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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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)?

For compounds listed in Schedules 2 or 3, do you agree or disagree with the listing or the conditions?

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 **16 June 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., avocados, 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:

- A new entry for **flumetsulam**, to set MRLs at 0.01 mg/kg in cereal grains, 0.1 mg/kg in eggs, 0.01 mg/kg in mammalian meat, 0.1 mg/kg in mammalian offal, 0.01 mg/kg in milk, 0.1 mg/kg in poultry meat, and 0.1 mg/kg in poultry offal;
- Amendment of the entry for **foramsulfuron**, to set new MRLs at 0.01 mg/kg in mammalian meat, mammalian fat, mammalian offal, and milk, and to delete the MRL for maize;
- Amendment of the entry for **mefentrifluconazole**, to set new MRLs at 0.07 mg/kg for grapes and 0.15 mg/kg for pome fruits;
- Amendment of the entry for **spinetoram**, to set new MRLs at 0.01 mg/kg for maize, 0.02 mg/kg in milk, 0.15 mg/kg in milk fats, 0.01 mg/kg in poultry meat, offal, and eggs, and 0.01 mg/kg in sweetcorn; amend the mammalian fat description to exclude milk fats and increase the MRL to 0.5 mg/kg; and to combine the mammalian kidney and liver MRLs into a single mammalian offal with an increase to 0.03 mg/kg;
- Amendment of the entry for **tetraniliprole**, to set a new MRL at 0.3 mg/kg for stone fruits; and
- A new entry for **thiencarbazone-methyl**, to set MRLs at 0.01 mg/kg for mammalian meat, mammalian fat, mammalian offal, and milk.

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

- The addition of three new entries, for aniseed oil, menthol, and sassafras oil, when used as topical liniments on horses.
- The addition of a new entry for luteinising hormone (LH), when used to manage reproduction in ruminants.

3 Proposals

3.1 Proposal to set MRLs for flumetsulam

It is proposed that a new MRL entry for flumetsulam is added to the Food Notice to support the GAP use of the compound in wheat and barley. Because these crops can be used as animal feed, the proposal also includes mammalian and poultry commodity MRLs.

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

Compound Common Name	CAS#	Residue to which the maximum residue level applies	Food	Maximum Residue Level (mg/kg)
Flumetsulam	98967-40-9	Flumetsulam	Cereal grains Eggs Mammalian meat Mammalian offal Milk Poultry meat Poultry offal	0.01(*) 0.1 0.01 0.1 0.01 0.1 0.1

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

3.1.1 Amendment Rationale

The proposed MRLs are to support a new use for selective broadleaf weed control in wheat and barley. Flumetsulam is currently approved for selective broadleaf control in new and established pasture, chicory, clover, lucerne and maize. The new animal commodity MRLs will support the existing GAP of flumetsulam in animal feeds uses while facilitating the GAP of the compound in wheat and barley.

3.1.2 Good Agricultural Practice

Flumetsulam is a triazolopyrimidine herbicide. The proposed new use is for selective broadleaf weed control in wheat and barley at a rate of up to 50 gai/ha as a single application any time after planting up to the end of tillering. A WHP of 28 days is supported as GAP for grain and animal feed.

The current GAP use for selective broadleaf control in new and established pasture, chicory, clover, lucerne and maize has been approved for many years with a withholding period of 14 days for grazing treated crops or pasture.

3.1.3 Residue Information

The residue data for the use of flumetsulam on wheat and barley were sufficient to conclude that, when used according to the proposed GAP, residues of flumetsulam should not exceed 0.01 mg/kg in the crop grouping ‘cereal grains’.

The residue data in cereals, together with previously supplied data for existing uses, are sufficient to establish MRLs for animal commodities at 0.1 mg/kg for mammalian offal, 0.01 mg/kg for mammalian meat, 0.01 mg/kg for mammalian milk, and 0.1 mg/kg in poultry meat, poultry offal, and eggs. It is considered these levels will support both GAP and trade according to the proposed use of the compound in all animal commodities.

The current residue definitions remain appropriate. For GAP compliance and dietary intake estimation in plant and animal commodities, the residue definition is ‘flumetsulam’.

3.1.4 Dietary Risk Assessment

The HBGV of 0.05 mg/kg bw/d was considered appropriate for use in the assessment.

