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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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 is relevant.

Submissions close at 5pm on **12 August 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. 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 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

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 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 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 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:

- The addition of a new entries in the Notice for the following compounds:
    - Altrenogest, to set MRLs at 0.004 mg/kg in horse fat, 0.001(*) mg/kg in horse meat, and 0.004 mg/kg in horse offal;
    - Isofetamid, to set MRLs at 0.08 mg/kg for grapes, 0.01(*) mg/kg for mammalian meat, 0.01(*) mg/kg for mammalian offal, and 0.01(*) mg/kg for milk; and
    - Oleandomycin, to set MRLs at 0.1 mg/kg for cattle meat, 0.1 mg/kg for cattle offal, and 0.05(*) mg/kg for cattle milk.
- The amendment of the existing entries in the Notice for the following compounds:
    - Abamectin, to set MRLs at 0.02 mg/kg for cattle liver, 0.01 mg/kg for cattle kidney, 0.003(*) mg/kg for milk, 0.02 mg/kg for deer liver, 0.01 mg/kg for deer kidney, 0.01 mg/kg for deer fat, and 0.01 mg/kg for deer meat;
    - Nitroxynil, to add a MRL of 0.02(*) mg/kg for cattle milk;
    - Maldison (Malathion), to align the crop grouping for 'Fruiting Vegetables' with that set by Codex;
    - Sulfoxaflor, to align the crop grouping for 'Fruiting Vegetables' with that set by Codex;
- The removal of the existing entries in the Notice for azocyclotin and kanamycin.

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

2.2.2 Amendment to Schedule 2: Agricultural Chemicals for which No Maximum Residue Level Applies

- MPI proposes to amend the existing entry for phosphorous acid, to adjust the wording of the condition of applied to the Schedule 2 listing to clarify its scope.

3 Proposals

3.1 PROPOSAL TO AMEND THE MRLS FOR ABAMECTIN

It is proposed that MRLs for abamectin are amended to better support the GAP use of the compound in cattle and deer.

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)
Abamectin	71751-42-2	Sum of: avermectin B1a and avermectin B1b	Avocados	0.02(*)
			Bulb onions	0.01
			Cattle fat	0.02
			Cattle kidney	**0.01**
			Cattle liver	**0.02**
			Cattle meat	0.01
			Deer fat	**0.01**
			Deer kidney	**0.01**
			Deer liver	**0.02**
			Deer meat	**0.01**
			Green onions	0.02(*)
			Kiwifruit	0.02(*)
			Milk	**0.003(*)**
			Pome fruits	0.02(*)
			Sheep fat	0.05
			Sheep kidney	0.02
			Sheep liver	0.025
			Sheep meat	0.02
			Strawberries	0.02(*)
			Tomatoes	0.1

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

3.1.1 Amendment Rationale

Abamectin has been used in cattle and deer in New Zealand for parasite control since 1996, with cattle kidney, milk, and all deer commodities subject to compliance with the New Zealand default MRL of 0.1 mg/kg. A review of the use of abamectin in cattle and deer has recently been undertaken to ensure the regulatory controls applied are appropriate, including MRLs and withholding periods. The revised entry is proposed to better reflect the residue profile expected in these species when used according to the use patterns considered as GAP in New Zealand. All other veterinary and horticultural uses were out of scope for the review and therefore no changes are proposed for other commodities.

3.1.2 Good Agricultural Practice

Abamectin is an avermectin which, when used as a veterinary medicine, acts as a parasiticide in ruminant helminths and ectoparasites by inhibiting neurotransmitters in the gamma-aminobutyric acid (GABA) system. It is approved for use in New Zealand in single-active topical products used in cattle and deer, and with other active ingredients in topical, oral, and systemic formulations for use in cattle, deer, sheep, and horses. Abamectin is used in ruminants at a dose rate of either 0.2 mg/kg when administered by oral administration or injection, or 0.5 mg/kg when applied topically. Cattle meat withholding periods range from 10 to 35 days depending on administration route, while topical administration to deer attracts a meat withholding period of 28 days.

