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: 2021/04

Prepared for public consultation
By New Zealand Food Safety

ISBN No: 978-1-99-100352-2 (online)
ISSN No: 2624-0157 (online)

April 2021

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 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 <u>at all</u> 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 **11 June 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 BACKGROUND

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.

2.2 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:

- Amoxicillin: 0.05 mg/kg in mammalian fat, 0.05 mg/kg in mammalian meat, 0.05 mg/kg in mammalian offal, and 0.004 mg/kg in milk.
- Ampicillin: 0.05 mg/kg in cattle fat, 0.05 mg/kg in cattle meat, 0.05 mg/kg in cattle offal, and 0.004 mg/kg in milk.
- Benzylpenicillins: 0.05 mg/kg in mammalian fat, 0.05 mg/kg in mammalian meat, 0.05 mg/kg in mammalian offal, and 0.004 mg/kg in milk.
- Cefquinome: 0.02 mg/kg in cattle milk.
- Clavulanic acid: 0.1 mg/kg in cattle fat, 0.1 mg/kg in cattle meat, 0.1 mg/kg in cattle offal, and 0.05(*) mg/kg in cattle milk.
- Clomazone: 0.05(*) in winter squash.
- Cloxacillin: 0.05 mg/kg in cattle fat, 0.1 mg/kg in cattle kidney, 0.05 mg/kg in cattle liver, 0.05 mg/kg in cattle meat, and 0.03 mg/kg in milk.
- Erythromycin: 0.05 mg/kg in eggs, 0.1 mg/kg in poultry fat, 0.1 mg/kg in poultry meat, and 0.1 mg/kg in poultry offal.
- Ethofumesate: 0.01(*) mg/kg in onions, bulb.
- Fludioxonil: 0.02 mg/kg in mammalian fat, 0.05 mg/kg in mammalian kidney, 0.05 mg/kg in mammalian liver, 0.01(*) mg/kg in mammalian meat, and 0.01(*) mg/kg in milk.
- Lasalocid: 0.15 mg/kg in eggs.
- Metobromuron: 0.01(*) mg/kg in potatoes.

- Pydiflumetofen: 0.2 mg/kg in grapes, 0.03 mg/kg in mammalian fat, 0.01(*) mg/kg in mammalian meat, 0.03 mg/kg in mammalian offal, 0.02 mg/kg in milk, and 0.01(*) mg/kg in potatoes.

- Tilmicosin: 0.05 mg/kg in cattle fat, 0.05 mg/kg in cattle meat, 0.3 mg/kg in cattle kidney, 1 mg/kg in cattle liver, 0.05 mg/kg in sheep fat, 0.05 mg/kg in sheep meat, 0.3 mg/kg in sheep kidney, 1 mg/kg in sheep liver, and 0.05 mg/kg in milk.

- Tulathromycin: 0.1 mg/kg in milk.

- Tylosin: 0.1 mg/kg in cattle fat, 0.1 mg/kg in cattle meat, 0.1 mg/kg in cattle offal, 0.3 mg/kg in eggs, 0.1 mg/kg in goat fat, 0.1 mg/kg in goat meat, 0.1 mg/kg in goat offal, 0.05(*) mg/kg milk, 0.1 mg/kg in pig fat, 0.1 mg/kg in pig meat, 0.1 mg/kg in pig offal, 0.1 mg/kg in poultry fat, 0.1 mg/kg in poultry meat, 0.1 mg/kg in poultry offal, 0.1 mg/kg in sheep fat, 0.1 mg/kg in sheep meat, and 0.1 mg/kg in sheep offal.

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

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

- MPI proposes to add an exemption for cod liver oil when used as a topical treatment for foot rot.

- MPI proposed to add an exemption for smectite clays when used for the purpose of binding mycotoxins in food-producing animals.

2.2.3 Other Amendments to the Notice

- MPI also proposes to amend the Schedule headings for Schedules 2 and 3 to better reflect the wording in the Food Regulations under which the Notice is set.

3 Proposals

3.1 PROPOSAL TO AMEND TERMINOLOGY IN THE NOTICE

It is proposed that the Notice is amended to change the headings to Schedules 2 and 3. The heading for Schedule 2 will be changed from "Exemptions from Maximum Residue Levels for Agricultural Chemicals" to "Agricultural Chemicals for which No Maximum Residue Level Applies". Similarly, the heading for Schedule 3 will be changed from "Exemptions from Maximum Residue Levels for Veterinary Medicines" to "Veterinary Medicines for which No Maximum Residue Level Applies."

These changes are being proposed to more closely align the language in the Notice with that used in the Food Regulations 2015 under which the Notice is set. This change does not impact the function or scope of either Schedule or its use and will not change any of the entries within the Schedules.

3.2 PROPOSAL TO AMEND THE MRLS FOR AMOXICILLIN

It is proposed that the Notice entry for amoxicillin is amended to better support the GAP use of the compound in food-producing animals.

The revised entry for amoxicillin 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)
Amoxicillin	26787-78-0	Amoxicillin	Mammalian fat Mammalian meat Mammalian offal Milk	0.05 0.05 0.05 0.004

3.2.1 Amendment Rationale

The new and amended MRLs are being proposed to support the use of amoxicillin in cattle, pigs, and sheep in accordance with the dose rates and use patterns considered as GAP in New Zealand. The changes to the existing 'meat' and 'edible offal' MRLs to 'mammalian fat,' 'mammalian meat,' and 'mammalian offal' MRLs are being proposed to more accurately and clearly represent New Zealand food commodities; the MRLs themselves remain unchanged. The new milk MRL is being proposed to support GAP in lactating animals as the compound is approved for use in dairy animals.

The promulgation of these MRLs is an outcome of a review of all existing approved uses for veterinary medicines containing antibiotic compounds to ensure their use conforms with the expectations of GAP and prudent use.

3.2.2 Good Agricultural Practice

Amoxicillin is a penicillin antibiotic used for the treatment of bacterial infections either as a sole therapeutic active ingredient or in combination with clavulanic acid in companion and food-producing animals. Oral liquid, oral tablet, injectable, and intramammary formulations are registered in New Zealand for use in companion animals, horses, cattle, sheep, and pigs. Amoxicillin dose rates for the oral and injectable formulations range between 7 mg/kg and 15 mg/kg, while intramammary treatment is administered at 200mg amoxicillin per quarter. Meat and milk withholding periods vary depending on the dose rate administered to each species

and class, and with periods set at between four and 28 days for meat and between 36 hours and 35 days for milk.

3.2.3 Residue Information

The residue data for the use of amoxicillin in food-producing species are sufficient to conclude that, when administered as per existing GAP use patterns and complying with the applicable withholding periods, residues can be expected to remain below 0.05 mg/kg in all tissue commodities and below 0.004 mg/kg in milk. The residue profile of amoxicillin does not differ significantly when administered as a sole active ingredient or in combination with clavulanic acid. This conclusion is based on a review of existing data on file for the registered products and all publicly available data and information relevant to GAP in New Zealand.

The existing residue definition of 'amoxicillin' is considered appropriate for both GAP compliance and dietary intake for all commodities including milk.

3.2.4 Dietary Risk Assessment

The HBGV of 0.1 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 amoxicillin, the NEDI is estimated to total less than 0.15% of the HBGV.

MPI has therefore determined that amoxicillin, when used 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)
Australia	Cattle milk Edible offal (mammalian) Meat (mammalian) Sheep milk	0.01 0.01 0.01 0.01
Canada	Pig kidney, liver, muscle, skin and fat	0.01
China	Mammalian muscle Mammalian fat Mammalian liver Mammalian kidney Milk	0.05 0.05 0.05 0.05 0.004
Codex	Cattle fat, liver, kidney, and muscle Cattle milk Pig fat/skin, liver, kidney, and muscle Sheep fat, liver, kidney, and muscle Sheep milk	0.05 0.004 0.05 0.05 0.004
EU	Edible tissues Milk	0.05 0.004
Japan	Mammalian muscle Mammalian fat Mammalian liver Mammalian kidney Mammalian edible offal Milk	0.05 0.05 0.05 0.05 0.05 0.004
United States	Cattle fat, kidney, liver, muscle, milk	0.01

3.3 PROPOSAL TO AMEND THE MRLS FOR AMPICILLIN

It is proposed that the Notice entry for ampicillin is amended to better support the GAP use of the compound in cattle.

