New Zealand Food Safety
Haumaru Kai Aotearoa

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

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by New Zealand Food Safety

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Te Kāwanatanga o Aotearoa
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Ministry for Primary Industries
Manatū Ahu Matua

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

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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.

**Do you agree or disagree with the proposed addition, amendment or deletion?**

**For compounds listed in Schedule 1, do you agree or disagree with the proposed MRL(s)?**

Please feel free to include with your answers above, any supporting discussion, data or examples that you feel are relevant.

Submissions close at 5pm on **13 November 2023**. 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. The Ministry for Primary Industries 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 lowest amount of an agricultural compound is used to consistently achieve its intended purpose. This will 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

MRLs are the maximum legal levels of agricultural compound residues permitted in food for sale in New Zealand and are set out in the Notice. The 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 efficacy, crop safety, and animal health and safety 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 MRLs in food commodities from treated crops and animals.

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 for approved or proposed agricultural compound uses. For veterinary medicines, MRLs may be proposed for animal products from 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. Similarly, for agricultural chemicals, an MRL may be set for an individual crop or crop product (e.g., avocado, wheat grains) or for a crop grouping (e.g., pome fruits). When it has been determined that assigning an MRL to a crop grouping is appropriate, the grouping used aligns with the Codex classifications of foods and animal feeds.

For agricultural chemicals used on a crop from which both food and animal feed commodities are derived, MRLs are proposed for both the food commodities intended for human consumption from the treated crop, and animal commodities for the species or species group to which the feed commodity is fed. If the compound for which the MRLs are set is also used as a veterinary medicine, all approved veterinary and agricultural chemical uses are

considered when setting the animal commodity MRLs. If an agricultural chemical is used on a crop from which only animal feed is harvested (e.g., pasture, fodder crops), 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 the 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 commonly reviewed and compared; for horticultural commodities, MRLs set by Codex and Australia are commonly reviewed and compared. Other international MRLs may also be reviewed and compared if there is a particular trade risk to be considered for those regions for any exported commodity.

Where there are relevant 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 of 0.1 mg/kg will apply 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 that are 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:

- Amendment of the entry for **fenpyrazamine**, to set the MRL for grapes to 0.05 mg/kg;
- Amendment of the entry for **fenpyroximate**, to set a new MRL at 0.15 mg/kg for avocado;
- Amendment of the entry for **fluxapyroxad**, to set MRLs at 0.15 mg/kg for wheat, ryecorn and triticale grain; and 0.9 mg/kg for barley and oat grain;
- Amendment of the entry for **mefentrifluconazole**, to set MRLs at 0.5 mg/kg for ryecorn and triticale grain; and 3 mg/kg for barley and oat grain; and
- Amendment of the entry for **sulfoxaflor**, to set MRLs at 0.01 mg/kg for eggs, poultry fat, and poultry meat; 0.03 mg/kg for poultry offal; and 0.2 mg/kg for mammalian offal which will replace existing MRLs for mammalian kidney and liver.

# 3 Proposals

## 3.1 Proposal to amend the MRLs for fenpyrazamine

It is proposed that the MRL for fenpyrazamine is amended to support the GAP use of the compound in grapes.

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) |
|---|---|---|---|---|
| Fenpyrazamine | 473798-59-3 | Fenpyrazamine | Grapes | **0.05** |

### 3.1.1 Amendment Rationale

The current MRL of 3 mg/kg in grapes was set as a result of a request from an overseas trading partner, where GAP includes later application timing (up to veraison). This had led to the need for a higher MRL than would be applied if use was limited to that considered GAP in New Zealand. Now that Codex has completed their review of fenpyrazamine and set an MRL of 3.0 mg/kg for grapes based on the overseas use pattern to facilitate trade, the New Zealand MRL for grapes for fenpyrazamine can be amended to 0.05 mg/kg to support domestic GAP.

### 3.1.2 Good Agricultural Practice

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

For the use of sheep for leaf plucking in vineyards, a 6 month slaughter interval has been established to manage residues in animal commodities.

### 3.1.3 Residue Information

The residue data for the use of fenpyrazamine on wine grapes are sufficient to conclude that, when used according to the current NZ GAP, residues of fenpyrazamine should not exceed 0.05 mg/kg in grapes. Residues are not expected in animal commodities as a result of sheep leaf-plucking in vineyards.