Based on the residue profile expected in food from crops treated with flumetsulam according to New Zealand GAP, the NEDI is estimated to total less than 0.7% of the HBGV.

New Zealand Food Safety has therefore determined that the use of flumetsulam on cereal crops in accordance with the GAP specified above, and complying with the proposed MRLs, is unlikely to pose any health risks from authorised use.

3.1.5 Relevant International MRLs for Flumetsulam

Authority	Food	Maximum Residue Level (mg/kg)
Australia	Barley	0.05
	Edible offal (mammalian)	0.3
	Eggs	0.1
	Maize	0.05
	Meat (mammalian)	0.1
	Milks	0.1
	Oats	0.05
	Poultry meat	0.1
	Poultry, edible offal of	0.1
	Rye	0.05
	Triticale	0.05
	Wheat	0.05
Japan	Barley	0.05
	All mammalian fat	0.1
	All mammalian kidney	0.3
	All mammalian liver	0.3
	All mammalian muscle	0.1
	All mammalian edible offal	0.3
	Milk	0.1
	Other cereal grains	0.05
	Rye	0.05
	Wheat	0.05

3.2 Proposal to amend the MRLs for foramsulfuron

It is proposed that new MRLs are set for foramsulfuron in mammalian meat, fat, offal, and milk to support the GAP use of the compound in fodder and sugar beets used as animal feed. The previously approved MRL for this compound, in maize, is also being proposed for deletion.

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)
Foramsulfuron	173159-57-4	Foramsulfuron	~~**Maize**~~ **Mammalian meat** **Mammalian fat** **Mammalian offal** **Milk**	~~**0.01(*)**~~ **0.01** **0.01** **0.01** **0.01**

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

3.2.1 Amendment Rationale

The new MRLs are being proposed to support the GAP use of foramsulfuron to control weeds in fodder and sugar beet crops intended for use as animal feed by managing residues in animal commodities.

The deletion of the maize MRL is being proposed because the compound has not been approved for use in maize since 2012. A foramsulfuron MRL for maize is therefore no longer required to manage the GAP use of the compound in New Zealand.

3.2.2 Good Agricultural Practice

Foramsulfuron is a pyrimidinyl sufonyl urea herbicide which acts by inhibiting the enzyme acetolactate synthase (ALS). Inhibiting ALS blocks protein synthesis and thereby plant growth and survival.

The proposed use of this compound is two applications of 15 gai in 200-300L water/ha, at the beginning of the weed flush when the crop is at the 2-4 leaf stage, and repeated 10-14 days later when the crop has up to 8 leaves. This use attracts a pre-grazing and -harvest interval of 70 days.

3.2.3 Residue Information

The residue data for the use of foramsulfuron on fodder and sugar beets are sufficient to conclude that, when used according to the proposed GAP, residues of foramsulfuron should not exceed 0.01 mg/kg in any animal commodities.

The proposed residue definition for MRL conformance and GAP compliance for animal commodities is ‘foramsulfuron’ as per the previous MRL residue definition for maize. The proposed residue definition for dietary intake estimation for animal commodities is ‘foramsulfuron and its metabolite AE F153745’.

3.2.4 Dietary Risk Assessment

The HBGV of 0.35 mg/kg bw/d was considered appropriate for use in the assessment.

Based on the residue profile expected in food from animals that have consumed feed treated with foramsulfuron according to GAP, the NEDI is estimated to total less than 0.02% of the HBGV.

New Zealand Food Safety has therefore determined that the use of foramsulfuron on fodder and sugar beet crops in accordance with the GAP specified above, and complying with the new animal commodity MRLs, is unlikely to pose any health risks from authorised use.

