New Zealand Food Safety
Haumaru Kai Aotearoa

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

New Zealand Food Safety Discussion Paper No: 2021/07

Prepared for public consultation
By New Zealand Food Safety

ISBN No: 978-1-99-102610-1 (online)
ISSN No: 2624-0157 (online)

**17 December 2021**

New Zealand Government

Ministry for Primary Industries
Manatū Ahu Matua

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# 1 Request for 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 (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.

**Do you oppose a MRL in Schedule 1 or listing in Schedule 3 being set or deleted <u>at all</u> for this compound or for a commodity?**

**If a MRL in Schedule 1 or listing in Schedule 3 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?**

**On balance, do you oppose any of the commodity MRLs in Schedule 1 or details of the listing in Schedules 3 proposed for this compound?**

Submissions close at 5pm on **15 February 2022**. 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 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 direct management of plants and animals, and include all agricultural chemicals (e.g. fungicides, herbicides, and insecticides), veterinary medicines, and other compounds used to maintain plant and animal health and productivity. Growers and farmers use these agricultural compounds to manage disease in animals and crops, protect the food supply, and maximise the quantity and quality of the food they grow.

Agricultural compound use can leave residues in the food harvested from treated crops and animals. To manage these residues, it is important to ensure that only the appropriate amount of an agricultural compound is used to achieve its intended purpose and leave the smallest amount of residue practicable without compromising the compound's efficacy. The set of principles and methods used to manage that balance is known as good agricultural practice (GAP). These principles apply to the production of safe and good quality horticultural, agricultural, and animal products. Maximum residue levels (MRLs) are then established for each compound/food commodity combination by evaluating the residues left in food commodities as a result of the highest authorised GAP use (the 'critical GAP'). This value is compared against the health-based guidance value before a maximum level of agricultural compound residue allowable in that food commodity is set. How the MRLs are determined, and how they are used once they have been set, are 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), proposals for new and amended MRLs are notified to the World Trade Organization. Any country may choose to comment if they believe a proposed MRL represents a barrier to their trade.

## 2.1 ESTABLISHING MAXIMUM RESIDUE LEVELS

### 2.1.1 Regulatory Structure

Maximum residue levels are the maximum legal levels of agricultural compound residues permitted in food for sale in New Zealand, and are set out in the New Zealand (Maximum Residue Levels for Agricultural Compounds) Food Notice. This Notice is updated up to four times a year to reflect changes in the use of agricultural compounds in the production of food. The 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 Notice, with the final decision on any changes to the Notice resting with the Director-General of MPI. The Notice is issued under section 405 of the Food Act 2014. When setting or amending MRLs, the Director-General must follow, as far as practicable, international best practice on dietary intake assessment and setting of maximum residue levels. The requirements for the content of the Notice are set out in Part 6

of the Food Regulations 2015 (the Food Regulations), allowing for the setting of MRLs for agricultural compounds as well as specifying compounds to which no MRL applies.

In addition to establishing the requirements for domestically produced foods, Part 6 of the Food Regulations also outlines the residue level compliance requirements for imported foods. Regulation 144 states that food must not contain residues of agricultural compounds unless the residue level does not exceed:

- the MRLs specified for that food in a notice set under the Food Act 2014 (regulation 144(1)(a)); or
- the default MRL of 0.1 mg/kg (regulation 144(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) (regulation 144(1)(d)).

These provisions allow for New Zealand Food Safety to set MRLs for imported food commodities when such levels are required. As imported food commodities can comply with either a Codex MRL or a MRL established in the Notice, New Zealand's obligations under the SPS Agreement are met.

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

### 2.1.2 Determining Maximum Residue Levels

The first step in determining MRLs for an agricultural compound is establishing GAP for the use of the compound in the target species or crop. New Zealand Food Safety establishes GAP by evaluating public health, crop safety, animal health and safety, occupational, and environmental safety considerations for the range of treatments and use patterns approved and proposed for each compound. Once GAP has been established for an agricultural compound, the residues resulting from the highest authorised dose or application rate and use pattern, which is likely to give rise to the highest residues (the 'critical GAP') is then used to determine the maximum residue levels (MRLs) in food commodities from treated crops and animals that will ensure conformance to New Zealand GAP.

Although the primary function of MRLs is to ensure conformance with established New Zealand GAP, the MRLs also play a role in managing dietary exposure and risks to trade in food commodities. To ensure the MRLs will effectively manage residues related to those risks, a national estimated daily intake or NEDI calculation is conducted to evaluate consumption risk and a review of all international MRLs for the compound/commodity combinations being considered is completed to evaluate trade risk. If it is found that the MRL being considered may pose a food safety or trade risk, the proposed MRL is not progressed.

