Ministry for Primary Industries
Manatū Ahu Matua

# Proposals to Amend the Maximum Residue Levels for Agricultural Compounds Food Notice December 2018

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By the Assurance Directorate of the Ministry for Primary Industries

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*Growing and Protecting New Zealand*

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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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# Contents

# 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 **6 August 2019**. Your comments should be sent to:

MRL Amendments
ACVM Programmes and Appraisals
MPI Assurance 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

Agricultural compounds are natural or synthetic substances used in the management of plants and animals, and include veterinary medicines, fertilisers, and pesticides (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 two to three 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: https://www.mpi.govt.nz/dmsdocument/19550-maximum-residue-levels-for-agricultural-compounds.

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 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 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)); or
- 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)).

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 use (GAP).

The possible implications for consumer health are considered during the toxicological and dietary risk assessments, by comparing the NEDI with a 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 (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, MPI uses the $PDE_{(food)}$ set by the 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 an MPI-determined ADI.

### 2.1.3 International MRLs and Trade

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 our major trading partners (Australia, Canada, China, Codex, the European Union, Japan, and the United States) 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 entry.

## 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:

- Clethodim: 0.02(*) mg/kg in grapes.
- Coumatetralyl: 0.001(*) mg/kg in any food.
- Difenoconazole: 0.05 mg/kg in grapes; 0.01 mg/kg in mammalian fat (except milk fat); 0.01 mg/kg in mammalian meat; 0.01 mg/kg in mammalian offal; and 0.01 mg/kg in milk.
- Difethialone: 0.001(*) mg/kg in any food.
- Diphacinone: 0.001(*) mg/kg in any food.
- Eprinomectin: 0.1 mg/kg in sheep fat; 0.05 mg/kg in sheep meat; 0.2 mg/kg in sheep offal; and 0.02 mg/kg in sheep milk.
- Flufenacet: 0.01(*) mg/kg in potatoes.
- Flumioxazin: 0.02(*) mg/kg in grapes; 0.02(*) mg/kg in kiwifruit; 0.02(*) mg/kg in pome fruits; 0.02(*) mg/kg in stone fruits; 0.02(*) mg/kg in mammalian fat, meat, and offal; and 0.02(*) mg/kg in milk.
- Flusilazole: 0.01(*) mg/kg in grapes, 0.05(*) mg/kg in mammalian fat, 0.01(*) mg/kg in mammalian meat, 0.01(*) mg/kg in mammalian offal, and 0.01(*) mg/kg in milk.
- Isoflucypram: 0.15 mg/kg in barley grain; 0.01(*) in eggs; 0.04(*) mg/kg in mammalian fat; 0.01(*) mg/kg in mammalian offal; 0.01(*) mg/kg in mammalian meat; 0.005(*) mg/kg in milk; 0.01(*) in poultry meat; 0.02 mg/kg in poultry offal; 0.02 mg/kg in wheat grain; and 0.02 mg/kg in triticale grain.
- Mandestrobin: 1.5 mg/kg in head lettuce; and 10 mg/kg in leafy lettuce.
- Metrafenone: 0.15 mg/kg in grapes; 0.01(*) mg/kg in mammalian fat; 0.01(*) mg/kg in mammalian meat; 0.01(*) mg/kg in mammalian offal; and 0.01(*) mg/kg in milk.
- Metribuzin: 0.01(*) mg/kg in potatoes.
- Pyroxasulfone: 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; 0.002(*) mg/kg in milk; 0.02(*) mg/kg in poultry meat; 0.02(*) mg/kg in poultry offal; 0.01(*) mg/kg in triticale; and 0.01 (*) mg/kg in wheat.
- Tetraniliprole: 0.2 mg/kg in pome fruits.

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

### 2.2.2 Amendments to Schedule 2: New and Amended Exemptions from Maximum Residue Levels for Agricultural Chemicals

- MPI proposes to add a new exemption for *Chromobacterium subtsugae* PRAA4-1T and its metabolites (including violacein) to the list of agricultural compounds in Schedule 2 of the Food Notice for which no maximum residue levels apply. The organism and its metabolites are used for the control of mealybugs on grape vines.

- MPI proposes to amend the current entry for bromochlorodimethylhydantoin in the list of agricultural compounds in Schedule 2 of the Food Notice, for which no maximum

residue levels apply. The amendment is being proposed to better represent the isomeric mixtures referred to as bromochlorodimethylhydantoin by including four additional Chemical Abstract Service (CAS) numbers associated with these mixtures.

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

- MPI proposes to add a new exemption for cross-linked polyacrylamide to the list of agricultural compounds in Schedule 3 of the Food Notice, for which no maximum residue levels apply. The compound is used as an intra-articular arthritis treatment in horses.

- MPI proposes to add a new exemption for antigens used in vaccines and for diagnostic purposes to the list of agricultural compounds in Schedule 3 of the Food Notice, for which no maximum residue levels apply.

# 3 Proposals

## 3.1 PROPOSAL TO AMEND THE MRLS FOR CLETHODIM

It is proposed that MRLs for clethodim are amended to include an MRL to support the GAP use of the compound on grapes.

The revised entry for clethodim 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) |
|---|---|---|---|---|
| Clethodim | 99129-21-2 | Sum of:<br>Clethodim and its metabolites containing 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones<br>Expressed as:<br>Clethodim | Brassica vegetables<br>Fruiting vegetables<br>**Grapes**<br>Leafy vegetables<br>Legume vegetables<br>Mammalian meat<br>Mammalian offal<br>Milk<br>Stem vegetables | 1<br>1<br>**0.02(*)**<br>1<br>1<br>0.2<br>0.2<br>0.05<br>1 |

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

### 3.1.1 Amendment Rationale

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

### 3.1.2 Good Agricultural Practice

Clethodim is a cyclohexene oxime herbicide sprayed around grape vines at a rate of 61-720 gai/ha. The compound is applied to control actively growing grass weeds by application to the base of vines before the start of flowering. Clethodim is not to be applied after the start of flowering, and therefore will not be applied when fruit is present.

### 3.1.3 Residue Information

The residue data for the use of clethodim to control weeds in vineyards are sufficient to conclude that, when applied as per the proposed GAP use pattern and complying with the use restrictions, residues of clethodim and its metabolites would not exceed the limit of analytical quantification of 0.02 mg/kg. The proposed MRL for grapes, set at 0.02 mg/kg, will therefore be sufficient to support GAP for this use pattern.

The proposed use of the compound in vineyards also adds to the potential for animal residues from vineyard grazing. A review of all available residue and dietary burden data confirmed that the existing animal commodity MRLs will be sufficient to manage residues in animals grazed in vineyards. There are no changes proposed for the animal commodity MRLs for clethodim.

The residue definition used for the other foods, which applies to both GAP compliance and dietary intake, can apply to the use of clethodim on grapes.

### 3.1.4 Dietary Risk Assessment

The HBGV of 0.005 mg/kg bw/d and the stated dietary intake residue definition, was considered appropriate for use in the assessment.

