

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

New Zealand Food Safety Discussion Paper No: 2019/10

Prepared for public consultation
By New Zealand Food Safety

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1 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.

For **each compound** you are commenting on, please clearly answer the following questions. Any additional comment is welcome, along with supporting discussion, and data or examples to illustrate particular points.

On balance, do you oppose any of the commodity MRLs proposed for this compound?

Do you oppose an MRL being set at all for this compound for the commodity?

If an MRL is to be set for this compound for the commodity, do you disagree with the particular level proposed? If so, why do you disagree?

Submissions close at 5pm on **11 February 2020**. Your comments should be sent to:

MRL Amendments
New Zealand Food Safety
Ministry for Primary Industries
PO Box 2526
Wellington 6140

Email: ACVM.Consultation@mpi.govt.nz.

Please include your name and address on your submission. If you are making comments on behalf of an organisation, also include your title and the name of the organisation.

Please make sure your comments can be clearly read, as a number of copies of your submission may be made.

The Official Information Act

The Official Information Act 1982 (the OIA) states that information is to be made available unless there are grounds for withholding it. The grounds for withholding information are outlined in the OIA. Submitters may wish to indicate any grounds for withholding information contained in their submission. Reasons for withholding information could include that information is commercially sensitive or that the submitters wish personal information such as names or contact details to be withheld. MPI will take such indications into account when determining whether or not to release information. Any decision to withhold information requested under the OIA may be reviewed by the Ombudsman.

2 Introduction

Agricultural compounds are natural or synthetic substances used in the management of plants and animals, and include veterinary medicines, fertilisers, and pesticides (fungicides, herbicides and insecticides). Growers and farmers use agricultural compounds to manage disease in animals and crops, protect the food supply, and maximise the quantity and quality of the food they grow.

Use of these agricultural compounds can leave residues in the food from those crops and animals that must be managed. To ensure only the appropriate amount of agricultural compounds are used to achieve their intended purpose, a set of principles and methods known as good agricultural practice (GAP) are utilised. GAP covers the production of safe and good quality horticultural and animal products.

GAP is established for each agricultural compound by evaluating public health, crop safety, animal health and safety, and occupational and environmental safety considerations for the range of treatments and use patterns. This involves determining the administration and application rates and ranges necessary for an agricultural compound to achieve its intended effects, while leaving the smallest amount of residue practicable without compromising that efficacy.

Once the GAP has been established for a use for an agricultural compound, the residues resulting from its use up to the highest authorised dose or application rate is then used to establish maximum residue levels (MRLs) in food commodities from crops and animals associated with that use. The MRLs are then compared against the health based guidance value in an evaluation commonly referred to as the dietary exposure (or dietary risk) assessment. This is explained in more detail below.

MRLs are the maximum legal levels for residues of agricultural compounds permitted in food for sale in New Zealand. They are established based on domestic uses of a particular compound, and are used to monitor GAP compliance in New Zealand while ensuring food safety. Because they are based on New Zealand authorised uses according to domestic GAP, MRLs may differ from those established overseas for a similar use because their GAP may be different. However, as noted below, imported food can also comply with Codex MRLs.

To meet New Zealand's obligations under the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) the proposed MRL will be notified to the World Trade Organization. Any country may choose to comment if they believe the proposed MRL represents a barrier to their trade.

2.1 BACKGROUND

MRLs are set out in the New Zealand (Maximum Residue Levels for Agricultural Compounds) Food Notice. This Notice is amended two to four times each year to reflect changes in the use of agricultural compounds in the production of food. The MRL Food Notice is available from the Ministry for Primary Industries (MPI) 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 MRL Food Notice, with the final decision on any changes to the Notice resting with the Director-General of MPI. The Food Notice is issued under section 405 of the Food Act 2014. When setting or amending MRLs, the Director-General must take into account:

- the need to protect public health;
- the desirability of avoiding unnecessary restrictions on trade;

- the desirability of maintaining consistency between New Zealand's food standards and those standards that apply internationally;
- New Zealand's obligations under any relevant international treaty, agreement, convention, or protocol, and, in particular, under the Australia-New Zealand Joint Food Standards Agreement; and
- such other matters as appropriate.

The requirements for the content of the MRL Food Notice are set out in Part 6 of the Food Regulations 2015, allowing for the promulgation of MRLs for agricultural compounds as well as the promulgation of exemptions from compliance with MRLs. In addition to establishing the requirements on domestically produced foods, Part 6 of the Food Regulations also outlines the residue level compliance requirements for imported foods. Clause 144 states that food must contain residues of agricultural compounds:

- no greater than the MRLs specified for that food in a notice set under the Food Act 2014 (section (1)(a)); or
- the default MRL of 0.1 mg/kg (section (1)(c)); or
- 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) (section (1)(d)).

As imported food commodities can comply with either a Codex MRL or a MRL established in the MRL Food Notice, New Zealand's obligations under the SPS Agreement are met.

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

2.1.1 National Estimated Dietary Intake

The chronic dietary exposure to a substance is estimated by the NEDI calculation, encompassing all authorised uses of the agricultural compound, and using food consumption data based upon the 1997 National Nutritional Survey for adults and the 1995 National Nutrition Survey of Australia, for children. The NEDI calculation is made in accordance with Guidelines for predicting dietary intake of pesticide residues (revised) [World Health Organization, 1997]. The NEDI calculation provides an estimation of the potential chronic exposure to toxicologically relevant residues in all food derived from crops/livestock treated with the agricultural compound according to the authorised GAP use.