It is noted that abamectin has been permitted for use in dairy animals for parasite control in New Zealand. As an outcome of the recent review, all products containing abamectin now

attract a 35 day milk withholding period for all administration routes, limiting the compound's use to only those animals outside of the lactation period. Setting the MRL to approximate the limit of quantification will act to further mitigate the potential for abamectin milk residues.

3.1.3 Residue Information

The residue data for the use of abamectin in cattle and deer are sufficient to conclude that, when used according to established GAP in these species and observing the applicable withholding periods, residues of abamectin according to the residue definition are expected to remain below 0.02 mg/kg in cattle and deer liver, 0.01 mg/kg in cattle kidney, deer kidney, deer fat, and dear meat, and 0.003 mg/kg in cattle milk. The current residue definition of 'Sum of: avermectin B1a and avermectin B1b' remains appropriate to for animal commodities for both GAP compliance and dietary intake assessment.

3.1.4 Dietary Risk Assessment

The HBGV of 0.002 mg/kg bw/d was considered appropriate for use in the assessment.

Based on the residue profile expected in food from animals treated with or exposed to abamectin when used according to GAP, the NEDI is estimated to total less than 9% of the HBGV.

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

3.1.5 Relevant International MRLs

Authority	Food	Maximum Residue Level (mg/kg)
Codex	Cattle liver Cattle fat Cattle kidney	0.1 0.1 0.05
Australia	Cattle fat Cattle meat Cattle milk Cattle, edible offal of	0.1 0.005 0.02 0.1
Canada	Fat of cattle Kidney of cattle Liver of cattle Muscle of cattle	0.1 0.05 0.05 0.01
European Union	Bovine fat Bovine liver	0.01 0.02
Japan	Cattle muscle Other terrestrial mammals, muscle Cattle fat Other terrestrial mammals, fat Cattle liver Other terrestrial mammals, liver Cattle kidney Other terrestrial mammals, kidney Cattle edible offal Other terrestrial mammals, edible offal Milk	0.02 0.01 0.1 0.1 0.1 0.05 0.06 0.01 0.06 0.01 0.02

3.2 PROPOSAL TO SET MRLS FOR ALTRENOGEST

It is proposed that MRLs are set for altrenogest to support the GAP use of the compound as a veterinary medicine in horses.

There is currently no entry for altrenogest in the Notice and therefore the default MRL applies. 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)
Altrenogest	850-52-2	Altrenogest	Horse fat Horse meat Horse offal	0.004 0.001(*) 0.004

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

3.2.1 Amendment Rationale

Altrenogest has been used in New Zealand as a veterinary medicine since the 1980s as a zootechnical agent to manage reproduction in horses. Because horses are a food-producing species, food commodities derived from treated animals have been subject to compliance with the New Zealand default MRL of 0.1 mg/kg. The new MRLs are being proposed to better support the use of altrenogest in horses in accordance with the dose rates and use patterns considered as GAP in New Zealand.

3.2.2 Good Agricultural Practice

Altrenogest is a synthetic steroidal progestomimetic compound used exclusively in New Zealand to manage oestrus and pregnancy in breeding mares. There are two forms of altrenogest available for use: oral formulations administered at 0.044 mg/kg/day for 10 to 15 days, and long-acting injectable formulations administered at 0.3 mg/kg every 5-7 days or 0.45 mg/kg every 10 days. Use of oral altrenogest attracts a withholding period of 28 days, while animals treated with injectable altrenogest attract a requirement that treated animals are not to be used to produce food for human consumption.

Altrenogest is not approved for use in any other species or for any other purposes in New Zealand.

3.2.3 Residue Information

The residue data for the use of oral altrenogest are sufficient to establish MRLs for the use patterns and withholding period considered GAP in New Zealand. When used according to GAP, and complying with the applicable withholding period, altrenogest residues will remain less than 0.001 mg/kg in meat and 0.004 mg/kg in all other tissues. A residue definition of 'altrenogest' has been determined to be appropriate to manage New Zealand GAP compliance and dietary intake in accordance with the residue definitions established by overseas authorities.

