New Zealand Food Safety
Haumaru Kai Aotearoa

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

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By New Zealand Food Safety

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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 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 or exemptions proposed for this compound?

Do you oppose a MRL or exemption being set at all for this compound or for a commodity?

If a MRL or exemption 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?

Submissions close at 5pm on **30 November 2021**. 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 management of plants and animals, and include veterinary medicines, fertilisers, and pesticides (e.g. 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 MRLs will be 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

MRLs are set out in the New Zealand (Maximum Residue Levels for Agricultural Compounds) Food Notice. This Notice is amended regularly 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 for 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 (NZ 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 NZ 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

Where MRLs are being set, 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.

Where MRL exemptions are proposed, the proposed exemptions from compliance with a MRL 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. Each proposal includes a discussion of the rationale behind the considerations for exemption, and a discussion of the assessed risks. New Zealand Food Safety has evaluated the potential food safety and dietary intake risks associated with promulgating an exemption and have determined that MRLs are not required to manage compliance to GAP or food safety risk.

2.1.4 Agricultural Compounds for Which No Maximum Residue Level Applies

There are some agricultural compounds for which it has been determined that their use in crops or animals does not require management through the application of a MRL. This may be because there are no residues present due to the compound being eliminated quickly or not being absorbed by the treated crop or animal, or because there is no food safety or trade risk associated with the residues that are present. Clause 141 of the Food Regulations allow

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 Food Notice, respectively.

Agricultural chemicals and veterinary medicines being considered for listing as compounds for which no MRL applies undergo scientific assessment of their use in the target crop or species similar to that conducted for other compounds to characterise their residue profiles and the potential risks posed to public health and trade. This may include an assessment of dietary exposure when considered necessary to fully assess the risks. When the outcome of that assessment is a determination that a MRL is not required, the compound is listed in Schedules 2 or 3 with conditions on their use to ensure the listing applies only to the situations that have been evaluated. If a compound listed in Schedules 2 or 3 is used in a way that does not meet the specified condition, the default MRL will apply to food derived from treated plants or animals.

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.

MPI 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

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

- Fluazinam: 0.01(*) mg/kg in apples
- Mandestrobin: 0.01(*) mg/kg in potatoes
- Pyriofenone: 0.01(*) mg/kg in apples and 0.05 mg/kg in grapes

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

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

- MPI proposes to amend the following entries in Schedule 2:
    - The entry for active ingredients that are foods or permitted food additives, to revise the wording of the substance description for clarity;
    - the entry for microbial active ingredients, to revise the wording to ensure the listing manages the associated risk without being unnecessarily restrictive; and
    - the entry for plant extracts (unrefined), to add three additional species to the list of plants from which extracts are derived that do not require the application of a MRL.

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

- MPI proposes to add a new entry for zeolite to the schedule for veterinary medicines for which no MRL applies. The compound would not require compliance to a MRL when used in cattle as a calcium binder to reduce the risk of milk fever and in food-producing species as a mycotoxin binder.
- MPI proposes to remove the entry for medroxyprogesterone acetate for intravaginal use in sheep, and replace it with one for progesterone for intravaginal use in sheep and cattle. Intravaginal progesterone is used in cattle and sheep to manage fertility status and anoestrus, and would not require compliance with a MRL when used in this manner.

3 Proposals

3.1 PROPOSAL TO AMEND THE MRLS FOR FLUAZINAM

It is proposed that MRLs for fluazinam are amended to establish a MRL to support the GAP use of the compound on apples.

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

Compound Common Name	CAS#	Residue to which the maximum residue level applies	Food	Maximum Residue Level (mg/kg)
Fluazinam	79622-59-6	Fluazinam	**Apples** Brassica vegetables Grapes Onions Potatoes Tomatoes	**0.01(*)** 0.02(*) 1 0.02 0.02(*) 0.02(*)

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

3.1.1 Amendment Rationale

The MRL is being proposed to support the use of fluazinam for the control of blackspot on apples in accordance with the use pattern and withholding period that are proposed as GAP for New Zealand.

3.1.2 Good Agricultural Practice

Fluazinam is a broad-spectrum pyridine fungicide which acts by inhibiting spore germination, hyphal penetration, and organism growth. It is currently used in New Zealand on grapes to control downy mildew, *Phomopsis* leafspot, and *Botrytis*, in potatoes to control blight, *Sclerotinia,* and powdery scab, in tomatoes to control *Botrytis, Sclerotinia,* and late blight, and in vegetable brassicas to control clubroot.