The possible implications for consumer health are considered during the toxicological and dietary risk assessments, by comparing the NEDI with a Health Based Guidance Value (HBGV). Provided the estimated dietary exposure of all toxicologically relevant residue components in all fresh and processed food is less than the HBGV, the use of an agricultural compound according to GAP is unlikely to pose a health risk to consumers.

2.1.2 Health Based Guidance Values

The HBGV used in determining the estimated dietary exposure may be either a Potential Daily Exposure (food) ($PDE_{(food)}$) or an Acceptable Daily Intake (ADI). The ADI and $PDE_{(food)}$ are largely equivalent, as they are determined using the same set of toxicology data and through a very similar scientific process. HBGVs are reported as milligrams of compound per kilogram bodyweight per day (mg/kg bw/d).

A $PDE_{(food)}$ is a value determined by a toxicological evaluation by the New Zealand Environmental Protection Authority (EPA) as part of its responsibility for managing public health under the Hazardous Substances and New Organisms Act 1996 (the HSNO Act). A

PDE_(food) gives the potential daily exposure a person may be subject to from a substance, via food.

An ADI is defined by the World Health Organization (WHO) as: “the daily intake which, during an entire lifetime, appears to be without appreciable risk on the basis of all the known facts at the time”. “Without appreciable risk” has been further defined as: “the practical certainty that injury will not result even after a lifetime of exposure”. ADIs are established by the WHO and Food and Agriculture Organization (FAO) of the United Nations joint expert committees, which are made up of toxicologists and residue specialists. The ADI information from these joint committees also feeds into the Codex Alimentarius Commission (Codex), which sets international MRLs.

As required by the HSNO Act in New Zealand, New Zealand Food Safety uses the PDE_(food) set by the EPA as the HBGV for the estimation of dietary exposure when one is available. If there is no PDE_(food), the estimated dietary exposure is compared with the ADI, set by the WHO/FAO joint expert committees, the Australian Pesticides and Veterinary Medicines Authority (APVMA), the European Food Safety Authority (EFSA), or another regulatory authority. If none of these are available, the HBGV used will be a New Zealand Food Safety-determined ADI.

2.1.3 International MRLs and Trade

The “Relevant International MRLs” table listed in each entry is a summary of the MRLs set by Codex and a selection of other international regulatory bodies reviewed to evaluate trade risk. For animal commodities, the MRLs set by Australia, Canada, China, Codex, the European Union, Japan, and the USA are reviewed and compared; for horticultural commodities, MRLs set by Codex and Australia are reviewed and compared. Other international MRLs are reviewed and reported in the table if there is a particular trade risk to be considered for those regions. If a particular international body or regulator does not have MRLs set for the species or crop for which a New Zealand MRL is being proposed, that international body or regulator is omitted from the “other international MRLs” section of the proposal entry.

2.2 SUMMARY OF PROPOSED AMENDMENTS

The proposed MRLs have been thoroughly assessed in accordance with international methodologies published by the Organisation for Economic Cooperation and Development (OECD), International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH), or FAO. Information on the technical assessment of each proposal is included in this document (refer section 3) and covers:

- rationale;
- chemical information;
- good agricultural practice;
- residues information;
- dietary risk assessment;
- toxicological/public health assessment; and
- MRLs set by Codex and other relevant authorities (e.g. Australia, Canada, China, EU, Japan, USA)

Where an existing entry is proposed for revision, new or revised MRLs are highlighted in bold print, and MRLs proposed for revocation are identified using a strikethrough.

New Zealand Food Safety has reviewed the estimated dietary exposure assessments associated with all authorised and proposed uses according to what has been established as GAP for New Zealand, compared them with the appropriate HBGV (the PDE_(food) or an ADI),

and has concluded that residues arising from these uses are unlikely to present any public health or food safety concerns.

2.2.1 Amendments to Schedule 1: New and Amended MRLs

New Zealand Food Safety proposes to add new MRLs to the Food Notice, and/or amend the existing entries, for the following compounds:

- Fenpicoxamid: 0.01(*) mg/kg in eggs, 0.01(*) mg/kg in mammalian fat, 0.02 mg/kg in mammalian kidney, 0.02 mg/kg in mammalian liver, 0.01(*) mg/kg in mammalian meat, 0.01(*) mg/kg in milk, 0.01(*) mg/kg in poultry meat, 0.01(*) mg/kg in poultry offal, and 0.3 mg/kg in wheat grain.
- Fludioxonil: 10 mg/kg in kumara.
- Flumioxazin: 0.01(*) mg/kg in bush berries, and 0.05(*) mg/kg in hops.
- Fluopyram: 0.2 mg/kg in parsnips.
- Fluralaner: amendment of the chicken eggs MRL from 1 mg/kg to 1.3 mg/kg.
- Indaziflam: 0.02(*) mg/kg in grapes, 0.02(*) mg/kg in pome fruits, and 0.02(*) mg/kg in stone fruits.
- Lambda-cyhalothrin: 0.2 mg/kg in brassica vegetables (transfer of the MRL currently promulgated under the 'cyhalothrin' entry).
- Oxyfluorfen: 0.01(*) mg/kg in potatoes.
- Prothioconazole: 0.01(*) mg/kg in mammalian fat, 0.01(*) mg/kg in mammalian meat, 0.02 mg/kg in mammalian offal, and 0.004(*) mg/kg in milk.
- Pyriofenone: 0.2 mg/kg in fruiting vegetables (cucurbits).