3.2.5 Relevant International MRLs for Foramsulfuron

Authority	Food	Maximum Residue Level (mg/kg)
European Union	All mammalian commodities including milk	0.01

3.3 Proposal to amend the MRLs for mefentrifluconazole

It is proposed that two new mefentrifluconazole MRLs are set to support a change in the GAP use of the compound in apples and pears, as the crop grouping 'pome fruits', and 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)
Mefentrifluconazole	1417782-03-6	Mefentrifluconazole	Barley grain Eggs **Grapes** Mammalian fat Mammalian kidney Mammalian liver Mammalian meat Milk **Pome fruits** Poultry fat Poultry meat Poultry offal Wheat grain	2 0.01(*) **0.07** 0.1 0.1 0.3 0.02 0.02 **0.15** 0.02 0.01(*) 0.02 0.5

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

3.3.1 Amendment Rationale

The MRL for pome fruits is being proposed to support a change in foliar spray application timing for the use of mefentrifluconazole to control black spot and powdery mildew in apples, and black spot in pears. The MRL for grapes is being proposed to better support the current use for control of powdery mildew.

3.3.2 Good Agricultural Practice

Mefentrifluconazole is a DMI triazole fungicide which acts by blocking ergosterol biosynthesis and is similar to epoxiconazole, propiconazole and tebuconazole. The proposed use in pome fruits is a change in application timing to control black spot and powdery mildew in apples, and black spot in pears. The current application rate of a maximum of 4 applications at 6 gai / 100 L water as a preventative treatment is unchanged, but the timing has been revised from an application interval of 7-10 days throughout the use period (until 80% petal fall) to 7-10 days through the ascospore release period. This lengthens the use of the compound to 14 days through to the end of season. The WHP has accordingly been revised from '80% petal fall' to 35 days for both apples and pears. This change is supported as Good Agricultural Practice.

The current use on grapes for control of powdery mildew is a maximum of 2 applications of 6 gai /100L water in a preventative programme up to pre-bunch closure. The associated WHP for grapes is to apply no later than pre-bunch closure.

A 6-month slaughter interval is required after sheep have been removed from the vineyard after leaf plucking, and a general grazing restriction is in place which does not allow animals to graze within treated orchards or vineyards until after harvest.

3.3.3 Residue Information

The residue data for the use of mefentrifluconazole on apples and pears are sufficient to conclude that, when used according to the proposed GAP, residues of mefentrifluconazole should not exceed 0.15 mg/kg in pome fruits and 0.07 mg/kg in grapes.

There is no change proposed for the current grazing withholding period. With the current grazing restrictions in place, the change in GAP for pome fruit is not expected to significantly

increase residue intake in animals when grazing in treated orchards or vineyards. The current MRLs for animal commodities, primarily to manage residues resulting from the use of mefentrifluconazole in cereals, remain appropriate.

The current residue definitions also remain appropriate. The residue definition applied for MRL compliance and GAP conformance in all plant and animal commodities is 'mefentrifluconazole', as is the dietary intake definition for plant and mammalian animal commodities. For dietary intake estimation in poultry commodities, the residue definition is 'mefentrifluconazole plus metabolite M750F022 and its fatty acid conjugates, expressed as mefentrifluconazole'.

3.3.4 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 6% of the HBGV.

New Zealand Food Safety has therefore determined that the use of mefentrifluconazole on pome fruit and grape crops 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.

3.3.5 Relevant International MRLs for Mefentrifluconazole

Authority	Food	Maximum Residue Level (mg/kg)
Australia	Apple	1
	Apple pomace, dry	5
	Dried grapes	3
	Grape pomace, dry	5
	Grapes	1

3.4 Proposal to amend the MRLs for spinetoram

It is proposed that the MRLs for spinetoram are amended to support the GAP use of the compound in maize and sweetcorn. Because these crops are also used as animal feed, the proposed changes include revised animal commodity MRLs.

The proposed changes include the setting of new maize and sweetcorn MRLs at 0.01 mg/kg; an increase in the mammalian fat MRL from 0.2 mg/kg to 0.5 mg/kg; combining the previous mammalian kidney and liver MRL entries to one 'mammalian offal' entry to recognise they were identical and increasing the MRL from 0.01 mg/kg to 0.03 mg/kg; and new milk (0.02 mg/kg), milk fat (0.15 mg/kg), poultry meat (0.01 mg/kg), poultry offal (0.01 mg/kg), and poultry eggs (0.01 mg/kg) MRLs.