3.2.4 Dietary Risk Assessment

The HBGV of 0.001 µg/kg bw/d, and the stated dietary intake residue definition, are considered appropriate for use in the dietary intake assessment. Based on the residue profile expected in food from horses treated with altrenogest, the NEDI is estimated to total less than 2% of the HBGV.

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

3.2.5 Relevant International MRLs

Authority	Food	Maximum Residue Level (mg/kg)
European Union	Equine fat	0.004
	Equine liver	0.004
Japan	Other terrestrial mammals, muscle	0.001
	Other terrestrial mammals, fat	0.004
	Other terrestrial mammals, liver	0.004
	Other terrestrial mammals, kidney	0.004
	Other terrestrial mammals, edible offal	0.004

3.3 PROPOSAL TO DELETE THE NOTICE ENTRY FOR AZOCYCLOTIN

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)
~~Azocyclotin~~	~~41083-11-8~~	~~Sum of: azocyclotin and cyhexatin~~ ~~Expressed as: cyhexatin~~	~~Fruits~~	~~2~~

3.3.1 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 azocyclotin was de-registered in 2008). Azocyclotin MRLs are therefore no longer required to manage the GAP use of the compound in New Zealand.

3.4 PROPOSAL TO SET MRLS FOR ISOFETAMID

It is proposed that MRLs are set for isofetamid to support the GAP use of the compound on grapes.

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

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Residue Level (mg/kg)
Isofetamid	**875915-78-9**	**Plant commodities: Isofetamid** **Animal commodities: Sum of isofetamid and 2-[3-methyl-4-[2-methyl-2-(3-methylthiophene-2-carboxamido) propanoyl]phenoxy]propanoic acid (PPA), expressed as isofetamid.**	**Grapes** **Mammalian meat** **Mammalian offal** **Milk**	**0.08** **0.01(*)** **0.01(*)** **0.01(*)**

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

3.4.1 Amendment Rationale

The MRLs are being proposed to support the use of the novel compound isofetamid in grapes. The proposed MRL for grapes will manage the use of the compound in accordance

with the use pattern and withholding period that are proposed as GAP in New Zealand. MRLs have been proposed for animal tissues to manage the practices of using sheep for leaf plucking in vineyards, and post-harvest grazing in vineyards.

3.4.2 Good Agricultural Practice

Isofetamid is a succinate dehydrogenase inhibitor (SDHI) fungicide which acts by inhibiting mitochondrial respiration in the *Ascomycetes* and *Deuteromycetes* fungal groups. The proposed use for isofetamid to control Botrytis and as a protectant against powdery mildew in grapes is for up to two applications at a rate of 37.5 gai/100L water, with a minimum 10 day interval, before bunch closure. The Withholding Period that applied is 'Do NOT apply after pre-bunch closure'. For the practice of using sheep for leaf plucking in vineyards, the applicable slaughter interval is 'Where vineyard leaf plucking is carried out, a 2-month clean feed interval before slaughter or collection of milk for human consumption must be observed after stock have been removed from the vineyard'. When stock are grazed post-harvest in vineyards, the label states that no clean feed slaughter or milking interval applies.

3.4.3 Residue Information

The residue data for the use of isofetamid are sufficient to conclude that, when applied according to the proposed GAP use pattern, residues of isofetamid should not exceed 0.08 mg/kg in grapes at harvest. The residue definition of 'isofetamid' (parent) is appropriate for plant commodities for GAP compliance and dietary intake assessment.