The revised entry for ampicillin 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)
Ampicillin	69-53-4 and 7177-48-2	Ampicillin	Cattle fat Cattle meat Cattle offal Cattle Milk	0.05 0.05 0.05 0.004

3.3.1 Amendment Rationale

The new and amended MRLs are being proposed to support the use of ampicillin in cattle in accordance with the dose rates and use patterns considered as GAP in New Zealand. The changes to the existing 'meat' and 'edible offal' MRLs to 'cattle meat,' and 'cattle offal' MRLs are being proposed to more accurately and clearly represent New Zealand food commodities since the compound is only approved for use in cattle; the MRLs themselves remain unchanged. The new milk MRL is being proposed to support the GAP use of ampicillin in lactating dairy cattle.

The promulgation of these MRLs is an outcome of a review of all existing approved uses for veterinary medicines containing antibiotic compounds to ensure their use conforms with the expectations of GAP and prudent use.

3.3.2 Good Agricultural Practice

Ampicillin is a penicillin antibiotic used in combination with cloxacillin for the treatment and prevention of mastitis in dairy cattle during the dry (non-lactating) period. The compound is approved for use exclusively in intramammary preparations for dry dairy cattle and is administered at doses of either 250mg or 300mg per quarter at the end of lactation. This use attracts a meat withholding period of 21 or 30 days, depending on the dose administered and the individual product's dose rate, formulation pharmacokinetics, and residue profile.

Intramammary treatments used in the dry period attract a two-part milk withholding period to manage residues depletion over the entire lactation cycle, with different periods set for the pre-calving interval (from treatment to calving), and from the onset of lactation (from calving onwards). The use of ampicillin as a dry cow treatment attracts milk withholding periods of either 30 days pre-calving plus eight milkings post-calving, or 49 days pre-calving plus eight milkings post-calving.

When an animal calves before the pre-calving period has elapsed, the entire withholding period must be observed before milk can be collected. For example, if a cow calves 45 days after treatment with a product attracting a milk withholding period of 49 days plus eight milkings, milk must be withheld for the four days remaining in the pre-calving period plus an additional eight milkings before it can enter the food chain. Like the meat withholding periods, the milk withholding periods are assigned based on each individual products' use and residue profile.

3.3.3 Residue Information

The residue data for the use of ampicillin in lactating cattle are sufficient to conclude that, when administered as per existing GAP use patterns and complying with the applicable withholding periods, residues can be expected to remain below 0.05 mg/kg in all tissue commodities and below 0.004 mg/kg in milk. This conclusion is based on a review of existing data on file for the registered products and all publicly available data and information relevant to GAP in New Zealand.

The existing residue definition of 'ampicillin' is considered appropriate for both GAP compliance and dietary intake for all commodities including milk.

3.3.4 Dietary Risk Assessment

The HBGV of 0.003 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 cattle treated with ampicillin, the NEDI is estimated to total less than 4% of the HBGV.

MPI has therefore determined that ampicillin, 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)
Australia	Cattle milk	0.01
Canada	Fat, kidney, liver, muscle, and milk of cattle	0.01
China	Mammalian muscle Mammalian fat Mammalian liver Mammalian kidney Milk	0.05 0.05 0.05 0.05 0.004
European Union	Edible tissues Milk	0.05 0.004
Japan	Cattle muscle Cattle fat Cattle liver Cattle kidney Cattle edible offal Milk	0.03 0.03 0.04 0.03 0.04 0.02
United States	Cattle fat, kidney, liver, muscle, milk	0.01

3.4 PROPOSAL TO SET MRLS FOR BENZYLPENICILLINS

It is proposed that MRLs are set for benzylpenicillin to support the GAP use of penethamate hydriodide, penicillin G benzathine, and penicillin G procaine as veterinary medicines.

There is currently no entry for benzylpenicillin 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)
Benzylpenicillins (includes penethamate hydriodide, penicillin G benzathine, and penicillin G procaine)	808-71-9, 54-35-3, 1538-09-6, and 6130-64-9	Benzylpenicillin	Mammalian fat Mammalian meat Mammalian offal Milk	0.05 0.05 0.05 0.004

Separate entries for penethamate hydriodide (CAS number 808-71-9), penicillin G benzathine (CAS number 1538-09-6), and penicillin G procaine (CAS numbers 54-35-3 and 6130-64-9) will be added to the Notice to reference back to the benzylpenicillin entry to avoid confusion. These reference entries will read:

Penethamate hydriodide	808-71-9	See Benzylpenicillins.

Penicillin G benzathine	1538-09-6	See Benzylpenicillins.

Penicillin G procaine	54-35-3 and 6130-64-9	See Benzylpenicillins.

3.4.1 Amendment Rationale

The new MRLs are being proposed to support the use of the benzylpenicillins penethamate hydriodide, penicillin G benzathine, and penicillin G procaine in food-producing animals in accordance with the dose rates and use patterns considered as GAP in New Zealand. The promulgation of these MRLs is an outcome of a review of all existing approved uses for veterinary medicines containing antibiotic compounds to ensure their use conforms with the expectations of GAP and prudent use.

3.4.2 Good Agricultural Practice

Penethamate hydriodide, penicillin G benzathine, and penicillin G procaine are benzylpenicillins belonging to the penicillin class of antibiotics. Penicillin G benzathine is benzylpenicillin combined with benzathine as a stabiliser, and penethamate hydriodide is a prodrug which is rapidly converted to benzylpenicillin after administration. Penicillin G procaine is a 1:1 combination of benzylpenicillin and procaine, with the former providing antimicrobial activity and the latter being a local anaesthetic. As per the approach of other regulatory authorities including Codex, MRLs specific to the procaine portion of penicillin G procaine is not required.

The benzylpenicillins are used for the treatment of Gram-positive bacterial infections in cattle, sheep, horses, pigs, and companion animals, as well as the treatment of mastitis by intramammary administration in lactating dairy cattle. Meat and milk withholding periods vary

depending on the dose rate administered to each species and class, and range between three days and 91 days for meat and between 48 hours and 35 days for milk.

3.4.3 Residue Information

The residue data for the use of the benzylpenicillins are sufficient to conclude that, when applied as per the proposed GAP use patterns and complying with the applicable withholding periods, residues of these compounds should not exceed 0.05 mg/kg in mammalian fat, meat, and offal, and 0.004 mg/kg in milk. These revised MRLs are based on residue data and information characterising the use of penethamate hydriodide, penicillin G benzathine, and penicillin G procaine in all approved food-producing species, either alone or in combination.

The common residue definition of 'benzylpenicillin' applies to all three compounds for both GAP compliance and dietary intake, and is consistent with the Codex approach for this group.

3.4.4 Dietary Risk Assessment

The HBGV of 0.03 mg/kg bw/d, and the stated dietary intake residue definition, are considered appropriate for use in the dietary intake assessment. The total NEDI from the use of all benzylpenicillins in food from animals treated with these compounds is estimated to total less than 1.4% of the HBGV.

