Ministry for Primary Industries
Manatū Ahu Matua

Proposals to Amend the Maximum Residue Levels for Agricultural Compounds Food Notice 2018

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1 Submissions

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

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

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

Do you oppose an MRL being set <u>at all</u> for this compound for the commodity?

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

Submissions close at 5pm on **18 November 2018**. Your comments should be sent to:

MRL Amendments
ACVM Programmes and Appraisals
MPI Assurance Directorate
PO Box 2526
Wellington 6140

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

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

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

The Official Information Act

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

2 Introduction

Maximum residue levels (MRLs) are the maximum legal levels for residues of agricultural compounds and veterinary medicines permitted in food for sale in New Zealand. MRLs are primarily a tool for monitoring the use of agricultural compounds in accordance with good agricultural practice (GAP).

In terms of agricultural compound use, GAP can be defined as the set of principles and methods that ensure the production of safe and good quality horticultural and animal products at any stage of production, storage, transport, and distribution. GAP is established for each compound and its uses by taking into account public health, crop and animal safety, and occupational and environmental safety considerations for a range of treatments up to the highest authorised use. This ensures that the compounds are used in a manner that leaves the smallest amount of residue practicable without compromising the ability of that compound to achieve the intended beneficial effect, and thereby ensuring that the GAP use is sufficiently protective of consumer health when compared to the health based guidance value (HBGV) to determine the national estimated dietary Intake (NEDI).

The New Zealand MRLs are established based on domestic uses of a particular compound, and are used to monitor GAP compliance in New Zealand. Because they are based on New Zealand authorised uses according to domestic GAP, they may differ from MRLs 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 proposed MRL will be notified to the World Trade Organization. Any country may choose to comment if they believe the proposed MRL represents a barrier to their trade.

Note that the presentation of this proposal document has changed. When an entry in Schedule 1 has been revised in previous proposal documents, this was presented by including a copy of the existing entry followed by the revised entry. This will now be presented as a single edited entry, with new and amended content added in bold, and removed commodities struck through. This will allow for a more clear and concise presentation of the information and changes being proposed.

2.1 BACKGROUND

MRLs are set out in the New Zealand (Maximum Residue Levels for Agricultural Compounds) Food Notice. The MRL Food Notice is amended a number of times each year to reflect changes in the use of agricultural compounds in the production of food. The MRL Food Notice is available from the Ministry for Primary Industries (MPI) Food Safety website at: https://www.mpi.govt.nz/dmsdocument/19550-maximum-residue-levels-for-agricultural-compounds.

MPI 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 applying internationally;

- New Zealand's obligations under any relevant international treaty, agreement, convention, or protocol, and, in particular, under the Australia-New Zealand Joint Food Standards Agreement; and
- such other matters as appropriate.

The requirements for the content of the MRL Food Notice are set out in Part 6 of the Food Regulations 2015, allowing for the promulgation of MRLs for agricultural compounds as well as the promulgation of exemptions from compliance with MRLs. In addition to establishing the requirements on domestically produced foods, Part 6 of the Food Regulations also outlines the residue level compliance requirements for imported foods. Clause 144 states that imported 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
- 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 Agreement on the Application of Sanitary and Phytosanitary Measures 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 use (GAP).

The possible implications for consumer health are considered during the toxicological and dietary risk assessments, by comparing the NEDI with a 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 (mg/kg).

A $PDE_{(food)}$ is a value determined by a toxicological evaluation by the New Zealand Environmental Protection Authority (EPA) as part of its responsibility for managing public health under the Hazardous Substances and New Organisms Act 1996 (the HSNO Act). A $PDE_{(food)}$ gives the potential daily exposure a person may be subject to from a substance, via food.

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

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

2.1.3 International MRLs and Trade

The “Relevant International MRLs” table listed in each entry is a summary of the MRLs set by Codex and a selection of other international regulatory bodies reviewed to evaluate trade risk. For animal commodities, the MRLs set by our major trading partners (Australia, Canada, China, Codex, the European Union, Japan, and the United States) are reviewed and compared; for horticultural commodities, MRLs set by Codex and Australia are reviewed and compared. Other international MRLs are 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 entry.

2.2 SUMMARY OF PROPOSED AMENDMENTS

The proposed MRLs have been thoroughly assessed in accordance with international methodologies published by the Organisation for Economic Cooperation and Development (OECD) 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 Amendment to terminology used in all parts of the Notice

MPI proposes to amend all references to “MRL exceptions” to “MRL exemptions” in the Introduction, Part 1, and Schedules 1-3 of the Notice.

