New Zealand Food Safety
Haumaru Kai Aotearoa

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

New Zealand Food Safety Discussion Paper No: 2022/01

Prepared for public consultation
By New Zealand Food Safety

ISBN No: 978-1-99-102651-4 (online)
ISSN No: 2624-0157 (online)

21 March 2022

New Zealand Government

Ministry for Primary Industries
Manatū Ahu Matua

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

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1 Request for submissions

New Zealand Food Safety invites public comment on this discussion document, which outlines proposals to amend the New Zealand (Maximum Residue Levels for Agricultural Compounds) Food Notice (Notice).

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

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

If a MRL in Schedule 1 or listing in Schedule 3 is to be set for this compound for the commodity, do you disagree with the levels or conditions proposed? If so, why do you disagree?

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

Submissions close at 5pm on **19 May 2022**. Your comments should be sent to:

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

Email: MaximumResidueLevels@mpi.govt.nz.

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

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

The Official Information Act

The Official Information Act 1982 (the OIA) states that information is to be made available unless there are grounds for withholding it. The grounds for withholding information are outlined in the OIA. Submitters may wish to indicate any grounds for withholding information contained in their submission. Reasons for withholding information could include that information is commercially sensitive or that the submitters wish personal information such as names or contact details to be withheld. MPI will take such indications into account when determining whether to release information. Any decision to withhold information requested under the OIA may be reviewed by the Ombudsman.

2 Introduction

Agricultural compounds are natural or synthetic substances used in the direct management of plants and animals, and include all agricultural chemicals (e.g. fungicides, herbicides, and insecticides), veterinary medicines, and other compounds used to maintain plant and animal health and productivity. Growers and farmers use these agricultural compounds to manage disease in animals and crops, protect the food supply, and maximise the quantity and quality of the food they grow.

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

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

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

2.1 ESTABLISHING MAXIMUM RESIDUE LEVELS

2.1.1 Regulatory Structure

Maximum residue levels are the maximum legal levels of agricultural compound residues permitted in food for sale in New Zealand, and are set out in the New Zealand (Maximum Residue Levels for Agricultural Compounds) Food Notice. This Notice is updated up to four times a year to reflect changes in the use of agricultural compounds in the production of food. The current 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. The following provisions of regulation 144 state that a person must not sell food containing residues of an agricultural compound unless one of the following applies:

- the residue level of the agricultural compound does not exceed the MRLs specified for that food in a notice set under the Food Act 2014 (regulation 144(1)(a)); or
- the residue level of the agricultural compound does not exceed the default MRL of 0.1 mg/kg (regulation 144(1)(c)), and there is no MRL otherwise specified in the notice; or
- for imported food, the residue level of the agricultural compound does not exceed MRLs specified in 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)).

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

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

2.1.2 Determining Maximum Residue Levels

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

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

Where it has been determined that MRLs can be set, those MRLs are proposed for inclusion in the Notice. Animal commodity MRLs will be proposed for the species in which a veterinary medicine is approved for use. MRLs may be proposed for a specific species (e.g. cattle, chicken) or a species group (e.g. mammalian, poultry) depending on the residue and metabolism profile of the agricultural compound being considered. Where an agricultural chemical is used on a crop from which both food and feed commodities are derived, MRLs will be proposed for both the crop intended for human consumption and animal commodities

for the species or species group to which the feed commodity is fed. If an agricultural chemical is only used on an animal feed commodity such as pasture from which there are no foods harvested for human consumption, only animal commodity MRLs will be proposed.

2.1.3 Estimating Chronic Dietary Exposure

National estimated daily intake

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

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

Health Based Guidance Values

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

A $PDE_{(food)}$ is a value determined by a toxicological evaluation by the New Zealand Environmental Protection Authority (NZ EPA) as part of its responsibility for managing public health under the Hazardous Substances and New Organisms Act 1996. A $PDE_{(food)}$ gives the potential daily exposure to a substance that a person may be subject to via food, and is the food-specific part of a set of values for different exposure pathways comprising the NZ EPA's assessment of acceptable daily exposure (ADE) for an agricultural compound.