The dietary exposure risk assessment was based on the residue profile expected in food from crops treated with clethodim, as well as in animal products from livestock that either consume treated animal feed crops or graze in treated vineyards. The assessment

concluded that the NEDI for clethodim would total less than 74% of the HBGV when the compound is used according to existing and proposed GAP uses.

MPI has therefore determined that the use of clethodim on grapes according to the GAP specified above, in addition to the previously approved uses, is unlikely to pose any health risks from authorised use.

### 3.1.5 Relevant International MRLs

There are no MRLs set by either Australia or Codex for grapes.

## 3.2 PROPOSAL TO SET MRLS FOR COUMATETRALYL

It is proposed that MRLs are set for coumatetralyl to support the GAP use of the compound as a rodenticide vertebrate toxic agent (VTA).

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

| Compound Common Name | CAS# | Residue to which the maximum residue limit applies | Food | Maximum Residue Level (mg/kg) |
|---|---|---|---|---|
| Coumatetralyl | 5836-29-3 | Coumatetralyl | Any food | 0.001(*) |

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

### 3.2.1 Amendment Rationale

The MRL is being proposed to support the use of coumatetralyl in the management of vertebrate pests in New Zealand according to approved use patterns that are considered GAP. Though the use of the compound is not novel, the MRL is being proposed to ensure compliance with GAP in food from exposed plants or animals.

### 3.2.2 Good Agricultural Practice

Coumatetralyl is a first-generation coumarin rodenticide used as a rodent bait on farm, commercial, and industrial buildings, and in private residences and refuse dumps. Sale and use of the compound is restricted to those approved by MPI as per the product label.

### 3.2.3 Residue Information

The established GAP for this compound dictates that it is used in such a way that there are no detectable residues in any food intended for human consumption. As such, the new MRL has been proposed to be set at the limit of analytical quantification to ensure a lack of residues in all food commodities.

The residue definition is proposed to be set as the parent compound for all foods, in line with international residue definitions for coumatetralyl.

### 3.2.4 Dietary Risk Assessment

There is no HBGV available to calculate the dietary intake exposure for coumatetralyl. However, given the proposed control means there are no quantifiable residues permitted in any food, the dietary exposure can be expected to be negligible when the compound is used according to GAP. MPI has therefore determined that the use of coumatetralyl as a rodenticide according established GAP is unlikely to pose any health risks from authorised use.

### 3.2.5 Relevant International MRLs

| Country | Food | Maximum Residue Level (mg/kg) |
|---|---|---|
| Australia | Pig fat<br>Pig liver<br>Pig meat<br>Pig offal (except liver) | 0.001<br>0.004<br>0.001<br>0.003 |
| European Union | Any food | 0.01 |
| Japan | Any food (uniform limit) | 0.01 |

## 3.3 PROPOSAL TO AMEND THE MRLS FOR DIFENOCONAZOLE

It is proposed that MRLs for difenoconazole are amended to support the GAP use of the compound on grapes. Because this compound has not previously been approved for use on animal feed crops or pasture, it is also proposed that the entry in the Notice is amended to include MRLs for animal commodities to manage residues from vineyard grazing.

The revised entry for difenoconazole 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) |
|---|---|---|---|---|
| Difenoconazole | 119446-68-3 | Plant commodities: Difenoconazole<br><br>Animal commodities: sum of difenoconazole and 1-[2-chloro-4-(4-chloro-phenoxy)- phenyl]-2-(1,2,4-triazol)-1-yl-ethanol), expressed as difenoconazole | Brassica vegetables<br>Grapes<br>Mammalian fat (except milk fat)<br>Mammalian meat<br>Mammalian offal<br>Milk | 0.2<br>0.05<br>0.01<br>0.01<br>0.01<br>0.01 |

### 3.3.1 Amendment Rationale

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

### 3.3.2 Good Agricultural Practice

Difenoconazole is a triazole fungicide used in vineyards as a single foliar spray of 6.25 gai/100L to manage powdery mildew. It is to be applied over the infection period during active leaf and berry growth, up to or just after bunch closure. Use of difenoconazole in this manner will attract a 56 day withholding period for grapes, and a two month pre-slaughter interval for animals grazed in treated vineyards.

### 3.3.3 Residue Information

The residue data for the use of difenoconazole on grapes are sufficient to conclude that, when applied as per the proposed GAP use pattern and complying with the use restrictions and withholding periods, difenoconazole residues should not exceed 0.03 mg/kg in grapes. As with brassica vegetables, the residue data in grapes demonstrated that the primary residue was parent difenoconazole and therefore the existing plant commodities residue definition will apply.

The animal metabolism studies demonstrated that the primary residues for difenoconazole in animal commodities were the parent compound and the 1-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-(1,2,4-triazol)-1-yl-ethanol metabolite, also known as CGA 205375, in all tissues and milk. This is consistent with the assessment conducted by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), which informed the Codex definition for both dietary intake and MRL compliance for animal commodities: the sum of difenoconazole and 1-[2-chloro-4-(4-chloro-phenoxy)- phenyl]-2-(1,2,4-triazol)-1-yl-ethanol), expressed as difenoconazole. This residue definition is considered appropriate to adopt for the promulgation of New Zealand MRLs for this compound.

Animal residue data demonstrated that concentrations of difenoconazole and its metabolite, when used on grape vines according to New Zealand GAP and observing the two month pre-slaughter interval, should not exceed 0.01 mg/kg in all tissues and milk. It is noted that the proposed New Zealand milk MRL exceeds that set by the EU. This is likely due to the difference in the residue definitions: the Codex residue definition, and that proposed for New Zealand, is the sum of the parent compound and its metabolite, whereas the EU residue definition is for parent compound only. The proposed GAP use of the compound in New Zealand would result in parent difenoconazole residues that can be expected to be compliant with the EU milk MRL of 0.005 mg/kg.

### 3.3.4 Dietary Risk Assessment

The HBGV of 0.005 mg/kg bw/d and the stated dietary intake residue definitions, was considered appropriate for use in the assessment.

Based on the residue profile expected in food from crops treated with difenoconazole, as well as in animal products from livestock that graze in treated vineyards, the NEDI for difenoconazole is estimated to total less than 11% of the HBGV when the compound is used according to existing and proposed GAP uses.

MPI has therefore determined that the use of difenoconazole on grape vines according to the GAP specified above, and the grazing of animals in treated vineyards, is unlikely to pose any health risks with authorised use.