2.2.2 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:

- Clethodim: 0.2 mg/kg in mammalian meat; 0.2 mg/kg in mammalian offal; and 0.05 mg/kg in milk.
- Dicamba: 0.05 mg/kg in mammalian fat (except milk fat); 0.5 mg/kg in mammalian kidney; 0.1 mg/kg in mammalian liver; 0.02 mg/kg in mammalian meat; and 0.1 mg/kg in milk.
- Fludioxonil: 7 mg/kg in pineapples for import.
- Halauxifen-methyl: 0.01 mg/kg (*) in mammalian meat; 0.01 mg/kg (*) in mammalian offal; and 0.01 mg/kg (*) in milk.
- Lambda-cyhalothrin: 0.5 mg/kg in mammalian fat; 0.02 mg/kg in mammalian offal; 0.01 mg/kg in mammalian meat; and 0.05 mg/kg in mammalian milk.
- Metamitron: 0.01 mg/kg (*) in pears.

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

2.2.3 Other Amendments to Schedule 1

- MPI proposes to amend the residue definition for lignocaine.

- MPI proposes to amend the residue definition for xylazine.

2.2.4 Amendments to Schedule 2: New and Amended Exemptions from Maximum Residue Levels for Agricultural Chemicals

- MPI proposes to add an exemption for paraffin oils, when used as an agricultural compound, to the list of agricultural compounds in Schedule 2 of the Food Notice, for which no maximum residue levels apply.

- MPI proposes to amend the current entry for formic acid in the list of agricultural compounds in Schedule 2 of the Food Notice, for which no maximum residue levels apply. The entry will be moved from Schedule 2 to Schedule 3, and revised to be more specific to control of *Varroa* mite as per the current exemption for thymol.

- MPI proposes to amend the current entry for oxalic acid in the list of agricultural compounds in Schedule 2 of the Food Notice, for which no maximum residue levels apply. The entry will be moved from Schedule 2 to Schedule 3, and revised to be more specific to control of *Varroa* mite as per the current exemption for thymol.

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

- MPI proposes to amend the exemption for thymol in the list of agricultural compounds in Schedule 3 of the Food Notice, for which no maximum residue levels apply. The entry is to be amended to broaden the substance definition to extracts of *Thymus vulgaris* (thyme) containing thymol, to allow for the use of thyme extracts such as thyme oil as agricultural compounds exempt from MRLs. The condition of exemption is also being revised to specify that the use as an agricultural compound for the control of *Varroa mite* is specifically derived from the presence of thymol.

3 Proposals

3.1 PROPOSAL TO AMEND TERMINOLOGY IN THE NOTICE

It is proposed that the Notice is amended to change the terminology used to reference agricultural compounds to which no maximum residue levels apply from "exception" to "exemption." This will allow for a better understanding of the content of the Notice by using the terminology commonly used to describe such compounds.

Although this change will administratively affect content in the Background and Document History sections, as well as the titles and content of Schedules 2 and 3, there is no change to the meaning or intent of the technical information previously referred to as "exceptions" in any part of the Notice.

3.2 PROPOSAL TO AMEND THE MRLS FOR CLETHODIM

It is proposed that MRLs for clethodim are amended to include animal commodity MRLs to support the GAP use of the compound on fodder and sugar beet.

The revised entry with changes shown in bold for clethodim 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)
Clethodim	99129-21-2	Sum of: Clethodim and its metabolites containing 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones Expressed as: Clethodim	Brassica vegetables Fruiting vegetables Leafy vegetables Legume vegetables **Mammalian meat** **Mammalian offal** **Milk** Stem vegetables	1 1 1 1 **0.2** **0.2** **0.05** 1

3.2.1 Amendment Rationale

The animal commodity MRLs are being proposed to support a new use for clethodim in accordance with the application rates and withholding periods that are proposed as GAP in New Zealand.

3.2.2 Chemical Information

Common name of compound	Clethodim
Use of compound	Herbicide
Chemical Abstract Services (CAS) Registry number	99129-21-2
Type of compound	Cyclohexene oxime
Administration method	Spray

3.2.3 Good Agricultural Practice

Clethodim is used as a herbicide on fodder and sugar beet at a rate of 61-480 gai/ha to control annual and perennial grass weeds, and up to 720 gai/ha for couch and paspalum, 6-8 weeks after sowing. Use of clethodim in fodder and sugar beet crops attracts a pre-grazing and pre-harvest withholding period of nine weeks.

3.2.4 Residue Information

The residue data for the use of clethodim on fodder crops are sufficient to conclude that, when applied as per the proposed GAP use pattern, residues of clethodim and its metabolites should not exceed 0.05 mg/kg in milk, 0.1 mg/kg in meat, and 0.2 mg/kg in liver, kidney, and fat from animals exposed to clethodim after the treatment of fodder or sugar beet crops.