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

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

2.1.4 International MRLs and Trade

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

For animal commodities, the MRLs set by Australia, Canada, China, Codex, the European Union, Japan, and the United States are reviewed and compared; for horticultural commodities, MRLs set by Codex and Australia are reviewed and compared. Other international MRLs are also reviewed and compared if there is a particular trade risk to be considered for those regions.

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

2.1.5 Agricultural Compounds for Which No Maximum Residue Level Applies

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

Agricultural chemicals and veterinary medicines being considered for listing as compounds for which no MRL applies undergo a similar scientific assessment of their use as that undertaken for MRL assessment. This assessment is done in accordance with international methodologies published by the Organisation for Economic Cooperation and Development (OECD), International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH), or FAO. It includes establishing the GAP use of the compound, the relevant metabolism and residue information, and the potential risks posed to public health and trade. The assessment may also include an assessment of dietary exposure when considered necessary to fully assess the risks.

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

2.2 SUMMARY OF PROPOSED AMENDMENTS

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

- the new or amended entry proposed for inclusion in the Notice;
- the rationale for the new entry or amendment being proposed;
- New Zealand good agricultural practice for the compound and target crop or species;
- the relevant residues information used in determining the proposed MRLs;
- a summary of the dietary risk and public health assessment; and
- the MRLs set by Codex and other authorities (e.g. Australia, Canada, China, EU, Japan, USA) relevant to the new or amended entry.

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

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

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

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

- The addition of new entries in the Notice for the following compounds:
    - Fenpyroximate, to set a MRL of 0.1 mg/kg for pome fruits;
    - Fluensulfone, to set MRLs at 0.6 mg/kg for carrots, 0.6 mg/kg for parsnips, and 0.4 mg/kg for tuberous and corm vegetables (Subgroup 16B)
    - Prednisolone, to set MRLs at 0.004 mg/kg for cattle fat, 0.01 mg/kg for cattle kidney, 0.01 mg/kg for cattle liver, 0.004 mg/kg for cattle meat, 0.004 mg/kg for goat fat, 0.01 mg/kg for goat kidney, 0.01 mg/kg for goat liver, 0.004 mg/kg for goat meat, 0.004 mg/kg for horse fat, 0.01 mg/kg for horse kidney, 0.01 mg/kg for horse liver, 0.004 mg/kg for horse meat, and 0.006 mg/kg for milk.
- The amendment of the existing entry in the Notice for the following compounds:
    - Fludioxonil, to add a MRL of 0.01(*) mg/kg for potatoes.
    - Fluopyram, to amend the MRL of 0.01(*) mg/kg to 0.07 mg/kg for bulb onions.

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

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

- MPI proposes to add a new entry for follicle stimulating hormone (FSH) to the schedule for veterinary medicines for which no MRL applies. FSH would not require compliance to an MRL when used to manage reproduction in ruminants.

- MPI proposes to add a new entry for melatonin to the schedule for veterinary medicines for which no MRL applies. Melatonin would not require compliance to an MRL when used to manage reproduction in sheep, deer and goats.

3 Proposals

3.1 PROPOSAL TO SET MRLS FOR FENPYROXIMATE

It is proposed that MRLs are set for fenpyroximate to support the GAP use of the compound on pome fruits.

There is currently no entry for fenpyroximate 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)
Fenpyroximate	134098-61-6	Fenpyroximate	Pome fruits	0.1

3.1.1 Amendment Rationale

Fenpyroximate has been used in New Zealand for the control of European red mite and two-spotted mite on pome fruit since 1994, with the use subject to compliance with the New Zealand default MRL of 0.1 mg/kg. The new entry is proposed to reflect the residue level in accordance with the use pattern considered as GAP in New Zealand. There are no other approved uses for fenpyroximate.

3.1.2 Good Agricultural Practice

Fenpyroximate is a pyrazole non-systemic miticide which acts on larvae, nymphs and adults of mites, mainly by contact and ingestion, and with some moulting inhibitory activity on larvae.

