New Zealand Food Safety
Haumaru Kai Aotearoa

Proposals to Amend the New Zealand (Maximum Residue Levels for Agricultural Compounds) Food Notice

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This publication is available on the Ministry for Primary Industries website at http://www.mpi.govt.nz/news-and-resources/publications/

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1 Submissions

New Zealand Food Safety 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 or exemptions proposed for this compound?

Do you oppose a MRL or exemption being set at all for this compound or for a commodity?

If a MRL or exemption is to be set for this compound for the commodity, do you disagree with the levels or conditions proposed? If so, why do you disagree?

Submissions close at 5pm on **20 September 2020**. Your comments should be sent to:

MRL Amendments
New Zealand Food Safety
Ministry for Primary Industries
PO Box 2526
Wellington 6140

Email: MaximumResidueLevels@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

Agricultural compounds are natural or synthetic substances used in the management of plants and animals, and include veterinary medicines, fertilisers, and pesticides (e.g. fungicides, herbicides and insecticides). Growers and farmers use agricultural compounds to manage disease in animals and crops, protect the food supply, and maximise the quantity and quality of the food they grow.

Use of these agricultural compounds can leave residues in the food from those crops and animals that must be managed. To ensure only the appropriate amount of agricultural compounds are used to achieve their intended purpose, a set of principles and methods known as good agricultural practice (GAP) are utilised. GAP covers the production of safe and good quality horticultural and animal products.

GAP is established for each agricultural compound by evaluating public health, crop safety, animal health and safety, and occupational and environmental safety considerations for the range of treatments and use patterns. This involves determining the administration and application rates and ranges necessary for an agricultural compound to achieve its intended effects, while leaving the smallest amount of residue practicable without compromising that efficacy.

Once the GAP has been established for a use for an agricultural compound, the residues resulting from its use up to the highest authorised dose or application rate is then used to establish maximum residue levels (MRLs) in food commodities from crops and animals associated with that use. The MRLs are then compared against the health based guidance value in an evaluation commonly referred to as the dietary exposure (or dietary risk) assessment. This is explained in more detail below.

MRLs are the maximum legal levels for residues of agricultural compounds permitted in food for sale in New Zealand. They are established based on domestic uses of a particular compound, and are used to monitor GAP compliance in New Zealand while ensuring food safety. Because they are based on New Zealand authorised uses according to domestic GAP, MRLs may differ from those established overseas for a similar use because their GAP may be different. However, as noted below, imported food can also comply with Codex MRLs.

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

2.1 BACKGROUND

MRLs are set out in the New Zealand (Maximum Residue Levels for Agricultural Compounds) Food Notice. This Notice is amended regularly 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) New Zealand Food Safety website at: https://www.mpi.govt.nz/dmsdocument/19550-maximum-residue-levels-for-agricultural-compounds.

New Zealand Food Safety 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 section 405 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 standards that apply 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.

The requirements for the content of the MRL Food Notice are set out in Part 6 of the Food Regulations 2015, allowing for the promulgation of MRLs for agricultural compounds as well as the promulgation of exemptions from compliance with MRLs. In addition to establishing the requirements on domestically produced foods, Part 6 of the Food Regulations also outlines the residue level compliance requirements for imported foods. Clause 144 states that 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)); or
- the default MRL of 0.1 mg/kg (section (1)(c)); or
- for imported food, 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)).

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 SPS Agreement are met.

On the whole, the Regulations allow for the management of residues in all foods consumed in New Zealand.

2.1.1 National Estimated Dietary Intake

The chronic dietary exposure to a substance is estimated by the NEDI calculation, encompassing all authorised uses of the agricultural compound, and using 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 potential chronic exposure to toxicologically relevant residues in all food derived from crops/livestock treated with the agricultural compound according to the authorised GAP use.

The possible implications for consumer health are considered during the toxicological and dietary risk assessments, by comparing the NEDI with a Health Based Guidance Value (HBGV). Provided the estimated dietary exposure of all toxicologically relevant residue components in all fresh and processed food is less than the HBGV, the use of an agricultural compound according to GAP is unlikely to pose a health risk to consumers.

2.1.2 Health Based Guidance Values

The HBGV used in determining the estimated dietary exposure 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. HBGVs are 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 New Zealand Environmental Protection Authority (NZ 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.

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

2.1.3 International MRLs and Trade

Where MRLs are being set, the “Relevant International MRLs” table listed in each entry is a summary of the MRLs set by Codex and a selection of other international regulatory bodies reviewed to evaluate trade risk. For animal commodities, the MRLs set by Australia, Canada, China, Codex, the European Union, Japan, and the USA are reviewed and compared; for horticultural commodities, MRLs set by Codex and Australia are reviewed and compared. Other international MRLs are reviewed and reported in the table if there is a particular trade risk to be considered for those regions. If 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 proposal entry.

Where MRL exemptions are proposed, the proposed exemptions from compliance with a MRL have been thoroughly assessed in accordance with international methodologies published by the Organisation for Economic Cooperation and Development (OECD), International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH), or FAO. Each proposal includes a discussion of the rationale behind the considerations for exemption, and a discussion of the assessed risks. New Zealand Food Safety has evaluated the potential food safety and dietary intake risks associated with promulgating an exemption, and determined that MRLs are not required to manage compliance to GAP or food safety risk.

2.2 SUMMARY OF PROPOSED AMENDMENTS

The proposed MRLs have been thoroughly assessed in accordance with international methodologies published by the Organisation for Economic Cooperation and Development (OECD), International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH), or FAO. 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 relevant authorities (e.g. Australia, Canada, China, EU, Japan, USA)

Where an existing entry is proposed for revision, new or revised MRLs are highlighted in bold print, and MRLs proposed for revocation are identified using a strikethrough.

MPI has reviewed the estimated dietary exposure assessments associated with all authorised and proposed uses according to what has been established as GAP for New Zealand, compared them with the appropriate HBGV (the $PDE_{(food)}$ or an ADI), and has concluded that residues arising from these uses are unlikely to present any public health or food safety concerns.