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)
Spinetoram	187166-40-1 + 187166-15-0	*Sum of:* XDE-175-J and XDE-175-L *Expressed as:* spinetoram.	Apples Bulb onions Citrus **Eggs** **Maize** Mammalian fat **(except milk fats)** **Mammalian offal** Mammalian meat **Milk** **Milk fats** Pears Potatoes **Poultry meat** **Poultry offal** Stone fruits **Sweetcorn** Tropical and subtropical fruits – inedible peel (except kiwifruit) Tomatoes Vegetable brassicas	0.05 0.01(*) 0.05 **0.01(*)** **0.01(*)** **0.5** **0.03** **0.03** **0.02** **0.15** 0.05 0.02(*) **0.01(*)** **0.01(*)** 0.2 **0.01(*)** 0.02(*) 0.02(*) 0.15

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

3.4.1 Amendment Rationale

The MRL changes are being proposed to support the GAP use of spinetoram for the control of fall armyworm. The new and amended MRLs will effectively support this use by managing residues in the crops to be treated (maize and sweetcorn) and in commodities from animals fed or grazed on treated crops.

3.4.2 Good Agricultural Practice

Spinetoram is a spinosyn insecticide comprised of two compounds, ethyl-spinosyn-J 9XDE-175-J) and ethyl-spinosyn-L (XDE-175-L), which act as nicotinic acetylcholine receptor agonists. Spinetoram is currently approved for use against a range of common pests on fruit crops, onions, potatoes, hort brassicas, fodder brassicas, and pasture. The proposed new use is for the control of fall armyworm on sweetcorn, and maize at a rate of 30-36 gai/ha in at least 100L/ha with a maximum of two applications 7 days apart. This use attracts a 28-day pre-harvest interval for grain, a 28-day pre-grazing interval for stover, and a 14-day pre-grazing interval for maize forage.

3.4.3 Residue Information

The residue data for the use of spinetoram are sufficient to conclude that, when used according to established New Zealand GAP on maize and sweetcorn and observing the applicable pre-harvest and pre-grazing intervals, residues of spinetoram should not exceed 0.01 mg/kg in maize, sweetcorn, or poultry commodities, 0.02 mg/kg in milk, 0.03 mg/kg in mammalian meat or offal, 0.15 mg/kg in milk fats, and 0.5 mg/kg in mammalian fat other than milk fat.

The current residue definition, ‘sum of XDE-175-J and XDE-175-L, expressed as spinetoram’ remains appropriate for all plant and animal commodities for both GAP conformance and dietary intake.

3.4.4 Dietary Risk Assessment

The HBGV of 0.017 mg/kg bw/d was considered appropriate for use in the assessment.

Based on the residue profile expected in food from crops treated with spinetoram according to New Zealand GAP, and in commodities from animals fed animal feed crops treated with spinetoram, the NEDI is estimated to total less than 3% of the HBGV.

New Zealand Food Safety has therefore determined that the use of spinetoram on horticultural crops and in animal feed crops 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 Spinetoram

Authority	Food	Maximum Residue Level (mg/kg)
Codex	Edible offal (mammalian)	0.1
	Eggs	0.01
	Maize	0.01
	Mammalian fats (except milk fats)	1
	Meat (from mammals other than marine mammals)	1
	Milk fats	0.15
	Milks	0.02
	Poultry fats	0.01
	Poultry meat	0.01
	Poultry, edible offal of	0.01
	Sweet corn (corn on the cob)(kernels plus cob with husk removed)	0.01
Australia	Edible offal (mammalian)	0.2
	Eggs	0.01
	Maize cereals	0.01
	Meat (mammalian) [in the fat]	2
	Milks	0.01
	Poultry meat [in the fat]	0.01
	Poultry, edible offal of	0.01
	Sweet corn (corn-on-the-cob)	0.01
Canada	Eggs	0.04
	Fat of cattle, sheep, goats, and horses	5.5
	Fat of hogs and poultry	0.04
	Field corn	0.04
	Liver of cattle, sheep, goats, and horses	0.85
	Meat byproducts of cattle, sheep, goats, and horses (except liver)	0.6
	Meat byproducts of hogs and poultry	0.04
	Meat of cattle, sheep, goats, and horses	0.2
	Meat of hogs and poultry	0.04
	Milk	0.3
	Milk fat	7.5
	Popcorn grain	0.04
	Sweet corn kernels plus cob with husks removed	0.04
China	Corn and fresh corn	0.01
European Union	Sweet corn	0.02
	Maize/corn	0.02
	All mammalian commodities including milk	0.02
	All poultry commodities including eggs	0.02
Japan	Corn (maize, including popcorn and sweet corn)	0.02
	All mammalian muscle	1
	All mammalian fat	1
	All mammalian liver, kidney, and edible offal	0.1
	Milk	0.02
	All poultry commodities including eggs	0.01
United States	Cattle, sheep, goat, and horse by products and kidney	0.6
	Cattle, sheep, goat, and horse fat	5.5
	Cattle, sheep, goat, and horse liver	0.85
	Cattle, sheep, goat, and horse meat	0.2
	Poultry and hog by products, kidney, liver, and meat	0.04
	Poultry fat	0.1
	Hog fat	0.4
	Corn (grain, pop, and sweet)	0.04
	Eggs	0.04
	Milk	7.5