The proposed MRLs of 0.2 mg/kg in mammalian kidney, 0.2 mg/kg in mammalian liver, 0.2 mg/kg in mammalian meat, and 0.05 mg/kg in milk are therefore sufficient to support GAP for the use of clethodim on fodder and sugar beet animal feed crops.

3.2.5 Dietary Risk Assessment

The HBGV of 0.005 mg/kg was considered appropriate for use in the assessment.

Based on the residue profile expected in food from crops treated with clethodim, as well as in animal products from livestock that consume to treated feed, the NEDI for clethodim is estimated at less than 74% of the HBGV when the compound is used according to existing and proposed GAP uses.

MPI has therefore determined that the use of clethodim on fodder and sugar beet crops intended for animal consumption, according to the GAP specified above, is unlikely to pose any health risks from authorised use.

3.2.6 Relevant International MRLs

Country	Food	Maximum Residue Level (mg/kg)
Australia (As Sethoxydim)	Edible offal (Mammalian) Meat [mammalian]	0.05 0.05 0.05
Canada	Meat of cattle, goats, horses, and sheep Meat byproducts of cattle, goats, horses, and sheep	0.2 0.2 0.05
Codex	Edible offal (mammalian) Meat (from mammals other than marine mammals)	0.2 0.2 0.05
European Union (As Sethoxydim)	Cattle, goat, horse, and sheep muscle Cattle, goat, horse, and sheep fat Cattle, goat, horse, and sheep liver Cattle, goat, horse, and sheep kidney Cattle, goat, horse, and sheep edible offals (other than liver and kidney)	0.2 0.2 0.2 0.2 0.2 0.05
United States	Cattle, goat, horse, and sheep meat Cattle, goat, horse, and sheep by products Cattle, goat, horse, and sheep fat Cattle, goat, horse, and sheep kidney Cattle, goat, horse, and sheep liver	0.2 0.2 0.2 0.2 0.2 0.05

3.3 PROPOSAL TO SET MRLS FOR DICAMBA

It is proposed that MRLs are set for animal commodities to support the GAP use of dicamba on plantain.

There is currently no entry for dicamba in Schedule 1 of the Notice.

The new entry for dicamba in Schedule1 of the Notice will read:

Compound Common Name	CAS#	Residue to which the maximum residue level applies	Food	Maximum Residue Level (mg/kg)
Dicamba	1918-00-9	Sum of dicamba and DCSA, expressed as dicamba	Mammalian fat (except milk fat) Mammalian kidney Mammalian liver Mammalian meat Milk	0.05 0.5 0.1 0.02 0.1

3.3.1 Amendment Rationale

The MRL is being proposed to support a new use for dicamba on plantain in accordance with the application rates and withholding periods that are proposed as GAP in New Zealand.

3.3.2 Chemical Information

Common name of compound	Dicamba
Use of compound	Herbicide
Chemical Abstract Services (CAS) Registry number	1918-00-9
Type of compound	Benzoic acid
Administration method	Spray

3.3.3 Good Agricultural Practice

Dicamba is used as a herbicide on pasture plantain at a rate of 300 gai/ha to manage broad-leaf weeds. It is applied when the plantain has at least two to four true leaves, and before weeds reach the four-leaf stage. Use of dicamba on pasture attracts a pre-grazing withholding period of 14 days.

3.3.4 Residue Information

The residue data for the use of dicamba on pasture plantain are sufficient to conclude that, when applied as per the proposed GAP use pattern, residues of dicamba and the 3,6-dichlorosalicylic acid (DCSA) metabolite should not exceed 0.08 mg/kg in milk, 0.02 mg/kg in muscle, 0.09 mg/kg in liver, 0.4 mg/kg in kidney, and 0.04 mg/kg in fat when grazed on or fed treated plantain.

The animal metabolism studies demonstrated that the primary residues for dicamba in animal commodities were parent dicamba and the DCSA metabolite. The 5-OH dicamba metabolite did not accumulate significantly enough to consider it as part of the GAP compliance or dietary intake residue definitions. This is consistent with the assessment conducted by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) which informed the Codex definition for both dietary intake and MRL compliance for animal commodities: the sum of dicamba and DCSA, expressed as dicamba. This residue definition is considered appropriate to adopt for promulgation of New Zealand MRLs for this compound.

3.3.5 Dietary Risk Assessment

The HBGV of 0.015 mg/kg was considered appropriate for use in the assessment.