There are currently two registered products containing the active ingredient fenpyroximate in New Zealand, both for the control of European red mite and two-spotted mite on pome fruits. The GAP use is for one application of 2.5 gai/100L water, in either November-December or during January. A withholding period of 14 days is considered to be GAP for pome fruit.

3.1.3 Residue Information

The residue data for the use of fenpyroximate on pome fruit are sufficient to conclude that, when applied according to the proposed GAP use pattern, residues of fenpyroximate should not exceed 0.1 mg/kg. The current residue definition of 'fenpyroximate' has been determined to be appropriate to apply to plant commodities for both GAP compliance and dietary intake assessment.

3.1.4 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 food from all foods treated with or exposed to fenpyroximate when used according to GAP, including the negligible residues expected in animal commodities, the NEDI is estimated to total less than 3% of the HBGV.

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

3.1.5 Relevant International MRLs

Country	Food	Maximum Residue Level (mg/kg)
Codex	Pome fruit	0.3
Australia	Apple Pear	0.3 0.3

3.2 PROPOSAL TO AMEND THE MRLS FOR FLUDIOXONIL

It is proposed that the Notice entry for fludioxonil is amended to support the GAP use of the compound as a seed treatment for potatoes.

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)
Fludioxonil	131341-86-1	Fludioxonil	Blackcurrants Blueberries Bulb onions Grapes Kumara Mammalian fat Mammalian kidney Mammalian liver Mammalian meat Milk Pineapples **Potatoes** Strawberries	0.8 0.5 0.01(*) 1 10 0.02 0.05 0.05 0.01(*) 0.01(*) 7 **0.01(*)** 1

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

3.2.1 Amendment Rationale

The MRL is being proposed to support the use of fludioxonil in potato seed tubers for the control of seed-borne diseases in accordance with the use pattern and withholding period that is currently accepted as GAP for New Zealand. The use for control of seed-borne fungal diseases when used as a seed treatment in potato has been approved in New Zealand for many years, with its use being subject to compliance with the New Zealand default MRL of 0.1 mg/kg. The new MRL in potato is being proposed to better reflect the residue level in accordance with the use pattern considered as GAP in New Zealand.

3.2.2 Good Agricultural Practice

Fludioxonil is a phenylpyrrole fungicide. It is non-systemic with long residual activity and limited uptake into the plant tissues. Activity is by the inhibition of conidia germination and, to a lesser extent, the germ tube and mycelial growth inhibition. The use for control of seed-borne diseases *Rhizoctonia solani* (stem canker and black scurf) and silver scurf when used as a seed treatment in potato has been approved in New Zealand since 1999.

Good agricultural practice for control of seed-borne diseases in potato is one application of 25 gai / tonne seed in a maximum of 2.75 L water/tonne. Application is made as a spray to seed tubers before planting, ensuring complete coverage of the tubers. A withholding period is not required when used as directed.

3.2.3 Residue Information

The residue data for the use of fludioxonil on potato are sufficient to conclude that, when applied according to the proposed GAP use pattern, residues of fludioxonil should not exceed the limit of quantification (0.01 mg/kg). The current residue definition of 'fludioxonil' has been determined to be appropriate to apply to potatoes for both GAP compliance and dietary intake assessment as per the other plant commodities in which it is used.

3.2.4 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 all foods treated with or exposed to fludioxonil when used according to GAP, the NEDI is estimated to total less than 12% of the HBGV.

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

3.2.5 Relevant International MRLs

Country	Food	Maximum Residue Level (mg/kg)
Codex	Potato	5
Australia	Potato	0.03

3.3 PROPOSAL TO SET MRLS FOR FLUENSULFONE

It is proposed that MRLs are set for fluensulfone to support the GAP use of the compound in carrot, kūmara/sweet potato, parsnip and potato.