3.5 Proposal to amend the MRLs for tetraniliprole

It is proposed that a new MRL for tetraniliprole is set to support the GAP use of the compound in the crop grouping 'stone fruits.' The proposed MRL is 0.3 mg/kg.

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)
Tetraniliprole	1229654-66--3	Tetraniliprole	Pome fruits **Stone fruits**	0.2 **0.3**

(*) 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 a new use to control Carpophilus beetle in stone fruits. Tetraniliprole is currently approved for use in pome fruits for control of codling moth, leafrollers and bronze beetle.

3.5.2 Good Agricultural Practice

Tetraniliprole is an anti-feedant diamide insecticide similar to chlorantraniliprole, cyantraniliprole and flubendiamide. The proposed use to control Carpophilus beetle in stone fruits requires 1-2 foliar applications of 3 g ai/100 L (60 g ai/ha) as fruit approaches maturity. A WHP of 4 days is consistent with the beetle behaviour and is supported as GAP.

3.5.3 Residue Information

The residue data for the use of tetraniliprole on peaches, nectarines, cherries, apricot and plum are sufficient to conclude that, when used according to the proposed GAP, residues of tetraniliprole should not exceed 0.3 mg/kg in the crop grouping 'stone fruits'.

The current residue definitions remain appropriate. The residue definition for MRL conformance and GAP compliance is 'tetraniliprole', while the definition for dietary intake estimation is 'sum of Tetraniliprole and its -quinazolinone metabolite (expressed as tetraniliprole)'. Animal commodity MRLs are not required as pome and stone fruits are not considered primary feed commodities in New Zealand.

3.5.4 Dietary Risk Assessment

The HBGV of 0.62 mg/kg bw/d was considered appropriate for use in the assessment.

Based on the residue profile expected in food from crops treated with tetraniliprole according to GAP, the NEDI is estimated to total less than 0.1% of the HBGV.

New Zealand Food Safety has therefore determined that the use of tetraniliprole on stone fruit crops 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 Tetraniliprole

Authority	Food	Maximum Residue Level (mg/kg)
Australia	Apricots, dried Cherries Prunes Stone fruits (except cherries)	3 1 3 0.7

3.6 Proposal to set MRLs for thiencarbazone-methyl

It is proposed that a new MRL entry is added to the Food Notice to support the GAP use of this novel active ingredient in fodder and sugar beets used as animal feed. The MRLs will be set in mammalian meat, fat, offal, and milk.

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

Compound Common Name	CAS#	Residue to which the maximum residue level applies	Food	Maximum Residue Level (mg/kg)
Thiencarbazone-methyl	**317815-83-1**	***Sum of:*** **Thiencarbazone-methyl and BYH 18636-MMT** ***Expressed as:*** **thiencarbazone-methyl**	**Mammalian meat** **Mammalian fat** **Mammalian offal** **Milk**	**0.01** **0.01** **0.01** **0.01**

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

3.6.1 Amendment Rationale

Thiencarbazone-methyl has not previously been registered for use in New Zealand. MRLs are being proposed to support the GAP use of the compound as a herbicide in fodder and sugar beet crops intended for use as animal feed by managing residues in animal commodities.

3.6.2 Good Agricultural Practice

Thiencarbazone-methyl is a triazolone herbicide which inhibiting the enzyme acetolactate synthase (ALS). Like foramsulfuron, this compound works by blocking protein synthesis to inhibit plant growth and survival, though thiencarbazone-methyl is active through foliar systemic activity and to a lesser extent activity in the soil.