Based on the residue profile expected in food from crops treated with dicamba, as well as in animal products from livestock that consume treated feed, the NEDI for dicamba is less than 6% of the HBGV when the compound is used according to existing and proposed GAP uses.

MPI has therefore determined that the use of dicamba on plantain intended for animal consumption, according to the GAP specified above, is unlikely to pose any health risks from authorised use.

3.3.6 Relevant International MRLs

Country	Food	Maximum Residue Level (mg/kg)
Australia	Edible offal (Mammalian)	0.05
	Meat [mammalian]	0.05
	Milks	0.1
Codex	Edible offal (mammalian)	0.7
	Mammalian fats (except milk fats)	0.07
	Meat (from mammals other than marine mammals)	0.03
	Milks	0.2
European Union	Cattle muscle	0.5
	Cattle, deer, sheep, goat, and horse fat	0.07
	Cattle, deer, sheep, goat, and horse liver	0.7
	Cattle, deer, sheep, goat, and horse kidney	0.7
	Cattle, deer, sheep, goat, and horse edible offals (other than liver and kidney)	0.7
	Deer, sheep and equine muscle	0.05
	Cattle milk	0.5
	Other milk	0.2
United States	Cattle, goat, horse, and sheep by products	3
	Cattle, goat, horse, and sheep fat	0.3
	Cattle, goat, horse, and sheep kidney	25
	Cattle, goat, horse, and sheep liver	3
	Cattle, goat, horse, and sheep meat	0.25
	Milk	0.2

3.4 PROPOSAL TO AMEND THE MRLS FOR FLUDIOXONIL

It is proposed that MRLs for fludioxonil are amended to set a MRL for use of the compound on imported pineapples.

The revised entry with changes shown in bold for fludioxonil in Schedule 1 of the Notice will read:

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

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

3.4.1 Amendment Rationale

The MRL is being proposed to support the importation of pineapples to New Zealand. The current application of the default 0.1 mg/kg MRL is considered to be too low to support trade when the overseas use patterns considered to be GAP for pineapple crops are taken into account. Sufficient information has been provided to establish that the proposed MRL will be appropriate to facilitate trade while still supporting the GAP use of fludioxonil in New Zealand and on imported produce.

3.4.2 Chemical Information

Common name of compound	Fludioxonil
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	131341-86-1
Type of compound	Phenylpyrrole
Application method	Spray/Seed treatment in New Zealand; post-harvest treatment of imported pineapples

3.4.3 Good Agricultural Practice

In New Zealand, fludioxonil is used as a spray to treat fungal disease in grapes, bulb onions, black currants, blueberries, and strawberries, and as an antifungal seed treatment. Fludioxonil is also used overseas as a post-harvest treatment for the control of saprophytic surface moulds on pineapples at a rate of 32 fluid ounces/100 gallons water (0.61 g fludioxonil per litre of water). Trials conducted using this application rate were evaluated to determine the appropriate import MRL for New Zealand.

3.4.4 Residue Information

The residue data for the use of fludioxonil on pineapples from the United States were sufficient to conclude that, when applied as per the established overseas GAP use pattern for post-harvest treatment, residues should not exceed 2.84 mg/kg. The European Food Safety Authority (EFSA) evaluated these same data, and applied an import MRL of 7 mg/kg; it is considered that adoption of this MRL is appropriate for New Zealand.

The proposed MRL of 7mg/kg is therefore sufficient to support the overseas GAP for the use of fludioxonil on pineapples.

3.4.5 Dietary Risk Assessment

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

Based on the residue profile of fludioxonil expected in food from crops treated with the compound according to domestic and overseas GAP uses, the NEDI for fludioxonil is estimated at less than 12% of the HBGV.

MPI has therefore determined that setting an import MRL for pineapple that has been treated with fludioxonil as a post-harvest treatment for mould, according to the GAP specified above, is unlikely to pose any health risks from authorised use.

3.4.6 Relevant International MRLs

Country	Food	Maximum Residue Level (mg/kg)
Canada	Pineapples	20
European Union	Pineapples	7
United States	Pineapple	20

3.5 PROPOSAL TO AMEND THE MRLS FOR HALAUXIFEN-METHYL

It is proposed that MRLs for halauxifen-methyl are amended to include animal commodity MRLs to support the GAP use of the compound on fodder brassicas.