Where it has been determined that MRLs can be set, those MRLs are proposed for inclusion in the Notice. Animal commodity MRLs will be proposed for the species in which a veterinary medicine is approved for use. MRLs may be proposed for a specific species (e.g. cattle, chicken) or a species group (e.g. mammalian, poultry) depending on the residue and metabolism profile of the agricultural compound being considered. Where an agricultural chemical is used on a crop from which both food and feed commodities are derived, MRLs will be proposed for both the crop intended for human consumption and animal commodities for the species or species group to which the feed commodity is fed. If an agricultural chemical is only used on an animal feed commodity such as pasture from which there are no foods harvested for human consumption, only animal commodity MRLs will be proposed.

### 2.1.3 Estimating Chronic Dietary Exposure

*National estimated daily intake*

The objective of the estimated chronic dietary exposure is to determine whether residues in food commodities will pose an unacceptable risk to consumers as a result of the authorised use of an agricultural compound according to established GAP. This exposure is estimated by calculating the national estimated daily intake (NEDI) in accordance with Guidelines for predicting dietary intake of pesticide residues (revised) [World Health Organization, 1997].

The NEDI calculation uses the total residues in food derived from all New Zealand authorised uses of an agricultural compound, including all toxicologically significant residues, and regional dietary consumption data derived from the 1997 National Nutritional Survey for adults and the 1995 National Nutrition Survey of Australia for children. The calculated NEDI is then compared with the health based guidance value (HBGV) associated with the compound; if the total residues derived from all uses of the agricultural compound is estimated to be less than the HBGV, the dietary exposure is unlikely to pose a health risk to consumers.

*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. Both values 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. A $PDE_{(food)}$ gives the potential daily exposure to a substance that a person may be subject to via food, and is the food-specific part of a set of values for different exposure pathways comprising the NZ EPA's assessment of acceptable daily exposure (ADE) for an agricultural compound.

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.

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 NEDI is compared with an ADI set by the WHO/FAO joint expert committees, the Australian Pesticides and Veterinary Medicines Authority, the European Food Safety Authority, or another regulatory authority. If none of these are available, the HBGV used will be a New Zealand Food Safety-determined ADI.

### 2.1.4 International MRLs and Trade

Because New Zealand MRLs are based on domestic GAP, they may differ from the MRLs established overseas for the use of the same compound in the same target species or crop if the GAP used to set those MRLs are different. To ensure the New Zealand MRLs will not unduly impact trade, the MRLs set by Codex and a selection of other international regulatory bodies are reviewed to evaluate trade risk.

For animal commodities, the MRLs set by 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 also reviewed and compared if there is a particular trade risk to be considered for those regions.

Where there are international MRLs to be considered in the trade assessment for the proposal, these are included in a table in the "Relevant International MRLs" section of each proposal entry. This table includes all MRLs for the agricultural compound/food commodity combinations for which new or amended New Zealand MRLs are being proposed; international MRLs for other commodities for which New Zealand MRLs already exist are not included. If there are no MRLs set by an international authority for a particular compound/commodity combination, the authority is not listed in the table.

### 2.1.5 Agricultural Compounds for Which No Maximum Residue Level Applies

Not all agricultural compounds require an MRL to manage their use in crops or animals. This may be because there are no residues present due to the properties of the compound such as rapid elimination from the plant, animal, or their environment, or because there are no food safety or trade risks associated with the residues that are present. Regulation 141 of the Food Regulations allows for the listing of specified compounds that fit these criteria as agricultural chemicals or veterinary medicines for which no MRL applies. These compounds are listed in Schedule 2 and Schedule 3 of the Notice, respectively, and the conditions of listing can be set for a particular use, a particular animal or crop, or general use as an agricultural chemical or veterinary medicine.

Agricultural chemicals and veterinary medicines being considered for listing as compounds for which no MRL applies undergo a similar scientific assessment of their use as that undertaken for MRL assessment. This assessment is done 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. It includes establishing the GAP use of the compound, the relevant metabolism and residue information, and the potential risks posed to public health and trade. The assessment may also include an assessment of dietary exposure when considered necessary to fully assess the risks.