2.2.1 Amendments to Schedule 1: New and Amended MRLs

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

- Amisulbrom: 0.02 mg/kg in head brassicas, 0.02 mg/kg in flowerhead brassicas, and 0.1 mg/kg in leafy vegetable brassicas.
- Azoxystrobin: 0.01(*) mg/kg in eggs, 0.01(*) mg/kg in mammalian fat, 0.01(*) mg/kg in mammalian meat, 0.01(*) mg/kg in mammalian offal, 0.005 mg/kg in milk, 0.01(*) mg/kg in poultry fat, 0.01(*) mg/kg in poultry meat, and 0.01(*) mg/kg in poultry offal.
- Cyantraniliprole: 0.02 mg/kg in mammalian kidney, 0.03 mg/kg in mammalian liver, and 0.02 mg/kg in milk.
- Diflufenican: 0.02(*) mg/kg in eggs, 0.02(*) mg/kg in mammalian fat, 0.02(*) mg/kg in mammalian meat, 0.02(*) mg/kg in mammalian offal, 0.01(*) mg/kg in milk, 0.01(*) mg/kg in peas (without pods), 0.02(*) mg/kg in poultry meat, and 0.02(*) mg/kg in poultry offal.
- Fluxapyroxad: 0.01(*) mg/kg in eggs, 0.03 mg/kg in mammalian offal, 0.01(*) mg/kg in poultry fat, 0.01(*) mg/kg in poultry meat, and 0.01(*) mg/kg in poultry offal.
- Folpet: 0.6 mg/kg in barley grain, 0.05(*) mg/kg in eggs, 0.05(*) mg/kg in mammalian meat, 0.05(*) mg/kg in mammalian offal, 0.05(*) mg/kg in milk, 0.05(*) mg/kg in poultry meat, and 0.05(*) mg/kg in poultry offal.
- Mefentrifluconazole: 2.0 mg/kg in barley grain, 0.01(*) mg/kg in eggs, 0.1 mg/kg in mammalian fat, 0.1 mg/kg in mammalian kidney, 0.3 mg/kg in mammalian liver, 0.02 mg/kg in mammalian meat, 0.02 mg/kg in milk, 0.02 mg/kg in poultry fat, 0.01(*) mg/kg in poultry meat, 0.02 mg/kg in poultry offal, and 0.5 mg/kg in wheat grain.
- Prosulfocarb: 0.01(*) mg/kg in potatoes.
- Metolachlor: 0.01(*) mg/kg in potatoes.
- Tebuconazole: 0.01(*) mg/kg in eggs, 0.01(*) mg/kg in mammalian fat, 0.01(*) mg/kg in mammalian kidney, 0.07 mg/kg in mammalian liver, 0.01(*) mg/kg in mammalian meat, 0.01(*) mg/kg in milk, 0.01(*) mg/kg in poultry fat, 0.01(*) mg/kg in poultry meat, and 0.01(*) mg/kg in poultry offal.

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

2.2.2 Amendments to Schedule 2: Exemptions from Maximum Residue Levels for Agricultural Chemicals

- MPI proposes to add the following new exemptions to the list of agricultural compounds in Schedule 2 of the Food Notice, for which no maximum residue levels apply:
    - 1-triacontanol, when used as a plant growth regulator on pasture;
    - Eugenol, when used as a fungicide on grapevines;
    - Geraniol, when used as a fungicide on grapevines; and
    - Thymol, when used as a fungicide on grapevines.
- MPI proposes to amend the current entry for hydrogen peroxide in the list of agricultural compounds in Schedule 2 of the Food Notice, for which no maximum residue levels apply. The entry will be amended to extend the exempted use of the compound as a fungicide and bactericide to include both fruits and vegetables.
- MPI proposes to remove the current entry for Didecyl Dimethyl Ammonium Chloride from the list of agricultural compounds in Schedule 2 of the Food Notice, for which no maximum residue levels apply. This compound is no longer approved for use as an agricultural compound under the Agricultural Compounds and Veterinary Medicines Act 1997.

2.2.3 Amendment to Schedule 3: Exemptions from Maximum Residue Levels for Veterinary Medicines

- MPI proposes to amend the current entry for Vaccine and Diagnostic Antigens in the list of agricultural compounds in Schedule 3 of the Food Notice, for which no maximum residue levels apply. The entry will be amended to allow for the exemption to include immunostimulants derived from bacterial cell wall components.

3 Proposals

3.1 PROPOSAL TO SET MRLS FOR AMISULBROM

It is proposed that MRLs are set for amisulbrom to support the GAP use of the compound on brassica crops. Amisulbrom is a new agricultural compound in New Zealand.

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

Compound Common Name	CAS#	Residue to which the maximum residue level applies	Food	Maximum Residue Level (mg/kg)
Amisulbrom	348635-87-0	Amisulbrom	Head brassicas Flowerhead brassicas Leafy vegetable brassicas	0.02 0.02 0.1

3.1.1 Amendment Rationale

The MRLs are being proposed to support the use of amisulbrom on vegetable and leafy vegetable brassica seedlings in accordance with the use patterns proposed as GAP in New Zealand.

3.1.2 Good Agricultural Practice

Amisulbrom is a 'quinone inside inhibitor' fungicide used as a root drench on vegetable and leafy vegetable brassica seedlings to control clubroot. The compound acts by inhibiting mitochondrial respiration in the target fungus, and is applied at a rate of 10 gai per 1000 seedlings within 48 hours prior to transplanting. Amisulbrom must be applied before seedlings are planted out, and attract a withholding period to enforce this.

3.1.3 Residue Information

The residue data for the use of amisulbrom on vegetable and leafy vegetable brassicas were sufficient to conclude that, when applied as per the proposed GAP use pattern and complying with the applicable withholding period, residues of parent amisulbrom should not exceed 0.02 mg/kg for head and flowerhead brassicas or 0.1 mg/kg for leafy vegetable brassicas.

Trial data evaluating the metabolism of the compound demonstrated that parent amisulbrom was the main residue detected in plant-derived food commodities. It is therefore considered that 'amisulbrom' is sufficient to function as both the residue definition for GAP compliance and dietary intake assessments for plant-derived commodities.

Animal commodity MRLs were not required as vegetable and leafy vegetable brassicas are not considered a primary animal feed.

3.1.4 Dietary Risk Assessment

The HBGV of 0.084 mg/kg bw/d, and the stated dietary intake residue definition, were considered appropriate for use in the dietary intake assessment. Based on the residue profile expected in food from crops treated with amisulbrom, the NEDI is estimated to total less than 0.02% of the HBGV.

MPI has therefore determined that the use of amisulbrom, when use according to the GAP specified above, is unlikely to pose any health risks from authorised use.

3.1.5 Relevant International MRLs

Country	Food	Maximum Residue Level (mg/kg)
Australia	Brassica (cole or cabbage) vegetables, head cabbages, and flowerhead brassicas	2

3.2 PROPOSAL TO AMEND THE MRLS FOR AZOXYSTROBIN

It is proposed that the Notice entry for azoxystrobin is amended to set MRLs for animal commodities to support the GAP use of the compound on fodder beets used as animal feed.

The revised entry for azoxystrobin in Schedule 1 of the Notice will read as follows. Changes are shown in bold:

Compound Common Name	CAS#	Residue to which the maximum residue level applies	Food	Maximum Residue Level (mg/kg)
Azoxystrobin	131860-33-8	**Plant commodities**: Azoxystrobin and its z-isomer **Animal commodities:** Azoxystrobin	Cereal grains (except maize) **Eggs** Grapes Maize **Mammalian fat** **Mammalian meat** **Mammalian offal** **Milk** Onions Peas (without pods) **Poultry fat** **Poultry meat** **Poultry offal** Potatoes Sweetcorn Tomatoes	0.2 0.01(*) 1 0.01(*) 0.01(*) 0.01(*) 0.01(*) 0.005 0.01(*) 0.02(*) 0.01(*) 0.01(*) 0.01(*) 0.02(*) 0.01(*) 0.01(*)

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

3.2.1 Amendment Rationale

The MRLs are being proposed to support an expansion of the use of azoxystrobin to fodder beets for animal consumption, in accordance with the use pattern proposed as GAP in New Zealand.