The revised entry with changes shown in bold for halauxifen-methyl in Schedule 1 of the Notice will read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Halauxifen-methyl	943831-98-9	Plant commodities: Halauxifen-methyl Animal commodities: 4-Amino-3-chloro-6(4-chloro-2-fluoro-3-hydroxphenyl)-pyridine-2-carboxylic acid, expressed as halauxifen-methyl	Barley grain Mammalian meat Mammalian offal Milk Triticale grain Wheat grain	0.01(*) 0.01(*) 0.01(*) 0.01(*) 0.01(*) 0.01(*)

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

3.5.1 Amendment Rationale

The MRL is being proposed to support a new use for halauxifen-methyl on fodder brassicas intended for animal consumption in accordance with the application rates and withholding periods that are proposed as GAP in New Zealand.

3.5.2 Chemical Information

Common name of compound	Halauxifen-methyl
Use of compound	Herbicide
Chemical Abstract Services (CAS) Registry number	943831-98-9
Type of compound	Arylpicolinate
Administration method	Spray

3.5.3 Good Agricultural Practice

Halauxifen-methyl is used as a herbicide on fodder brassicas at a rate of 5 gai/ha to manage broad-leaf weeds post-emergence. The compound is applied to actively growing crops at the 3-4 leaf stage (BBCH 13-14), as soon as possible after weed emergence. Use of halauxifen-methyl on fodder brassica crops attracts a pre-grazing and pre-harvest withholding period of 14 days.

3.5.4 Residue Information

The residue data for the use of halauxifen-methyl are sufficient to conclude that, when applied as per the proposed GAP use pattern and complying with the 14 day withholding period, residues of the4-Amino-3-chloro-6(4-chloro-2-fluoro-3-hydroxphenyl)-pyridine-2-carboxylic acid metabolite of halauxifen-methyl should not exceed 0.01 mg/kg in all commodities from animals fed treated fodder brassicas.

The proposed MRLs of 0.01(*) mg/kg in mammalian fat, kidney, liver, meat and milk are therefore sufficient to support GAP for the use of halauxifen-methyl on fodder brassicas.

A separate residue definition is proposed for animal commodities to regulate the primary metabolite in those commodities as evidenced in the residue data, and to align with the residue definition used overseas.

3.5.5 Dietary Risk Assessment

The HBGV of 0.0406 mg/kg was considered appropriate for use in the assessment.

The NEDI for halauxifen-methyl is estimated at less than 0.3% of the HBGV. This is based on the residue profile of halauxifen-methyl in plant commodities, and 4-Amino-3-chloro-6(4-chloro-2-fluoro-3-hydroxphenyl)-pyridine-2-carboxylic acid expected in animal products from livestock exposed to feed treated according to existing and proposed GAP uses.

MPI has therefore determined that the use of halauxifen-methyl on fodder brassicas, according to the GAP specified above, is unlikely to pose any health risks from authorised use.

3.5.6 Relevant International MRLs

Country	Food	Maximum Residue Level (mg/kg)
Australia	Edible offal (Mammalian)	0.01
	Meat (mammalian)	0.01
	Milks	0.01
European Union	Muscle, all species	0.02
	Fat, all species	0.02
	Liver, all species	0.02
	Kidney, all species	0.02
	Edible offal (other than liver and kidney), all species	0.02
	Milk, all species	0.02

3.6 PROPOSAL TO AMEND THE MRLS FOR LAMBDA-CYHALOTHRIN

It is proposed that MRLs for lambda-cyhalothrin are amended to include animal commodity MRLs to support the GAP use of the compound on plantain and plantain/clover swards.

The revised entry with changes shown in bold for lambda-cyhalothrin 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)
Lambda-cyhalothrin	91465-08-6	Lambda-cyhalothrin	Citrus fruits	0.01(*)
			Grapes	0.01(*)
			Kumara	0.01(*)
			Maize	0.01(*)
			Mammalian fat	**0.5**
			Mammalian offal	**0.02**
			Mammalian meat	**0.01**
			Milk	**0.05**
			Onions	0.01(*)
			Potatoes	0.01(*)
			Pumpkins	0.01(*)
			Sweetcorn	0.01(*)
			Winter squash	0.01(*)

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

3.6.1 Amendment Rationale

The MRL is being proposed to support a new use for lambda-cyhalothrin on plantain and mixed plantain/cover pasture in accordance with the application rates and withholding periods that are proposed as GAP in New Zealand.

3.6.2 Chemical Information

Common name of compound	Lambda-cyhalothrin
Use of compound	Insecticide
Chemical Abstract Services (CAS) Registry number	91465-08-6
Type of compound	Synthetic pyrethroid
Administration method	Spray

3.6.3 Good Agricultural Practice

Lambda-cyhalothrin is used as an insecticide on plantain and plantain/clover swards for the control of plantain moth. The compound is applied at a rate of 5 gai/ha as soon as caterpillars are noticed when clover is not in flower, and repeated as necessary avoiding the flowering period. Use of lambda-cyhalothrin on plantain pasture attracts a pre-grazing withholding period of 14 days.