Where New Zealand Food Safety has determined that an MRL is not required, the compound is proposed for listing in Schedule 2 (for agricultural chemicals) or Schedule 3 (for veterinary medicines) with conditions on their use to ensure the listing applies only to those situations that have been evaluated. If a compound listed in Schedule 2 or 3 is used in a way that does not meet the specified condition, the default MRL applies to food derived from treated plants or animals. Each proposal for inclusion in Schedule 2 or 3 includes a discussion of the rationale behind the considerations for listing, and a discussion of the assessed risks and proposed conditions.

## 2.2 SUMMARY OF PROPOSED AMENDMENTS

The proposed MRLs have been thoroughly assessed in accordance with international methodologies published by the OECD, VICH, or FAO. Information on the technical assessment of each proposal is included in this document (refer section 3) and covers:

- the new or amended entry proposed for inclusion in the Notice;
- the rationale for the new entry or amendment being proposed;
- New Zealand good agricultural practice for the compound and target crop or species;
- the relevant residues information used in determining the proposed MRLs;

- a summary of the dietary risk and public health assessment; and
- the MRLs set by Codex and other authorities (e.g. Australia, Canada, China, EU, Japan, USA) relevant to the new or amended entry.

Where an existing entry is proposed for revision, new or revised entry content is listed in bold print, and content proposed for removal is identified by a strikethrough.

The MRL compliance and dietary risk assessment residue definitions are included in the residues information section of the proposal. The HBGV used to compare to the NEDI calculation and determine the potential public health risk is included in the dietary risk and public health assessment section of the proposal.

### 2.2.1 Amendments to Schedule 1: Maximum Residue Levels for Agricultural Compounds

MPI proposes to make the following changes to Schedule 1 of the Notice:

- The amendment of the existing entries in the Notice for the following compounds:
    - Chloramphenicol, to amend the MRL for 'any food' from 0.0003(*) mg/kg to 0.00015(*) mg/kg;
    - Febantel, to amend the MRLs to 0.05 mg/kg in mammalian fat, 0.05 mg/kg in mammalian kidney, 0.5 mg/kg in mammalian liver, and 0.05 mg/kg in mammalian meat;
    - Mefentrifluconazole, to set MRLs at 0.07 mg/kg in grapes, and 0.01(*) mg/kg in pome fruits; and
    - Methomyl, to remove the MRL for 'pome fruits'.
- The removal of the entries in the Notice for azaconazole, fenarimol, fenbuconazole, and tolylfluanid.

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

### 2.2.2 Amendments to Schedule 3: Veterinary Medicines for which No Maximum Residue Level Applies

- MPI proposes to add a new entry for adenosine and its 5'-mono-, 5'-di-, and 5'-triphosphates to the schedule for veterinary medicines for which no MRL applies. These compounds would not require compliance to an MRL when used in food-producing species as a vasodilator.
- MPI proposes to add a new entry for performic acid to the schedule for veterinary medicines for which no MRL applies. Performic acid would not require compliance to an MRL when used as an active ingredient in a teat sanitiser on dairy cattle.

# 3 Proposals

## 3.1 PROPOSAL TO DELETE THE NOTICE ENTRY FOR AZACONAZOLE

It is proposed that the following entry is deleted from Schedule 1 of the Notice:

| Compound Common Name | CAS# | Residue to which the maximum residue level applies | Food | Maximum Residue Level (mg/kg) |
|---|---|---|---|---|
| ~~Azaconazole~~ | ~~60207-31-0~~ | ~~Azaconazole~~ | ~~Citrus fruits~~<br>~~Pome fruits~~<br>~~Tomatoes~~ | ~~0.02(*)~~<br>~~0.02(*)~~<br>~~0.05~~ |

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

### 3.1.1 Amendment Rationale

The deletion is being proposed because the compound is no longer used as an agricultural compound in New Zealand (the last registered agricultural compound containing azaconazole was de-registered in 2017). Azaconazole MRLs are therefore no longer required to manage GAP use of the compound in New Zealand.

## 3.2 PROPOSAL TO AMEND THE MRL FOR CHLORAMPHENICOL

It is proposed that the Notice entry for chloramphenicol is amended to better enforce the exclusion of the compound from food commodities.

The revised 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) |
|---|---|---|---|---|
| Chloramphenicol | 56-75-7 | *Sum of:*<br>chloramphenicol,<br>chloramphenicol glucuronide<br>*Expressed as:*<br>chloramphenicol | Any food | **0.00015(*)** |

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

### 3.2.1 Amendment Rationale

The revised entry is being proposed to align the MRL for chloramphenicol with expectations established by the EU and other overseas authorities. The compound is not approved for use as an agricultural compound in New Zealand, and therefore the MRL exists solely to prevent residues of chloramphenicol in any food commodities. It is considered that alignment of the New Zealand MRL with the lower level expected by international authorities will better support that initiative.