MPI has therefore determined that the additional use of benzylpenicillins, when that use is 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)
Australia [Benzyl G penicillin]	Mammalian meat Mammalian edible offal Milks	0.06 0.06 0.0015
Australia [Procaine penicillin]	Mammalian meat Mammalian edible offal Milks	0.1 0.1 0.0025
Canada [Penicillin G]	Cattle fat, meat, kidney, and liver Pig fat, meat, kidney, and liver Sheep fat, meat, kidney, and liver Milk	0.05 0.05 0.05 0.01
China [Benzylpenicillin/ Procaine benzylpenicillin]	Cattle kidney, liver, and muscle Cattle milk Pig kidney, liver, and muscle	0.05 0.004 0.05
Codex [Benzylpenicillin/ Procaine benzylpenicillin]	Cattle kidney, liver, and muscle Cattle milk Pig kidney, liver, and muscle	0.05 0.004 0.05
European Union [Benzylpenicillin and penethamate]	All food producing species: muscle, fat, liver, and kidney All food producing species: milk	0.05 0.004
Japan [Benzylpenicillin]	Cattle and pig muscle and fat Other terrestrial mammal muscle and fat Cattle and pig liver and kidney Other terrestrial mammals, liver and kidney Cattle and pig edible offal Other terrestrial mammals, edible offal Milk	0.05 0.003 0.05 0.003 0.05 0.003 0.004
United States [Penicillin]	Cattle fat, kidney, liver, and muscle	0.05

3.5 PROPOSAL TO AMEND THE MRLS FOR CEFQUINOME

It is proposed that the Notice entry for cefquinome is amended to establish a revised MRL for the compound in milk.

The revised entry for cefquinome 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)
Cefquinome	84957-30-2	Cefquinome	Cattle fat Cattle kidney Cattle liver Cattle meat Cattle milk Pig fat Pig kidney Pig liver Pig meat	0.05 0.2 0.1 0.05 **0.02** 0.05 0.2 0.1 0.05

3.5.1 Amendment Rationale

The revised MRL is being proposed to align with that established by overseas markets to better support the GAP use of the compound while facilitating trade in accordance with the use considered as GAP in New Zealand. The amendment of the cattle milk MRL is an outcome of a review of all existing approved uses for veterinary medicines containing antibiotic compounds to ensure their use conforms with the expectations of GAP and prudent use.

3.5.2 Good Agricultural Practice

Cefquinome is a fourth generation cephalosporin antibiotic used for the treatment of respiratory disease, digital dermatitis and acute interdigital necrobacillosis in cattle at a dose rate of 1 mg cefquinome/kg bodyweight, and to treat mastitis in cattle either with a 1 mg/kg injection or by intramammary infusion of 75 mg cefquinome per infected quarter. Cefquinome is also used to treat respiratory infections and Mastitis-Metritis-Agalactia syndrome in pigs at a dose rate of 1-2 mg cefquinome per kg bodyweight. These uses attract withholding periods of five days for cattle meat, two days for pig meat, and 24 hours for milk after injectable administration, and two days for meat and 96 hours for milk from cattle treated by intramammary administration.

3.5.3 Residue Information

The residue data for the use of cefquinome in cattle and pigs are sufficient to conclude that, when used according to the established GAP and observing the applicable withholding periods, residues of cefquinome should not exceed the applicable MRLs including the proposed 0.02 mg/kg MRL in milk.

The existing residue definition of ‘cefquinome’ is considered appropriate for both GAP compliance and dietary intake for all commodities including milk.

3.5.4 Dietary Risk Assessment

The HBGV of 0.0019 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 cefquinome, the NEDI is estimated to total less than 11.2% of the HBGV.

MPI has therefore determined that the use of cefquinome in cattle and pigs, when use according to the GAP specified above, is unlikely to pose any health risks from authorised use.

3.5.5 Relevant International MRLs

Country	Food	Maximum Residue Level (mg/kg)
China	Cattle/Swine muscle	0.05
	Cattle/Swine fat	0.05
	Cattle/Swine liver	0.1
	Cattle/Swine kidney	0.2
	Cattle milk	0.02
European Union	Bovine and porcine muscle	0.05
	Bovine and porcine fat	0.05
	Bovine and porcine liver	0.1
	Bovine and porcine kidney	0.2
	Bovine milk	0.02
Japan	Cattle muscle	0.02
	Pig muscle	0.05
	Cattle fat	0.02
	Pig fat	0.05
	Cattle liver	0.02
	Pig liver	0.1
	Cattle kidney	0.02
	Pig kidney	0.2
	Cattle edible offal	0.02
	Pig edible offal	0.2
	Milk	0.02

3.6 PROPOSAL TO SET MRLS FOR CLAVULANIC ACID

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

There is currently no entry for clavulanic acid 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)
Clavulanic acid	58001-44-8	Clavulanic acid	Cattle fat	0.1
			Cattle meat	0.1
			Cattle offal	0.1
			Cattle milk	0.05(*)

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

3.6.1 Amendment Rationale

Clavulanic acid has been used in New Zealand as a veterinary medicine for several years, with its use in cattle being subject to compliance with the New Zealand default MRL of 0.1 mg/kg. The new MRLs are being proposed to provide transparency for, and support the use of, clavulanic acid in cattle in accordance with the dose rates and use patterns considered as GAP in New Zealand.

The promulgation of these MRLs are the result of a review of all existing approved uses for veterinary medicines containing antibiotic compounds to ensure their use conforms with the expectations of GAP and prudent use.

3.6.2 Good Agricultural Practice

Clavulanic acid is a β-lactamase inhibitor always used in combination with amoxicillin to extend that antibiotic's therapeutic spectrum. It is approved for oral or parenteral use in companion animals and cattle to potentiate amoxicillin's treatment of bacterial infections at a dose range of 1.75-2.5 mg/kg, and for intramammary administration to lactating cattle for the treatment of mastitis at a dose rate of 50 mg clavulanic acid per infected quarter. The withholding periods applicable to clavulanic-acid-containing products are driven by the residues of its co-formulant amoxicillin, and vary depending on dose rate, administration route, and class. The withholding periods applicable to amoxicillin are between four and 28 days for meat, and between 36 hours and 35 days for milk.

3.6.3 Residue Information

The residue data for the use of clavulanic acid in cattle are sufficient to conclude that, when administered as per existing GAP use patterns and complying with the applicable withholding periods, residues can be expected to remain below 0.1 mg/kg in all tissues and 0.05 mg/kg in milk. The highest administered dose rate, 50mg clavulanic acid per infected quarter by intramammary infusion, results in residues less than 0.05 mg/kg by 48 hours post-treatment.

Data characterising parenteral and oral administration of the compound at lower rates (up to 2.5 mg/kg) confirmed rapid elimination within the withholding periods assigned to New Zealand registered amoxicillin/clavulanic acid veterinary medicines. These conclusions are based on a review of existing data on file for the registered products and all publicly available data and information relevant to GAP in New Zealand.

The parent compound 'clavulanic acid' is considered the most appropriate marker residue for both GAP compliance and dietary intake.

3.6.4 Dietary Risk Assessment

The HBGV of 0.005 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 cattle treated with clavulanic acid, the NEDI is estimated to total less than 8.1% of the HBGV.

MPI has therefore determined that clavulanic acid, when used according to the GAP specified above, is unlikely to pose any health risks from authorised use.

3.6.5 Relevant International MRLs

Country	Food	Maximum Residue Level (mg/kg)
Australia	Cattle meat, edible offal, and milk	0.01
European Union	Cattle fat and muscle	0.1
	Cattle liver	0.2
	Cattle kidney	0.4
	Cattle milk	0.2
	Pig fat/skin and muscle	0.1
	Pig liver	0.2
	Pig kidney	0.4
Japan	Cattle and pig fat and muscle	0.05
	Cattle and pig liver	0.1
	Cattle and pig kidney	0.2
	Cattle edible offal	0.1
	Pig edible offal	0.05
	Milk	0.05

3.7 PROPOSAL TO AMEND THE MRLS FOR CLOMAZONE

It is proposed that the Notice entry for clomazone is amended to amend the MRL for 'squash' to 'winter squash' to align with the approved uses of this compound. This is because there are currently no approved uses of clomazone in summer squash crops.