3.6.4 Residue Information

The residue data for the use of lambda-cyhalothrin are sufficient to conclude that, when applied as per the proposed GAP use pattern and complying with the 14 day pre-grazing withholding period, residues of parent compound lambda-cyhalothrin in animal commodities should not exceed 0.01 mg/kg in meat, 0.02 mg/kg in liver and kidney, 0.5 mg/kg in fat, and 0.05 mg/kg in milk.

The proposed MRLs of 0.01 mg/kg in mammalian meat, 0.02 mg/kg in mammalian offal, 0.5 mg/kg in mammalian fat, and 0.05 mg/kg in milk are therefore sufficient to support GAP for the use of lambda-cyhalothrin on plantain and plantain/clover swards.

3.6.5 Dietary Risk Assessment

The HBGV of 0.0004 mg/kg was considered appropriate for use in the assessment.

Based on the residue profile expected in food from crops treated with lambda-cyhalothrin, as well as in animal products from livestock that consume treated feed, the NEDI for lambda-cyhalothrin is less than 59% of the HBGV when the compound is used according to existing and proposed GAP uses.

MPI has therefore determined that the use of lambda-cyhalothrin on plantain and plantain/clover swards, according to the GAP specified above, is unlikely to pose any health risks from authorised use.

3.6.6 Relevant International MRLs

Country	Food	Maximum Residue Level (mg/kg)
Australia	Cattle milk	0.01
	Edible offal (Mammalian)	0.7
	Meat [mammalian]	0.05
Canada	Fat of goats, horses, cattle, and sheep	5
	Meat byproducts of goats, horses, cattle, and sheep	0.2
	Meat of goats, horses, cattle, and sheep	0.2
	Milk	0.5
	Milk fat	12
Codex	Kidney of cattle, goats, pigs, and sheep	0.2
	Liver of cattle, goats, pigs, and sheep	0.05
	Meat (from mammals other than marine mammals)(fat)	3
	Milks	0.2
European Union	Muscle, all mammalian species	0.5
	Fat, all mammalian species	0.5
	Liver, all mammalian species	0.5
	Kidney, all mammalian species	0.5
	Edible offals (other than liver and kidney), all mammalian species	0.5
	Milk	0.05
United States	By products, all mammalian species	0.2
	Fat, all mammalian species	3
	Kidney, all mammalian species	0.2
	Liver, all mammalian species	0.2
	Meat, all mammalian species	0.2
	Milk	10

3.7 PROPOSAL TO AMEND THE MRLS FOR METAMITRON

It is proposed that MRLs for metamitron are amended to support the GAP use of the compound on pears.

The revised entry with the change shown in bold for metamitron in Schedule 1 of the Notice will read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Metamitron	41394-05-2	Metamitron	Apples	0.01(*)
			Pears	0.01(*)

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

3.7.1 Amendment Rationale

The MRL is being proposed to support a new use for metamitron on pears in accordance with the application rates and withholding periods that are proposed as GAP in New Zealand.

3.7.2 Chemical Information

Common name of compound	Metamitron
Use of compound	Plant Growth Regulator
Chemical Abstract Services (CAS) Registry number	41394-05-2
Type of compound	Triazinone
Administration method	Spray

3.7.3 Good Agricultural Practice

Metamitron is used as a plant growth regulator for fruitlet thinning at a rate of 165 to 330 gai/ha when fruitlets are 8-14 millimetres in diameter. The compound is to be applied no later than 30 days after full bloom.

3.7.4 Residue Information

The residue data for the use of metamitron are sufficient to conclude that, when applied as per the proposed GAP use pattern, residues of parent compound metamitron should not exceed the 0.01 mg/kg limit of detection in pears from treated trees.

The proposed MRL of 0.01(*) mg/kg in pears is therefore sufficient to support GAP for the use of metamitron on pear trees.

3.7.5 Dietary Risk Assessment

The HBGV of 0.015 mg/kg was considered appropriate for use in the assessment.

Based on the residue profile of metamitron expected in food from crops treated according to existing and proposed GAP uses, the NEDI is estimated at less than 1% of the HBGV.

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

3.7.6 Relevant International MRLs

There are no Codex or Australian MRLs for metamitron.

3.8 PROPOSAL TO AMEND THE RESIDUE DEFINITION FOR LIGNOCAINE

It is proposed that the residue definition for lignocaine is amended to support the GAP use of the compound in the harvest of deer velvet.