### 3.3.5 Relevant International MRLs

| Country | Food | Maximum Residue Level (mg/kg) |
|---|---|---|
| Australia | Edible offal (mammalian) | 0.05 |
| | Meat (mammalian) | 0.05 |
| | Milks | 0.01 |
| Canada | Liver of ruminants | 0.1 |
| | Meat byproducts of ruminants | 0.05 |
| | Meat of ruminants | 0.05 |
| Codex | Edible offal (mammalian) | 1.5 |
| | Grapes | 3 |
| | Meat (from mammals other than marine mammals, as fat) | 0.2 |
| | Milks | 0.02 |
| European Union | Ruminant muscle | 0.05 |
| | Ruminant fat | 0.05 |
| | Ruminant liver | 0.2 |
| | Ruminant kidney | 0.2 |
| | Ruminant edible offals (other than liver and kidney) | 0.2 |
| | Milk | 0.005 |
| Japan | Mammalian muscle | 0.2 |
| | Mammalian fat | 0.2 |
| | Mammalian liver | 2 |
| | Mammalian kidney | 2 |
| | Mammalian edible offal | 2 |
| | Milk | 0.01 |
| United States | Cattle, goat, and sheep by products | 0.1 |
| | Cattle, goat, and sheep fat | 0.1 |
| | Cattle, goat, horse, and sheep kidney | 0.1 |
| | Cattle, goat, horse, and sheep liver | 0.4 |
| | Cattle, goat, horse, and sheep meat | 0.05 |
| | Milk | 0.02 |

## 3.4 PROPOSAL TO SET MRLS FOR DIFETHIALONE

It is proposed that MRLs are set for difethialone to support the GAP use of the compound as a rodenticide VTA.

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

| Compound Common Name | CAS# | Residue to which the maximum residue limit applies | Food | Maximum Residue Level (mg/kg) |
|---|---|---|---|---|
| Difethialone | 104653-34-1 | Difethialone | Any food | 0.001(*) |

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

### 3.4.1 Amendment Rationale

The MRL is being proposed to support the use of difethialone in the management of vertebrate pests in New Zealand according to approved use patterns that are considered GAP. Though the use of the compound is not novel, the MRL is being proposed to ensure compliance with GAP.

### 3.4.2 Good Agricultural Practice

Difethialone is a 4-thiochromenone rodenticide used in buildings and refuse dumps in bait form to manage rodent pests. Sale and use of the compound is restricted to those approved by MPI as per the product label.

### 3.4.3 Residue Information

The established GAP for this compound dictates that it is used in such a way that there are no detectable residues in any food intended for human consumption. As such, the MRL has been proposed to be set at the limit of analytical quantification in New Zealand to ensure a lack of residues in all food commodities.

The residue definition is proposed to be set as the parent compound for all foods, in line with international residue definitions for difethialone.

### 3.4.4 Dietary Risk Assessment

There is no HBGV available to calculate the dietary intake exposure for difethialone. Given the proposed control means there are no quantifiable residues permitted in any food however, the dietary exposure can be expected to be negligible when the compound is used according to GAP. MPI has therefore determined that the use of difethialone as a rodenticide according established GAP is unlikely to pose any health risks from authorised use.

### 3.4.5 Relevant International MRLs

| Country | Food | Maximum Residue Level (mg/kg) |
|---|---|---|
| European Union | Any food | 0.01 |
| Japan | Any food (uniform limit) | 0.01 |

## 3.5 PROPOSAL TO SET MRLS FOR DIPHACINONE

It is proposed that MRLs are set for diphacinone to support the GAP use of the compound as a rodenticide VTA.

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

| Compound Common Name | CAS# | Residue to which the maximum residue limit applies | Food | Maximum Residue Level (mg/kg) |
|---|---|---|---|---|
| Diphacinone | 82-66-6 | Diphacinone | Any food | 0.001(*) |

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

### 3.5.1 Amendment Rationale

The MRL is being proposed to support the use of diphacinone in the management of vertebrate pests in New Zealand according to approved use patterns that are considered GAP. Though the use of the compound is not novel, the MRL is being proposed to ensure compliance with GAP.

### 3.5.2 Good Agricultural Practice

Diphacinone is a first-generation indandione anticoagulant rodenticide used as a rodent bait in farm, commercial, and industrial buildings, as well as sewer lines, scrubland, forestry and

shelter belts, and other open areas. Sale and use of the compound is restricted to those approved by MPI as per the product label.

### 3.5.3 Residue Information

The established GAP for this compound dictates that it is used in such a way that there are no detectable residues in any food intended for human consumption. As such, the MRL has been proposed to be set at the or near the limit of analytical quantification in New Zealand to ensure a lack of residues in all food commodities.

The residue definition is proposed to be set as the parent compound for all foods, in line with international residue definitions for diphacinone.

### 3.5.4 Dietary Risk Assessment

There is no HBGV available to calculate the dietary intake exposure for diphacinone. Given the proposed control means there are no quantifiable residues permitted in any food however, the dietary exposure can be expected to be negligible when the compound is used according to GAP. MPI has therefore determined that the use of diphacinone as a rodenticide according established GAP is unlikely to pose any health risks from authorised use.

### 3.5.5 Relevant International MRLs

| Country | Food | Maximum Residue Level (mg/kg) |
|---|---|---|
| European Union | Any food | 0.01 |
| Japan | Any food (uniform limit) | 0.01 |

## 3.6 PROPOSAL TO AMEND THE MRLS FOR EPRINOMECTIN

It is proposed that MRLs for eprinomectin are amended to set MRLs for use of the compound in sheep.

The revised entry for eprinomectin 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 limit applies | Food | Maximum Residue Level (mg/kg) |
|---|---|---|---|---|
| Eprinomectin | 123997-26-2 | Eprinomectin B1a | Cattle fat<br>Cattle kidney<br>Cattle liver<br>Cattle meat<br>Cattle milk<br>Sheep fat<br>Sheep meat<br>Sheep offal<br>Sheep milk | 0.25<br>0.3<br>1.5<br>0.05<br>0.02<br>0.1<br>0.05<br>0.2<br>0.02 |

### 3.6.1 Amendment Rationale

The MRLs are being proposed to support a new use for eprinomectin in sheep, in accordance with the use pattern and withholding periods that are proposed as GAP in New Zealand.

### 3.6.2 Good Agricultural Practice

Eprinomectin is an avermectin endoparasiticide used in food-producing and companion animals in New Zealand. When used in sheep, the compound will be administered orally at a dose rate of 0.2 mg eprinomectin/kg body weight, when used in a multi-active formulation with oxfendazole and levamisole, which will attract a meat withholding period of 16 days and a milk withholding period of 35 days.

### 3.6.3 Residue Information

The residue data for the use of eprinomectin in sheep are sufficient to conclude that, when administered as per the proposed GAP use pattern and observing the established withholding periods, residues should not exceed 0.1 mg/kg in fat, 0.2 mg/kg in kidney, 0.2 mg/kg in liver, 0.05 mg/kg in meat, and 0.02 mg/kg in milk from treated sheep. The data confirmed that the existing residue definition will be sufficient to manage GAP compliance in sheep.

The residue data also confirmed that the residue definition for cattle, which applies to both GAP compliance and dietary intake, can be applied to sheep.

### 3.6.4 Dietary Risk Assessment

The HBGV of 0.01 mg/kg bw/d and the stated dietary intake residue definition, was considered appropriate for use in the assessment.