There is currently no entry for fluensulfone 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)
Fluensulfone	**318290-98-1**	**Sum of fluensulfone and 3,4,4-trifluorobut-3-ene-1-sulfonic acid (BSA), expressed as fluensulfone equivalents**	**Carrots** **Parsnips** **Tuberous and corm vegetables**	**0.6** **0.6** **0.4**

3.3.1 Amendment Rationale

The MRL is being proposed to support use of the new active ingredient fluensulfone to control nematodes in carrot, kūmara/sweet potato, parsnip, and potato. The proposed MRL will manage the use of the compound in carrot, kūmara/sweet potato, parsnip, and potatoes in accordance with the use patterns and withholding periods that are proposed as GAP in New Zealand.

3.3.2 Good Agricultural Practice

Fluensulfone is a nematicide from the fluoroalkenyl thioether chemical group that acts as a metabolic inhibitor in the pathway that the plant parasitic nematode uses to access its energy reserves. The proposed use for fluensulfone is as a single application pre-emergence of 1.92 - 3.84 kgai/ha in a minimum of 200L water/ha, applied evenly to soil and incorporated to a depth of 15-20 cm, a minimum of 3 days prior to sowing or planting. This use has a Withholding Period of "Do not use on varieties maturing earlier than 80 days after planting". The following plant back restrictions are also proposed:

CROP	PLANT-BACK INTERVAL
Carrots, kūmara/sweet potato, parsnip, potato	No restriction
Cereals for animal forage (greenfeed)	120 days
Cereals for grain; pasture	180 days
Lettuce	180 days
All other crops	270 days

3.3.3 Residue Information

Plant metabolism data have been provided for fluensulfone which show a similar metabolic pathway in crops either directly planted into treated soil, or subsequently planted as rotational crops. Fluensulfone is largely converted into thiazole sulfonic acid (TSA) and butene sulfonic acid (BSA).

The following residue definitions are considered to be appropriate: 'Sum of fluensulfone and 3,4,4-trifluorobut-3-ene-1-sulfonic acid (BSA), expressed as fluensulfone equivalents' for GAP-compliance in plant commodities; and 'fluensulfone' for dietary intake risk estimation in plant commodities.

The residue definition proposed for GAP-compliance and dietary intake risk estimation in animal commodities is 'fluensulfone'.

Residue data for the use of fluensulfone are sufficient to conclude that, when applied according to the proposed GAP use pattern, residues of up to 0.4 mg/kg fluensulfone equivalents are expected in potatoes and sweet potatoes (and by extrapolation in other tuberous and corm vegetables included in subgroup 16B of the Codex Classification of Foods and Animal Feeds), and up to 0.6 mg/kg in carrots (and by extrapolation in parsnips). Residues of fluensulfone equivalents are not expected to occur over the default MRL of 0.1 mg/kg in rotational crops planted subsequently, when the relevant plant back interval is applied.

Animal commodity MRLs are not required as a result of the proposed use, as carrot, kūmara/sweet potato, parsnip, and potato are not considered to be a primary animal feed in New Zealand. No detectable parent fluensulfone residues are expected in any animal feed commodity from rotational crops.

3.3.4 Dietary Risk Assessment

The HBGV of 0.0105 mg/kg bw/day was considered appropriate for use in the assessment.

Based on the residue profile expected in food from crops treated with fluensulfone, the NEDI is estimated to total less than 0.7% of the HBGV for the average New Zealand adult.

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

3.3.5 Relevant International MRLs

Country	Food	Maximum Residue Level (mg/kg)
Codex	Carrot	4
	Parsnip	4
	Potato	0.8
	Root and tuber vegetables (not specified elsewhere)	3
	Sweet potato	0.8
Australia	Root and tuber vegetables	2

3.4 PROPOSAL TO AMEND MRLS FOR FLUOPYRAM

It is proposed that the Notice entry for fluopyram is amended to support the GAP use of the compound as a fungicide on bulb onions.