The GAP use of fluazinam on apples is up to two foliar applications at a maximum rate of 420g ai/ha from tight cluster up until king fruit have reached 30 mm in size, with a 7-14 day interval between applications. This use attracts a withholding period of 70 days, with a restriction that fluazinam is not to be applied after king fruit have reached 30 mm in size and not less than 70 days before harvest. Although livestock may be grazed in treated orchards, a livestock withholding period was not considered necessary to manage animal transfer residues given the low potential for exposure to grazing animals.

3.1.3 Residue Information

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

The potential for agricultural chemical residues to transfer to animal commodities was considered for this use because animals may be grazed in apple orchards. After a review of available data characterising the potential for fluazinam residues to transfer to animal commodities through grazing, it was determined that animal commodity MRLs were not required due to the negligible residue profile in treated orchards and the lack of detectable residues in any animal commodities from exposed livestock.

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 fluazinam when used according to GAP, including the negligible residues expected in animal commodities, the NEDI is estimated to total less than 11% of the HBGV.

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

3.1.5 Relevant International MRLs

Authority	Food	Maximum Residue Level (mg/kg)
Australia	Pome fruits	0.01

There is no Codex MRL for fluazinam in apples.

3.2 PROPOSAL TO AMEND THE MRLS FOR MANDESTROBIN

It is proposed that MRLs for mandestrobin are amended to establish a MRL to support the GAP use of the compound on potatoes.

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

Compound Common Name	CAS#	Residue to which the maximum residue level applies	Food	Maximum Residue Level (mg/kg)
Mandestrobin	173662-97-0	Mandestrobin	Beans (with pods) Bulb onions Head lettuce Leafy lettuce **Potatoes**	0.7 0.01(*) 1.5 10 **0.01(*)**

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

3.2.1 Amendment Rationale

The MRL is being proposed to support the use of mandestrobin on potatoes for the control of early blight in accordance with the use pattern and withholding period that are proposed as GAP for New Zealand.

3.2.2 Good Agricultural Practice

Mandestrobin is a systemic strobilurin fungicide which acts by inhibiting mitochondrial respiration and disrupting the production of ATP in the fungal organism. It is currently used in New Zealand on beans and lettuce for the control of *Sclerotinia,* and on bulb onions for the control of white rot and downy mildew.

The GAP use of mandestrobin on potatoes is 375g ai/ha for a maximum of two applications at 7-10 day intervals. This use attracts a withholding period of seven days.

3.2.3 Residue Information

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

Animal residue transfer information was not required or assessed for the use of mandestrobin in potatoes as they are not considered a primary feed commodity in New Zealand.

3.2.4 Dietary Risk Assessment

The HBGV of 0.133 mg/kg bw/d was considered appropriate for use in the assessment.

Based on the residue profile expected in food from all horticultural crops treated with mandestrobin including potatoes, the NEDI is estimated to total less than 1% of the HBGV.

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

3.2.5 Relevant International MRLs

There are no Codex or Australian MRLs for mandestrobin in potatoes.

3.3 PROPOSAL TO AMEND THE MRLS FOR PYRIOFENONE

It is proposed that MRLs for pyriofenone are amended to establish MRLs to support the GAP use of the compound on apples and grapes.

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

Compound Common Name	CAS#	Residue to which the maximum residue level applies	Food	Maximum Residue Level (mg/kg)
Pyriofenone	688046-61-9	Pyriofenone	**Apples** Fruiting vegetables (cucurbits) **Grapes**	**0.01(*)** 0.2 **0.05**

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

3.3.1 Amendment Rationale

The MRL is being proposed to support the use of pyriofenone for the control of powdery mildew on apples and grapevines in accordance with the use pattern and withholding periods that are proposed as GAP for New Zealand.

3.3.2 Good Agricultural Practice

Pyriofenone is a benzoylpyridine fungicide which acts by inhibiting actin/myosin/fimbrin function to disrupt hyphal growth in the target organism. It is currently used in New Zealand for the control of powdery mildew on cucurbits.

The GAP use of pyriofenone on apples and grapes is a maximum of two applications of 9 gai/100L to the point of runoff at 10-14 day intervals. In grapes, this use attracts a restriction that it is applied up to pre-bunch closure, and a withholding period of at least 65 days before harvest; in apples, the use of pyriofenone attracts a withholding period of 65 days.

Because livestock may be grazed in treated orchards and vineyards, GAP for pyriofenone also includes a pre-slaughter interval of two months and a restriction that stock are not to be grazed within treated vineyards or orchards until after harvest. With these controls in place, the residue profile in exposed animals was negligible and thereby did not require the establishment of animal commodity MRLs.