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

New Zealand Food Safety also proposes to remove MRLs from the Food Notice for the following compounds:

- Cyhalothrin, after transfer of the current 0.2 mg/kg MRL in 'brassica vegetables' to the lambda-cyhalothrin entry.
- Lindane, to remove the 2 mg/kg MRL in 'fats (except milk fats)'.

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

- New Zealand Food Safety proposes to add a new exemption for vitamins, minerals, and essential trace elements used for nutritional supplementation in Schedule 3 of the Food Notice, for which no maximum residue levels apply. These are used in a variety of food-producing animal species for nutritional supplementation for the purposes of supporting general animal health.

3 Proposals

3.1 PROPOSAL TO REMOVE THE MRL FOR CYHALOTHRIN

It is proposed that Notice entry for cyhalothrin is removed, and the MRL for its use in brassica vegetables is moved to the entry for lambda-cyhalothrin. Details of this change are presented as part of the discussion of the lambda-cyhalothrin entry amendment, in section 3.8 of this consultation document.

3.2 PROPOSAL TO SET MRLS FOR FENPICOXAMID

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

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

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Fenpicoxamid	517875-34-2	Fenpicoxamid	Eggs Mammalian fat Mammalian kidney Mammalian liver Mammalian meat Milk Poultry meat Poultry offal Wheat grain	0.01(*) 0.01(*) 0.02 0.02 0.01(*) 0.01(*) 0.01(*) 0.01(*) 0.3

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

3.2.1 Amendment Rationale

The MRLs are being proposed to support the use of fenpicoxamid as a fungicide on wheat crops in accordance with the use patterns proposed as GAP in New Zealand.

3.2.2 Good Agricultural Practice

Fenpicoxamid is a 'quinone inside inhibitor' fungicide used on wheat crops to control speckled leaf blotch, and suppress brown leaf rust. The compound is applied at a rate of up to 100g ai/ha as a preventative spray when conditions favour speckled leaf blotch, or at the first sign of disease. A second application 3-4 weeks later is indicated if disease pressure persists or re-infection occurs. Fenpicoxamid is applied between first node (BBCH30) and early post flower (BBCH69) growth stages, and is recommended for use in combination with a suitable tank mix partner for resistance management purposes.

Good agricultural practice for fenpicoxamid dictates that the compound must not be applied after the early post flower growth stage (BBCH69). For animal feed purposes, the grazing or cutting of fodder or green feed must not occur until two weeks after the last application, though the use of grain and straw does not require a withholding period when the compound is used according to GAP.

3.2.3 Residue Information

The residue data for the use of fenpicoxamid in wheat were sufficient to conclude that, when applied as per the proposed GAP use pattern and complying with the applicable withholding period, residues of parent fenpicoxamid should not exceed 0.3 mg/kg in wheat grain.

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

Trial data evaluating the metabolism of the compound demonstrated that parent fenpicoxamid was the main residue detected in plant-derived food commodities. It is therefore considered that 'fenpicoxamid' is sufficient to function as both the residue definition for GAP compliance and dietary intake assessments for these commodities.

The metabolism of fenpicoxamid in animals was well characterised in the data. The absorption of fenpicoxamid is minimal, with the only quantifiable residues present being for metabolites of fenpicoxamid, primarily in liver and kidney in both ruminant and poultry species. While a parent-only residue definition will be sufficient to monitor animal commodities for GAP compliance, the residue definition used to evaluate dietary intake will be set at the sum of parent fenpicoxamid and the main metabolites in the exposed animal species: X12326349, 13495S-3S, X12264475 and X642188 for mammalian-derived commodities, and X11963422, X696872, X129300, and X12264475 for the poultry-derived commodities.

3.2.4 Dietary Risk Assessment

The HBGV of 0.035 mg/kg bw/d, and the stated dietary intake residue definitions, were considered appropriate for use in the assessment.

Based on the residue profile expected in food from crops treated with fenpicoxamid, as well as in animal products from livestock that are grazed on or fed treated crops or crop products, the NEDI is estimated to total less than 2% of the HBGV.

New Zealand Food Safety has therefore determined that the use of fenpicoxamid, when use 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	Bovine, sheep, and poultry muscle	0.01
	Bovine, sheep, and poultry fat	0.01
	Bovine liver	0.01
	Bovine kidney	0.02
	Bovine edible offals (other than liver and kidney)	0.01
	Sheep liver	0.02
	Sheep kidney	0.02
	Sheep edible offals (other than liver and kidney)	0.01
	Poultry liver	0.01
	Poultry kidney	0.01
	Poultry edible offals (other than liver and kidney)	0.01
	Milk	0.01
	Birds eggs	0.01
	All other farmed terrestrial species	0.01

3.3 PROPOSAL TO AMEND THE MRLS FOR FLUDIOXONIL

It is proposed that the Notice entry for fludioxonil is amended to set a MRL to support the GAP use of the compound on kumara.

The revised entry for fludioxonil in Schedule 1 of the Notice will read as follows. Changes are shown in bold:

Compound Common Name	CAS#	Residue to which the maximum residue level applies	Food	Maximum Residue Level (mg/kg)
Fludioxonil	131341-86-1	Fludioxonil	Blackcurrants Blueberries Bulb onions Grapes Kumara Pineapples Strawberries	0.8 0.5 0.01(*) 1 10 7 1

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

3.3.1 Amendment Rationale

The MRL is being proposed to support an expansion of the use of fludioxonil to kumara. The proposed MRL will manage the use of the compound as a post-harvest treatment of kumara tubers for the control of *Rhizopus* rot, in accordance with the use pattern proposed as GAP in New Zealand.