The current residue definitions for plant commodities remain appropriate. The definition for GAP compliance is ‘Fenpyrazamine’ (parent only); and for dietary intake risk assessment the definition is ‘fenpyrazamine plus its S-2188-DC metabolite, expressed as parent compound’. The correction factor for the metabolite is 1.43. No residue definitions have been proposed in animal commodities, and no animal commodity MRLs are required.

### 3.1.4 Dietary Risk Assessment

The HBGV of 0.091 mg/kg bw/d was considered appropriate for use in the assessment.

Based on the proposed MRL, the NEDI for fenpyrazamine is equivalent to less than 0.2% of the HBGV. It is therefore concluded that the risk associated with chronic dietary exposure is small and is unlikely to pose any health risks from authorised use.

### 3.1.5 Relevant International MRLs for Fenpyrazamine

| Authority | Food | Maximum Residue Level (mg/kg) |
|---|---|---|
| Australia | Dried Grapes (currants, raisins, and sultanas)<br>Table Grapes<br>Wine Grapes | 10<br>3<br>0.05 |
| Codex | Grapes | 3 |

## 3.2 Proposal to amend the MRLs for fenpyroximate

It is proposed that a new MRL is set to support a new use of the compound in avocado.

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) |
|---|---|---|---|---|
| Fenpyroximate | 134098-61-6 | Fenpyroximate | **Avocado**<br>Pome fruits | **0.15**<br>0.1 |

### 3.2.1 Amendment Rationale

An MRL is being proposed to support a new use to control six-spotted mite in avocado.

### 3.2.2 Good Agricultural Practice

Fenpyroximate is a phenoxy pyrazole insecticide, used as a non-systemic miticide with knockdown and residual activity in mobile stages of mites and moulting of immature stages at lower doses. The proposed use pattern for control of six-spotted mite in avocado is one foliar application of 3.75 gai/100 L water per season once mite thresholds have been reached, with a withholding period of 14 days. The current use is for control of European red mite and two-spotted mite on pome fruit.

### 3.2.3 Residue Information

The residue data for the use of fenpyroximate on avocado are sufficient to conclude that, when used according to the proposed GAP, residues of fenpyroximate should not exceed 0.15 mg/kg in avocado.

The current residue definition of 'fenpyroximate' for GAP compliance and dietary intake estimation remains appropriate for plant and animal commodities. Animal commodity MRLs are not required as the target crops are not considered animal feed commodities.

### 3.2.4 Dietary Risk Assessment

The HBGV of 0.025 mg/kg bw/d was considered appropriate for use in the assessment.

Based on the residue profile expected in food from crops treated with fenpyroximate the NEDI is estimated to total less than 6% of the HBGV for average adult New Zealander. The use of fenpyroximate is unlikely to pose any health risks from authorised use.

### 3.2.5 Relevant International MRLs for Fenpyroximate

| Authority | Food | Maximum Residue Level (mg/kg) |
|---|---|---|
| Australia | All other foods except animal commodities | 0.1 |
| Codex | Avocado | 0.2 |

## 3.3 Proposal to amend the MRLs for fluxapyroxad

It is proposed that MRLs are set to support use of the compound in triticale, ryecorn and oats, and a change in withholding period when used in cereal crops.

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)* |
|---|---|---|---|---|
| Fluxapyroxad | 907204-31-3 | Fluxapyroxad | Apples | 0.02 |
| | | | **Barley grain** | **0.9** |
| | | | Bulb vegetables | 0.2 |
| | | | Eggs | 0.01(*) |
| | | | Mammalian offal | 0.03 |
| | | | Mammalian fat | 0.05 |
| | | | Mammalian meat | 0.01(*) |
| | | | Milk | 0.005 |
| | | | **Oat grain** | **0.9** |
| | | | Pears | 0.02 |
| | | | Poultry fat | 0.01(*) |
| | | | Poultry meat | 0.01(*) |
| | | | Poultry offal | 0.01(*) |
| | | | **Rye grain** | **0.15** |
| | | | Stone fruits | 0.01(*) |
| | | | **Triticale grain** | **0.15** |
| | | | **Wheat grain** | **0.15** |
| | | | Winter squash | 0.01(*) |

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

### 3.3.1 Amendment Rationale

MRLs are proposed to support the control of rust and scald fungal diseases in the additional crops ryecorn, triticale and oats, and extend the current application timing in wheat and barley.