The revised entry for clomazone 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)
Clomazone	81777-89-1	Clomazone	Beans Brassica vegetables Carrots Potatoes Pumpkin **Winter** squash	0.05(*) 0.01(*) 0.02 0.05(*) 0.05(*) 0.05(*)

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

3.7.1 Amendment Rationale

The change from 'squash' to 'winter squash' is intended to more accurately align with the approved uses of this compound, which do not currently include summer squash varieties. The MRL value remains unchanged. The proposed MRLs will manage the use of the compound when used in winter squash in accordance with the use pattern currently accepted as GAP in New Zealand.

3.7.2 Good Agricultural Practice

The GAP use of clomazone remains unchanged. Clomazone is a pre-emergent isoxazolidinone systemic herbicide, taken up by plant roots and shoots and moves into the xylem, inhibiting carotenoid synthesis. GAP in winter squash and pumpkins is currently accepted as one application of up to 200 gai/ha, applied immediately after sowing. This use attracts a restriction that the compound is only to be used at the pre-crop and weed emergence period. When used according to GAP, clomazone residues are not expected to be found at quantifiable levels in the harvested crop.

3.7.3 Residue Information

The residue data for the use of clomazone in winter squash are sufficient to conclude that, when applied as per the proposed GAP use pattern, residues of parent clomazone are not expected in winter squash and should not exceed the limit of analytical quantification (0.05 mg/kg).

Animal commodity MRLs were not considered as winter squash is not a primary animal feed.

3.7.4 Dietary Risk Assessment

The HBGV of 0.015 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 crops treated with clomazone, the NEDI is estimated to total less than 0.9% of the HBGV.

MPI has therefore confirms that the continued use of clomazone, 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 established by either Codex or Australia for clomazone in winter squash.

3.8 PROPOSAL TO SET MRLS FOR CLOXACILLIN

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

There is currently no entry for cloxacillin 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)
Cloxacillin	61-72-3	Cloxacillin	Cattle fat Cattle kidney Cattle liver Cattle meat Cattle milk	0.05 0.1 0.05 0.05 0.03

3.8.1 Amendment Rationale

Cloxacillin 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 provide transparency for and support the use of cloxacillin in cattle in accordance with the dose rates and use patterns considered as GAP in New Zealand.

The promulgation of these MRLs are the result of a review of all existing approved uses for veterinary medicines containing antibiotic compounds to ensure their use conforms with the expectations of GAP and prudent use.

3.8.2 Good Agricultural Practice

Cloxacillin is a semi-synthetic antibiotic in the penicillin class, primarily used to treat mastitis in lactating cattle and to treat and prevent mastitis in cattle during the dry period. In lactating animals, cloxacillin is administered by intramammary infusion to the infected quarter for up to six treatments once a day, a use that attracts milk withholding periods of up to 96 hours after the last treatment and a meat withholding period of three days.

For animals in the non-lactating or dry period, cloxacillin is administered alone or in combination with ampicillin at the end of the lactation period. The dry period use attracts milk withholding periods of up to 35 days pre-calving plus eight milkings post calving for the cloxacillin products, and up to 49 days pre-calving plus eight milkings post-calving for the cloxacillin/ampicillin products. When an animal calves before the pre-calving period has elapsed, the entire withholding period must be observed before milk can be collected. For example, if a cow calves 45 days after treatment with a product attracting a milk withholding period of 49 days plus eight milkings, milk must be withheld for the four days remaining in the pre-calving period plus an additional eight milkings before it can enter the food chain. Products used in the dry period attract meat withholding periods of up to 30 days.

There is also one New Zealand product containing cloxacillin that is approved for use as a topical eye ointment in cattle, sheep, horses, and companion animals for the treatment of bacterial keratoconjunctivitis. Because the dose of cloxacillin administered by topical ocular application is small and does not get systemically absorbed, it is used in food-producing animals without attracting a withholding period.

3.8.3 Residue Information

The residue data for the use of cloxacillin, alone or in combination with ampicillin, 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, cloxacillin residues will remain less than 0.05 mg/kg in liver, meat, and fat, less than 0.1 mg/kg in kidney, and less than 0.03 mg/kg in milk. A residue definition of 'cloxacillin' 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.

Although the topical use of cloxacillin is approved in sheep and horses, residue data has confirmed that this does not result in detectable residues in any commodity when used according to New Zealand GAP. As such, it has been determined that it is not necessary to establish commodity specific MRLs for foods derived from sheep and horses.

A residue definition of 'cloxacillin' is considered appropriate for both GAP compliance and dietary intake for all commodities including milk.

3.8.4 Dietary Risk Assessment

The HBGV of 0.1 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 cloxacillin, the NEDI is estimated to total less than 0.3% of the HBGV.

MPI has therefore determined that the use of cloxacillin, when use alone or in combination with ampicillin according to the GAP specified above, is unlikely to pose any health risks from authorised use.

3.8.5 Relevant International MRLs

Country	Food	Maximum Residue Level (mg/kg)
Australia	Cattle milk	0.01
Canada	Fat of cattle	0.01
	Kidney of cattle	0.01
	Liver of cattle	0.01
	Muscle of cattle	0.01
European Union	Muscle	0.3
	Fat	0.3
	Liver	0.3
	Kidney	0.3
	Milk	0.03
Japan	Cattle muscle	0.04
	Cattle fat	0.04
	Cattle liver	0.04
	Cattle kidney	0.04
	Cattle edible offal	0.04
	Milk	0.02
United States	Cattle fat	0.01
	Cattle kidney	0.01
	Cattle liver	0.01
	Cattle muscle	0.01
	Cattle milk	0.01

3.9 PROPOSAL TO SET MRLS FOR ERYTHROMYCIN

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

There is currently no entry for erythromycin 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)
Erythromycin	114-07-8	Erythromycin A	Eggs Poultry fat Poultry meat Poultry offal	0.05 0.1 0.1 0.1

3.9.1 Amendment Rationale

The MRLs are being proposed to support the continued GAP use of erythromycin in poultry in accordance with the use patterns considered GAP in New Zealand. The promulgation of these MRLs are the result of a review of all existing approved uses for veterinary medicines containing antibiotic compounds to ensure their use conforms with the expectations of GAP and prudent use.

3.9.2 Good Agricultural Practice

Erythromycin is a macrolide antibiotic which acts by inhibiting protein synthesis and thereby cell growth by binding bacterial ribosomes. It is approved for use in New Zealand under veterinary authorisation for the treatment of respiratory disease in poultry at dose rates of 15-20 mg/kg. This use attracts a meat withholding period of three days and an egg withholding period of three days.

3.9.3 Residue Information

The residue data for the use of erythromycin in poultry are sufficient to conclude that, when used according to the use pattern and withholding periods considered GAP in New Zealand, residues of erythromycin A are not expected to exceed 0.05 mg/kg in eggs or 0.1 mg/kg in all other tissues. This conclusion is based on a review of existing data on file for the registered products and all publicly available data and information relevant to GAP in New Zealand.

The residue definition of ‘erythromycin A’ is considered appropriate for both GAP compliance and dietary intake assessment.

3.9.4 Dietary Risk Assessment

The HBGV of 0.0025 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 poultry treated with erythromycin, the NEDI is estimated to total less than 17% of the HBGV.

MPI has therefore determined that the use of erythromycin in poultry, when used according to the GAP specified above, is unlikely to pose any health risks from authorised use.

3.9.5 Relevant International MRLs

Country	Food	Maximum Residue Level (mg/kg)
Australia	Poultry meat Poultry, edible offal of	0.3 0.3
Canada	Kidney, liver, muscle, skin, and fat of chickens Kidney, liver muscle, skin, and fat of turkeys	0.125 0.125
China	Chicken muscle, fat, liver, and kidney Turkey muscle, fat, liver, and kidney Chicken egg	0.1 0.1 0.05
Codex	Chicken kidney, liver, fat, and muscle Turkey kidney, liver fat, and muscle Chicken eggs	0.1 0.1 0.05
European Union	Muscle, fat, liver, and kidney Eggs	0.2 0.15
Japan	Muscle, fat, liver, kidney, and edible offal of chicken and other poultry Eggs of chickens and other poultry	0.1 0.05
United States	Chicken fat, kidney liver, muscle, and skin Turkey fat, kidney, liver, muscle, and skin Chicken and turkey eggs	0.125 0.125 0.025

3.10 PROPOSAL TO SET MRLS FOR ETHOFUMESATE

It is proposed that an MRL is set for ethofumesate to support the GAP use of the compound on bulb onions.