Based on the residue profile expected in products derived from livestock treated with eprinomectin, the NEDI is estimated to total less than 6% of the HBGV when the compound is used according to existing and proposed GAP uses.

MPI has therefore determined that the use of eprinomectin in sheep according to the GAP specified above is unlikely to pose any health risks with authorised use.

### 3.6.5 Relevant International MRLs

| Country | Food | Maximum Residue Level (mg/kg) |
|---|---|---|
| European Union | Ruminant fat | 0.25 |
| | Ruminant kidney | 0.3 |
| | Ruminant liver | 1.5 |
| | Ruminant meat | 0.05 |
| | Milk | 0.02 |
| Japan | Other terrestrial mammals, fat | 0.1 |
| | Other terrestrial mammals, kidney | 0.3 |
| | Other terrestrial mammals, liver | 0.3 |
| | Other terrestrial mammals, meat | 0.1 |
| | Milk | 0.02 |

## 3.7 PROPOSAL TO AMEND THE MRLS FOR FLUFENACET

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

The revised entry for flufenacet 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 limit applies | Food | Maximum Permitted Residue Level (mg/kg) |
|---|---|---|---|---|
| Flufenacet | 142459-58-3 | Sum of: Flufenacet, flufenacet sulfonic acid, flufenacet thioglycolate sulfoxide and flufenacet oxalate<br><br>Expressed as: Flufenacet | Barley<br>**Potatoes**<br>Wheat | 0.05(*)<br>**0.01(*)**<br>0.05(*) |

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

### 3.7.1 Amendment Rationale

The MRL is being proposed to support a new use for flufenacet on potatoes in accordance with the application rates and controls that are proposed as GAP in New Zealand.

### 3.7.2 Good Agricultural Practice

Flufenacet is an oxyacetamide herbicide in potato crops at a rate of 600 gai/ha, together with 440 gai/ha of metribuzin. The compound is used as a pre-emergent broadcast soil treatment, and is applied as a spray to manage a number of weed species in planted potato fields. Use of flufenacet on potato crops attracts a restriction that it is not to be used after crop emergence.

### 3.7.3 Residue Information

The residue data for the use of flufenacet on potato crops are sufficient to conclude that, when applied as per the proposed GAP use pattern and complying with the use restriction, residues of flufenacet and its metabolites should not exceed the limit of quantification of 0.01mg/kg in potatoes. The proposed MRL will therefore be sufficient to ensure compliance with GAP.

The residue metabolism profile for potatoes confirmed that the residue definition already set for barley and wheat, which applies to both GAP and dietary intake, can also apply to potatoes.

### 3.7.4 Dietary Risk Assessment

The HBGV of 0.0035 mg/kg bw/d and the stated dietary intake residue definition, was considered appropriate for use in the assessment.

Based on the residue profile expected in food from crops treated with flufenacet, the NEDI for the compound is estimated to total less than 4% of the HBGV when the compound is used according to existing and proposed GAP uses.

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

### 3.7.5 Relevant International MRLs

There are no MRLs set by either Australia or Codex for potatoes.

## 3.8 PROPOSAL TO SET MRLS FOR FLUMIOXAZIN

It is proposed that MRLs are set for flumioxazin to support the GAP use of the compound on grapes, kiwifruit, pome fruit, and stone fruit, and to set MRLs in animal commodities to manage residues resulting from vineyard grazing.

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

| Compound Common Name | CAS# | Residue to which the maximum residue limit applies | Food | Maximum Residue Level (mg/kg) |
|---|---|---|---|---|
| Flumioxazin | 103361-09-7 | Flumioxazin | Grapes | 0.02(*) |
| | | | Kiwifruit | 0.02(*) |
| | | | Mammalian fat | 0.02(*) |
| | | | Mammalian meat | 0.02(*) |
| | | | Mammalian offal | 0.02(*) |
| | | | Milk | 0.02(*) |
| | | | Pome fruits | 0.02(*) |
| | | | Stone fruits | 0.02(*) |

(*) 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 the novel compound flumioxazin on fruit, in accordance with the application rates, restrictions, and withholding periods that are proposed as GAP in New Zealand.

### 3.8.2 Good Agricultural Practice

Flumioxazin is a benzoxazine herbicide used as a contact and soil treatment to control a number of weeds in grape, kiwifruit, pome fruit, and stone fruit crops. The compound is applied at a rate of 420 gai/ha as a spray, at a maximum of one application per year between final harvest and bud break in all crops. Use of flumioxazin attracts a restriction that it is not to be applied after the start of flowering, a two month pre-grazing interval for orchard grazing, and a two month clean feed period for animals that have been grazed in vineyards.

### 3.8.3 Residue Information

The residue data for the use of flumioxazin are sufficient to conclude that, when applied as per the proposed GAP use pattern and complying with the applicable restrictions, residues of parent compound flumioxazin should not exceed 0.02 mg/kg in any fruit crops. When the pre- and post-grazing periods proposed as GAP are observed in grazing animals, flumioxazin residues in animal commodities should not exceed 0.02 mg/kg in any tissues or milk.

The residue studies conducted in animals confirmed that the parent compound residues were the only residues that quantifiably accumulated in all tissues and milk. A residues definition limited to parent flumioxazin will therefore be sufficient to manage GAP compliance and dietary intake in both plant and animal commodities.

### 3.8.4 Dietary Risk Assessment

The HBGV of 0.014 mg/kg bw/d and the stated dietary intake residue definitions, was considered appropriate for use in the assessment.

Based on the residue profile expected in food from crops treated with flumioxazin, as well as in animal products from livestock that are grazed in treated orchards and vineyards, the NEDI for the compound is estimated to total less than 2% of the HBGV.

MPI has therefore determined that the use of flumioxazin, 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 | Edible offal (Mammalian) | 0.01 |
| | Grapes | 0.01 |
| | Meat [mammalian] | 0.01 |
| | Milks | 0.01 |
| Codex | Edible offal (mammalian) | 0.02 |
| | Grapes | 0.02 |
| | Mammalian fats (except milk fats) | 0.02 |
| | Meat (from mammals other than marine mammals) | 0.02 |
| | Milks | 0.02 |
| | Pome fruits | 0.02 |
| | Stone fruits | 0.02 |
| European Union | Muscle, all mammalian species | 0.02 |
| | Fat, all mammalian species | 0.02 |
| | Liver, all mammalian species | 0.02 |
| | Kidney, all mammalian species | 0.02 |
| | Edible offals (other than liver and kidney), all mammalian species | 0.02 |
| | Milk | 0.02 |

## 3.9 PROPOSAL TO AMEND THE MRLS FOR FLUSILAZOLE

It is proposed that MRLs for flusilazole are amended to support the GAP use of the compound on grapes, and to set MRLs in animal commodities to manage residues resulting from vineyard grazing.