Chloramphenicol is not approved for use in New Zealand as a veterinary medicine.

## 3.3 PROPOSAL TO AMEND THE MRLS FOR FEBANTEL

It is proposed that the Notice entry for febantel is amended to align the MRLs with those established for fenbendazole and oxfendazole.

The revised 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) |
|---|---|---|---|---|
| Febantel | 58306-30-2 | *Sum of:*<br>Fenbenzole<br>Oxfendazole<br>Fenbendazole sulphone<br>*Expressed as:*<br>Fenbendazole sulphone | **Mammalian fat**<br>**Mammalian kidney**<br>**Mammalian liver**<br>**Mammalian meat** | **0.05**<br>**0.05**<br>**0.5**<br>**0.05** |

### 3.3.1 Amendment Rationale

The revised entry is being proposed to align the MRLs for febantel with those set for the other two agricultural compounds that share the same residue definition: fenbendazole and oxfendazole. This change will align the approach to these three compounds with that established by Codex and other international authorities.

Febantel is a benzimidazole pro-drug used as an endoparasiticide in companion animal and food-producing species at similar dose rate to fenbendazole. Febantel and fenbendazole also share a common metabolic pathway and residue profile as febantel is converted to fenbendazole in the animal after administration. As such, it is expected that residues from the administration of febantel will remain less than 0.5 mg/kg in liver and 0.05 mg/kg in all other tissues. The residue definition remains appropriate for both GAP compliance and dietary intake assessment for animal commodities.

### 3.3.2 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 assessment of the more stratified febantel MRLs. Based on the residue profile expected from all animal commodities, the NEDI is estimated to total less than 22% of the HBGV.

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

### 3.3.3 Relevant International MRLs

| Country | Food | Maximum Residue Level (mg/kg) |
|---|---|---|
| Codex<br>(Febantel/Fenbendazole/Oxfendazole) | Cattle, goat, horse, pig, and sheep muscle, fat, and kidney<br>Cattle, goat, horse, pig, and sheep liver<br>Cattle and sheep milk | 0.1<br>0.5<br>0.1 |
| China<br>(Febantel/Fenbendazole/Oxfendazole) | Cattle/Sheep/Swine/Horse Muscle<br>Cattle/Sheep/Swine/Horse Fat<br>Cattle/Sheep/Swine/Horse Liver<br>Cattle/Sheep/Swine/Horse Kidney<br>Cattle/Sheep Milk | 0.1<br>0.1<br>0.5<br>0.1<br>0.1 |
| EU<br>(Febantel) | All ruminants, porcine, *Equidae* muscle<br>All ruminants, porcine, *Equidae* fat<br>All ruminants, porcine, *Equidae* Liver<br>All ruminants, porcine, *Equidae* kidney<br>All ruminants milk | 0.05<br>0.05<br>0.5<br>0.05<br>0.01 |

| Country | Food | Maximum Residue Level (mg/kg) |
|---|---|---|
| Japan<br>(Oxfendazole, febantel, and fenbendazole) | Cattle, pig, and other terrestrial mammals, muscle<br>Cattle, pig, and other terrestrial mammals, fat<br>Cattle, pig, and other terrestrial mammals, liver<br>Cattle, pig, and other terrestrial mammals, kidney<br>Cattle, pig, and other terrestrial mammals, edible offal<br>Milk | 0.1<br>0.1<br>0.5<br>0.1<br>0.1<br>0.1 |

## 3.4 PROPOSAL TO DELETE THE NOTICE ENTRY FOR FENARIMOL

It is proposed that the following entry is deleted from Schedule 1 of the Notice:

| Compound Common Name | CAS# | Residue to which the maximum residue level applies | Food | Maximum Residue Level (mg/kg) |
|---|---|---|---|---|
| ~~Fenarimol~~ | ~~60168-88-9~~ | ~~Fenarimol~~ | ~~Grapes~~<br>~~Pome fruits~~ | ~~0.1~~<br>~~0.1~~ |

### 3.4.1 Amendment Rationale

The deletion is being proposed because the compound is no longer used as an agricultural compound in New Zealand (the last registered agricultural compound containing fenarimol was de-registered in 2009). Fenarimol MRLs are therefore no longer required to manage GAP use of the compound in New Zealand.