There is currently no entry for ethofumesate 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)
Ethofumesate	26225-79-6	Ethofumesate	Onions, bulb	0.01(*)

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

3.10.1 Amendment Rationale

The MRL is being proposed to support an expansion of the use of ethofumesate to include bulb onions. The proposed MRL will manage the use of the compound in the crop bulb onions in accordance with the use pattern and withholding period that are proposed as GAP in New Zealand.

3.10.2 Good Agricultural Practice

Ethofumesate belongs to the benzofuranyl alkylsulfonate group of herbicides used to manage broadleaf weeds and grass weeds in arable crops. The proposed use for ethofumesate in bulb onions is for application at a rate of 450-600 gai/ha to onions from 1st true leaf onwards at 7- to14-day intervals, with a maximum of 3 applications per crop. This use attracts a withholding period of 90 days.

3.10.3 Residue Information

The residue data for the use of ethofumesate are sufficient to conclude that, when applied according to the proposed GAP use pattern, quantifiable residues of ethofumesate are not expected in bulb onions. The residue definition of 'ethofumesate' remains appropriate for plant commodities for GAP compliance and dietary intake assessment.

Animal commodity MRLs are not required as a result of the proposed use, as bulb onions are not considered to be a primary animal feed in New Zealand.

3.10.4 Dietary Risk Assessment

The HBGV of 0.15 mg/kg bw/day was considered appropriate for use in the assessment.

Based on the residue profile expected in food from crops treated with ethofumesate the NEDI is estimated to total less than 0.1% of the HBGV for the average New Zealand adult.

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

3.10.5 Relevant International MRLs

Authority	Food	Maximum Residue Level (mg/kg)
Australia	Bulb vegetables	0.1(*)

There are no MRLs set by Codex for ethofumesate in bulb onions.

3.11 PROPOSAL TO AMEND THE MRLS FOR FLUDIOXONIL

It is proposed that the Notice entry for fludioxonil is amended to set MRLs in animal commodities to manage residues arising from leaf plucking and vineyard grazing practices.

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	Plant Commodities: Fludioxonil Animal Commodities: Sum of fludioxonil and metabolites determined as 2,2-difluorobenzo[1,1]dioxole-4-carboxylic acid, expressed as fludioxonil	Blackcurrants Blueberries Bulb onions Grapes Kumara Mammalian fat Mammalian kidney Mammalian liver Mammalian meat Milk Pineapples Strawberries	0.8 0.5 0.01(*) 1 10 0.02 0.05 0.05 0.01(*) 0.01(*) 7 1

(*) 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 practice of leaf plucking and grazing by sheep in vineyards. The proposed MRLs will manage the residues in sheep when exposed to fludioxonil used in accordance with the use pattern proposed as GAP for vineyard treatment in New Zealand.

3.11.2 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.

Fludioxonil is currently used in grapes, either alone or in combination with fluazinam or cyproconazole, with label claims in NZ for use on grapes up to 21-28 days before harvest.

The proposed new use in grapes is one foliar application of 25 g ai/hL up to 80% cap-fall, as a high-volume spray (or an equivalent rate/ha as a concentrate spray) in combination with pydiflumetofen. This use also allows for the practice of leaf plucking by sheep to thin the leaves around the bunches, and grazing of interrow grass, with sheep introduced into treated vineyards immediately after spraying. This practice attracts a two-month slaughter interval for exposed sheep, during which they must be placed on grazing free of any residues ("clean feed").

3.11.3 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 the current 1 mg/kg MRL in grapes. The current residue definition of 'fludioxonil' remains appropriate for plant commodities (for both GAP compliance and dietary intake assessment).

Animal metabolism and feeding study data characterising the residue transfer potential to animal commodities following exposure to fludioxonil. These data are sufficient to conclude that use of the compound on grapes and subsequent vineyard grazing and leaf plucking practices will not result in residues above the proposed animal commodity MRLs. The proposed residue definitions applicable in New Zealand for animal commodities align with those established by Codex: *the sum of fludioxonil and metabolites determined as 2,2-difluorobenzo[1,1]dioxole-4-carboxylic acid, expressed as fludioxonil* for both GAP compliance and dietary intake.

3.11.4 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 horticultural crops treated with fludioxonil and animal commodities from sheep exposed to fludioxonil, the NEDI is estimated to total less than 13% 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.

3.11.5 Relevant International MRLs

Authority	Food	Maximum Residue Level (mg/kg)
Australia	Grapes	2
	Edible offal (mammalian)	0.1
	Meat (mammalian)	0.05
	Milks	0.05
Canada	Kidney, liver, and fat of cattle and sheep	0.05
	Meat of cattle and sheep	0.01
	Milk	0.01

Authority	Food	Maximum Residue Level (mg/kg)
Codex	Grapes	2
	Edible offal (mammalian)	0.1
	Mammalian fats (except milk fats)	0.02
	Meat (from mammals other than marine mammals)	0.02
	Milks	0.04
EU	Bovine and ovine muscle	0.04
	Bovine and ovine fat	0.02
	Bovine and ovine liver	0.2
	Bovine and ovine kidney	0.2
	Bovine and ovine edible offals (other than liver and kidney)	0.1
	Milk	0.04
Japan	Mammalian muscle	0.01
	Mammalian fat	0.05
	Mammalian liver	0.05
	Mammalian kidney	0.05
	Mammalian edible offal	0.05
	Milk	0.01
United States	Cattle byproducts, fat, kidney, and liver	0.05
	Cattle meat	0.01
	Milk	0.01
	Sheep byproducts, fat, kidney, liver, and meat	0.01

3.12 PROPOSAL TO AMEND THE MRLS FOR LASALOCID

It is proposed that the Notice entry for lasalocid is amended to set a MRL for eggs to support the GAP use of the compound.

The revised entry for lasalocid 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)
Lasalocid (or its sodium salt)	25999-31-9 or 25999-20-6	Lasalocid as free acid	Edible offal of poultry **Eggs** Poultry fat Poultry meat	5 **0.15** 0.2 0.2

3.12.1 Amendment Rationale

The MRL is being proposed to better support the use patterns approved as GAP in New Zealand, which include the treatment of replacement layer pullets. The other changes to the entry are to add the CAS number specific to lasalocid sodium, and to adjust wording in the common name and residue definition for clarity.

3.12.2 Good Agricultural Practice

Lasalocid is a divalent polyether ionophore antiprotozoal compound, which acts by inducing osmotic lysis of coccidial cells. It is used for the prevention of coccidiosis caused by *Eimeria* species in broiler chickens, turkeys, and replacement layer and breeder pullets at a dose of 75 to 125 mg lasalocid/kg feed. For broiler chickens and turkeys, treatment is administered continuously in the feed; for replacement layer and broiler breeder pullets, treatment is administered for 1-2 weeks, and is discontinued at least 14 days before the onset of egg lay.

The use of lasalocid in broiler chickens and turkeys attracts a nil meat withholding period, and the replacement layer pullet use attracts a 14-day egg withholding period to enforce GAP.

3.12.3 Residue Information

The residue data for the use of lasalocid in chickens are sufficient to conclude that, when used according to the existing GAP use pattern and conforming to the applicable withholding period, residues of lasalocid can be expected to conform to a MRL of 0.15 mg/kg in eggs.

The GAP compliance and residue dietary intake definitions, 'lasalocid as the free acid', will remain unchanged.