The revised entry for flusilazole 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 limit applies | Food | Maximum Permitted Residue Level (mg/kg) |
|---|---|---|---|---|
| Flusilazole | 85509-19-9 | Plant commodities: Flusilazole<br><br>Animal commodities: flusilazole plus [bis(4-fluorophenyl)methyl]silanol | Citrus fruits | 0.1 |
| | | | Grapes | 0.01(*) |
| | | | Mammalian fat | 0.05(*) |
| | | | Mammalian meat | 0.01(*) |
| | | | Mammalian offal | 0.01(*) |
| | | | Milk | 0.01(*) |

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

### 3.9.1 Amendment Rationale

The MRLs are being proposed to support a new use for flusilazole on grapes in accordance with the application rates, controls, and withholding periods that are proposed as GAP in New Zealand.

### 3.9.2 Good Agricultural Practice

Flusilazole is an organosilicon fungicide used to control dieback in grapes. The compound will be used as a spray at an application rate of 4 gai/100L of water during the dormant period after pruning and before sap flow. Flusilazole attracts a use restriction to the stated period, and a requirement that the compound is not applied once buds begin to swell. A six month slaughter interval and clean feed period also applies to animals grazed in treated vineyards.

### 3.9.3 Residue Information

The residue data for the use of flusilazole on grapes are sufficient to conclude that, when applied as per the proposed GAP use pattern, residues of parent compound flusilazole should not exceed the 0.01 mg/kg limit of quantification. The proposed MRL of 0.01 mg/kg in grapes is therefore sufficient to support GAP for the use of flusilazole in vineyards. The residue definition applicable to the existing plant commodities, apples and onions, can also apply to the use of flusilazole on grapes.

Animal metabolism and elimination studies demonstrated that the primary residues were parent flusilazole and its silanol metabolite. Feeding studies evaluating flusilazole consumption in cattle found that tissue residue uptake was minimal when used according to the New Zealand use pattern, with no evidence of bioaccumulation of the compound or its metabolite. Given the use pattern on grape vines, data to support limited absorption and rapid elimination in exposed ruminants, and the application of a six-month slaughter interval, MRLs set at the limit of detection for animal tissues will be sufficient to support GAP for vineyard grazing. As the silanol metabolite was a significant contributor to the residue profile, it is proposed that the residue definition includes both flusilazole and its metabolite. This aligns with the Codex residue definition for animal commodities.

### 3.9.4 Dietary Risk Assessment

The HBGV of 0.0005 mg/kg bw/d and the stated dietary intake residue definitions, was considered appropriate for use in the assessment.

Based on the residue profile of flusilazole expected in food from crops treated according to existing and proposed GAP uses, and in animal commodities after exposure to the compound through vineyard grazing, the NEDI is estimated to total less than 6% of the HBGV when the compound is used according to existing and proposed GAP uses.

MPI has therefore determined that the use of flusilazole on grapes, 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) |
|---|---|---|
| Codex | Edible offal (mammalian) | 2 |
| | Grapes | 0.2 |
| | Meat (from mammals other than marine mammals, in fat) | 1 |
| | Milks | 0.05 |
| European Union | Muscle, all mammalian species | 0.02 |
| | Fat, all mammalian species | 0.02 |
| | Liver, all mammalian species | 0.02 |
| | Kidney, all mammalian species | 0.02 |
| | Edible offals (other than liver and kidney), all mammalian species | 0.02 |
| | Milk | 0.02 |
| Canada | Meat of cattle | 0.01 |
| | Meat byproducts of cattle | 0.01 |
| China | Mammalian meat (except marine mammals) expressed as residue in fat | 1 |
| | Mammalian offal | 2 |
| | Milk | 0.05 |
| Japan | Muscle, all mammalian species | 0.1 |
| | Fat, all mammalian species | 1 |
| | Liver, all mammalian species | 2 |
| | Kidney, all mammalian species | 2 |
| | Edible offals (other than liver and kidney), all mammalian species | 2 |
| | Milk | 0.05 |

## 3.10 PROPOSAL TO SET MRLS FOR ISOFLUCYPRAM

It is proposed that MRLs are set for isoflucypram to support the GAP use of the compound on wheat, barley, triticale, and ryegrass seed crops, and to set MRLs in animal commodities to manage residues stemming from treated crops being used as animal feed.

There is currently no entry for isoflucypram in the Notice. The new entry 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) |
|---|---|---|---|---|
| Isoflucypram | 1255734-28-1 | Isoflucypram | Barley grain | 0.15 |
| | | | Eggs | 0.01(*) |
| | | | Mammalian fat | 0.04 |
| | | | Mammalian offal | 0.01(*) |
| | | | Mammalian meat | 0.01(*) |
| | | | Milk | 0.005(*) |
| | | | Poultry meat | 0.01(*) |
| | | | Poultry offal | 0.02 |
| | | | Wheat grain | 0.02 |
| | | | Triticale grain | 0.02 |

(*) 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 the use of the novel compound isoflucypram on grain crops in accordance with the application rates and withholding periods that are proposed as GAP in New Zealand.

### 3.10.2 Good Agricultural Practice

Isoflucypram is a pyrazole-carboxamide fungicide used on wheat, barley, triticale and ryegrass seed crops to control rusts, leaf blotches, and leaf spots. The compound is applied at a rate of 75 gai/ha as a single foliar spray application at the first appearance of disease, and can be applied up to early flowering (BBCH61) in barley and ryegrass seed crops and up to the end of flowering (BBCH69) in wheat and triticale. Use of isoflucypram attracts withholding periods of 56 days for barley grain, 42 days for triticale and wheat grain, 42 days for barley forage, 28 days for triticale and wheat forage, and 49 days for ryegrass seed crops as animal feed.

### 3.10.3 Residue Information

The residue data for the use of isoflucypram are sufficient to conclude that, when applied as per the proposed GAP use pattern and complying with the applicable withholding period, residues of parent isoflucypram should not exceed 0.13 mg/kg in barley grain and 0.02 mg/kg in wheat or triticale grain. Parent isoflucypram was the only residue detected in plant-derived food commodities, and is therefore sufficient to function as both the residue definition for GAP compliance and dietary intake assessments for these commodities.

For animals fed grain or other animal feeds derived from treated crops, residues of parent isoflucypram should not exceed 0.04 mg/kg in fat, 0.01 mg/kg in mammalian meat and offal, 0.005 mg/kg in milk, 0.02 mg/kg in poultry offal, and 0.01 mg/kg poultry meat and eggs when the applicable withholding periods are observed.

The metabolism of isoflucypram in animals was well characterised in the data. Though the parent compound was a dominant residue in tissues, there were also quantifiable concentrations of nine metabolites in various animal tissues, most significantly in animal livers. While a parent-only residue definition will be sufficient to manage GAP compliance due to parent isoflucypram being the most common residue in all animal tissues, the dietary intake definition will also need to include isoflucypram metabolites to ensure the dietary exposure residues are sufficiently evaluated. Animal commodities will therefore be subject to

a dietary intake residue definition evaluating the sum of isoflucypram and its free and conjugated –propanol, -2-propanol, -desmethyl-propanol metabolites, and its –desmethyl-propandiol, –carboxylic and -desmethyl-carboxylic acid metabolites, expressed as isoflucypram.