The proposed use of this compound is two applications of 15 gai in 200-300L water/ha, at the beginning of the weed flush when the crop is at the 2-4 leaf stage, and repeated 10-14 days later when the crop has up to 8 leaves. This use attracts a pre-grazing and -harvest interval of 70 days.

3.6.3 Residue Information

The residue data for the use of thiencarbazone-methyl on fodder and sugar beets are sufficient to conclude that, when used according to the proposed GAP, residues of thiencarbazone-methyl should not exceed 0.01 mg/kg in any animal commodities.

The proposed residue definition for MRL conformance and GAP compliance and dietary intake estimation for animal commodities is ‘sum of thiencarbazone-methyl and BYH 18636-MMT, expressed as thiencarbazone-methyl’.

3.6.4 Dietary Risk Assessment

The HBGV of 1.05 mg/kg bw/d was considered appropriate for use in the assessment.

Based on the residue profile expected in food from animals that have consumed feed treated with foramsulfuron according to GAP, the NEDI is estimated to total less than 0.01% of the HBGV.

New Zealand Food Safety has therefore determined that the use of thiencarbazone-methyl on fodder and sugar beet crops in accordance with the GAP specified above, and complying with the new animal commodity MRLs, is unlikely to pose any health risks from authorised use.

3.6.5 Relevant International MRLs for Thiencarbazone-methyl

Authority	Food	Maximum Residue Level (mg/kg)
Canada	All mammalian commodities including milk	0.02
European Union	All mammalian commodities including milk	0.01
United States	All mammalian commodities including milk	0.02

3.7 Proposal to set entries for aniseed oil, menthol, and sassafras oil in Schedule 3

It is proposed three entries are added to Schedule 3 of the Notice to identify aniseed oil, menthol, and sassafras oil as veterinary medicines to which no MRL applies. All three compounds are used as active ingredients in liniment products used as topically applied rubs to manage soft tissue sprains and strains.

Aniseed oil is used in many human food products such as dairy products, confectionary items, and liqueurs as a flavouring agent. Its use in this manner is generally recognised as safe by international authorities. Menthol is used commonly in cough and cold remedies as well as some foods and attracts a higher acceptable daily intake than aniseed. The principal substance in sassafras oil is safrole, which is found in food for human consumption such as nutmeg, parsley oil, and star anise, with safrole extracts used as food flavourings and in cosmetics.

When used as liniment compounds on horses, the three compounds are applied topically at very low concentrations. This results in a low amount of compound in contact with the horse's skin, and a negligible level of the compounds available for systemic absorption. With listing in Schedule 3 restricted to topical application, and only on horses, it is considered that residues from aniseed oil, menthol, and sassafras oil do not need to be managed through the application of MRLs.

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

Substance	CAS#	Condition
Aniseed oil	**8007-70-3**	**When used as a topical liniment on horses**

Substance	CAS#	Condition
Menthol	**89-78-1**	**When used as a topical liniment on horses**

Substance	CAS#	Condition
Sassafras oil	**8006-80-2**	**When used as a topical liniment on horses**

3.8 Proposal to set an entry for luteinising hormone (LH) in Schedule 3

It is proposed that luteinising hormone (LH) is added to Schedule 3 of the Notice to identify it as a veterinary medicine to which no MRL applies. LH is a naturally occurring gonadotropin hormone which regulates ovarian maturation and the reproductive cycle in mammals. As a

veterinary medicine, LH is usually used in conjunction with follicle stimulating hormone (FSH) in cattle to manage fertility status.

When administered to cattle as a veterinary medicine, the introduced LH is indistinguishable from the endogenously released compound and rapidly eliminated within hours. In addition, assessments of the use of compounds like LH as a veterinary medicine by international authorities have determined that MRLs are not required given to manage residues or food safety. As such, the use of LH as a veterinary medicine is not expected to pose risks to either food safety or trade. The condition of exemption will reflect the use of the compound as a zootechnical agent to manage reproduction in ruminant species.

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

Substance	CAS#	Condition
Luteinising hormone (LH)	**n/a**	**When used to manage reproduction in ruminants**