3.3.3 Residue Information

The residue data for the use of pyriofenone on apples and grapes are sufficient to conclude that, when applied according to the proposed GAP use pattern, residues of pyriofenone should not exceed the limit of quantification (0.01 mg/kg) in apples or 0.05 mg/kg in grapes. The current residue definition of 'fluazinam' has been determined to be appropriate to apply to apples and grapes for both GAP compliance and dietary intake assessment as per the other crop commodities in which it is used.

The potential for agricultural chemical residues to transfer to animal commodities was considered for this use because animals may be grazed in apple orchards and vineyards. As described above, the residue data confirmed that with the application of the pre-slaughter interval and grazing restrictions considered part of GAP for pyriofenone, residues in animal commodities were negligible. It was therefore determined that animal commodity MRLs were not required for these uses.

3.3.4 Dietary Risk Assessment

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

Based on the residue profile expected in food from all foods treated with or exposed to pyriofenone when used according to GAP, including the negligible residues expected in animal commodities, the NEDI is estimated to total less than 0.3% of the HBGV.

New Zealand Food Safety has therefore determined that the use of pyriofenone on apples and grapes, 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)
Australia	Dried grapes Grapes	2 0.5
Codex	Dried grapes Small fruit vine climbing	2.5 0.8

3.4 PROPOSAL TO AMEND THE ENTRY FOR ACTIVE INGREDIENTS THAT ARE FOODS OR PERMITTED FOOD ADDITIVES IN SCHEDULE 2

It is proposed that the description of the substance in column 1 of the entry for active ingredients that are foods or permitted food additives in Schedule 2 is amended to clarify the intent of the entry. The entry will be revised to remove the "and/or" part of the substance description, to ensure it is understood that either classification as a novel food as per section 1.1.2 in the Australia New Zealand Food Standards Code or identification of the active ingredient as one that deviates from the common physiochemical range or has undergone refinement will mean the compound attracts compliance with a MRL. Only those foods or permitted food additives that do conform to either of these classifications can be considered compounds for which MRLs do not apply.

The proposed revised entry in Schedule 2 will read as follows:

Substance	CAS#	Condition
Active ingredients that are foods or permitted food additives when the treated commodity at sale will be compliant with the Australia New Zealand Food Standards Code. Except where **either of the following apply**: The food is deemed a novel food as defined in section 1.1.2 of the Australia New Zealand Food Standards Code; ~~**And/**~~or; The composition of the active ingredient deviates from the physicochemical range, or has undergone refining to a level exceeding that accepted as common for the food.	n/a	Used as an agricultural compound

3.5 PROPOSAL TO AMEND THE ENTRY FOR MICROBIAL ACTIVE INGREDIENTS IN SCHEDULE 2

It is proposed that the description of the substance in column 1 of the entry for microbial active ingredients in Schedule 2 is amended to better reflect the use of these compounds in crops. The entry will be revised to extend the exemption to allow quantifiable residues to be present at over background levels, providing that the levels are not considered to be a dietary intake concern.

The existing exemption wording is difficult to comply with for any microbial active ingredient (MAI) which has quantifiable metabolites when applied close to harvest, even where the metabolite is non-pathogenic or non-toxic to humans. This has the consequence of restricting exemptions to MAIs with quantifiable metabolites to those with earlier application timings. However, GAP for MAIs commonly involves application close to harvest as part of an Integrated Pest Management programme. The revised wording will allow MAIs with

quantifiable metabolites to be exempt when used closer to harvest, providing the residue levels are not considered to be a dietary intake concern.

The current scope, exclusion and condition will remain unchanged.

The proposed revised entry in Schedule 2 will read as follows:

Substance	CAS#	Condition
Microbial Active Ingredients (any organism classified as a microorganism including but not limited to bacteria, protozoa, fungi and viruses, or the genetically modified or naturally occurring mutants of any of these microorganisms. This includes whole organisms (either viable or non-viable), organism organelles, organism metabolites, organism spores, or occlusion bodies.) ~~**This exemption applies when the Microbial Active Ingredient:**~~ ~~• **leaves no quantifiable residue of toxins or metabolites exceeding that of expected background levels; and**~~ ~~• **is non-pathogenic or non-toxic to humans.**~~ **This exemption applies when the Microbial Active Ingredient leaves no residues of the parent organism, its metabolites or toxins on the treated crop at levels that are considered a dietary intake concern.** This exemption does not include metabolites produced by a microorganism that have been isolated as an independent active ingredient.	n/a	When used as the active ingredient in an agricultural compound registered under the Agricultural Compounds and Veterinary Medicines Act 1997, and intended for use as an agricultural chemical.