## 3.5 PROPOSAL TO DELETE THE NOTICE ENTRY FOR FENBUCONAZOLE

It is proposed that the following entry is deleted from Schedule 1 of the Notice:

| Compound Common Name | CAS# | Residue to which the maximum residue level applies | Food | Maximum Residue Level (mg/kg) |
|---|---|---|---|---|
| ~~Fenbuconazole~~ | ~~114369-43-6~~ | ~~Fenbuconazole~~ | ~~Pome fruits~~ | ~~0.02~~ |

### 3.5.1 Amendment Rationale

The deletion is being proposed because compound is no longer used as an agricultural compound in New Zealand (the last registered agricultural compound fenbuconazole was de-registered in 2015). Fenbuconazole MRLs are therefore no longer required to manage GAP use of the compound in New Zealand.

## 3.6 PROPOSAL TO AMEND THE MRLS FOR MEFENTRIFLUCONAZOLE

It is proposed that the Notice entry for mefentrifluconazole is amended to support the GAP use of the compound on pome fruits and grapes.

The revised 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) |
|---|---|---|---|---|
| Mefentrifluconazole | 1417782-03-6 | Mefentrifluconazole | Barley grain | 2 |
| | | | Eggs | 0.01(*) |
| | | | **Grapes** | **0.07** |
| | | | Mammalian fat | 0.1 |
| | | | Mammalian kidney | 0.1 |
| | | | Mammalian liver | 0.3 |
| | | | Mammalian meat | 0.02 |
| | | | Milk | 0.02 |
| | | | **Pome fruits** | **0.01(*)** |
| | | | Poultry fat | 0.02 |
| | | | Poultry meat | 0.01(*) |
| | | | Poultry offal | 0.02 |
| | | | Wheat grain | 0.5 |

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

### 3.6.1 Amendment Rationale

The revised entry is being proposed to support the use of mefentrifluconazole for control of powdery mildew in grapes and apples, and black spot in apples and pears, as part of a preventative programme in accordance with the use patterns and withholding periods considered GAP in New Zealand.

### 3.6.2 Good Agricultural Practice

Mefentrifluconazole belongs to the DMI triazole group of fungicides, and acts by blocking ergosterol biosynthesis. It is a systemically acting compound with protectant activity, and is currently approved for control of certain fungal diseases in barley and wheat.

Good agricultural practice for control of powdery mildew on grapes in New Zealand has been determined to be use of mefentrifluconazole for a maximum of two foliar applications of 6 gai/100L water up to pre-bunch closure (BBCH 77-78). To control powdery mildew and black spot in apples, and black spot in pears, GAP use is a maximum of four foliar applications of 6 gai/100L water up till 80% petal fall (BBCH 67-68) in a preventative programme incorporating fungicides with a different mode of action.

The withholding periods considered GAP for use of mefentrifluconazole on crops are application no later than pre-bunch closure in grapes, and application no later than 80% petal fall in apples and pears. The withholding periods associated with animal grazing are a six-month slaughter withholding period after leaf plucking from when stock has been removed from the vineyard, and a restriction that stock must not be allowed to graze within treated crops until after harvest.

### 3.6.3 Residue Information

The residue data for mefentrifluconazole were sufficient to conclude that, when used on apples, pears and grapes as per GAP and complying with the applicable withholding periods, residues of mefentrifluconazole should not exceed 0.07 mg/kg in grapes and not exceed the limit of quantification (0.01 mg/kg) in apples and pears. The residue data supplied for apples and pears were sufficient for extrapolation to the pome fruits crop grouping.

The additional potential dietary residue burden in animals was considered in light of the new uses, with potential feed exposure through vineyard and orchard grazing and the use of grape pomace as animal feed. After an evaluation of the established GAP and the GAP for the new uses with respect to animal grazing and feed consumption, it was determined that the new uses had a negligible impact on the estimated feed residue burden. With the application of the proposed six-month slaughter interval for sheep used in vineyard leaf plucking, and the label statement restricting 'general grazing' until after harvest, it is considered that the existing animal commodity MRLs will be complied with.

The residue definition of 'mefentrifluconazole' remains appropriate for both GAP compliance and dietary intake assessment for plant and animal commodities.

### 3.6.4 Dietary Risk Assessment

The HBGV of 0.025 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 from all horticultural and animal commodities, the NEDI is estimated to total less than 5% of the HBGV.

MPI has therefore determined that the authorised use of mefentrifluconazole is unlikely to pose any health risks from authorised use.