The revised entry with the change shown in bold for lignocaine in Schedule 1 of the Notice will read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Lignocaine (lidocaine)	137-58-6	**Lignocaine**	Deer Velvet	5

3.8.1 Amendment Rationale

The change to the residue definition is being proposed following a review of the use of lignocaine and xylazine in the harvesting of deer velvet, and the residues present in velvet as a result. It is considered that revision of the residue definition to parent compound lignocaine

is sufficient to manage use of the compound according to GAP and regulatory compliance with the MRL, which is the purpose of the MRL listed in the Notice. The metabolite 2,6-dimethylaniline, which will be removed from the regulatory compliance residue definition, will still be considered in the dietary intake calculations for the compound.

3.8.2 Chemical Information

Common name of compound	Lignocaine
Use of compound	Anaesthetic
Chemical Abstract Services (CAS) Registry number	137-58-6
Type of compound	Amide
Administration method	Injection as a local anaesthetic

3.8.3 Good Agricultural Practice

There is no change to GAP for lignocaine as previously established. Current GAP for the use of lignocaine in deer for the purposes of harvesting velvet requires the application of a tourniquet, followed by administering lignocaine as a local anaesthetic. The lignocaine is administered by the ring block technique at a rate of 20 mg lignocaine per centimetre of antler pedicle circumference, at the base of the antler between the top of the head and the tourniquet. This use does not attract the need for a withholding period for lignocaine in the harvested velvet.

3.8.4 Residue Information

The residue data for the concurrent use of lignocaine and xylazine in the harvesting of deer velvet confirmed that 2,6-dimethylaniline, also known as 2,6-xylidine, comprised no more than 0.003 mg/kg of the total recovered residue. The metabolite, which is common to both lignocaine and xylazine, is necessary for the complete evaluation of dietary intake, and therefore will be retained in the dietary intake residue definition for this compound.

The residue definition listed in the Food Notice however is used for regulatory MRL compliance, to ensure use of the compound conforms to the dose rate and use pattern established as GAP in New Zealand. Given that the 2,6-dimethylaniline metabolite can be expected to comprise less than 0.1% of the total lignocaine residue, its inclusion in the regulatory compliance limit is not required. As such, a residue definition that includes only parent compound lignocaine as the target compound is considered sufficient to manage the use of lignocaine in deer velvet harvest as per established GAP.

3.8.5 Dietary Risk Assessment

The dietary risk associated with the use of lignocaine in the harvesting of deer velvet has not changed; the dietary risk assessment will still be based on the sum of lignocaine and 2,6-dimethylaniline and a HBGV of 0.021 mg/kg.

The NEDI for the concurrent use of lignocaine and xylazine for deer velvet harvesting is equivalent to less than 40% of the HGBV for the sum of parent compound lignocaine, parent compound xylazine, and their common 2,6-dimethylaniline metabolite. MPI has therefore determined that the use of lignocaine for deer velvet harvesting, according to the GAP specified above, is unlikely to pose any health risks from authorised use.

3.8.6 Relevant International MRLs

There are no international MRLs for lignocaine (or lidocaine) in deer velvet.

3.9 PROPOSAL TO AMEND THE RESIDUE DEFINTION FOR XYLAZINE

It is proposed that the residue definition for xylazine is amended to support the GAP use of the compound in the harvest of deer velvet.

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

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Xylazine	7361-61-7	Xylazine	Deer Velvet	0.5

3.9.1 Amendment Rationale

Like the proposed change to the residue definition for lignocaine in section 3.8 of this document, a change is also proposed for the residue definition for xylazine. This is due to the lack of significant 2,6-dimethylaniline residues following the GAP use of xylazine in deer velvet harvesting that would require the compound's inclusion in the regulatory compliance residue definition. The metabolite will still be considered in the dietary intake calculations for xylazine's use as a veterinary medicine.

3.9.2 Chemical Information

Common name of compound	Xylazine
Use of compound	Sedative and analgesic
Chemical Abstract Services (CAS) Registry number	7361-61-7
Type of compound	Alpha-2 agonist
Administration method	Systemic injection

3.9.3 Good Agricultural Practice

There is no change to GAP for xylazine as previously established. Current GAP for the harvesting of deer velvet is the administration of up to 0.75 mg/kg xylazine, with the harvest commencing after the animal has been determined to be sufficiently sedated. This is then followed by administration of the local anaesthetic lignocaine according to GAP (section 3.8.3 of this proposal). The use of xylazine as a sedative in food-producing animals does attract a withholding period for meat and milk, but there is no withholding period for deer velvet.