3.2.2 Good Agricultural Practice

Azoxystrobin is a methoxyacrilate strobiliurin currently used to control fungal disease in peas, onions, potatoes, tomatoes, grapes, and cereal crops. The compound acts by inhibiting mitochondrial respiration and thereby inhibiting spore germination and mycelial growth. The new use has been proposed to manage rust, powdery mildew, and *Cercospora* infections in fodder beet crops grown solely for animal consumption. For this additional use, the compound is applied as a foliar spray at a rate of 120 gai/ha (co-formulated with 200 gai/ha tebuconazole) when disease first becomes active in the crop, and no sooner than 14 days later. A withholding period of 28 days applies to this use for both harvest and grazing of the crop.

3.2.3 Residue Information

The residue data for the use of azoxystrobin were sufficient to conclude that, when applied according to the proposed GAP use pattern and the withholding period is observed, residues of azoxystrobin should not exceed 0.01 mg/kg in all animal commodities or 0.005 mg/kg in milk. Animal metabolism and feeding studies confirmed that parent azoxystrobin will be sufficient to manage both GAP compliance and dietary intake for animal commodities, in line with the residue definitions established by Codex.

3.2.4 Dietary Risk Assessment

The HBGV of 0.1 mg/kg bw/d, and the stated dietary intake residue definition, were considered appropriate for use in the dietary intake assessment. Based on the residue profile expected in animal commodities after consumption of feed crops treated with azoxystrobin, the NEDI is estimated to total less than 4% of the HBGV.

MPI has therefore determined that the use of azoxystrobin on animal feed crops, when use according to the GAP specified above, is unlikely to pose any health risks from authorised use.

3.2.5 Relevant International MRLs

Country	Food	Maximum Residue Level (mg/kg)
Australia	Edible offal (mammalian)	0.03
	Eggs	0.01
	Meat (mammalian) [in the fat]	0.02
	Milks	0.005
	Poultry meat and edible offal	0.01
Canada	Meat of cattle, sheep, horses, and hogs	0.01
	Kidney of cattle, sheep, horses, and hogs	0.06
	Liver of cattle, sheep, horses and hogs	0.3
	Meat byproducts of cattle, sheep, horses, and hogs	0.01
	Milk	0.006
	Fat, meat, and liver of poultry	0.01
	Eggs	0.01
China	Meat from mammals (with the exception of marine mammal), expressed as residue in the fat	0.05
	Viscera of mammal animals (with the exception of marine mammal)	0.07
	Poultry meat and viscera	0.01
	Eggs	0.01
	Raw milk	0.01
	Milk fat	0.03
Codex	Edible offal (mammalian)	0.07
	Eggs	0.01
	Meat (from mammals other than marine mammals)	0.05
	Milk fats	0.03
	Milks	0.01
	Poultry meat	0.01
	Poultry, edible offal of	0.01
EU	Swine, bovine, sheep, goat and equine muscle	0.01
	Swine, bovine, sheep, goat and equine fat	0.05
	Swine, bovine, sheep, goat and equine liver	0.07
	Swine, bovine, sheep, goat and equine kidney	0.07
	Swine, bovine, sheep, goat and equine edible offals (other than liver and kidney)	0.07
	Milk	0.01
	Poultry muscle, fat, liver, kidney, and edible offals (other than liver and kidney)	0.01
	Eggs	0.01
Japan	Cattle, pig, and other terrestrial mammal muscle	0.05
	Cattle, pig, and other terrestrial mammal fat	0.05
	Cattle, pig, and other terrestrial mammal liver	0.07
	Cattle, pig, and other terrestrial mammal kidney	0.07
	Cattle, pig, and other terrestrial mammal edible offal	0.07
	Milk	0.01
	All chicken and other poultry commodities, including eggs	0.01
United States	Cattle, goat, horse, and sheep by products	0.07
	Cattle, goat, horse, and sheep kidney	0.07
	Cattle, goat, horse, and sheep liver	0.07
	Cattle, goat, horse, and sheep meat	0.01
	Goat, horse, and sheep fat	0.03
	Hog by products, fat, kidney, liver and meat	0.01
	Milk	0.006

3.3 PROPOSAL TO AMEND THE MRLS FOR CYANTRANILIPROLE

It is proposed that the Notice entry for cyantraniliprole is amended to set MRLs to support the GAP use of the compound on fodder beets.

The revised entry for cyantraniliprole in Schedule 1 of the Notice will read as follows. Changes are shown in bold:

Compound Common Name	CAS#	Residue to which the maximum residue level applies	Food	Maximum Residue Level (mg/kg)
Cyantraniliprole	736994-63-1	Cyantraniliprole	Bulb onions Mammalian fat Mammalian kidney Mammalian liver Mammalian meat Milk Potatoes Tomatoes	0.01(*) 0.01(*) 0.02 0.03 0.01(*) 0.02 0.01(*) 0.1

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

3.3.1 Amendment Rationale

The MRLs are being proposed to support the use of cyantraniliprole as an insecticide for control of European leaf miner on fodder beets in accordance with the use pattern proposed as GAP in New Zealand, and to take into account new information on residues in rotational crops used for animal feed.

3.3.2 Good Agricultural Practice

Cyantraniliprole belongs to the diamide class of insecticides, selectively activating and binding to the ryanodine receptors in insect muscle cells. Cyantraniliprole is an established insecticide with the same use pattern and withholding period in fodder brassicas for control of European leaf miner and other pests. There are also approved uses in field tomatoes, potatoes and onions.

The proposed use in fodder beets is for application of 15 gai/ha cyantraniliprole when pest monitoring indicates that trigger levels of pest insects have been reached, with a maximum of three applications per season, and a withholding period of 28 days after last application for grazing or treated crop being fed to livestock.

3.3.3 Residue Information

The residue data for the use of cyantraniliprole were sufficient to conclude that, when applied as per the proposed GAP use pattern and complying with the applicable withholding period, residues of cyantraniliprole should not exceed 0.02 mg/kg in mammalian kidney, 0.03 mg/kg in mammalian liver, and 0.02 mg/kg in milk. These revised MRLs are based on all potential sources of cyantraniliprole in animal feed, including the data provided to support the new use in fodder beets, and new information that cereal crops grown as rotational crops after cyantraniliprole use and used for animal feed will contribute to the animal dietary burden to a larger extent than previously reported. The revised MRLs are therefore a more accurate representation of New Zealand GAP and the residue profile expected in animal commodities.