### 3.6.5 Relevant International MRLs

| Country | Food | Maximum Residue Level (mg/kg) |
|---|---|---|
| Australia | Apple<br>Grapes | 1<br>1 |

## 3.7 PROPOSAL TO AMEND THE MRL FOR METHOMYL

It is proposed that the entry for methomyl is amended to remove the MRL in pome fruits.

The revised 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) |
|---|---|---|---|---|
| Methomyl | 16752-77-5 | Sum of: Methomyl and thiodicarb<br>Expressed as: Methomyl | Beans<br>Berries and other small fruits<br>Brassica vegetables<br>Cereal grains<br>Fruiting vegetables (cucurbits)<br>Fruiting vegetables (except cucurbits)<br>Lettuce<br>~~**Pome fruits**~~ | 0.2<br>0.5<br>0.2<br>0.2<br>0.2<br>0.5<br>0.2<br>~~**1**~~ |

### 3.7.1 Amendment Rationale

The revision is being proposed due to the compound not being approved for use in pome fruits under the Agricultural Compounds and Veterinary Medicines Act 1997 (the ACVM Act). A specified MRL for pome fruit is therefore no longer required to manage GAP use of the compound in New Zealand.

## 3.8 PROPOSAL TO DELETE THE NOTICE ENTRY FOR TOLYLFLUANID

It is proposed that the following entry is deleted from Schedule 1 of the Notice:

| Compound Common Name | CAS# | Residue to which the maximum residue level applies | Food | Maximum Residue Level (mg/kg) |
|---|---|---|---|---|
| ~~Tolylfluanid~~ | ~~731-27-1~~ | ~~Tolylfluanid~~ | ~~Grapes~~<br>~~Pome fruits~~ | ~~0.02(*)~~<br>~~0.1~~ |

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

### 3.8.1 Amendment Rationale

The deletion is being proposed because the compound is no longer used as an agricultural compound in New Zealand (the last registered agricultural compound containing tolylfluanid was de-registered in 2012). Tolylfluanid MRLs are therefore no longer required to manage GAP use of the compound in New Zealand.

## 3.9 PROPOSAL TO ADD AN ENTRY FOR ADENOSINE AND ITS 5'-MONO-, 5'-DI-, AND 5'-TRIPHOSPHATES TO SCHEDULE 3

It is proposed that adenosine and its 5'-mono-, 5'-di-, and 5' triphosphates are added to Schedule 3 of the Notice to identify these compounds as veterinary medicines to which no MRL applies. Adenosine 5'-mono- and 5'-diphosphate are natural endogenous compounds which play a key role in cellular metabolism as a component of adenosine 5'-triphosphate (ATP). As a veterinary medicine, adenosine 5'-monophosphate is used as a vasodilator primarily to increase cardiac and skeletal muscle circulation and thereby prevent and manage exercise-induced pathology.

When administered to food-producing animals, adenosine 5'-monophosphate is rapidly converted to adenosine 5'-diphosphate and then ATP within minutes, with the adenosine phosphate compounds being indistinguishable from naturally occurring endogenous nucleotides and their metabolic breakdown products. As such, the use of adenosine 5'-monophosphate, and its 5'-di and 5'-triphosphate derivatives, is not expected to pose risks to either food safety or trade when used as a veterinary medicine. These compounds can therefore be listed in Schedule 3 as veterinary medicines for which no MRL applies, with a general condition of use as a veterinary medicine in food-producing animals. This is the same approach taken to these compounds as other overseas authorities such as the EU.

The proposed new entry in Schedule 3 will read as follows:

| Substance | CAS# | Condition |
|---|---|---|
| **Adenosine and its 5'-mono-, 5'-di-, and 5' triphosphates** | **n/a** | **When used as a veterinary medicine.** |

## 3.10 PROPOSAL TO ADD AN ENTRY FOR PERFORMIC ACID TO SCHEDULE 3

It is proposed that performic acid is added to Schedule 3 of the Notice to identify it as a veterinary medicine to which no MRL applies. When used as a post-milking teat sanitiser performic acid is rapidly converted to formic acid and hydrogen peroxide, compounds which are naturally present in milk. Due to the rapid clearance of the compound and a lack of systemic absorption after topical use, it is expected that residues of performic acid in both milk and tissues will be negligible after use. It is therefore considered that residues of

performic acid do not need to be managed through the application of a MRL when the compound is used as a teat sanitiser.

The proposed new entry in Schedule 3 will read as follows:

| Substance | CAS# | Condition |
|---|---|---|
| **Performic acid** | **107-32-4** | **When used as a teat sanitiser in dairy cattle** |