3.3.2 Good Agricultural Practice

Fludioxonil is a non-systemic phenylpyrrole fungicide, with long residual activity and limited uptake into plant tissues. The mode of action is inhibition of conidia germination, and to a lesser extent, germ tube and mycelial growth inhibition. It is currently used as a pre-plant potato seed treatment, and in co-formulations with cyprodinil or fluazinam for use in grapes, blackcurrants, blueberries, strawberries and bulb onions. For the additional use in kumara, the compound is applied at a rate of 60g ai/100L as a post-harvest in-line dip/drench or spray over the brush bed, with or without wax, to soil-free tubers. A specific withholding period is not required on the label when used as directed in kumara.

3.3.3 Residue Information

The residue data for the use of fludioxonil are sufficient to conclude that, when applied according to the proposed GAP use pattern, residues of fludioxonil should not exceed 10 mg/kg in kumara tubers. The current residue definition of 'fludioxonil' remains appropriate for plant commodities (for both GAP-compliance and dietary intake assessment).

Animal commodity MRLs are not proposed as kumara are not considered to be a primary animal feed.

3.3.4 Dietary Risk Assessment

The HBGV of 0.0165 mg/kg bw/d was considered appropriate for use in the assessment.

Based on the residue profile expected in food from crops treated with fludioxonil, the NEDI is estimated to total less than 12% of the HBGV.

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

3.3.5 Relevant International MRLs

Authority	Food	Maximum Residue Level (mg/kg)
Codex	Sweet potato	10

3.4 PROPOSAL TO AMEND THE MRLS FOR FLUMIOXAZIN

It is proposed that the Notice entry for flumioxazin is amended to set MRLs to support the GAP use of the compound on hops and bush berries.

The revised entry for flumioxazin in Schedule 1 of the Notice will read as follows. Changes are shown in bold:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Residue Level (mg/kg)
Flumioxazin	103361-09-7	Flumioxazin	Bush berries Grapes Hops Kiwifruit Mammalian fat Mammalian meat Mammalian offal Milk Pome fruits Stone fruits	0.01(*) 0.02(*) 0.05(*) 0.02(*) 0.02(*) 0.02(*) 0.02(*) 0.02(*) 0.02(*) 0.02(*)

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

3.4.1 Amendment Rationale

The MRL is being proposed to support the expansion of use of the herbicide flumioxazin. The proposed MRLs will manage the use of the compound as a post-planting herbicide on bush berries and hops, in accordance with the use patterns and withholding periods that are proposed as GAP in New Zealand.

3.4.2 Good Agricultural Practice

Flumioxazin is a phenylthalamide protoporphyrinogen oxidase inhibitor, used for residual pre-emergent control of a range of broad-leaf weeds and suppression of some grass weed species. It has been used in orchard and vineyard situations, and its use will be extended to weed management in bush fruit (blueberries, currants, and gooseberries) and hop crops.

The primary assessment has concluded that the Good Agricultural Practice is for a single application of 0.42kg ai/ha flumioxazin for bush berries. The compound is used as a within-row banded soil application before bud break, generally as a pre-emergent treatment to bare ground but also in combination with knockdown herbicides when small weeds are present. This use attracts a withholding period restricting application to before the start of flowering in spring for deciduous varieties, and a requirement that spray and spray drift does not come in contact with fruit, foliage, or green bark on evergreen varieties.

In hops, flumioxazin is also applied at 0.42kg ai/ha as a pre-emergent treatment to bare ground before sucker emergence, and is also indicated for use in combination with knockdown herbicides for small weeds. The withholding period applied to this use is a requirement to restrict treatment to before sucker emergence.

The current livestock restriction for the use of flumioxazin in other fruit crops is a 60 day pre-grazing interval. This same restriction is considered adequate to support the new use in bush fruit and hops.

3.4.3 Residue Information

The residue data for the use of flumioxazin on the specified fruits are sufficient to conclude that, when applied according to the proposed GAP use pattern, residues of flumioxazin should not be quantifiable in mature bush berries at harvest or dried cones from hops. The current residue definition of 'flumioxazin' remains appropriate for plant commodities (for both GAP compliance and dietary intake assessment).

The current MRLs for animal commodities are sufficient to manage residues in animals exposed to flumioxazin through grazing in treated bush fruit and hop gardens. The use of 'flumioxazin' for GAP compliance is still considered appropriate.

3.4.4 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 crops treated with flumioxazin, the NEDI is estimated to total less than 2% of the HBGV.

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

3.4.5 Relevant International MRLs

Authority	Food	Maximum Residue Level (mg/kg)
Codex	Bush berries	0.02

3.5 PROPOSAL TO AMEND THE MRLS FOR FLUOPYRAM

It is proposed that the Notice entry for fluopyram is amended to set a MRL to support the GAP use of the compound on parsnips.