The current residue definitions remain unchanged. These are ‘cyantraniliprole’ for GAP compliance in plant and animal commodities and dietary intake in plant commodities; and ‘Sum of cyantraniliprole, 2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-3,4-dihydro-3,8-dimethyl-4-oxo-6-quinazolinecarbonitrile [IN-J9Z38], 2-[3-Bromo-1-(3-chloro-2-pyridinyl)- 1H-pyrazol-5-yl]-1,4-dihydro-8-methyl-4-oxo-6-quinazolinecarbonitrile [IN-MLA84], 3- Bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-(hydroxymethyl)-6- [(methylamino)carbonyl]phenyl]-1H-pyrazole-5-carboxamide [IN- N7B69] and3-Bromo-1- (3-chloro-2-pyridinyl)-N-[4-cyano-

2[[(hydroxymethyl)amino]carbonyl]-6-methylphenyl]-1Hpyrazole-5-carboxamide [IN-MYX98], expressed as cyantraniliprole' for dietary intake assessments in animal commodities.

3.3.4 Dietary Risk Assessment

The HBGV of 0.007 mg/kg bw/d, and the stated dietary intake residue definitions, were considered appropriate for use in the dietary intake assessment. The total NEDI from all horticultural and animal commodities is estimated to total less than 4% of the HBGV.

MPI has therefore determined that the additional use of cyantraniliprole, when used according to the GAP specified above, is unlikely to pose any health risks from authorised use.

3.3.5 Relevant International MRLs

Country	Food	Maximum Residue Level (mg/kg)
Canada	Meat byproducts of goats, sheep, horses, and cattle	0.4
	Fat of goats, sheep, horses and cattle	0.1
	Meat of goats, sheep, horses, and cattle	0.1
	Meat and meat byproducts of hogs	0.01
	Milk	0.2
Codex	Edible offal (mammalian)	1.5
	Mammalian fats (except milk fats)	0.5
	Meat (from mammals other than marine mammals)	0.2
	Milks	0.6
EU	Swine, bovine, sheep, goat, and equine muscle	0.2
	Swine, bovine, sheep, goat, and equine fat	0.5
	Swine, bovine, sheep, goat, and equine liver	1.5
	Swine, bovine, sheep, goat, and equine kidney	1.5
	Swine, bovine, sheep, goat, and equine edible offals (other than liver and kidney)	1.5
	Milk	0.02
Japan	Cattle and other terrestrial mammal muscle	0.2
	Cattle and other terrestrial mammal fat	0.5
	Cattle and other terrestrial mammal liver	2
	Cattle and other terrestrial mammal kidney	2
	Cattle and other terrestrial mammal edible offal	2
	Milk	0.6
United States	Cattle, goat, horse, and sheep by products	0.4
	Cattle, goat, horse, and sheep kidney	0.4
	Cattle, goat, horse, and sheep liver	0.4
	Cattle, goat, horse, and sheep meat	0.1
	Goat, horse, and sheep fat	0.1
	Milk	0.2

3.4 PROPOSAL TO AMEND THE MRLS FOR DIFLUFENICAN

It is proposed that the Notice entry for diflufenican is amended to set MRLs for animal commodities to support the GAP use of the compound on peas for processing.

The revised entry for diflufenican in Schedule 1 of the Notice will read as follows. Changes are shown in bold:

Compound Common Name	CAS#	Residue to which the maximum residue level applies	Food	Maximum Residue Level (mg/kg)
Diflufenican	83164-33-4	Diflufenican	Barley Eggs Mammalian fat Mammalian meat Mammalian offal Milk Peas (without pods) Poultry meat Poultry offal Wheat	0.01(*) 0.02(*) 0.02(*) 0.02(*) 0.02(*) 0.01(*) 0.01(*) 0.02(*) 0.02(*) 0.01(*)

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

3.4.1 Amendment Rationale

The MRL is being proposed to support an expansion of the use of diflufenican to peas for processing. The proposed MRLs will manage the use of the compound as a herbicide for the control of broad leaf weeds in accordance with the use pattern proposed as GAP in New Zealand.

3.4.2 Good Agricultural Practice

Diflufenican is an anilide herbicide which acts by inhibiting carotenoid biosynthesis and thereby preventing photosynthesis in the target plant. The compound is currently used in the management of a broadleaf weeds in pasture grasses and cereal crops. For the additional use in peas, the compound is applied at a rate of 100 gai/ha to control weeds post-emergence up to the 4-leaf stage. This use is restricted to treatment before the fifth node growth stage (BBCH 35). As pea crops would not be grazed or harvested prior to this stage, an animal feed related withholding period is not required.

3.4.3 Residue Information

The residue data for the use of diflufenican on peas are sufficient to conclude that, when applied according to the proposed GAP use pattern and observing the restriction, residues of diflufenican should not exceed the limit of detection of 0.01 mg/kg. The current residue definition of ‘diflufenican’ remains appropriate for plant commodities (for both GAP compliance and dietary intake assessment).

Because peas including their vines is used as an animal feed, the potential for residue transfer for animal commodities was evaluated. Animal metabolism study data in ruminants and poultry found that diflufenican is mainly excreted with a small amount of residues remaining in tissues; that retained residue is largely parent diflufenican. The GAP compliance and dietary intake definitions for animal commodities can therefore align with plant commodities as parent diflufenican.

The metabolism study data also confirmed that, at the estimated New Zealand animal dietary burden for both pea crops and cereal crops, residues in both ruminant and poultry commodities can be expected to remain below the limits of quantification. For animal commodities, these are 0.01 mg/kg in milk and 0.02 mg/kg in all tissue commodities and eggs. This approach is in line with that used in the EU for animal commodity MRLs.

3.4.4 Dietary Risk Assessment

The HBGV of 0.1 mg/kg bw/d, and the stated dietary intake residue definition, were considered appropriate for use in the dietary intake assessment. Based on the residue profile expected in food from all horticultural and animal commodities, the NEDI is estimated to total less than 0.3% of the HBGV.

MPI has therefore determined that the use of diflufenican on peas without pods, when use according to the GAP specified above, is unlikely to pose any health risks from authorised use.

3.4.5 Relevant International MRLs

Country	Food	Maximum Residue Level (mg/kg)
Australia	Edible offal (mammalian)	0.1
	Eggs	0.02
	Meat (mammalian) [in the fat]	0.05
	Milks	0.01
	Peas	0.05
	Poultry meat	0.02
	Poultry, edible offal of	0.02
EU	All animal commodities except milk	0.02
	Milk	0.01

3.5 PROPOSAL TO AMEND THE MRLS FOR FLUXAPYROXAD

It is proposed that the Notice entry for fluxapyroxad is amended to set MRLs to better support the GAP use of the compound on wheat and barley.

The revised entry for fludioxonil in Schedule 1 of the Notice will read as follows. Changes are shown in bold:

Compound Common Name	CAS#	Residue to which the maximum residue level applies	Food	Maximum Residue Level (mg/kg)
Fluxapyroxad	907204-31-3	Fluxapyroxad	Apples	0.02
			Barley grain	0.3
			Bulb vegetables	0.2
			Eggs	**0.01(*)**
			Mammalian offal	**0.03**
			Mammalian fat	0.05
			Mammalian meat	0.01(*)
			Milk	0.005
			Pears	0.02
			Poultry fat	**0.01(*)**
			Poultry meat	**0.01(*)**
			Poultry offal	**0.01(*)**
			Stone fruits	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 Amendment Rationale

Although the use of fluxapyroxad on wheat and barley is not new, it is considered that poultry commodity MRLs are required to support the use of the compound on grain crops. The amendment establishes poultry MRLs to support new and existing uses of fluxapyroxad on these crops.