Animal metabolism and feeding study data characterising residues in animal commodities following exposure to isofetamid were assessed and were sufficient to conclude that use of the compound on grapes and subsequent vineyard grazing and leaf plucking practices will not result in residues above 0.01 mg/kg in animal commodities. The proposed residue definitions applicable in New Zealand for animal commodities align with those established by Codex: *'Sum of isofetamid and 2-[3-methyl-4-[2-methyl-2-(3-methylthiophene-2-carboxamido) propanoyl]phenoxy]propanoic acid (PPA), expressed as isofetamid'* for both GAP compliance and dietary intake.

3.4.4 Dietary Risk Assessment

The HBGV of 0.035 mg/kg bw/day was considered appropriate for use in the assessment. Based on the residue profile expected in food from crops treated with isofetamid the NEDI is estimated to total less than 0.2% of the HBGV for the average New Zealand adult.

New Zealand Food Safety has therefore determined that the use of isofetamid according to the GAP specified above is unlikely to pose any health risks from authorised use.

3.4.5 Relevant International MRLs

Authority	Food	Maximum Residue Level (mg/kg)
Codex	Edible offal (mammalian)	0.07
	Mammalian fats (except milk fats)	0.02
	Meat (from mammals other than marine mammals)	0.02
	Milks	0.01
	Small fruit vine climbing	3
Australia	Edible offal (mammalian)	0.02
	Meat (mammalian) [in the fat]	0.02
	Milks	0.02
	Milk fats	0.02
Canada	Fat of cattle, goats, and sheep	0.01
	Meat byproducts of cattle, goats and sheep	0.01
	Meat of cattle, goats and sheep	0.01
	Milk	0.01

Authority	Food	Maximum Residue Level (mg/kg)
European Union	All bovine, sheep, and goat commodities, including milk	0.01
Japan	All animal commodities, including milk	0.01

3.5 PROPOSAL TO DELETE THE NOTICE ENTRY FOR KANAMYCIN

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)
~~Kanamycin~~	~~59-01-8~~	~~Kanamycin A~~	~~Milk~~	~~0.15~~

3.5.1 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 kanamycin was de-registered in 2006). Kanamycin MRLs are therefore no longer required to manage GAP use of the compound in New Zealand.

3.6 PROPOSAL TO AMEND THE MRLS FOR MALDISON (MALATHION)

It is proposed that MRLs for maldison (malathion) are amended to align the crop grouping for 'Fruiting vegetables' with the new Codex food classification.

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)
Maldison (malathion)	121-75-5	Maldison	Asparagus Avocados Broccoli Brussels sprouts Bulb vegetables Cabbages Cattle fat Cauliflowers Celery Cereal grains Citrus fruits Cucumbers Eggs Fruiting vegetables (except cucumbers, melons, ~~mushrooms,~~ sweet peppers, ~~sweetcorn~~, and tomatoes) Grapes Horse fat Leafy vegetables Legume vegetables Melons	1 2 8 8 5 5 1 5 5 8 5 0.2 1 8 5 1 5 3 2

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Residue Level (mg/kg)
			Mushrooms	1
			Peppers (sweet)	1
			Pig fat	1
			Pome fruits	0.5
			Root vegetables	3
			Stone fruits	5
			Sweetcorn	1
			Tomatoes	5
			Tuber vegetables	3
			Meat, fat or offal from any other animal	0.5
			Milk	0.5

3.6.1 Amendment Rationale

The amendment is proposed to clarify existing MRLs and align with Codex crop groupings. As sweetcorn and mushrooms are no longer included in the Codex crop grouping for 'Fruiting vegetables', it is proposed that they are removed from the description as they no longer need to be specifically stated as exceptions from the 'Fruiting vegetables' crop group. Separate MRLs of 1 mg/kg for the approved uses for sweetcorn and mushrooms are currently listed in the table. The proposed wording change will not alter the MRL which applies for any of the foods listed.

3.6.2 Good Agricultural Practice

Maldison (known elsewhere in the world as malathion, the approved ISO common name) is a broad spectrum, non-systemic organophosphorous insecticide with activity against a wide range of insect pests of agricultural crops and animals. Maldison has been used in New Zealand since 1979. There are currently four registered products containing the active ingredient maldison in New Zealand, with uses for control of black field crickets in pasture; control of a wide range of insects in fruit crops, field crops, and vegetables; and control of grain storage pests in stored grain and silos. The current GAP remains unchanged.