### 3.3.2 Good Agricultural Practice

Fluxapyroxad is a broad-spectrum pyrazole-carboxamide fungicide. It stunts fungus growth by inhibiting the succinate dehydrogenase enzyme. It is proposed that fluxapyroxad is used in the additional cereal crops ryecorn, triticale and oats for control of fungal diseases, and the application timing is changed to allow application to be made up to a week later. The current GAP for fluxapyroxad in wheat and barley is for 2 foliar applications of 75 g ai/ha, applied 3-5 weeks apart, up to end of flowering (GS69) with a 42-day withholding period for grain and straw and a 28-day livestock withholding period for green feed/silage. It is proposed that application can be made up until early dough (BBCH 83) for wheat, ryecorn and triticale, and up to late milk (BBCH79) in barley and oats. The WHP will accordingly be reduced from 42 days after last application to 35 days for cereal grain and straw/stubble. For cereal green feed/silage the WHP will remain as 28 days after last application.

### 3.3.3 Residue Information

The residue data for the use of fluxapyroxad on wheat, ryecorn, triticale, barley and oats are sufficient to conclude that, when used according to the proposed GAP, residues of fluxapyroxad should not exceed 0.15 mg/kg in wheat, rye and triticale grain, and 0.9 mg/kg in barley and oat grain.

The current MRLs for animal commodities, primarily to manage residues resulting from the use of fluxapyroxad in cereals, remain appropriate.

The current residue definitions remain appropriate. The residue definition in plant and animal commodities for MRL compliance in plant and animal commodities is 'Fluxapyroxad.' For dietary intake estimation in plant commodities, the residue definition is 'Sum of fluxapyroxad, M700F008 and M700F048, expressed as parent'. For dietary intake estimation in animal commodities, the residue definition is 'Sum of fluxapyroxad and M700F008, expressed as parent'.

### 3.3.4 Dietary Risk Assessment

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

Based on the residue profile expected in food from all crops treated with fluxapyroxad according to New Zealand GAP, the NEDI is estimated to total less than 2% of the HBGV.

New Zealand Food Safety has therefore determined that the use of fluxapyroxad in cereals in accordance with the GAP specified above is unlikely to pose any health risks from authorised use.

### 3.3.5 Relevant International MRLs for Fluxapyroxad

| Authority | Food | Maximum Residue Level (mg/kg) |
|---|---|---|
| Australia | Barley | 3 |
| | Barley bran, unprocessed | 0.5 |
| | Oats | 0.2 |
| | Rye | 3 |
| | Wheat | 0.3 |
| Codex | Barley | 2 |
| | Oats | 2 |
| | Rye | 0.3 |
| | Triticale | 0.3 |
| | Wheat | 0.3 |

## 3.4 Proposal to amend the MRLs for mefentrifluconazole

It is proposed that MRLs are set to support use of the compound in triticale, ryecorn and oats, and a change in withholding period when used in cereal crops.

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) |
|---|---|---|---|---|
| Mefentrifluconazole | 1417782-03-6 | Mefentrifluconazole | **Barley grain** | **3** |
| | | | 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 |
| | | | **Oat grain** | **3** |
| | | | Pome fruits | 0.15 |
| | | | Poultry fat | 0.02 |
| | | | Poultry meat | 0.01(*) |
| | | | Poultry offal | 0.02 |
| | | | **Rye grain** | **0.5** |
| | | | **Triticale grain** | **0.5** |
| | | | **Wheat grain** | **0.5** |

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

### 3.4.1 Amendment Rationale

MRLs are proposed to support the control of rust and scald fungal diseases in the additional crops ryecorn, triticale and oats, and extend the current application timing in wheat and barley.