It is noted that the entry for the 'edible offal' MRL is being amended to change the name of the commodity to 'mammalian offal'. This change is being made to align the terminology with that commonly used in the rest of the Notice. The value of the MRL for this commodity remains as previously promulgated.

3.5.2 Good Agricultural Practice

Fluxapyroxad is a pyrazole-carboxamide fungicide used to control disease in apples, pears, onions winter, squash, stone fruit, barley, and wheat crops, and is used as a seed treatment on cereals. For wheat and barley, the compound is applied at a rate of 75 gai/ha (co-formulated with 150gai /ha mefentrifluconazole) as a single foliar spray in at least 150L water/ha on the first appearance of rusts, powdery mildew, leaf blotches, and leaf spots, up to the end of flowering. The withholding periods applied to this use are 42 days for grain and stubble/straw, and 28 days for green feed and silage.

3.5.3 Residue Information

The residue data for the use of fluxaypyroxad are sufficient to conclude that, when applied according to the proposed GAP use pattern and complying with the applicable withholding periods, residues of parent fluxapyroxad should not exceed the limit of quantification (0.01 mg/kg) in any poultry commodity including eggs. The current residue definition of 'fluxapyroxad' remains appropriate for plant and animal commodities (for both GAP-compliance and dietary intake assessment).

3.5.4 Dietary Risk Assessment

The HBGV of 0.014 mg/kg bw/d, and the stated dietary intake residue definition, were considered appropriate for use in the dietary intake assessment. Based on the residue profile expected from all horticultural and animal commodities, the NEDI is estimated to total less than 2% of the HBGV.

MPI has therefore determined that the use of fluxapyroxad, when use according to the GAP specified above, is unlikely to pose any health risks from authorised use.

3.5.5 Relevant International MRLs

Country	Food	Maximum Residue Level (mg/kg)
Australia	Eggs	0.005
	Poultry meat [in the fat]	0.01
	Poultry, edible offal of	0.01
Canada	Eggs	0.002
	Meat of poultry	0.01
	Meat byproducts of poultry	0.01
Codex	Eggs	0.02
	Poultry fats	0.05
	Poultry meat	0.02
	Poultry, edible offal of	0.02
European Union	Poultry muscle	0.02
	Poultry fat	0.05
	Poultry liver and kidney	0.02
	Poultry edible offals (other than liver and kidney)	0.02
	Eggs	0.02
Japan	Poultry muscle	0.02
	Poultry fat	0.05
	Poultry liver, kidney and edible offal	0.02
	Eggs	0.02
United States	All chicken and turkey commodities including eggs	0.01

3.6 PROPOSAL TO AMEND THE MRLS FOR FOLPET

It is proposed that the Notice entry for folpet is amended to set MRLs for animal commodities to support the GAP use of the compound on barley.

The revised entry for folpet in Schedule 1 of the Notice will read as follows. Changes are shown in bold:

Compound Common Name	CAS#	Residue to which the maximum residue level applies	Food	Maximum Residue Level (mg/kg)
Folpet	133-07-3	Plant commodities: Folpet Animal commodities: sum of folpet and phthalimide, expressed as folpet	Apples **Barley grain** Berries and other small fruits, except grapes and currants (black, red, white) Citrus Fruits Currants (black, red, white) **Eggs** Grapes **Mammalian meat** **Mammalian offal** **Milk** **Poultry meat** **Poultry offal**	10 **0.6** 15 10 30 **0.05(*)** 25 **0.05(*)** **0.05(*)** **0.05(*)** **0.05(*)** **0.05(*)**

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

3.6.1 Amendment Rationale

The MRL is being proposed to support an expansion of the use of folpet to barley. The proposed MRLs will manage the use of the compound as a fungicide for the control of scald and *Ramularia* in accordance with the use pattern proposed as GAP in New Zealand.

3.6.2 Good Agricultural Practice

Folpet is a non-systemic phthalimide fungicide which acts by inhibiting microorganism cell division. It is currently used in the management of a broad range of fungal diseases in mostly fruit crops and ornamental plants in New Zealand. For the additional use in barley, the compound is applied at a rate of 750 gai/ha as a preventative treatment when conditions favour infection, with reapplication in 3-4 weeks if disease pressure continues or reinfection occurs. This use is restricted to treatment before BBCH59, and attracts a withholding period of 28 days for grazing and feeding to livestock.

3.6.3 Residue Information

The residue data for the use of folpet on barley are sufficient to conclude that, when applied according to the proposed GAP use pattern and observing the restrictions and withholding period, residues of folpet should not exceed 0.6 mg/kg in barley grain. The current residue definition of ‘folpet’ remains appropriate for plant commodities (for both GAP compliance and dietary intake assessment).

Because barley is used as an animal feed, the potential for residue transfer for animal commodities was evaluated. Animal metabolism study data in ruminants found that folpet is mainly excreted through urine and faeces, with the small amount of absorbed residue being extensively metabolised into phthalimide. The GAP compliance and dietary intake definitions for animal commodities will therefore be the sum of folpet and its metabolite phthalimide, expressed as folpet.

The metabolism study data also confirmed that, at the estimated New Zealand animal dietary burden, residues in ruminant animal commodities including milk can be expected to be 0.05 mg/kg (the limit of quantification) or less when folpet is used according to GAP and observing the restriction and withholding periods. Although no data exists to characterise the residue

profile of folpet in poultry, the very low (more than 100x less than that for ruminants) estimated dietary burden indicates that the same use of the limit of quantification as the MRLs to manage GAP for poultry commodities can apply. This approach is in line with that used in the EU for animal commodity MRLs.

3.6.4 Dietary Risk Assessment

The HBGV of 0.05 mg/kg bw/d, and the stated dietary intake residue definitions, were considered appropriate for use in the dietary intake assessment. Based on the residue profile expected in food from all horticultural and animal commodities, the NEDI is estimated to total less than 83% of the HBGV.

MPI has therefore determined that the use of folpet on barley, when use according to the GAP specified above, is unlikely to pose any health risks from authorised use.

3.6.5 Relevant International MRLs

Country	Food	Maximum Residue Level (mg/kg)
EU	Barley All mammalian and poultry commodities, including milk and eggs	1 0.05

3.7 PROPOSAL TO SET MRLS FOR MEFENTRIFLUCONAZOLE

It is proposed that MRLs are set for mefentrifluconazole to support the GAP use of the compound on wheat and barley crops. Mefentrifluconazole is a new agricultural compound in New Zealand.