The revised entry for fluopyram in Schedule 1 of the Notice will read as follows. Changes are shown in bold:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Residue Level (mg/kg)
Fluopyram	658066-35-4	Plant commodities: Fluopyram Animal commodities: Sum of fluopyram and 2-(trifluoromethyl) benzamide, expressed as fluopyram	Bulb onions Cereal grains Carrots Eggs Fruiting vegetables (except cucurbits) Grapes Mammalian fat Mammalian kidney Mammalian liver Mammalian meat Milk Parsnips Stone fruits	0.01(*) 0.01(*) 0.2 0.3 1.0 0.05 0.5 0.7 3 0.5 0.3 0.2 0.7

(*) 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 an expansion of the use of fluopyram to parsnips. The proposed MRL will manage the use of the compound in parsnips in accordance with the use pattern and withholding period that are proposed as GAP in New Zealand.

3.5.2 Good Agricultural Practice

Fluopyram is a succinate dehydrogenase inhibitor (SDHI) used to manage fungal diseases in a number of fruit and vegetable crops in New Zealand as well as for the suppression of root knot nematodes in carrots. The new use for fluopyram in parsnips is also for root knot nematode suppression, applied at a rate of 500g ai/ha as broadcast spray for immediately incorporation into the soil prior to planting. This use attracts a withholding period of 100 days.

3.5.3 Residue Information

The residue data for the use of fluopyram are sufficient to conclude that, when applied according to the proposed GAP use pattern, residues of fluopyram should not exceed 0.2 mg/kg in parsnips. The current residue definition of 'fluopyram' remains appropriate for plant commodities for GAP compliance, with 'fluopyram+benzamide' to be used for dietary intake assessment.

Current animal commodity MRLs do not require amendment as parsnips are not considered to be a primary animal feed.

3.5.4 Dietary Risk Assessment

The HBGV of 0.0084 mg/kg bw/d was considered appropriate for use in the assessment.

Based on the residue profile expected in food from crops treated with fluopyram the NEDI is estimated to total less than 45% of the HBGV.

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

3.5.5 Relevant International MRLs

There are no MRLs set by Codex or Australia for fluopyram in parsnips.

3.6 PROPOSAL TO AMEND THE MRLS FOR FLURALANER

It is proposed that the Notice entry for fluralaner is amended to adjust the MRL for eggs to better support the GAP use of the compound on layer hens.

The revised entry for fluralaner in Schedule 1 of the Notice will read as follows. Changes are shown in bold:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Residue Level (mg/kg)
Fluralaner	864731-61-3	Fluralaner	Chicken eggs Chicken fat/skin Chicken kidney Chicken liver Chicken meat	1.3 0.6 0.4 0.6 0.06

3.6.1 Amendment Rationale

The revised egg MRL is being proposed to better support the use of fluralaner in layer hens in accordance with the use pattern and withholding periods that are considered GAP in New Zealand.

3.6.2 Good Agricultural Practice

Fluralaner is an isoxazoline ectoparasiticide used in companion animals and layer hens in New Zealand. When used in hens, the compound is administered at a dose of 0.5 mg/kg in water for a total of two treatments seven days apart. The use of fluralaner in layer hens attracts a meat withholding period of 14 days and no withholding period in eggs. There is also a restriction that fluralaner is not to be used in broiler chickens.

3.6.3 Residue Information

The fluralaner residue data in animal commodities was reviewed to determine whether the existing MRLs were sufficient to manage the GAP use of the compound in layer hens. Although the data in eggs conformed to the 1 mg/kg MRL overall, some study data demonstrated that residues up to 1.3 mg/kg were possible at the GAP dose rate and interval. As such, the MRL for eggs is being adjusted to 1.3 mg/kg to ensure that better reflects GAP. All other MRLs will remain unchanged as the review confirmed that residues in those commodities will always conform to the established limits.

3.6.4 Dietary Risk Assessment

The HBGV of 0.01 mg/kg bw/d was considered appropriate for use in the assessment.

Based on the residue profile expected in products derived from layer hens treated with fluralaner, and the adjustment to the egg MRL, the NEDI is estimated to total less than 8% of the HBGV when the compound is used according to existing GAP uses.

New Zealand Food Safety has therefore determined that the use of fluralaner in layer hens according to the GAP specified above is unlikely to pose any health risks with authorised use.

3.6.5 Relevant International MRLs

Authority	Food	Maximum Residue Level (mg/kg)
European Union	Poultry Muscle	0.065
	Poultry skin and fat in natural proportions	0.65
	Poultry liver	0.65
	Poultry kidney	0.42
	Poultry eggs	1.3
Japan	Chicken, muscle	0.07
	Chicken, fat	0.7
	Chicken liver	0.7
	Chicken, kidney	0.4
	Chicken, edible offal	0.7
	Chicken eggs	1

3.7 PROPOSAL TO SET MRLS FOR INDAZIFLAM

It is proposed that MRLs are set for indaziflam to support the GAP use of the compound on pome and stone fruit orchards and vineyards.

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

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Indaziflam	950782-86-2	Sum of indaziflam and 1-fluoroethyl diaminotriazine (FDAT), expressed as indaziflam	Grapes Pome fruits Stone fruits	0.02(*) 0.02(*) 0.02(*)

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

3.7.1 Amendment Rationale

The MRLs are being proposed to support the use of the compound indaziflam on pome and stone fruit orchards and vineyards in accordance with the use patterns and withholding periods that are proposed as GAP in New Zealand.

3.7.2 Good Agricultural Practice

Indaziflam is a fluoroalkyltriazole herbicide, inhibiting cell wall synthesis in actively growing tissues. The compound is applied at a rate of 75g ai/ha, either as a single application on its own to bare soil as a single application pre-emergence, or in combination with a knock-down herbicide if small weeds are present. Use of indaziflam attracts withholding periods of 56 days for apples and pears, 30 days for stone fruit and 70 days for grapes.