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)
Fluopyram	658066-35-4	Plant commodities: Fluopyram Animal commodities: Sum of fluopyram and 2-(trifluoromethyl) benzamide, expressed as fluopyram	Bulb onions	**0.07**
			Cereal grains	0.01(*)
			Carrots	0.2
			Eggs	0.3
			Fruiting vegetables (except cucurbits)	1.0
			Grapes	0.05
			Mammalian fat	0.5
			Mammalian kidney	0.7
			Mammalian liver	3
			Mammalian meat	0.5
			Milk	0.3
			Parsnips	0.2
			Stone fruits	0.7

(*) 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 use of fluopyram in bulb onions for the control of white rot in accordance with the use pattern and withholding period that is currently accepted as GAP for New Zealand. The use for control of white rot in bulb onions has been approved in New Zealand for many years, in combination with triadimenol. The use is currently subject to compliance with an MRL of 0.01(*) mg/kg as residues were estimated to be below quantifiable levels at harvest. However, recent information has been received which indicates that low quantifiable levels are present when used in accordance with GAP, possibly due to uptake from previously treated soil. The new MRL in bulb onions is being proposed to better reflect the residue level in accordance with the use pattern considered as GAP in New Zealand.

3.4.2 Good Agricultural Practice

Fluopyram 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 for control of white rot in bulb onions, suppression of root knot nematodes in carrots and parsnips, and in co-

formulations with cyprodinil or fluazinam for use in grapes, blackcurrants, blueberries, and strawberries. For the current use in bulb onions, the compound is applied at a rate of 250 gai/ha, co-formulated with 250 gai/ha triadimenol, as a broadcast spray with the first application at 100-150 Onion White Rot Degree Days (approx 4-8 weeks after sowing), and a second a month later. This use pattern has an associated withholding period of 70 days.

3.4.3 Residue Information

The original residue data for the use of fluopyram in bulb onions indicated that, when applied according to the GAP use pattern, quantifiable residues of fluopyram are not expected in bulb onions. However, new information suggests that low, but quantifiable, fluopyram residue levels have been found when used according to the GAP use pattern, which should not exceed 0.07 mg/kg in bulb onions. The proposed MRL aligns with Codex. The current residue definition of 'fluopyram' remains appropriate for plant commodities for GAP compliance, with 'fluopyram+benzamide' for dietary intake assessment. Current animal tissue MRLs are not affected as bulb onions are not considered to be a primary animal feed.

3.4.4 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 43% of the HBGV.

MPI 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.

3.4.5 Relevant International MRLs

Country	Food	Maximum Residue Level (mg/kg)
Codex	Onion, bulb	0.07
Australia	All other foods	0.2

3.5 PROPOSAL TO SET MRLS FOR PREDNISOLONE

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

There is currently no entry for prednisolone 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)
Prednisolone	**50-24-8**	**Prednisolone**	**Cattle fat** **Cattle kidney** **Cattle liver** **Cattle meat** **Goat fat** **Goat kidney** **Goat liver** **Goat meat** **Horse fat** **Horse kidney**	**0.004** **0.01** **0.01** **0.004** **0.004** **0.01** **0.01** **0.004** **0.004** **0.01**

			Horse liver **Horse meat** **Milk**	**0.01** **0.004** **0.006**

3.5.1 Amendment Rationale

Prednisolone has been used in New Zealand as a veterinary medicine for several years, with its use in food-producing species being subject to compliance with the New Zealand default MRL of 0.1 mg/kg. The new MRLs are being proposed to better reflect the residue levels expected with the use of prednisolone in cattle, goats, and horses in accordance with the dose rates and use patterns considered as GAP in New Zealand.

3.5.2 Good Agricultural Practice

Prednisolone is a synthetic glucocorticosteroid used in veterinary medicine to treat inflammation associated with allergic reactions and bacterial infections. In New Zealand, most veterinary medicines containing prednisolone are antibiotic formulations used to treat mastitis in lactating dairy cattle by intramammary infusion into the infected quarter for three to five consecutive treatments. Additional prednisolone-based treatments registered for use in food-producing species include a topical ointment intended for the treatment of dermatological infections, and an oral granule product intended for the management of inflammatory conditions in horses at doses of 0.5-2 mg/kg for up to three weeks to manage chronic allergic and non-infectious respiratory inflammatory disease.