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

Compound Common Name	CAS#	Residue to which the maximum residue level applies	Food	Maximum Residue Level (mg/kg)
Mefentrifluconazole	1417782-03-6	Mefentrifluconazole	Barley grain Eggs Mammalian fat Mammalian kidney Mammalian liver Mammalian meat Milk Poultry fat Poultry meat Poultry offal Wheat grain	2 0.01(*) 0.1 0.1 0.3 0.02 0.02 0.02 0.01(*) 0.02 0.5

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

3.7.1 Amendment Rationale

The MRLs are being proposed to support the use of mefentrifluconazole as a fungicide for the control of rusts, powdery mildew, leaf blotches, and leaf spots in wheat and barley in accordance with the use patterns proposed as GAP in New Zealand.

3.7.2 Good Agricultural Practice

Mefentrifluconazole is a demethylation inhibitor (DMI) triazole which acts by inhibiting sterol biosynthesis in fungal cell membranes. It is used to treats rust, powdery mildew, leaf blotch, and leaf spot infections as a single foliar spray at a rate of 150gai /ha (co-formulated with 75 gai/ha fluxapyroxad), applied at the first appearance of disease up to the end of flowering.

The withholding periods applied to this use are 42 days for grain and stubble/straw, and 28 days for green feed and silage.

3.7.3 Residue Information

The residue data for the use of mefentrifluconazole in wheat and barley were sufficient to conclude that, when applied as per the proposed GAP use pattern and complying with the applicable withholding period, residues of parent mefentrifluconazole should not exceed 0.5 mg/kg in wheat grain or 2 mg/kg in barley grain. The residue and metabolism data confirmed that the primary residue in grain from treated crops was parent mefentrifluconazole, allowing the parent compound to be used as the GAP compliance and dietary intake residue definitions.

The animal metabolism studies demonstrated that the primary residues for mefentrifluconazole in animal commodities were the parent compound and its metabolites M750F022 and M750F001 (1,2,4-triazole). The dietary intake definition for animal commodities will therefore be mefentrifluconazole and its M750F022 and M750F001 metabolites, expressed as mefentrifluconazole. Like plant commodities, the parent compound mefentrifluconazole will be sufficient to ensure GAP compliance and will be used as the MRL residue definition.

Animal residue transfer data demonstrated that concentrations of mefentrifluconazole, when used according to GAP and observing the withholding periods, should not exceed the proposed MRLs in mammalian tissues, poultry tissues, milk, and eggs.

3.7.4 Dietary Risk Assessment

The HBGV of 0.025 mg/kg bw/d, and the stated dietary intake residue definitions, were considered appropriate for use in the dietary intake assessment. Based on the residue profile expected from all horticultural and animal commodities, the NEDI is estimated to total less than 5% of the HBGV.

MPI has therefore determined that the use of mefentrifluconazole, when use according to the GAP specified above, is unlikely to pose any health risks from authorised use.

3.7.5 Relevant International MRLs

Country	Food	Maximum Residue Level (mg/kg)
Australia	Edible offal (mammalian)	0.02
	Eggs	0.01
	Meat (mammalian) [in the fat]	0.02
	Milks	0.01
	Poultry meat [in the fat]	0.01
	Poultry, edible offal of	0.02
Canada	Barley	4
	Wheat	0.3
	Eggs	0.01
	Fat of cattle, sheep, goats and horses	0.2
	Meat and fat of poultry	0.01
	Meat of cattle, sheep, goats and horses	0.02
	Meat fat, and meat byproducts of hogs	0.01
	Meat byproducts of cattle, sheep, goats, and horses	0.3
	Milk	0.02
	Milk fat	0.1

European Union	Barley	0.6
	Wheat	0.05
	All swine commodities	0.01
	Bovine and horse muscle	0.04
	Bovine and horse fat	0.2
	Bovine and horse liver	0.4
	Bovine and horse kidney	0.1
	Bovine edible offals (other than liver and kidney)	0.1
	Sheep and goat muscle	0.06
	Sheep and goat fat	0.4
	Sheep and goat liver	0.7
	Sheep and goat kidney	0.3
	Sheep and goat edible offals (other than liver and kidney)	0.3
	Poultry muscle	0.015
	Poultry fat	0.03
	Poultry liver	0.03
	Poultry kidney	0.03
	Poultry edible offals (other than liver and kidney)	0.03
	Cattle and horse milk	0.02
	Sheep and goat milk	0.03
	Eggs, all species	0.015
United States	Barley	4
	Wheat	0.3
	Cattle, goat, sheep and horse by products	0.3
	Hog by products	0.03
	Cattle, goat, sheep and horse fat	0.2
	Hog fat	0.015
	Cattle, goat, sheep and horse kidney	0.3
	Hog kidney	0.03
	Cattle, goat, sheep and horse liver	0.3
	Hog liver	0.03
	Cattle, goat, sheep and horse meat	0.03
	Hog meat	0.01
	Milk	0.8
	Chicken and turkey by products	0.01
	Chicken and turkey fat	0.015
	Chicken and turkey kidney	0.01
	Chicken and turkey liver	0.01
	Chicken and turkey meat	0.01
	Chicken and turkey eggs	0.01

3.8 PROPOSAL TO SET MRLS FOR PROSULFOCARB

It is proposed that MRLs are set for prosulfocarb to support the GAP use of the compound on potatoes. Prosulfocarb is a new agricultural compound in New Zealand.

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

Compound Common Name	CAS#	Residue to which the maximum residue level applies	Food	Maximum Residue Level (mg/kg)
Prosulfocarb	52888-80-9	Prosulfocarb (parent only)	Potato	0.01 (*)

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

3.8.1 Amendment Rationale

The MRLs are being proposed to support the use of prosulfocarb in potatoes in accordance with the use pattern proposed as GAP in New Zealand.

3.8.2 Good Agricultural Practice

Prosulfocarb is a thiocarbamate herbicide used as pre-emergent herbicide that acts by inhibiting lipid synthesis in meristematic tissue after application to soil and absorption by roots and leaves. In potatoes, prosulfocarb is used for control of annual ryegrass and other grass and broadleaf weeds. The compound is applied to moist soil after planting at a rate of 3.2 – 4.0 kgai /ha (co-formulated with 0.48 - 0.6 kgai/ha S-metolachlor) after the first cultivation but no later than 25% potato shoot emergence.

Good agricultural practice for the proposed use of prosulfocarb dictates that the compound must be applied after the first cultivation but no later than 25% potato shoot emergence. Accordingly, the associated WHP is “Not required when used as directed”.

3.8.3 Residue Information

The residue data for the use of prosulfocarb in potatoes were sufficient to conclude that, when applied as per the proposed GAP use pattern and complying with the applicable withholding period, residues of parent prosulfocarb are not expected in potatoes and should not exceed the limit of analytical quantification (0.01 mg/kg).

Trial data evaluating the metabolism supports a ‘prosulfocarb (parent only)’ residue definition for GAP compliance and dietary intake assessments for plant commodities. This is consistent with the residue definitions in the EU and Australia.

Animal commodity MRLs were not considered as potatoes are not a primary animal feed.