3.12.4 Dietary Risk Assessment

The HBGV of 0.005 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 poultry treated with lasalocid, the NEDI is estimated to total less than 21% of the HBGV.

MPI has therefore determined that the use of lasalocid in poultry, when use according to the GAP specified above, is unlikely to pose any health risks from authorised use.

3.12.5 Relevant International MRLs

Country	Food	Maximum Residue Level (mg/kg)
Australia	Eggs	0.05
EU	Eggs	0.15
Japan	Chicken eggs	0.2
Singapore	Eggs	0.15

3.13 PROPOSAL TO SET MRLS FOR METOBROMURON

It is proposed that an MRL is set for metobromuron to support the GAP use of the compound on potatoes.

There is currently no entry for metobromuron 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)
Metobromuron	3060-89-7	4-bromophenylurea	Potatoes	0.01(*)

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

3.13.1 Amendment Rationale

The MRL is being proposed to support the use of the novel active ingredient metobromuron in potatoes. The proposed MRL will manage the use of the compound in potatoes in accordance with the use pattern and withholding period that are proposed as GAP in New Zealand.

3.13.2 Good Agricultural Practice

Metobromuron is a pre-emergent urea herbicide, which is taken up by roots and acts by inhibiting photosynthesis. The proposed use in New Zealand is as a herbicide in potatoes, applied at a rate of 1.5-2 kg ai/ha as a single pre-emergence spray to soil at last ridging. This use attracts a withholding period of 'Before crop emergence'.

3.13.3 Residue Information

The residue data for the use of metobromuron are sufficient to conclude that, when applied according to the proposed GAP use pattern, quantifiable residues of metobromuron are not expected in potato tubers at harvest. A residue definition of '4-bromophenylurea' has been proposed for plant commodities for GAP compliance. For dietary intake assessment in plant commodities, the proposed residue definition is the 'sum of parent metobromuron, desmethoxy- metobromuron, desmethyl- metobromuron and 4-bromophenylurea', with residues being measured as 4-bromophenylurea and expressed as metobromuron (using a conversion factor of 3.4).

Animal commodity MRLs are not required to support the proposed use as potatoes are not considered to be a primary animal feed in New Zealand.

3.13.4 Dietary Risk Assessment

The HBGV of 0.021 mg/kg bw/d, and the stated dietary intake residue definition, are considered appropriate for use in the assessment. Based on the residue profile expected in food from crops treated with metobromuron, the NEDI is estimated to total less than 0.2% of the HBGV.

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

3.13.5 Relevant International MRLs

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

3.14 PROPOSAL TO SET MRLS FOR PYDIFLUMETOFEN

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

There is currently no entry for pydiflumetofen 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)
Pydiflumetofen	1228284-64-7	Pydiflumetofen	Grapes Mammalian fat Mammalian meat Mammalian offal Milk Potatoes	0.2 0.03 0.01(*) 0.03 0.02 0.01(*)

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

3.14.1 Amendment Rationale

The MRLs are being proposed to support the use of the compound pydiflumetofen in grapes for powdery mildew and *Botrytis* control, and in potatoes for early blight control in accordance with the use pattern and withholding periods that are proposed as GAP in New Zealand. The proposed MRLs will manage the use of the compound in grapes and potatoes, and residues in animal commodities resulting from the practice of introducing sheep for leaf plucking and grazing in vineyards.

3.14.2 Good Agricultural Practice

Pydiflumetofen is a carboxamide succinate dehydrogenase inhibitor (SDHI) fungicide with protectant activity against a range of fungal diseases. It is a 50:50 mixture of R- and S-enantiomers, both being biologically active.

The compound is used to control early blight in potatoes with the application of three foliar sprays of 50 gai/ha at 7- to 14-day intervals, or 75 gai/ha at 14-21 days intervals, as part of a full season protectant programme. The withholding period applied to this use is 14 days. It is also currently approved for use at a maximum of two applications of 4 g ai/100 L for powdery mildew control on grapes, applied before the start of flowering, at a 14- to 21-day interval. The withholding period applied to this use is "Do not apply after flowering has commenced".

The proposed new use pattern is a single application of 15 gai/hL for control of *Botrytis cinerea* in grapes, in combination with fludioxonil. The proposed withholding period in grapes of "up to 80% capfall" reflects this use and is considered to be Good Agricultural Practice for vineyard treatment. When used in vineyards, the use patterns allow for the practice of leaf plucking by sheep to thin leaves around the bunches, and for grazing of interrow grass. This practice attracts a two-month slaughter interval for exposed sheep, during which they must be placed on grazing free of any residues ("clean feed"). This applies to both the powdery mildew and *Botrytis* control uses.

3.14.3 Residue Information

The residue data for the use of pydiflumetofen are sufficient to conclude that, when applied according to the proposed GAP use pattern, residues of pydiflumetofen should not exceed 0.2 mg/kg in grapes. In potatoes used according to the proposed GAP use pattern, measurable residues of pydiflumetofen are not expected in tubers (or any processed commodities) from treated crops. The residue definition of 'pydiflumetofen' is appropriate for plant commodities (for both GAP compliance and dietary intake assessment).

Animal metabolism and feeding study data characterising the residue transfer potential to animal commodities following exposure to pydiflumetofen are sufficient to conclude that use of the compound on grapes and subsequent vineyard grazing and leaf plucking practices will not result in residues above the proposed animal commodity MRLs.

The proposed residue definitions applicable in New Zealand align with those established by Codex. For GAP compliance in both plant and animal commodities, and for dietary intake estimation in plant commodities, the residue definition is proposed to be pydiflumetofen. For dietary intake estimation in animal commodities, the proposed residue definitions are: *the sum of pydiflumetofen, 2,4,6-TCP and its conjugates, and 3-(difluoromethyl)-N-methoxy-1-methyl-N-[1-methyl-2-(2,4,6-trichloro-3-hydroxy- phenyl) ethyl]pyrazole-4-carboxamide (SYN547897) and its conjugates, expressed as pydiflumetofen* for liver and kidney; and *the sum of pydiflumetofen and 2,4,6-TCP and its conjugates, expressed as pydiflumetofen,* for all other animal commodities.

The potato use will have no impact on animal commodity residues, as potatoes are not considered to be a primary animal feed in New Zealand.

3.14.4 Dietary Risk Assessment

The HBGV of 0.06 mg/kg bw/d, and the stated dietary intake residue definitions, are considered appropriate for use in the assessment. Based on the residue profile expected in food from horticultural crops treated with pydiflumetofen and animal commodities from sheep exposed to pydiflumetofen, the NEDI is estimated to total less than 0.8% of the HBGV.

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

3.14.5 Relevant International MRLs

Authority	Food	Maximum Residue Level (mg/kg)
Australia	Grapes Root and tuber vegetables	2 0.05
Canada	Fat of sheep and cattle Meat byproducts of sheep and cattle Meat of cattle and sheep Milk	0.03 0.03 0.01 0.03
Codex	Small fruit vine climbing	1.5
Japan	Mammalian muscle Mammalian fat Mammalian liver Mammalian kidney Mammalian edible offal Milk	0.01 0.03 0.03 0.03 0.03 0.03
United States	Cattle by products, fat, kidney, and liver Sheep by products, fat, kidney, and liver Cattle and sheep meat Milk	0.03 0.03 0.01 0.03

3.15 PROPOSAL TO AMEND THE MRLS FOR TILMICOSIN

It is proposed that the Notice entry for tilmicosin is amended to set MRLs to support the existing GAP uses of the compound in cattle and sheep.

The revised entry for tilmicosin 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)
Tilmicosin	108050-54-0	Tilmicosin	**Cattle fat** **Cattle kidney** **Cattle liver** **Cattle meat** **Milk** **Sheep fat** **Sheep kidney** **Sheep liver** **Sheep meat** Pig fat Pig kidney Pig liver Pig meat	0.05 0.3 1 0.05 0.05 0.05 0.3 1 0.05 0.1 1 1.5 0.1

3.15.1 Amendment Rationale

The MRLs are being proposed to support the continued GAP use of tilmicosin in cattle, sheep, and pigs in accordance with the use patterns considered GAP in New Zealand. The promulgation of these MRLs are the result of a review of all existing approved uses for veterinary medicines containing antibiotic compounds to ensure their use conforms with the expectations of GAP and prudent use.