3.9.4 Residue Information

The residue data associated with the concurrent use of xylazine and lignocaine for deer velvet harvest is discussed in section 3.8.4 of this document. Further to that information, data evaluating the residue profile of xylazine alone confirmed that residues of parent compound xylazine did not exceed 0.2 mg/kg when used as per GAP, and residues of 2,6-dimethylaniline stemming solely from the administration of xylazine remained less than 0.00056 mg/kg. As such, the regulatory compliance residue definition, which is used to confirm the use of xylazine according to GAP, does not require the retention of the 2,6-dimethylaniline metabolite.

3.9.5 Dietary Risk Assessment

The dietary risk associated with the use of xylazine in the harvesting of deer velvet has not changed; the dietary risk assessment will still be based on the sum of xylazine and 2,6-dimethylaniline and a HBGV of 0.021 mg/kg.

The NEDI for the concurrent use of lignocaine and xylazine for deer velvet harvesting is equivalent to less than 40% of the HGBV for the sum of parent compound lignocaine, parent compound xylazine, and their common 2,6-dimethylaniline metabolite. MPI has therefore

determined that the use of xylazine for deer velvet harvesting, according to the GAP specified above, is unlikely to pose any health risks from authorised use.

3.9.6 Relevant International MRLs

There are no international MRLs for xylazine in deer velvet.

3.10 PROPOSAL TO EXEMPT PARAFFIN OILS

It is proposed that paraffin oil be included in Schedule 2 of the Notice, to establish it as an agricultural chemical compound for which no MRLs apply.

Paraffin oils are chemically inert substances with a low toxicity profile. When used as an agricultural compound, they are not considered to be of toxicological concern and do not require an acceptable daily intake to manage exposure. The quality and purity of the paraffin oils used as agricultural compounds are evaluated as part of the technical assessment of the chemistry of trade name products at registration, ensuring that any food safety risks associated with potential impurities are appropriately managed.

It is considered that paraffin oils fall outside the scope of the existing exemption for C9-C16 alkanes because they can be cyclic, therefore requiring their own exemption for agricultural compound use.

There is currently no entry in Schedule 2 for paraffin oil.

The proposed entry in Schedule 2 will read:

Substance	CAS#	Condition
Paraffin oils	64742-46-7; 72623-86-0; 8042-47-5; and 97862-82-3	When used as an agricultural compound.

3.11 PROPOSAL TO AMEND THE EXEMPTION FOR FORMIC ACID

It is proposed that the exemption from compliance with an MRL for formic acid is removed from Schedule 2 of the Notice and added to Schedule 3, and its condition revised. This will allow for it to be positioned with the similar exemptions for oxalic acid (see entry 3.12) and thyme extracts (see entry 3.13), and align its condition of exemption with those entries.

The entry in Schedule 2 will be removed.

The revised entry in Schedule 3 will read as follows:

Substance	CAS#	Condition
Formic acid	64-18-6	When used as an agricultural compound for the control of *Varroa* mite (*Varroa destructor*) in beehives

This amendment will better align the similar exemptions with each other, and position them in the Schedule that addresses the treatment of food-producing animals. It also allows for a more specific condition associated with the compound's use as an agricultural compound.

3.12 PROPOSAL TO AMEND THE EXEMPTION FOR OXALIC ACID

It is proposed that the exemption from compliance with an MRL for oxalic acid is also removed from Schedule 2 of the Notice and added to Schedule 3, and its condition revised.

The entry in Schedule 2 will be removed.

The revised entry in Schedule 3 will read as follows:

Substance	CAS#	Condition
Oxalic acid	144-62-7	When used as an agricultural compound for the control of *Varroa* mite (*Varroa destructor*) in beehives

This amendment will better align the similar exemptions with each other, and position them in the Schedule that addresses the treatment of food-producing animals. It also allows for a more specific condition associated with the compound's use as an agricultural compound.

3.13 PROPOSAL TO AMEND THE EXEMPTION FOR THYMOL

It is proposed that the exemption from compliance with an MRL for thymol in Schedule 3 is revised to better reflect the compound, and similar extracts of thyme, in both substance definition and use.

The revised entry in Schedule 3 will read as follows:

Substance	CAS#	Condition
Extracts of *Thymus vulgaris* (thyme) containing thymol	N/A	When used as an agricultural compound for the control of *Varroa* mite (*Varroa destructor*) in beehives where the primary mode of action derives from the presence of thymol

This amendment will allow for the use of thyme oil and other extracts of the thyme plant for the control of *Varroa* mite in beehives, when such extracts rely on the presence of thymol to derive its efficacy. It is considered that these extracts of thyme will have the same risk profile as its derivative thymol.