3.8.4 Dietary Risk Assessment

The HBGV of 0.0035 mg/kg bw/d, and the stated dietary intake residue definition, were considered appropriate for use in the dietary intake assessment. Based on the residue profile expected in food from crops treated with prosulfocarb, the NEDI is estimated to total less than 1% of the HBGV.

MPI has therefore determined that the use of prosulfocarb, when use according to the GAP specified above, is unlikely to pose any health risks from authorised use.

3.8.5 Relevant International MRLs

Country	Food	Maximum Residue Level (mg/kg)
Australia	Potato	0.01

3.9 PROPOSAL TO AMEND MRLS FOR METOLACHLOR

It is proposed that the Notice entry for metolachlor is amended to set a MRL to support the GAP use of the compound on potatoes.

The revised entry for metolachlor in Schedule 1 of the Notice will read as follows. Changes are shown in bold:

Compound Common Name	CAS#	Residue to which the maximum residue level applies	Food	Maximum Residue Level (mg/kg)
Metolachlor	51218-45-2	Metolachlor and its enantiomers, expressed as metolachlor	Asparagus **Potatoes** Pumpkins Sweetcorn Summer squash Winter squash	0.05(*) **0.01(*)** 0.05(*) 0.05(*) 0.05(*) 0.05(*)

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

3.9.1 Amendment Rationale

The MRL is being proposed to support the use of S-metolachlor as a pre-emergent herbicide for control of annual ryegrass and other grass and broadleaf weeds in potatoes in accordance with the use pattern proposed as GAP in New Zealand.

3.9.2 Good Agricultural Practice

S-metolachlor belongs to the chloroacetanilide group of compounds, which acts by inhibiting chlorophyll and protein synthesis in target plants. The compound is most active during germination and seedling emergence from the soil. S-metolachlor is an established pre-emergent selective grass herbicide with current uses in maize, sweetcorn, asparagus, pumpkins and squash. For the proposed use in potatoes, the compound is applied to moist soil after planting at a rate of 0.48 - 0.6 kgai/ha (co-formulated with 3.2 - 4.0 kgai /ha prosulfocarb) after the first cultivation but no later than 25% potato shoot emergence.

Good agricultural practice for the proposed use of S-metolachlor dictates that the compound must be applied after the first cultivation but no later than 25% potato shoot emergence. Accordingly, the associated WHP is “Not required when used as directed”.

3.9.3 Residue Information

The residue data for the use of S-metolachlor in potatoes were sufficient to conclude that, when applied as per the proposed GAP use pattern and complying with the applicable withholding period, residues of metolachlor are not expected in potatoes and should not exceed 0.01(*) mg/kg.

Trial data evaluating the metabolism supports the residue definition of ‘metolachlor’ for GAP compliance and dietary intake assessments for plant commodities, which includes S-metolachlor as well as the R- and RS- enantiomers. Because mixed isomer formulations of metolachlor are no longer registered in New Zealand, the residue definition is being amended to ensure it is clear that the enantiomers are captured. This is to reflect the use of S-metolachlor as an agricultural compound in its own right in New Zealand, while recognising the similarities between the enantiomers and the analytical methods used in the New Zealand residue monitoring programme.

Animal commodity MRLs were not considered as potatoes are not a primary animal feed.

3.9.4 Dietary Risk Assessment

The HBGV of 0.07 mg/kg bw/d, and the stated dietary intake residue definition, were considered appropriate for use in the dietary intake assessment. Based on the residue profile expected in food from crops treated with S-metolachlor, the NEDI is estimated to total less than 0.1% of the HBGV.

MPI has therefore determined that the use of metolachlor, when use according to the GAP specified above, is unlikely to pose any health risks from authorised use.

3.9.5 Relevant International MRLs

Country	Food	Maximum Residue Level (mg/kg)
Australia	Potato	0.01

Note: the Australian MRLs capture both metolachlor and S-metolachlor, and the residue definition is metolachlor.

3.10 PROPOSAL TO AMEND THE MRLS FOR TEBUCONAZOLE

It is proposed that the Notice entry for tebuconazole is amended to set MRLs for animal commodities to support the GAP use of the compound on fodder and sugar beets used as animal feed.

The revised entry for tebuconazole in Schedule 1 of the Notice will read as follows. Changes are shown in bold:

Compound Common Name	CAS#	Residue to which the maximum residue level applies	Food	Maximum Residue Level (mg/kg)
Tebuconazole	107534-96-3	Tebuconazole	Bulb vegetables Cereal grains Eggs Mammalian fat Mammalian kidney Mammalian liver Mammalian meat Milk Peas Poultry fat Poultry meat Poultry offal Stone fruits	0.2 0.05(*) 0.01(*) 0.01(*) 0.01(*) 0.07 0.01(*) 0.01(*) 0.2 0.01(*) 0.01(*) 0.01(*) 1

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

3.10.1 Amendment Rationale

The MRLs are being proposed to support an expansion of the use of tebuconazole to fodder beets for animal consumption, in accordance with the use pattern proposed as GAP in New Zealand.

3.10.2 Good Agricultural Practice

Tebuconazole is a DMI triazole fungicide which inhibits fungal cell wall synthesis. The compound is used on its own or with other compounds for the control of fungal diseases in peas, onions, stone fruit, pome fruit, kiwifruit, grapes, and cereal crops, as well as ryegrass and seed crops and on pasture. The new use has been proposed to manage rust, powdery mildew, and *Cercospora* infections in fodder beet crops grown solely for animal consumption. For this additional use, the compound is applied as a foliar spray at a rate of 200 gai/ha (co-formulated with 120 gai/ha azoxystrobin) when disease first becomes active in the crop, and no sooner than 14 days later. A withholding period of 28 days applies to this use for both harvest and grazing of the crop.

3.10.3 Residue Information

To establish the animal commodity MRLs for this compound, data was reviewed for both the new use in fodder beets as well as existing uses in cereal grains and pasture. This was to ensure the animal commodity MRLs are reflective of all GAP uses of the compound.

The residue data for the use of tebuconazole in crops used as animal feed were sufficient to conclude that, when used according to the proposed and existing GAP use patterns, residues of tebuconazole should not exceed 0.07 mg/kg in mammalian liver or the limit of quantification (0.01 mg/kg) in all other animal commodities. The animal metabolism confirmed that the current plant commodity residue definition of 'Tebuconazole' is appropriate to use as the residue definition for animal commodities (for both GAP-compliance and dietary intake assessment).

3.10.4 Dietary Risk Assessment

The HBGV of 0.02 mg/kg bw/d, and the stated dietary intake residue definition, were considered appropriate for use in the dietary intake assessment. Based on the residue profile expected from all horticultural and animal commodities, the NEDI is estimated to total less than 2% of the HBGV.

MPI has therefore determined that the use of tebuconazole, when use according to the GAP specified above, is unlikely to pose any health risks from authorised use.