3.6 PROPOSAL TO AMEND THE ENTRY FOR PLANT EXTRACTS (UNREFINED) IN SCHEDULE 2

It is proposed that *Beta vulgaris* (sugar beet, beetroot, and chard), *Undaria pinnatifida* (Wakame or edible seaweed), and *Ribes nigrum* (Blackcurrant) are added to the list of plants from which extracts can be considered compounds for which no MRL applies. The entry concerns the use of plant extracts as compound intended for use as an agricultural chemical, rather than as a food commodity.

It is considered that because these plants are edible commodities in their own right, residues from their use as agricultural chemicals are unlikely to present a concern for human health requiring management through the application of a MRL. As such, it is proposed that these plants are added to the list of species from which extracts may be derived for use as agricultural chemicals to which no MRL applies.

The proposed revised entry in Schedule 2 will read as follows:

Substance	CAS#	Condition
Plant extracts (unrefined)	n/a	Except where listed in Schedule 1 of this Notice: Where the extract is in a product registered under the Agricultural Compounds and Veterinary Medicines Act 1997 and intended for use as an agricultural chemical, and; Where the extract is derived from plants of the following species: ***Beta vulgaris* (Sugar beet, beetroot, and chard)** *Camellia sinesis* (Tea) *Clitorea ternatea* (Butterfly Pea) *Fallopia sachalinensis* (Giant knotweed) *Melaleuca alternifolia* (Tea Tree) *Optuntia linheimeri* (Texas prickly pear) *Quercus falcate* (Southern red oak) *Rhus aromatica* (Fragrant sumac) ***Ribes nigrum* (Blackcurrant)** *Rhizophoria mangle* (Red mangrove) ***Undaria pinnatifida* (Wakame)**

3.7 PROPOSAL TO ADD AN ENTRY FOR ZEOLITES TO SCHEDULE 3

It is proposed that zeolites, including both naturally occurring and synthetically manufactured substances, are added to Schedule 3 of the notice to identify these compounds as veterinary medicines to which no MRL applies. The zeolites are a group of hydrated crystalline alumino-silicate compounds containing exchangeable cations of group IA and IIA elements such as sodium, potassium, magnesium and calcium. These compounds are used in veterinary medicine as calcium binders administered orally to cattle to reduce the risk of hypocalcaemia (milk fever) around the time of calving, and as gastrointestinal adsorbents administered orally to bind mycotoxins to prevent mycotoxicosis in food-producing species.

When administered to food-producing animals, absorption of the aluminium component is minimal (<1%) and rapidly eliminated by the kidneys, with no residues expected in edible tissues. Administration of zeolites to lactating cattle for the prevention of hypocalcaemia, resulted in aluminium milk residues that were not greater than the aluminium levels present in the normal diet.

It is therefore concluded that the use of zeolites for the binding of ingested mycotoxins in food-producing animals and for the management of hypocalcaemia in lactating dairy cattle do not present residue levels requiring management through the application of MRLs. As such, these compounds can be listed in Schedule 3 as veterinary medicines for which no MRL applies, with a condition that no MRL applies when the compound is administered orally to food-producing species for the purposes of calcium binding or mycotoxin binding.

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

Substance	CAS#	Condition
Zeolites	**n/a**	**When used in food-producing animals as an orally administered calcium binder or mycotoxin binder**

3.8 PROPOSAL TO REMOVE THE ENTRY FOR MEDROXYPROGESTERONE ACETATE AND ADD AN ENTRY FOR PROGESTERONE TO SCHEDULE 3

It is proposed that the entry for medroxyprogesterone acetate for intravaginal use in sheep in Schedule 3 is removed, and a new entry for progesterone for intravaginal use in sheep and cattle is added. Medroxyprogesterone acetate was used to manage anoestrus and fertility status by the administration of an intravaginal implant impregnated with the compound, but is no longer registered for use in New Zealand. The Schedule 3 entry for medroxyprogesterone acetate is therefore no longer required.

Current GAP for the management of reproductive cycles and fertility status in cattle and sheep is the use of progesterone-based intravaginal implants. This use can be expected to produce progesterone residues at levels similar to normal physiological levels, and therefore does not require a MRL to manage GAP or food safety. As such, it is proposed that progesterone is included in Schedule 3 as a veterinary medicine for which no MRL applies, with a condition that no MRL applies when the compound is used intravaginally in cattle and sheep.

The Schedule 3 entry to be removed is the following:

Substance	CAS#	Condition
Medroxyprogesterone acetate	**71-58-9**	**For intravaginal use in sheep**

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

Substance	CAS#	Condition
Progesterone	**57-83-0**	**For intravaginal use in cattle and sheep**