The grazing of sheep in treated vineyards treated with indaziflam attracts a six month clean feed period. Because grazing in treated orchards is not an approved activity on the label, animal withholding periods have not been established for this use.

3.7.3 Residue Information

Metabolism studies indicate that the main metabolite in plant tissue following soil application and root uptake is 1-fluoroethyl diaminotriazine (FDAT) in all exposed crops, with the metabolite residues being proportionally greater than the parent residues. Because residues of the FDAT metabolite are a significant portion of the residue profile, it is considered that the residue definition 'Sum of indaziflam and 1-fluoroethyl diaminotriazine (FDAT), expressed as indaziflam' is appropriate to manage dietary intake and GAP compliance in food from treated crops.

The residue data for the use of indaziflam are sufficient to conclude that, when applied as per the proposed GAP use pattern and complying with the applicable withholding period, residues of indaziflam plus FDAT, calculated as indaziflam, should not exceed the limit of quantification, 0.02(*) mg/kg, in pome fruit, stone fruit or grapes.

The residue data supporting the use of indaziflam in orchards and vineyards has confirmed that when a six month default clean feed period is applied to exposed animals, there are no detectable residues expected in commodities from grazed sheep. As such, no animal commodity residue definition or animal commodity MRLs have been proposed for indaziflam.

3.7.4 Dietary Risk Assessment

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

Based on the residue profile expected in food from crops treated with indaziflam, the NEDI is estimated to total less than 0.2% of the HBGV.

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

3.7.5 Relevant International MRLs

There are no MRLs set by either Australia or Codex for indaziflam in pome fruit, stone fruit, or grapes.

3.8 PROPOSAL TO AMEND THE MRLS FOR LAMBDA-CYHALOTHRIN

It is proposed that the Notice entry for lambda-cyhalothrin is amended to support the GAP use of the compound on the specified food commodities.

The revised entry for lambda-cyhalothrin in Schedule 1 of the Notice will read as follows. Changes are shown in bold:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Residue Level (mg/kg)
Lambda- cyhalothrin	91465-08-6	Lambda-cyhalothrin	Brassica vegetables	0.2
			Citrus fruits	0.01(*)
			Grapes	0.01(*)
			Kumara	0.01(*)
			Maize	0.01(*)
			Mammalian fat	0.5
			Mammalian meat	0.01
			Mammalian offal	0.02
			Milk	0.05
			Onions	0.01(*)
			Potatoes	0.01(*)
			Pumpkins	0.01(*)
			Sweetcorn	0.01(*)
			Winter squash	0.01(*)

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

3.8.1 Amendment Rationale

The revised entry is being proposed to support the use of lambda-cyhalothrin on brassica vegetables, in accordance with the use patterns and withholding periods considered GAP in New Zealand.

The specific change being proposed is to combine the Notice entries for cyhalothrin and lambda-cyhalothrin. Cyhalothrin, which exists as a mixture of isomers, has been phased out as an agricultural compound in its own right in favour of formulations using the active isomer lambda-cyhalothrin. The merging of the two entries allows for a more accurate representation of compound use as it is today, and eliminates an otherwise redundant entry.

3.8.2 Good Agricultural Practice

Lambda-cyhalothrin is a synthetic pyrethroid insecticide approved for use on a range of fruit, vegetable, and arable crops including animal feed crops for the control of sucking and chewing insects. The GAP established for the use of lambda-cyhalothrin in these crops has not changed from that previously approved.

The use pattern considered GAP for lambda-cyhalothrin on vegetable brassicas is 5-10g ai/ha applied to seedbeds at two week intervals to control aphids, diamondback moth and

white butterflies, or applied at the base of the plants and surrounding soil to control cutworm once insect damage occurs. The use of lambda-cyhalothrin on vegetable brassicas attracts a three day withholding period.

3.8.3 Residue Information

Residue data on file for the use of both cyhalothrin and lambda-cyhalothrin in brassica vegetables were reviewed to determine the appropriate MRL for the Notice entry merge. As the main active component of the cyhalothrin isomer mix was lambda-cyhalothrin, the residue profile is similar between the two compounds. The residue data available was therefore sufficient to conclude that, when used on vegetable brassicas as per the established GAP use pattern and complying with the applicable withholding period, residues of lambda-cyhalothrin should not exceed 0.2 mg/kg. The residue definition 'lambda-cyhalothrin' is considered appropriate to apply to the transferred brassica vegetables MRL.

3.8.4 Dietary Risk Assessment

The HBGV of 0.0004 mg/kg bw/d, and the stated dietary intake residue definition, were considered appropriate for use in the assessment.

Based on the residue profile expected in food from crops treated with lambda-cyhalothrin, the NEDI is estimated to total less than 59% of the HBGV.

New Zealand Food Safety has therefore determined that the use of lambda-cyhalothrin, when use 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	Brassica (cole or cabbage) vegetables, head cabbages, flowerhead brassicas	0.1
Codex	Cabbages, head	0.3
	Flowerhead brassicas (includes Broccoli: Broccoli, Chinese and cauliflower)	0.5

3.9 PROPOSAL TO REMOVE THE MRL FOR LINDANE

It is proposed that the Notice entry for lindane is removed as it is no longer required to manage the potential for residues in animal commodities in New Zealand.