### 3.10.4 Dietary Risk Assessment

The HBGV of 0.028 mg/kg bw/d, and the stated dietary intake residue definitions, were considered appropriate for use in the assessment.

Based on the residue profile expected in food from crops treated with isoflucypram, as well as in animal products from livestock that are grazed on or fed treated crops or crop products, the NEDI is estimated to total less than 0.9% of the HBGV.

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

### 3.10.5 Relevant International MRLs

There are no MRLs set for isoflucypram by any international authority.

## 3.11 PROPOSAL TO AMEND THE MRLS FOR MANDESTROBIN

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

The revised entry for mandestrobin 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 limit applies | Food | Maximum Permitted Residue Level (mg/kg) |
|---|---|---|---|---|
| Mandestrobin | 173662-97-0 | Mandestrobin | Beans (with pods)<br>Bulb onions<br>**Head lettuce**<br>**Leafy lettuce** | 0.7<br>0.01(*)<br>**1.5**<br>**10** |

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

### 3.11.1 Amendment Rationale

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

### 3.11.2 Good Agricultural Practice

Mandestrobin is a strobilurin fungicide used to control white rot and downy mildew on bulb onions and *Sclerotina sclerotiorum* on beans. The new use for which MRLs are required is the control of *Sclerotinia* on head and leafy lettuce. The compound will be used as a spray at an application rate of 300 gai/ha prior to disease development after transplanting and at 7-14 day intervals, with no more than two consecutive applications per season. The use of mandestrobin on lettuces attracts a seven day withholding period.

### 3.11.3 Residue Information

The residue data for the use of mandestrobin on lettuces are sufficient to conclude that, when applied as per the proposed GAP use pattern and the withholding period is observed, residues of parent compound mandestrobin should not exceed 1.1 mg/kg in head lettuce and

8 mg/kg in leafy lettuce. The proposed MRLs of 1.5 mg/kg in head lettuce and 10 mg/kg in leafy lettuce are therefore sufficient to support GAP for the use of mandestrobin in lettuces.

The residue definition of parent mandestrobin for GAP compliance and mandestrobin plus its 4-OH-, 2-CH2OH- and De-Xy- metabolites for dietary intake were previously assessed as sufficient to manage residues in vegetables. Based on metabolism data in the new crops, these definitions are also considered appropriate to manage residues in lettuces. The current residue definition can therefore remain unchanged.

### 3.11.4 Dietary Risk Assessment

The HBGV of 0.133 mg/kg bw/d and the stated dietary intake residue definition, was considered appropriate for use in the assessment.

Based on the residue profile of mandestrobin expected in food from crops treated according to existing and proposed GAP uses, the NEDI is estimated to total less than 0.9% of the HBGV when the compound is used according to existing and proposed GAP uses.

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

### 3.11.5 Relevant International MRLs

There are no MRLs set for mandestrobin in head lettuce or leafy lettuce by Australia or Codex.

## 3.12 PROPOSAL TO AMEND THE MRLS FOR METRAFENONE

It is proposed that the MRLs for metrafenone are amended to support a revised GAP use of the compound on grapes. Because this compound has the potential for animal exposure, it is also proposed that the entry in the Notice is amended to include MRLs for animal commodities to manage residues from vineyard grazing.

The revised entry for metrafenone 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 limit applies | Food | Maximum Permitted Residue Level (mg/kg) |
|---|---|---|---|---|
| Metrafenone | 220899-03-6 | Metrafenone | Grapes<br>Mammalian fat<br>Mammalian meat<br>Mammalian offal<br>Milk<br>Pumpkin<br>Winter Squash | 0.15<br>0.01(*)<br>0.01(*)<br>0.01(*)<br>0.01(*)<br>0.01(*)<br>0.01(*) |

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

### 3.12.1 Amendment Rationale

The MRLs are being proposed to support a revised use for metrafenone on grapes, in accordance with the application rates and withholding periods that are proposed as GAP in New Zealand.

### 3.12.2 Good Agricultural Practice

Metrafenone is a benzophenone fungicide used to control powdery mildew in grapes. The compound was previously used at a rate of 10gai/100L of water sprayed at 14-21 day

intervals up to 80% cap-fall, with a maximum of two applications per season. The revised GAP for metrafenone uses the same application rate and maximum applications per season, but reduces the retreatment interval to 10-21 days and the withholding period to 42 days pre-harvest. A 14 day pre-grazing interval and a two month slaughter interval and clean feed period will apply to animals grazed in treated vineyards.

### 3.12.3 Residue Information

The residue data for the use of metrafenone on grapes are sufficient to conclude that, when applied as per the proposed GAP use pattern, residues of parent compound metrafenone should not exceed 0.1 mg/kg. The proposed MRL of 0.15 mg/kg in grapes is therefore sufficient to support GAP for the use of metrafenone in vineyards.

The information provided to support the revised use pattern was sufficient to confirm the risk of metrafenone residues in animal commodities will be similar to that previously assessed even with the change to the pre-grazing and slaughter intervals. Although the animal residue profile is essentially unchanged, animal commodity MRLs are being proposed to support GAP related to vineyard grazing and to provide clarity and transparency regarding animal exposure and MRL compliance. The animal metabolism and feeding study data is sufficient to conclude residues in all commodities from animals grazed in metrafenone-treated vineyards will remain below the limit of quantification, which is 0.01 mg/kg in all tissues and milk.

The residue definition, parent metrafenone, is sufficient to support GAP compliance and dietary intake for both plant and animal commodities in New Zealand.

### 3.12.4 Dietary Risk Assessment

The HBGV of 0.18 mg/kg bw/d and the stated dietary intake residue definition, was considered appropriate for use in the assessment.

Based on the residue profile of metrafenone expected in food from crops treated according to existing and proposed GAP uses, and in animal commodities exposed to the compound through vineyard grazing, the NEDI is estimated to total less than 0.04% of the HBGV when the compound is used according to existing and proposed GAP uses.

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

### 3.12.5 Relevant International MRLs

| Country | Food | Maximum Residue Level (mg/kg) |
|---|---|---|
| Australia | Edible offal (Mammalian) | 0.05 |
| | Grapes | 1 |
| | Meat [mammalian] [in the fat] | 0.05 |
| | Milks | 0.01 |
| Codex | Edible offal (mammalian) | 0.01 |
| | Grapes | 5 |
| | Meat (from mammals other than marine mammals, in fat) | 0.01 |
| | Milks | 0.01 |
| European Union | Muscle, all mammalian species | 0.01 |
| | Fat, all mammalian species | 0.01 |
| | Liver, all mammalian species | 0.01 |
| | Kidney, all mammalian species | 0.01 |
| | Edible offals (other than liver and kidney), all mammalian species | 0.01 |
| | Milk | 0.01 |
| Japan | Muscle, all mammalian species | 0.01 |
| | Fat, all mammalian species | 0.01 |
| | Liver, all mammalian species | 0.01 |
| | Kidney, all mammalian species | 0.01 |
| | Edible offal (other than liver and kidney), all mammalian species | 0.01 |
| | Milk | 0.01 |

## 3.13 PROPOSAL TO SET MRLS FOR METRIBUZIN

It is proposed that MRLs are promulgated for metribuzin to support the GAP use of the compound on potatoes.