3.6.3 Relevant International MRLs

Authority	Food	Maximum Residue Level (mg/kg)
Codex	Cucumber	0.2
	Peppers	0.1
	Sweet corn (corn-on-the-cob)	0.02
	Tomato	0.5
Australia	Cucumber	3
	Fruiting vegetables, cucurbits {except cucumber}	2
	Fruiting vegetables, other than cucurbits {except Peppers, sweet [capsicum]}	3
	Peppers, sweet [capsicum]	T5

3.7 PROPOSAL TO AMEND THE MRLS FOR NITROXYNIL

It is proposed that MRLs for nitroxynil are amended to better support the GAP use of the compound in cattle.

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)
Nitroxynil	1689-89-0	Nitroxynil	Cattle fat Cattle kidney Cattle liver Cattle meat **Cattle milk**	0.2 0.4 0.02 0.4 **0.02(*)**

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

3.7.1 Amendment Rationale

Nitroxynil has been approved for use in cattle in New Zealand for parasite control since 2009, with cattle fat, kidney, liver, and meat commodities attracting set withholding periods. The compound is however not permitted for use in lactating cattle, so a milk MRL was not previously set. The revised entry is proposed to better reflect the GAP use of nitroxynil in cattle, with the setting of the milk MRL at the limit of analytical quantification to indicate the exclusion of use in dairy cattle.

3.7.2 Good Agricultural Practice

Nitroxynil is a halogenated phenol fasciolicide which acts by uncoupling oxidative phosphorylation in the target parasite. It is used in veterinary medicine as a treatment for *Fasciola hepatica* in cattle at a dose rate of 10.2 mg/kg, in combination with ivermectin and clorsulon. Use of this combination attracts a meat withholding period of 56 days, with a restriction that the product must not be used in lactating cows or pregnant cattle that may in the future produce milk for human consumption.

3.7.3 Residue Information

Because the compound is not permitted for use in dairy cattle, the proposed MRL will be set to ensure a lack of residues in milk rather than a level conforming to GAP use. As such, it was not necessary to evaluate milk residue data for nitroxynil.

3.7.4 Dietary Risk Assessment

The HBGV of 0.005 mg/kg bw/d was considered appropriate for use in the assessment. Based on the residue profile expected in food from animals treated with nitroxynil when used according to GAP, the NEDI is estimated to total less than 17% of the HBGV.

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

3.7.5 Relevant International MRLs

Authority	Food	Maximum Residue Level (mg/kg)
Australia	Cattle meat Cattle edible offal	1 1
European Union	Bovine muscle Bovine fat Bovine liver Bovine kidney Milk	0.4 0.2 0.02 0.4 0.02
Japan	Cattle muscle Cattle fat Cattle liver Cattle kidney Cattle edible offal	0.5 0.6 0.5 0.5 0.5

3.8 PROPOSAL TO SET MRLS FOR OLEANDOMYCIN

It is proposed that MRLs are set for oleandomycin to support the GAP use of the compound in cattle.

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

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Residue Level (mg/kg)
Oleandomycin	**3922-90-5**	**Oleandomycin**	**Cattle meat** **Cattle offal** **Cattle milk**	**0.1** **0.1** **0.05(*)**

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

3.8.1 Amendment Rationale

Oleandomycin has been registered for use in New Zealand cattle since the late 1960s and has been subject to compliance with the New Zealand default MRL of 0.1 mg/kg. While the GAP use of the compound has not changed over time, the new MRLs are being proposed to better support the use of the compound in cattle to provide better visibility of the expected residue levels with that GAP use and observing the applicable withholding periods.