Lindane, also termed gamma-hexachlorocyclohexane (γ -BCH/HCH), is an organochlorine compound which was previously used as an insecticide on some animal species, fruit and vegetable crops, and pasture. This use attracted a MRL in 'fats (except milk fats)' at 2 mg/kg. The compound is no longer approved for use in New Zealand, and there have been no detections reported through New Zealand Food Safety's residue monitoring programmes for a number of years.

Any potential for exposure through residual environmental contamination can be effectively managed through other controls.

3.10 PROPOSAL TO AMEND THE MRLS FOR OXYFLUORFEN

It is proposed that the Notice entry for oxyfluorfen is amended to set a MRL to support the GAP use of the compound on potatoes.

The revised entry for oxyfluorfen in Schedule 1 of the Notice will read as follows. Changes are shown in bold:

Compound Common Name	CAS#	Residue to which the maximum residue level applies	Food	Maximum Residue Level (mg/kg)
Oxyfluorfen	42874-03-3	Oxyfluorfen	Brassica vegetables Grapes Kiwifruit Onions Pome fruits Potatoes Stone fruits	0.01(*) 0.01(*) 0.01(*) 0.01(*) 0.01(*) 0.01(*) 0.01(*)

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

3.10.1 Amendment Rationale

The MRL is being proposed to support the expansion of the use of oxyfluorfen to potatoes. The proposed MRL will manage the use of the compound as a post-plant herbicide on potatoes, in accordance with the application rates and withholding periods that are proposed as GAP in New Zealand.

3.10.2 Good Agricultural Practice

Oxyfluorfen is a diphenyl ether herbicide used for broad spectrum pre- and post-emergent control of broadleaf and grassy weeds through inhibition of the enzyme protoporphyrinogen oxidase. It is currently used in a range of situations including orchards, vineyards, onions, brassica vegetables, conservation tillage, and forest nurseries. For the additional use in potatoes, the compound is applied at a rate of 250-500g ai/ha as a single application to moist, firm, well cultivated soil at any time up to seven days after planting. A specific withholding period is not required on the label when used as directed in potatoes.

3.10.3 Residue Information

The residue data for the use of oxyfluorfen are sufficient to conclude that, when applied according to the proposed GAP use pattern, residues of oxyfluorfen should not be quantifiable in mature potato tubers at harvest. The current residue definition of 'oxyfluorfen' remains appropriate for plant commodities (for both GAP-compliance and dietary intake assessment).

Animal tissue MRLs are not proposed as potatoes are not considered to be a primary animal feed.

3.10.4 Dietary Risk Assessment

The HBGV of 0.0125 mg/kg bw/d and the stated dietary intake residue definitions, were considered appropriate for use in the assessment.

Based on the residue profile expected in food from all crops treated with oxyfluorfen the NEDI is estimated to total less than 3% of the HBGV.

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

3.10.5 Relevant International MRLs

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

3.11 PROPOSAL TO AMEND THE MRLS FOR PROTHIOCONAZOLE

It is proposed that the Notice entry for prothioconazole is amended to set MRLs in animal commodities to support the GAP use of the compound on cereal grains.

The revised entry for prothioconazole in Schedule 1 of the Notice will read as follows. Changes are shown in bold:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Prothioconazole	178928-70-6	Prothioconazole-desthio	Barley grain Cereal grains (except barley grain) Mammalian fat Mammalian meat Mammalian offal Milk	0.1 0.01(*) 0.01(*) 0.01(*) 0.02 0.004(*)

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

3.11.1 Amendment Rationale

The MRLs are being proposed to support the use of prothioconazole on barley, wheat, triticale, and ryegrass in accordance with the use patterns and withholding periods that are proposed as GAP in New Zealand.

3.11.2 Good Agricultural Practice

Prothioconazole is a triazolinthione fungicide used to rust, leaf blotches, and leaf spots on wheat, barley, triticale, and ryegrass seed crops. The compound is used at a rate of 150g ai/ha up to BBCH 69 (end of flowering) on wheat and triticale seed crops, and up to BBCH 61 (early flowering) on barley and ryegrass seed crops. These uses attract the following withholding periods: 56 days in barley grain and straw/stubble; 42 days in barley green feed/silage; 42 days in wheat and triticale grain and straw/stubble; 28 days in wheat and triticale green feed/silage; 49 days in ryegrass seed crops (regrowth); and 35 days in ryegrass seed crops (straw/stubble).

It is noted that the GAP and residue profiles of prothioconazole's use in New Zealand have not changed from that previously assessed.

3.11.3 Residue Information

The residue data for the use of prothioconazole on cereal crops were sufficient to conclude that, when applied as per the proposed GAP use pattern, residues of the marker metabolite prothioconazole-desthio should not exceed 0.1 mg/kg in barley grain and 0.01 mg/kg in all other cereal grains. The existing MRLs are therefore sufficient to support GAP for the use of prothioconazole in grain crops.

Animal metabolism and residue data presented were sufficient to assess the animal transfer residue profile prothioconazole, and confirm that the appropriate residue definition to use for GAP compliance in animal commodities is prothioconazole-desthio. Although the animal residue profile is essentially unchanged from that previously evaluated for residues transferred through animal feed consumption, animal commodity MRLs are being proposed to support GAP related animal feed uses and to provide clarity and transparency regarding animal exposure and MRL compliance. The animal residue data were sufficient to conclude that residues in commodities from animals grazed on or fed products made from prothioconazole-treated crops should remain below the limit of quantification for mammalian fat (0.01 mg/kg), meat (0.01 mg/kg) and milk (0.004 mg/kg), and below 0.02 mg/kg in mammalian offal.