### 3.4.2 Good Agricultural Practice

Mefentrifluconazole is a DMI triazole fungicide which acts by blocking ergosterol biosynthesis and is similar to epoxiconazole, propiconazole and tebuconazole. It is proposed that mefentrifluconazole is used in the additional cereal crops ryecorn, triticale and oats for control of scald and rust fungal diseases, and the application timing is changed to allow application to be made up to a week later. The current GAP for mefentrifluconazole in wheat and barley is for 2 foliar applications of 150 g ai/ha, applied 3-5 weeks apart, up to end of flowering (GS69) with a 42-day withholding period for grain and straw and a 28-day livestock withholding period for green feed/silage. It is proposed that application can be made up until early dough (BBCH 83) for wheat, ryecorn and triticale, and up to late milk (BBCH79) in barley and oats. The WHP will accordingly be reduced from 42 days after last application to 35 days for cereal grain and straw/stubble. For cereal green feed/silage the WHP will remain as 28 days after last application.

### 3.4.3 Residue Information

The residue data for the use of mefentrifluconazole on wheat, ryecorn, triticale, barley and oats are sufficient to conclude that, when used according to the proposed GAP, residues of mefentrifluconazole should not exceed 0.5 mg/kg in wheat, rye and triticale grain, and 3 mg/kg in barley and oat grain.

The current MRLs for animal commodities, primarily to manage residues resulting from the use of mefentrifluconazole in cereals, remain appropriate.

The residue definition for GAP compliance in plant and animal commodities is ‘mefentrifluconazole,’ as is the dietary intake definition for plant commodities. For dietary intake estimation in animal commodities, the residue definition is ‘mefentrifluconazole plus metabolite M750F022 and its conjugates’.

### 3.4.4 Dietary Risk Assessment

The HBGV of 0.025 mg/kg bw/d was considered appropriate for use in the assessment.

Based on the residue profile expected in food from crops treated with mefentrifluconazole according to New Zealand GAP, the NEDI is estimated to total less than 7% of the HBGV.

New Zealand Food Safety has therefore determined that the use of mefentrifluconazole in accordance with the GAP specified above, and complying with the established and revised MRLs, is unlikely to pose any health risks from authorised use.

### 3.4.5 Relevant International MRLs for Mefentrifluconazole

| Authority | Food | Maximum Residue Level (mg/kg) |
|---|---|---|
| Australia | Barley, similar grains, and pseudocereals with husks<br>Wheat, similar grains, and pseudocereals without husks | 4<br>0.3 |

## 3.5 Proposal to amend the MRLs for sulfoxaflor

It is proposed that MRLs are set to support a changed use pattern for the compound before animals can graze or be fed treated forage brassica crops, resulting in a change to animal commodity MRLs. Poultry MRLs are proposed to reflect the existing use in cereal grain.

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) |
|---|---|---|---|---|
| Sulfoxaflor | 946578-00-3 | Sulfoxaflor | Barley grain<br>Cauliflower<br>Cucurbits (except pumpkins and winter squash)<br>**Eggs**<br>Head lettuce<br>Fruiting vegetables (other than cucurbits)<br>Leafy vegetables (except head lettuce)<br>Mammalian fat<br>~~**Mammalian kidney**~~<br>~~**Mammalian liver**~~<br>Mammalian meat<br>**Mammalian offal**<br>Milk<br>**Poultry fat**<br>**Poultry meat**<br>**Poultry offal**<br>Root and tuber vegetables<br>Vegetable brassicas (except cauliflower)<br>Wheat grain | 0.01(*)<br>0.1<br>0.5<br>**0.01(*)**<br>1.0<br>1.0<br>5<br>0.04<br>~~**0.1**~~<br>~~**0.2**~~<br>0.07<br>**0.2**<br>0.03<br>**0.01(*)**<br>**0.01(*)**<br>**0.03**<br>0.05<br>3<br>0.01(*) |

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

### 3.5.1 Amendment Rationale

MRLs are proposed to support a changed use pattern for forage brassicas as a result of a new product which combines two known active ingredients. While most of the mammalian MRLs for sulfoxaflor are unchanged, it is proposed that the existing MRLs for mammalian kidney is increased and a single MRL for mammalian offal will replace the separate MRLs for mammalian kidney and liver. MRLs for poultry commodities are proposed to reflect existing uses in cereal grain.