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

| Compound Common Name | CAS# | Residue to which the maximum residue limit applies | Food | Maximum Permitted Residue Level (mg/kg) |
|---|---|---|---|---|
| Metribuzin | 21087-64-9 | Metribuzin | Potatoes | 0.01(*) |

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

### 3.13.1 Amendment Rationale

The MRL is being proposed to support a new use for metribuzin in potatoes in accordance with the application rates and controls that are proposed as GAP in New Zealand.

### 3.13.2 Good Agricultural Practice

Metribuzin is a triazinone herbicide currently used on a variety of vegetable crops. The new use is as a pre-emergent broadcast soil treatment for potato crops at a rate of 440 gai/ha, together with 600 gai/ha of flufenacet. Use of metribuzin on potato crops attracts a restriction that it is not to be used after crop emergence.

### 3.13.3 Residue Information

The residue data for the use of metribuzin are sufficient to conclude that, when applied as per the proposed GAP use pattern and complying with the use restriction, residues of

metribuzin should not exceed the limit of quantification of 0.01 mg/kg in potatoes. The proposed MRL will therefore be sufficient to ensure compliance with GAP.

The data confirmed that the primary residue in potatoes is parent metribuzin. The residue definition can therefore be set at metribuzin for both GAP compliance and dietary intake.

### 3.13.4 Dietary Risk Assessment

The HBGV of 0.009 mg/kg bw/d and the stated dietary intake residue definition, was considered appropriate for use in the assessment.

Based on the residue profile expected in food from crops treated with metribuzin, the NEDI for the compound is estimated at less than 3% of the HBGV when the compound is used according to existing and proposed GAP uses.

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

### 3.13.5 Relevant International MRLs

| Country | Food | Maximum Residue Level (mg/kg) |
|---|---|---|
| Australia | Potato | 0.05 |

## 3.14 PROPOSAL TO SET MRLS FOR PYROXASULFONE

It is proposed that MRLs are set for pyroxasulfone to support the GAP use of the compound on wheat and triticale, and to set MRLs in animal commodities to manage residues resulting from treated crops being used as animal feed.

There is currently no entry for pyroxasulfone in the Notice. The new entry 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) |
|---|---|---|---|---|
| Pyroxasulfone | 447399-55-5 | Plant Commodities:<br>Pyroxasulfone and its M-1 metabolite ((5-difluoromethoxy-1-methyl-3-trifluoromethyl-1H-pyrazol-4-yl)methanesulfonic acid), expressed as pyroxasulfone.<br><br>Animal Commodities:<br>Pyroxasulfone and its M-3 (5-Difluoromethoxy-1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxylic acid) metabolite, expressed as pyroxasulfone | Eggs<br>Mammalian fat<br>Mammalian meat<br>Mammalian offal<br>Milk<br>Poultry meat<br>Poultry offal<br>Wheat grain<br>Triticale grain | 0.02(*)<br>0.02(*)<br>0.02(*)<br>0.02(*)<br>0.002(*)<br>0.02(*)<br>0.02(*)<br>0.01(*)<br>0.01(*) |

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

### 3.14.1 Amendment Rationale

The MRLs are being proposed to support the use of the novel compound pyroxasulfone on grain crops in accordance with the application rates, controls, and withholding periods that are proposed as GAP in New Zealand.

### 3.14.2 Good Agricultural Practice

Pyroxasulfone is an isoxazoline pre-emergent herbicide used on wheat and triticale to control grass weeds. The compound is applied at a rate of 106-128 gai/ha as a single broadcast spray application before crop emergence and not after the end of July. Use of pyroxasulfone attracts a 42 day livestock withholding period for forage and green feed.

### 3.14.3 Residue Information

The residue data for the use of pyroxasulfone are sufficient to conclude that, when applied as per the proposed GAP use pattern and complying with the applicable controls and withholding periods, residues of parent compound and its metabolites should not exceed 0.13 mg/kg in barley grain and 0.01 mg/kg in wheat or triticale grain. The residue trial work demonstrated that the predominant residues were low levels of the parent compound the M1 ((5-difluoromethoxy-1-methyl-3-trifluoromethyl-1H-pyrazol-4-yl)methanesulfonic acid) metabolite in grain crops. It is therefore considered that the parent compound and its M1 metabolite are appropriate markers for GAP compliance in plant commodities. Because the M3 (5-Difluoromethoxy-1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxylic acid) metabolite could also be present in low levels in food, parent pyroxasulfone residues and the residues of both the M1 and M3 metabolites are included in the residue definition for dietary intake purposes.

For animals fed grain or other animal feeds derived from treated crops, residues of parent pyroxasulfone should not exceed the limits of quantification specified in the proposed MRLs: 0.02 mg/kg for all animal tissues, 0.02 mg/kg in eggs, and 0.002 mg/kg in milk. The animal metabolism studies demonstrated that for animal commodities, the parent compound and the M3 metabolite were the most consistently detected (at very low levels), and are therefore the most appropriate compounds to target for GAP compliance. As with the plant commodities, both the M1 and M3 metabolites can occur in animal commodities and are therefore both are included in the dietary intake residue definition.

### 3.14.4 Dietary Risk Assessment

The HBGV of 0.0014 mg/kg bw/d, and the stated dietary intake residue definitions, were considered appropriate for use in the assessment.

Based on the residue profile expected in food from crops treated with pyroxasulfone, as well as in animal products from livestock that are grazed on or fed treated crops or crop products, the NEDI is estimated to total less than 8% of the HBGV.

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

### 3.14.5 Relevant International MRLs

| Country | Food | Maximum Residue Level (mg/kg) |
|---|---|---|
| Australia | Cereal Grains | 0.01 |
| | Edible offal (Mammalian) | 0.02 |
| | Eggs | 0.02 |
| | Meat [mammalian] | 0.002 |
| | Milks | 0.02 |
| | Poultry, Edible offal of | 0.02 |
| | Poultry meat | 0.01 |
| Canada | Meat and fat of horses | 0.1 |
| | Meat of sheep, goats, poultry, hogs, and cattle | 0.01 |
| | Fat of poultry | 0.1 |
| | Fat of sheep, goats, hogs, and cattle | 0.01 |
| | Meat byproducts of sheep, goats, poultry, hogs, cattle, and horses | 0.01 |
| | Milk | 0.001 |
| | Eggs | 0.01 |
| United States | Milk | 0.003 |

## 3.15 PROPOSAL TO SET MRLS FOR TETRANILIPROLE

It is proposed that MRLs are set for tetraniliprole to support the GAP use of the compound on pome fruits.