As per the Codex definition, the residue definition for dietary intake purposes is the sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-desthio-4-hydroxy and their conjugates, expressed as prothioconazole-desthio.

3.11.4 Dietary Risk Assessment

The HBGV of 0.007 mg/kg bw/d and the stated dietary intake residue definition, was considered appropriate for use in the assessment.

Based on the residue profile of prothioconazole expected in food from crops treated according to existing and proposed GAP uses, and in animal commodities exposed to the compound through animal feed and grazing, the NEDI is estimated to total less than 2% of the HBGV when the compound is used according to existing and proposed GAP uses.

New Zealand Food Safety has therefore determined that the use of prothioconazole on cereal crops according to the GAP specified above, and the use of those crops as animal feed, is unlikely to pose any health risks from authorised use.

3.11.5 Relevant International MRLs

Authority	Food	Maximum Residue Level (mg/kg)
Australia	Edible offal (Mammalian)	0.2
	Meat [mammalian] [in the fat]	0.02
	Milks	0.004
Canada	Meat of horses, sheep, cattle, and goats	0.02
	Meat byproducts of horses, sheep, cattle, and goats	0.2
	Fat of horses, sheep, cattle, and goats	0.1
	Milk	0.02
Codex	Edible offal (mammalian)	0.3
	Mammalian fats (except milk fats)	0.02
	Meat (from mammals other than marine mammals)	0.01
	Milks	0.004
European Union	Muscle, all mammalian species	0.01
	Fat, all mammalian species	0.02
	Liver, all mammalian species	0.5
	Kidney, all mammalian species	0.5
	Edible offals (other than liver and kidney), all mammalian species	0.5
	Milk	0.01
Japan	Muscle, all mammalian species	0.01
	Fat, all mammalian species	0.05
	Liver, all mammalian species	0.6
	Kidney, all mammalian species	0.6
	Edible offal (other than liver and kidney), all mammalian species	0.6
	Milk	0.004
United States	Meat of horses, sheep, cattle, and goats	0.02
	Meat by products of horses, sheep, cattle, and goats	0.2
	Fat of horses, sheep, cattle, and goats	0.1
	Milk	0.02

3.12 PROPOSAL TO SET MRLS FOR PYRIOFENONE

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

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

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Pyriofenone	688046-61-9	Pyriofenone	Fruiting vegetables (cucurbits)	0.2

3.12.1 Amendment Rationale

The MRLs are being proposed to support the use of the novel compound pyriofenone as a fungicide on cucurbits in accordance with the application rates and withholding periods that are proposed as GAP in New Zealand.

3.12.2 Good Agricultural Practice

Pyriofenone is a benzoylpyridine fungicide with protectant activity against powdery mildew in cucurbits. The compound is applied at a rate of 120g ai/ha in a protectant programme at 14 day intervals when conditions favour disease development, with a maximum of three applications per crop. Use of this compound in cucurbits for powdery mildew prevention attracts a one day WHP.

3.12.3 Residue Information

The residue data for the use of pyriofenone are sufficient to conclude that, when applied as per the proposed GAP use pattern and complying with the applicable withholding period, residues of parent pyriofenone should not exceed 0.2 mg/kg in cucurbits. Parent pyriofenone was the predominant residue detected in plant-derived food commodities, and is therefore sufficient to function as both the residue definition for GAP compliance and dietary intake assessments for these commodities.

Animal tissue MRLs are not proposed as cucurbits are not considered to be a primary animal feed.

3.12.4 Dietary Risk Assessment

The HBGV of 0.05 mg/kg bw/d, and the stated dietary intake residue definitions, were considered appropriate for use in the assessment.

Based on the residue profile expected in food from crops treated with pyriofenone, the NEDI is estimated to total less than 0.2% of the HBGV.

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

3.12.5 Relevant International MRLs

Authority	Food	Maximum Residue Level (mg/kg)
Australia	Fruiting vegetables, cucurbits	0.7
Codex	Fruiting vegetables, cucurbits	0.2

3.13 PROPOSAL TO EXEMPT VITAMINS, MINERALS, AND ESSENTIAL TRACE ELEMENTS USED FOR NUTRITIONAL SUPPLEMENTATION FROM COMPLIANCE WITH A MRL

It is proposed that vitamins, minerals, and essential trace elements used as nutritional supplements in animals be exempt from compliance with an MRL by addition to Schedule 3 of the Notice. Compounds used for nutritional supplementation are administered to animals at very low doses intended to maintain normal physiological levels, which are unlikely to produce residues that will impact food safety. An exemption is therefore proposed to ensure residues remain at levels low enough to have a negligible impact on food safety, without needing to apply residue limits to veterinary medicines solely used for nutritional supplementation.

The proposed entry in Schedule 3 will read as follows:

Substance	CAS#	Condition
Vitamins, Minerals, and Essential Trace Elements Vitamins, minerals and essential trace elements defined as essential for human nutrition in the current edition of <i>Nutrient Reference Values for Australia and New Zealand</i> .	n/a	When the vitamin, mineral, or trace element is used as a veterinary medicine for the purpose of dietary supplementation to ensure normal physiological levels. The concentrations present in food from treated animals must not exceed the relevant upper level of intake as set out in the current edition of <i>Nutrient Reference Values for Australia and New Zealand</i> .