isolated as an independent active ingredient.	n/a	When used as the active ingredient in an agricultural compound registered under the Agricultural Compounds and Veterinary Medicines Act 1997, and is intended for use as an agricultural chemical.

On review of the previously promulgated exception, it was determined that the aspects of the conditions of exception for these compounds were actually defining the substance itself. The entry has therefore been revised to retain the condition that the compound is used as an agricultural chemical in the condition, and move the second and third bullet point of that previously promulgated as the condition to the definition of the substance.

The intent of the exception as a whole, and the compounds which are captured by it, are not affected by these changes.