3.10.5 Relevant International MRLs

Country	Food	Maximum Residue Level (mg/kg)
Australia	Edible offal (mammalian)	0.5
	Eggs	0.1
	Meat (mammalian) [in the fat]	0.1
	Milks	0.05
	Poultry meat	0.1
	Poultry, edible offal of	0.5
Canada	Meat of cattle, sheep, horses, goats and hogs	0.2
	Meat byproducts of cattle, sheep, horses, goats and hogs	0.2
	Milk	0.1
	Meat of poultry	0.1
	Meat byproduct of poultry	0.1
	Eggs	0.1
Codex	Edible offal (mammalian)	0.2
	Eggs	0.05
	Meat (from mammals other than marine mammals)	0.05
	Milks	0.01
	Poultry meat	0.05
	Poultry, edible offal of	0.05
EU	Swine, bovine, sheep, goat, and horse muscle	0.1
	Swine, bovine, sheep, goat, and horse fat	0.1
	Swine, bovine, sheep, goat, and horse liver	0.2
	Swine, bovine, sheep, goat, and horse kidney	0.2
	Swine, bovine, sheep, goat, and horse edible offals (other than liver and kidney)	0.2
	Poultry muscle, fat, liver, kidney, and edible offals (other than liver and kidney)	0.1
	Milk	0.02
	Eggs	0.1
Japan	Cattle, pig, and other terrestrial mammal muscle	0.05
	Cattle, pig, and other terrestrial mammal fat	0.05
	Cattle, pig, and other terrestrial mammal liver	0.2
	Cattle, pig, and other terrestrial mammal kidney	0.2
	Cattle, pig, and other terrestrial mammal edible offal	0.2
	Milk	0.01
	All chicken and other poultry commodities including eggs	0.05
United States	Cattle, goat, horse, and sheep by products	0.2
	Cattle, goat, horse, and sheep kidney	0.2
	Cattle, goat, horse, and sheep liver	0.2
	Milk	0.1

3.11 PROPOSAL TO EXEMPT 1-TRIACONTANOL FROM COMPLIANCE WITH A MRL

It is proposed that 1-triacontanol is exempt from compliance with an MRL by amendment to Schedule 2 of the Notice. The compound is a long-chain fatty alcohol which is naturally present in plant cuticle waxes, and used as plant growth regulator on pasture. 1-triacontanol is readily metabolised by grazing animals with no accumulation in animal tissues. The NZ EPA has evaluated this substance and concluded that a health based guidance value was not required to manage dietary exposure.

The proposed entry in Schedule 2 will read as follows:

Substance	CAS#	Condition
1-Triacontanol	593-50-0	When used as a plant growth regulator on pasture.

3.12 PROPOSAL TO EXEMPT EUGENOL FROM COMPLIANCE WITH A MRL

It is proposed that eugenol is exempt from compliance with an MRL by amendment to Schedule 2 of the Notice when used as a fungicide on grapevines. Eugenol is an allylbenzene compound extracted from cloves and other herbs and spices, and has been shown to have fungicidal activity. Data were provided confirming residue levels of eugenol and its toxic impurity methyl-eugenol were not persistent and not likely to be distinguishable from background levels when used on grapevines.

The proposed entry in Schedule 2 will read as follows:

Substance	CAS#	Condition
Eugenol	97-53-0	When used as a fungicide on grapevines.

3.13 PROPOSAL TO EXEMPT GERANIOL FROM COMPLIANCE WITH A MRL

It is proposed that geraniol is exempt from compliance with an MRL by amendment to Schedule 2 of the Notice when used as a fungicide on grapevines. Geraniol is a monoterpene alcohol which is naturally occurring in rose oil and a number of other essential oils derived from plants. Like eugenol, data confirmed post-treatment residue levels of geraniol in grapes were not persistent and were not likely to be distinguishable from background levels.

The proposed entry in Schedule 2 will read as follows:

Substance	CAS#	Condition
Geraniol	106-24-1	When used as a fungicide on grapevines.

3.14 PROPOSAL TO AMEND THE EXEMPTION FOR HYDROGEN PEROXIDE

Hydrogen peroxide is currently subject to an exemption from compliance with a MRL in Schedule 2 of the Notice when used as a spray-on bactericide or fungicide in fruit. It is proposed that the exemption is amended to also allow its use for the same purpose on vegetable crops without the need to comply with a MRL. Because hydrogen peroxide is of

low oral toxicity, is not mutagenic and is not carcinogenic, the proposed amendment to include vegetables is unlikely to produce residues that will negatively impact food safety.

The revised entry in Schedule 2 will read as follows. The changes are in bold:

Substance	CAS#	Condition
Hydrogen peroxide	7722-84-1	When used as a spray-on fungicide and bactericide on fruits **and vegetables**.

3.15 PROPOSAL TO EXEMPT THYMOL FROM COMPLIANCE WITH A MRL

It is proposed that thymol is exempt from compliance with an MRL by amendment to Schedule 2 of the Notice when used as a fungicide on grapevines. Thymol is a monoterpenoid phenol found in essential oils extracted from thyme as well as some other plants, and has been shown to have fungicidal activity. Post-treatment residues of thymol were not persistent in grapes and were not likely to be distinguishable from background levels.

The proposed entry in Schedule 2 will read as follows:

Substance	CAS#	Condition
Thymol	89-83-8	When used as a fungicide on grapevines

3.16 PROPOSAL TO REMOVE THE EXEMPTION FOR DIDECYL DIMETHYL AMMONIUM CHLORIDE

It is proposed that the exemption for didecyl dimethyl ammonium chloride, also known as DDAC, is removed from Schedule 2 of the Notice. This is because there are no approved uses of this compound under the Agricultural Compounds and Veterinary Medicines Act 1997.

The following entry will be deleted from Schedule 2:

Substance	CAS#	Condition
Didecyl Dimethyl Ammonium Chloride	7173-51-5	When applied as a fungicide on fruits and vegetables

3.17 PROPOSAL TO AMEND THE EXEMPTION FOR VACCINE AND DIAGNOSTIC ANTIGENS

It is proposed that the exemption from compliance with a MRL for vaccine and diagnostic antigens in Schedule 3 of the Notice is amended. The current exemption allows for the use of microorganism-derived compounds to be used as vaccine antigens and as antigens in diagnostic tests for the management of diseases in animals. It is proposed that the condition of exemption is amended to make it clear that bacterial cell wall components may be used as immunostimulants as well as vaccine antigens targeting a specific disease.

Because bacterial cell wall components are already captured in the phrasing of the exemption, this extension only addresses how the components may be used in veterinary medicines. As such, the change is not expected to pose any additional residue risks in commodities from treated animals.

The revised entry in Schedule 3 will read as follows. The changes are in bold:

Substance	CAS#	Condition
Vaccine and Diagnostic Antigens This exemption applies when the antigen is derived from a viable or non-viable microorganism.	n/a	When derived from whole attenuated or killed microorganisms, inactivated microorganisms or fractions of microorganisms, or other biological-derived proteins, and used as a veterinary medicine. **Includes bacterial cell wall components used as an immunostimulant**