3.15.2 Good Agricultural Practice

Tilmicosin is a macrolide antibiotic which acts by inhibiting protein synthesis and cell growth by binding to bacterial ribosomes. It is approved for use in New Zealand under veterinary authorisation for the treatment bovine respiratory disease (BRD) in cattle, the treatment of footrot in sheep, and the treatment of pneumonia in pigs. Tilmicosin is used at a dose rate of 10 mg/kg in cattle, 5 mg/kg in sheep, and 8-24 mg/kg in pigs. The withholding periods applicable to these uses are 28 days and 42 days for meat from cattle and sheep, respectively, 14 days for meat from pigs, and 35 days for milk from cattle and sheep.

3.15.3 Residue Information

The residue data for the use of tilmicosin in the approved target species are sufficient to conclude that, when used according to the use patterns and observing the withholding periods considered GAP in New Zealand, residues of tilmicosin are not expected to exceed the proposed MRLs in commodities derived from cattle and sheep including milk. The MRLs applicable to pig-derived commodities will remain unchanged from those already established for tilmicosin at levels that align with MRLs established by Codex. These conclusions are based on a review of existing data on file for the registered products and all publicly available data and information relevant to GAP in New Zealand.

The residue definition of 'tilmicosin' is considered appropriate to apply to all animal commodities for both GAP compliance and dietary intake assessment.

3.15.4 Dietary Risk Assessment

The HBGV of 0.002 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 tilmicosin, the NEDI is estimated to total less than 22% of the HBGV.

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

3.15.5 Relevant International MRLs

Country	Food	Maximum Residue Level (mg/kg)
Australia	Cattle and pig meat	0.05
	Cattle and pig, edible offal of	1
Canada	Fat and muscle of cattle	0.1
	Kidney and liver of cattle	1
	Fat and muscle of sheep	0.1
	Kidney and liver of sheep	1
	Kidney of swine	1
	Liver of swine	1.5
	Muscle, skin, and fat of swine	0.1
China	Cattle and sheep muscle	0.1
	Cattle and sheep fat	0.1
	Cattle and sheep liver	1
	Cattle and sheep kidney	0.3
	Pig muscle and fat	0.1
	Pig liver	1.5
	Pig kidney	1
	Milk	0.05
Codex	Cattle muscle and fat	0.1
	Cattle liver	1
	Cattle kidney	0.3
	Pig muscle and fat	0.1
	Pig liver	1.5
	Pig kidney	1
	Sheep muscle and fat	0.1
	Sheep liver	1
	Sheep kidney	0.3
EU	Mammalian muscle	0.05
	Mammalian fat	0.05
	Mammalian liver and kidney	1
	Milk	0.05
Japan	Cattle, pig, and sheep muscle	0.1
	Cattle, pig, and sheep fat	0.1
	Cattle and sheep liver	1
	Pig liver	1.5
	Cattle and sheep kidney	0.3
	Pig kidney	1
	Cattle edible offal	0.5
	Sheep edible offal	0.3
	Pig edible offal	1
	Milk	0.05
United States	Cattle and sheep liver	1.2
	Cattle and sheep muscle	0.1
	Pig liver	7.5
	Pig muscle	0.1

3.16 PROPOSAL TO AMEND THE MRLS FOR TULATHROMYCIN

It is proposed that the Notice entry for tulathromycin is amended to set MRLs to support the existing GAP use of the compound in cattle.

The revised entry for tilmicosin 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)
Tulathromycin	217500-96-4	Sum of residues converted to (2R,3S,4R,5R,8R,10R,11R,12S, 13S,14R)-2-ethyl-3,4,10,13-tetrahydroxy-3,5,8,10,12,14-hexamethyl-11-[[3,4,6-trideoxy-3(dimethylamino)-β-D-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one, expressed as tulathromycin equivalents	Cattle fat Cattle kidney Cattle liver Cattle meat Milk Pig fat/skin Pig kidney Pig liver Pig meat Sheep fat Sheep liver Sheep kidney Sheep meat	0.1 3 3 0.1 0.1 0.3 3 2 0.5 0.25 5.4 1.8 0.45

3.16.1 Amendment Rationale

Tulathromycin has been used in New Zealand as a veterinary medicine for several years, with its use in cattle being subject to compliance with established MRLs for tissue commodities and the New Zealand default MRL of 0.1 mg/kg for milk. The new MRL is being proposed to provide transparency for and support the use of tulathromycin in cattle in accordance with the dose rates and use patterns considered as GAP in New Zealand. All other MRLs will remain unchanged.

The promulgation of this MRL is an outcome of a review of all existing approved uses for veterinary medicines containing antibiotic compounds to ensure their use conforms with the expectations of GAP and prudent use.

3.16.2 Good Agricultural Practice

Tulathromycin is a macrolide antibiotic which, like other macrolides, acts by inhibiting protein synthesis and cell growth by binding to bacterial ribosomes. It has been approved for use in New Zealand since 2013 in cattle, sheep, and pigs, for the treatment of respiratory disease and infectious bovine keratoconjunctivitis in cattle, respiratory disease in pigs, and footrot in sheep. The compound is used at a dose rate of 2.5 mg/kg in cattle, and 2.5 mg/kg in pigs and sheep, and attracts withholding periods of 35 days for meat and 70 days for milk in cattle, 14 days for meat in pigs, and 21 days for meat in sheep.

Tulathromycin is not approved for use in sheep producing or intending to produce milk for human consumption.

3.16.3 Residue Information

The residue data for the use of tulathromycin in the approved target species and commodities are sufficient to conclude that, when used according to the use patterns and observing the withholding periods considered GAP in New Zealand, residues are not expected to exceed the existing and proposed MRLs in animal commodities. Milk is currently expected to conform to a MRL of 0.1 mg/kg (the default MRL), so setting a MRL for it in Schedule 1 reflects the existing expectation as dictated by residue data. It is noted that the 70-day cattle milk withholding period applied to tulathromycin will mean the compound is effectively excluded for use in cattle producing milk for human consumption.

The residue definition has been slightly revised from '*(2R,3S,4R,5R,8R,10R,11R,12S, 13S,14R)-2-ethyl-3,4,10,13-tetrahydroxy-3,5,8,10,12,14-hexamethyl-11-[[3,4,6-trideoxy-*

3(dimethylamino)-β-D-xylo-hexopyranosyl]oxy]-1-oxa- 6-azacyclopentadecan-15-one Expressed as: tulathromycin equivalents' to '***sum of residues converted to*** *(2R,3S,4R,5R,8R,10R,11R,12S, 13S,14R)-2-ethyl-3,4,10,13-tetrahydroxy-3,5,8,10,12,14-hexamethyl-11-[[3,4,6-trideoxy-3(dimethylamino)-β-D-xylo-hexopyranosyl]oxy]-1-oxa- 6-azacyclopentadecan-15-one, expressed as tulathromycin equivalents'*. This change is to reflect that definition captures the sum of metabolites that may be hydrolysed to that compound, aligning it with overseas definitions. This definition is considered appropriate for both GAP compliance and dietary intake.

The change to the end of the definition is a minor administrative change only, to link the 'expressed as' portion to the rest of the definition.

3.16.4 Dietary Risk Assessment

The HBGV of 0.05 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 tulathromycin, the NEDI is estimated to total less than 3% of the HBGV.