### 3.5.2 Good Agricultural Practice

Sulfoxaflor is a systemic insecticide with activity against sap-sucking insects. It is currently used for control of a large range of sap-sucking insects on wheat, barley, forage brassicas and vegetable crops. The existing use of forage brassicas is for two applications at 24 gai/ha with a minimum 14 day interval, for control of aphids. The new use pattern proposed is an increase in application rate to 25 gai/ha, in combination with spinetoram, for control of caterpillars, leaf miner, springtails, aphids and *Nysius huttoni*. The WHPs 'Meat: do not graze treated crops until 14 days after application' and 'Milk: do not graze within 28 days after application' will remain unchanged.

### 3.5.3 Residue Information

The residue data for the use of sulfoxaflor on forage brassicas are sufficient to conclude that, when used according to the proposed GAP, residues of sulfoxaflor should not exceed 0.2 mg/kg in mammalian offal from all existing uses. The current MRLs for mammalian tissues and milk remain appropriate. For poultry commodities, which were not previously set, residue data for current uses are sufficient to conclude that residues of sulfoxaflor will not exceed 0.03 mg/kg in poultry offal, and are not expected in eggs, poultry fat or poultry meat.

The residue definition for GAP compliance and dietary intake estimation in plant and animal commodities is 'sulfoxaflor.'

### 3.5.4 Dietary Risk Assessment

Based on the residue profile expected in food from animals exposed to sulfoxaflor from feed treated according to GAP, and with all existing and proposed MRLs incorporated into the calculation, the NEDI is estimated to total 9.984% of the HBGV for the NZ adult average and 21.447% for the NZ child average.

The HBGV of 0.028 mg/kg bw/d was considered appropriate for use in the assessment.

Based on the residue profile expected in food from animals exposed to sulfoxaflor from feed treated according to GAP, and with all existing and proposed MRLs incorporated into the calculation, the NEDI is estimated to total less than 10% of the HBGV.

New Zealand Food Safety has therefore determined that the use of sulfoxaflor in accordance with the GAP specified above, and complying with the established and revised MRLs, is unlikely to pose any health risks from authorised use.

### 3.5.5 Relevant International MRLs for Sulfoxaflor

| Authority | Food | Maximum Residue Level (mg/kg) |
|---|---|---|
| Australia | Edible offal (mammalian) | 2 |
| | Eggs | 0.01(*) |
| | Poultry, edible offal of | 0.02 |
| | Poultry meat | 0.7 |
| Canada | Eggs | 0.01 |
| | Fat of poultry | 0.01 |
| | Meat byproducts of cattle, goats, horses, and sheep | 0.05 |
| | Meat byproducts of hogs | 0.01 |
| | Meat byproducts of poultry | 0.02 |
| | Meat of poultry | 0.01 |
| China | Viscera of mammals (with the exception of marine mammal) | 0.6 |
| | Poultry meat | 0.1 |
| | Poultry viscera | 0.3 |
| | Poultry fat | 0.03 |
| | Eggs | 0.1 |

| | | |
|---|---|---|
| Codex | Edible offal (mammalian) | 1 |
| | Eggs | 0.1 |
| | Poultry fats | 0.03 |
| | Poultry meat | 0.7 |
| | Poultry, edible offal of | 0.3 |
| European Union | Swine, bovine, sheep, goat, and equine offal (liver, kidney, and edible offals) | 0.6 |
| | Poultry muscle | 0.1 |
| | Poultry fat | 0.03 |
| | Poultry offal (liver, kidney, and edible offals) | 0.3 |
| | Eggs | 0.1 |
| Japan | Liver, kidney, and edible offal of cattle, pigs, and other terrestrial mammals | 1 |
| | Chicken and poultry muscle | 0.7 |
| | Chicken and poultry fat | 0.05 |
| | Liver, kidney, and edible offal of Chicken and poultry | 0.3 |
| | Eggs | 0.1 |
| United States | Cattle, goat, horse and sheep meat byproducts | 0.8 |
| | Hog meat byproducts | 0.6 |
| | Egg | 0.06 |
| | Poultry meat byproducts | 0.3 |
| | Poultry fat | 0.2 |
| | Poultry meat | 0.1 |

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