3.8.2 Good Agricultural Practice

Oleandomycin is a macrolide antibiotic which works by binding the 50s subunit of bacterial ribosomes to inhibit protein synthesis. It is used in New Zealand in dairy cattle in the management of acute and chronic mastitis requiring intervention with a macrolide antibiotic at an intramammary dose rate of 100mg per infected quarter once daily for three days.

As a macrolide, oleandomycin is classed as a critically important antibiotic. GAP use of a critically important antibiotic is to reserve the use of the compound for conditions that respond poorly to other classes of antibiotic following culture and sensitivity testing with use limited to only the minimum period needed to meet the clinical objective.

3.8.3 Residue Information

The residue data for the use of oleandomycin are sufficient to conclude that, when used in dairy cattle according to the established GAP and observing the applicable withholding periods, residues of oleandomycin should not exceed 0.1 mg/kg in meat and offal and below the limit of quantification (0.05 mg/kg) in milk. The residue definition of 'oleandomycin' is considered appropriate for both GAP compliance and dietary intake assessment.

3.8.4 Dietary Risk Assessment

The HBGV of 0.0075 mg/kg bw/day was considered appropriate for use in the assessment. Based on the residue profile expected in food from cattle treated with oleandomycin, the NEDI is estimated to total less than 6% of the HBGV for the average New Zealand adult.

New Zealand Food Safety has therefore determined that the use of oleandomycin according to the GAP specified above is unlikely to pose any health risks from authorised use.

3.8.5 Relevant International MRLs

Authority	Food	Maximum Residue Level (mg/kg)
Australia	Edible offal (mammalian) Meat (mammalian)	0.1 0.1

3.9 PROPOSAL TO AMEND THE MRLS FOR SULFOXAFLOR

It is proposed that MRLs for sulfoxaflor are amended to align the crop grouping for 'Fruiting vegetables' with the new Codex food classification.

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

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

3.9.1 Amendment Rationale

The amendment is proposed to clarify existing MRLs and align with Codex crop groupings. As sweetcorn and mushrooms are no longer included in the Codex crop grouping for 'Fruiting vegetables', it is proposed that they are removed from the description. Separate MRLs are not required as there are no approved uses for either sweetcorn or mushrooms. Instead, it is proposed that cucurbits are specifically excluded from the 'Fruiting vegetables' grouping, as there is an existing MRL for the 'Cucurbits' subgroup. The proposed wording change will not alter the MRL which applies for any of the foods listed.

3.9.2 Good Agricultural Practice

Sulfoxaflor is a sulfoximine insecticide with systemic activity against sap-sucking insects which has been used in New Zealand since 2013. There is currently one registered product containing the active ingredient sulfoxaflor in New Zealand, with uses for control of aphids and whitefly on wheat, barley, forage brassicas, cucurbits (excluding pumpkins and winter squash), fruiting vegetables, leafy vegetables, root and tuber vegetables and vegetable brassicas. The current GAP remains unchanged.

3.9.3 Relevant International MRLs

Authority	Food	Maximum Residue Level (mg/kg)
Codex	Cucurbits Fruiting vegetables, other than cucurbits	0.5 1.5
Australia	Fruiting vegetables, cucurbits Fruiting vegetables, other than cucurbits [except sweet corn (corn-on-the-cob)]	0.5 1

3.10 PROPOSAL TO AMEND THE ENTRY FOR PHOSPHOROUS ACID IN SCHEDULE 2

It is proposed that the entry for phosphorous acid in Schedule 2 of the Notice is amended to clarify the intended scope of the entry regarding its condition of listing. When the entry was extended in 2011, the intent of the change was to allow for the listing to apply when either the compound is directly applied as an agricultural compound or to manage residues arising from the use of fosetyl aluminium. The change being proposed to this entry is to better represent this intent by making it clearer that the entry applies to two separate situations.

The amended entry in Schedule 2 will read as follows:

Substance	CAS#	Condition
Phosphorous acid	10294-56-1 or 13598-36-2	When directly used as an agricultural compound, **or when** representative of the use of fosetyl aluminium as an agricultural compound.