All but the oral granule product for horses are co-formulated with antibiotic compounds, with the antibiotic compounds dictating the withholding periods associated with treatment.

3.5.3 Residue Information

The residue data for the use of prednisolone, alone or in combination with antibiotic therapy, are sufficient to establish MRLs for the use patterns and withholding periods considered GAP in New Zealand. When used according to GAP, and complying with the applicable withholding periods, prednisolone depletes rapidly and is often less than the limit of quantification at the point where the antibiotic compound is compliant with its respective MRLs. As such, it can be expected that prednisolone residues will remain less than 0.004 mg/kg in meat and fat, 0.01 mg/kg in liver and kidney, and 0.006 mg/kg in milk after all uses. A residue definition of 'prednisolone' 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.

3.5.4 Dietary Risk Assessment

The HBGV of 0.0002 mg/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 animals treated with prednisolone, the NEDI is estimated to total less than 16.4% of the HBGV.

MPI has therefore determined that the use of prednisolone according to the authorised uses established as GAP is unlikely to pose any health risks.

3.5.5 Relevant International MRLs

Country	Food	Maximum Residue Level (mg/kg)
European Union	Bovine muscle	0.004
	Bovine fat	0.004
	Bovine liver	0.01
	Bovine kidney	0.01

	Milk	0.006
	Equine muscle	0.004
	Equine fat	0.008
	Equine liver	0.006
	Equine kidney	0.015
Japan	Cattle, muscle	0.004
	Other terrestrial mammals, muscle	0.001
	Cattle, fat	0.004
	Other terrestrial mammals, fat	0.001
	Cattle, liver	0.01
	Other terrestrial mammals, liver	0.001
	Cattle, kidney	0.01
	Other terrestrial mammals, kidney	0.001
	Cattle edible offal	0.01
	Other terrestrial mammals, offal	0.001
	Milk	0.006

3.6 PROPOSAL TO ADD AN ENTRY FOR FOLLICLE STIMULATING HORMONE (FSH) TO SCHEDULE 3

It is proposed that follicle stimulating hormone (FSH) is added to Schedule 3 of the Notice to identify these compounds as veterinary medicines for which no MRL applies. FSH is a naturally occurring gonadotropin hormone which regulates ovarian maturation and the reproductive cycle in mammals. As a veterinary medicine, FSH is used in cattle, sheep, and goat reproductive management to increase ovulation rates.

When administered to ruminants as a veterinary medicine, the introduced FSH is indistinguishable from the endogenously-released compound and rapidly eliminated within hours. In addition, assessments of the use of FSH as a veterinary medicine conducted by international authorities such as the European Food Safety Authority (EFSA) have determined that MRLs are not required to manage residues. As such, the use of FSH is not expected to pose risks to either food safety or trade when used as a veterinary medicine and can therefore be listed in Schedule 3 as veterinary medicines for which no MRL applies. The condition of exemption will reflect the use of the compound as a zootechnical agent to manage reproduction in food-producing species.

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

Substance	CAS#	Condition
Follicle stimulating hormone (FSH)	**9002-68-0**	**When used to manage reproduction in ruminants**

3.7 PROPOSAL TO ADD AN ENTRY FOR MELATONIN TO SCHEDULE 3

It is proposed that melatonin is added to Schedule 3 of the Notice to identify it as a veterinary medicine for which no MRL applies. Melatonin is a naturally occurring hormone released by the pineal gland which regulates day-night perception and, in sheep, deer, and goats, seasonal reproductive cycles. When administered as a veterinary medicine, melatonin is used to increase reproductive performance in sheep by altering the reproductive seasonal rhythm and extending the breeding season. Like FSH, administered melatonin is indistinguishable from endogenous melatonin and is eliminated quickly. It has been determined by the EFSA and other overseas authorities not to require a MRL.

It is therefore proposed that melatonin is added to Schedule 3 as follows:

Substance	CAS#	Condition
Melatonin	**73-31-4**	**When used to manage reproduction in sheep, deer, and goats**