There is currently no entry for tetraniliprole in the Notice. The new entry 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) |
|---|---|---|---|---|
| Tetraniliprole | 1229654-66-3 | Tetraniliprole | Pome fruits | 0.2 |

### 3.15.1 Amendment Rationale

The MRLs are being proposed to support the use of the novel compound tetraniliprole on pome fruits in accordance with the application rate and withholding period that are proposed as GAP in New Zealand.

### 3.15.2 Good Agricultural Practice

Tetraniliprole is a diamide insecticide used on apples, pears, and nashi to control codling moth, leafroller caterpillars, and bronze beetles. The compound is applied at a rate of 3 gai/ha as a foliar spray application up to three times: once after petal fall, a repeat treatment applied at least 21 days later if required, and the option of a further application up to 14 days before harvest for late season control. Use of tetraniliprole attracts a 14 day withholding period.

### 3.15.3 Residue Information

The residue data for the use of tetraniliprole are sufficient to conclude that, when applied as per the proposed GAP use pattern and complying with the applicable withholding period, residues of tetraniliprole should not exceed 0.13 mg/kg in any fruit from treated crops. As such, the proposed MRL of 0.2 mg/kg will be sufficient to manage the GAP use of the compound.

The predominant residue in treated crops was parent tetraniliprole, with the tetraniliprole-N-methyl-quinazolinone metabolite being detectable in some plant commodities and processed food commodities at low levels. The residue definition for GAP compliance is therefore proposed to be set at parent tetraniliprole only, with the dietary intake definition to be set at the sum of tetraniliprole and its –quinazolinone metabolite expressed as tetraniliprole.

### 3.15.4 Dietary Risk Assessment

The HBGV of 0.62 mg/kg bw/d, and the stated dietary intake residue definition, were considered appropriate for use in the assessment.

Based on the residue profile expected in food from crops treated with tetraniliprole, the NEDI is estimated to total less than 0.02% of the HBGV.

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

### 3.15.5 Relevant International MRLs

There are no MRLs set for tetraniliprole by either Australia or Codex.

## 3.16 PROPOSAL TO EXEMPT CHROMOBACTERIUM SUBTSUGAE PRAA4-1T AND ITS METABOLITES (INCLUDING VIOLACEIN)

It is proposed that *Chromobacterium subtsugae* PRAA4-1T and its metabolites, including violacein, are included in Schedule 2 of the Notice. This will establish that the organism and its metabolites will be considered an agricultural chemical compound for which no MRLs apply.

*Chromobacterium subtsugae* PRAA4-1T is a soil isolate that is used as a biological insecticide on grape vines. The use of this organism and its metabolites falls outside the scope of the existing exemption for microbial active ingredients in Schedule 2 of the Notice because the residues of the metabolite violacein may exceed what would be expected of background levels. This means that the use of the organism and its metabolites, including violacein, requires its own exemption.

Because the organism loses viability during processing for agricultural chemical use, the final compound does not contain any living cells. The killed *Chromobacterium subtsugae* PRAA4-1T organisms themselves do not pose any food safety risks since at application they are non-viable, and when alive do not form spores and do not produce any toxic metabolites. The only quantifiable metabolite produced by the organism, violacein, has a very short half-life and is therefore unlikely to accumulate or be detectable in food. Furthermore, in the unlikely occurrence of detectable residues, the available data confirmed that violacein is unlikely to result in toxicity with any exposure level.

Based on the available data on the organism and its metabolites, it is therefore concluded that an exemption is appropriate.

There is currently no entry in Schedule 2 for *Chromobacterium subtsugae* PRAA4-1T or its metabolites.

The proposed entry in Schedule 2 will read:

| Substance | CAS# | Condition |
|---|---|---|
| *Chromobacterium subtsugae* PRAA4-1T and its metabolites, including violacein.<br>Excludes metabolites that have been isolated as independent compounds. | 64-18-6 | When used as an agricultural chemical. |

## 3.17 PROPOSAL TO AMEND THE EXEMPTION FOR BROMOCHLORODIMETHYLHYDANTOIN

It is proposed that the exemption from compliance with an MRL for Bromochlorodimethylhydantoin (BCDMH) in Schedule 2 of the Notice is amended by including all four CAS numbers associated with the compound in the entry. BCDMH was originally exempted based on how the compound is used in New Zealand and the low toxicity profile associated with that use. The use pattern and condition of exemption remains unchanged from that previously promulgated.

BCDMH is an isomeric mixture of four individual compounds in equilibrium, rather than a single compound attributed to one CAS number as it is currently entered into the schedule. The isomeric mixture includes the following constituents:

- 1-bromo-3-choloro-5,5-dimethyl-imidazolidine-2,4-dione (CAS number 16079-88-2);
- 3-bromo-1-choloro-5,5-dimethyl-imidazolidine-2,4-dione (CAS number 126-06-7);
- 1,3-dicholoro-5,5-dimethyl-imidazolidine-2,4-dione (CAS number 118-52-5);
- 1,3-dibromo-5,5-dimethyl-imidazolidine-2,4-dione (CAS number 77-48-5); and
- CAS number 32718-18-6, a mixture of CAS numbers 16079-88-2 and 126-06-7 above.

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

| Substance | CAS# | Condition |
|---|---|---|
| Bromochlorodimethylhydantoin | 77-48-5; 118-52-5; 126-06-7; 16079-88-2; and 32718-18-6 | When applied as a biocide to fruits and vegetables. |

This amendment will better reflect the actual mixture of isomers that make up BCDMH when it is used as an agricultural chemical.

## 3.18 PROPOSAL TO EXEMPT CROSS-LINKED POLYACRYLAMIDE

It is proposed that cross-linked polyacrylamide is added to Schedule 3 of the Notice. Poly acrylamide is used in the form of an intra-articular injectable hydrogel as a treatment for arthritis in horse. When used in this manner, the compound is locally administered, locally acting, and is not systemically absorbed. This results in no quantifiable systemic residues from animals treated with polyacrylamide, and therefore no need to manage residues with the application of a MRL.

The entry will be specific to cross-linked polyacrylamide and the intra-articular use pattern, and will not apply to any other acrylamide compounds or agricultural compound uses.

The proposed entry in Schedule 3 will read as follows:

| Substance | CAS# | Condition |
|---|---|---|
| Cross-linked polyacrylamide | 9003-05-8 | When used as an intra-articular injectable veterinary medicine in horses. |

## 3.19 PROPOSAL TO EXEMPT VACCINE AND DIAGNOSTIC ANTIGENS

It is proposed that vaccine and diagnostic antigens are made exempt from compliance with an MRL in Schedule 3 of the Notice. Antigens are cells, subunits, or proteins administered to elicit an immune response in the treated animal. These antigens do not result in residues in treated animals and therefore do not pose residue risks for animal-derived commodities. This exemption is being proposed to ensure clarity regarding veterinary vaccines, and the management of residues in veterinary medicines that contain both biological and chemical active ingredients.

The proposed entry in Schedule 3 will read as follows:

| Substance | CAS# | Condition |
|---|---|---|
| Vaccine and Diagnostic Antigens<br>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. |