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

3.16.5 Relevant International MRLs

Country	Food	Maximum Residue Level (mg/kg)
Australia	Cattle fat and muscle	0.1
	Cattle kidney	1
	Cattle liver	3
	Pig fat/skin	0.3
	Pig muscle	0.5
	Pig kidney	3
	Pig liver	2
Canada	Kidney of cattle	4
	Liver of cattle	2
	Muscle of cattle	1
	Kidney of swine	5
	Liver of swine	4
	Muscle of swine	1.5
EU	Bovine muscle	0.3
	Bovine fat	0.2
	Bovine liver	4.5
	Bovine kidney	3
	Porcine muscle	0.8
	Porcine skin + fat	0.3
	Porcine liver	4
	Porcine kidney	8
Japan	Cattle muscle	0.3
	Pig muscle	2
	Cattle fat	0.2
	Pig fat	0.3
	Cattle liver	5
	Pig liver	4
	Cattle kidney	3
	Pig kidney	9
	Cattle edible offal	3
	Pig edible offal	5
United States	Cattle liver	5.5
	Swine kidney	15

3.17 PROPOSAL TO SET MRLS FOR TYLOSIN

It is proposed that MRLs are set for tylosin to support the GAP use of the compound in food-producing animals.

There is currently no entry for tylosin 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)
Tylosin	1401-69-0	Tylosin A	Cattle fat	0.1
			Cattle meat	0.1
			Cattle offal	0.1
			Eggs	0.3
			Goat fat	0.1
			Goat meat	0.1
			Goat offal	0.1
			Milk	0.05(*)
			Pig fat	0.1
			Pig meat	0.1
			Pig offal	0.1
			Poultry fat	0.1
			Poultry meat	0.1
			Poultry offal	0.1
			Sheep fat	0.1
			Sheep meat	0.1
			Sheep offal	0.1

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

3.17.1 Amendment Rationale

The MRLs are being proposed to support the continued GAP use of tylosin in cattle, goats, sheep, pigs, and poultry, in accordance with the use patterns considered GAP in New Zealand. The promulgation of these MRLs is an outcome of a review of all existing approved uses for veterinary medicines containing antibiotic compounds to ensure their use conforms with the expectations of GAP and prudent use.

3.17.2 Good Agricultural Practice

Tylosin is a macrolide antibiotic which, like other macrolides, acts by inhibiting protein synthesis and cell growth by binding to bacterial ribosomes. It has been approved for use in New Zealand under veterinary authorisation for many years in cattle, goats, sheep, pigs, and poultry, for the treatment of a number of clinically significant bacterial respiratory and gastrointestinal diseases.

The compound is administered as a parenteral injectable treatment in all species except poultry at doses between 5 mg/kg and 10 mg/kg for up to five days; administered via water to pigs and poultry at 100 mg/L drinking water and up to 500 mg/L drinking water, respectively; and administered via feed to beef cattle (up to 90 mg/head/day), pigs (up to 100 ppm), and poultry (most commonly up to 100 ppm).

The residue profile of tylosin varies between target species, method of administration, and dose rates, but meat from treated animals attract withholding periods up to 28 days, milk from treated animals attract withholding periods up to 35 days, and eggs from treated layer hens do not require a withholding period.

3.17.3 Residue Information

The residue data for the use of tylosin in the approved target species and commodities are sufficient to conclude that, when used according to the use patterns and observing the withholding periods considered GAP in New Zealand, residues of tylosin A are not expected to exceed the proposed MRLs in animal commodities. This conclusion is based on a review of existing data on file for the registered products and all publicly available data and information relevant to GAP in New Zealand.

The residue definition of 'Tylosin A' is considered appropriate to apply to all animal commodities for both GAP compliance and dietary intake assessment.

3.17.4 Dietary Risk Assessment

The HBGV of 0.03 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 tylosin, the NEDI is estimated to total less than 3% of the HBGV.

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

3.17.5 Relevant International MRLs

Country	Food	Maximum Residue Level (mg/kg)
Australia	Cattle meat and edible offal	0.1
	Eggs	0.2
	Milk	0.05
	Pig fat	0.1
	Pig meat and edible offal	0.2
	Poultry fats	0.1
	Poultry meat and edible offal	0.2
Canada	Fat, kidney, liver, and muscle of cattle	0.2
	Kidney, liver, muscle, skin, and fat of chickens	0.2
	Kidney, liver, muscle, skin, and fat of swine	0.2
	Kidney, liver, muscle, skin, and fat of turkeys	0.2
Codex	Cattle liver, fat, muscle, and kidney	0.1
	Cattle milk	0.1
	Chicken liver, muscle, kidney, fat and skin	0.1
	Chicken eggs	0.3
	Pig liver, fat, muscle, and kidney	0.1
	Sheep liver, muscle, and kidney	0.1
EU	Bovine muscle, fat, liver, and kidney	0.1
	Bovine milk	0.05
	Porcine muscle, skin + fat, liver, and kidney	0.1
	Poultry muscle, skin + fat, liver, kidney	0.1
	Poultry eggs	0.2
Japan	Cattle, pig, and other terrestrial mammal muscle	0.1
	Cattle, pig, and other terrestrial mammal fat	0.1
	Cattle, pig, and other terrestrial mammal liver	0.1
	Cattle, pig, and other terrestrial mammal kidney	0.1
	Cattle, pig, and other terrestrial mammal edible offal	0.1
	Milk	0.1
	Chicken muscle, fat, liver, kidney, and edible offal	0.1
	Chicken eggs	0.3
United States	Cattle fat, kidney, liver, and muscle	0.2
	Chicken and turkey fat, kidney, liver, and muscle	0.2
	Chicken and turkey eggs	0.2
	Swine fat, kidney, liver, and muscle	0.2

3.18 PROPOSAL TO EXEMPT COD LIVER OIL FROM COMPLIANCE WITH A MRL IN SCHEDULE 3

It is proposed that cod liver oil is exempt from compliance with an MRL by amendment to Schedule 3 of the Notice when it is used as a topical antifungal and antibacterial treatment. The compound is an extract comprised of the omega-3 fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) as well as vitamins A and D. It is commonly used as a human dietary supplement.

When used as a veterinary medicine, cod liver oil is applied as a topical spray with very little potential for systemic absorption and therefore not expected to result in residues in animal commodities. While there are dosing limits when consumed as a dietary supplement, the levels of cod liver oil and its components present in treated animals would not approach these levels and therefore not pose any food safety risks.

The proposed entry in Schedule 3 will read as follows:

Substance	CAS#	Condition
Cod liver oil	8001-69-2	When used as a topical antifungal or antibacterial treatment

3.19 PROPOSAL TO EXEMPT SMECTITE CLAYS FROM COMPLIANCE WITH A MRL IN SCHEDULE 3

It is proposed that smectite clays are exempt from compliance with an MRL by amendment to Schedule 3 of the Notice. The exemption will attract a condition that it is only exempt from MRL compliance when used as a mycotoxin binder in food-producing animals.

Smectite clays are phyllosilicate compounds comprised of montmorillonite in varying quantities, in addition to other mineral compounds and various elemental constituents. These clays are used in food-producing animals as gastrointestinal adsorbents, primarily for the binding of fungal toxins for the prevention of mycotoxicosis. Smectite clays possess no pharmacological activity and are not systemically adsorbed and are therefore not expected to cause residues in treated animals.

Bentonite, one of the most commonly used smectite clays, is recognised as GRAS under 21CFR582.1155 when used in accordance with good manufacturing or feeding practice. It is also included on the FDA approved inactive ingredient register and is approved for inclusion in tablets at up to 355mg. Given the term bentonite is widely used in literature without specificity it is considered that the GRAS status applies equally to all clays in the smectite group.

As naturally mined substances, smectite clays have the potential to contain heavy metals and dioxins. These contaminants are managed as part of the registration process for veterinary medicines like mycotoxin binders, and therefore do not preclude the promulgation of an exemption.

The proposed entry in Schedule 3 will read as follows:

Substance	CAS#	Condition
Smectite clays	n/a	When used for the purpose of binding mycotoxins in food-producing animals