New Zealand Food Safety
Haumaru Kai Aotearoa

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

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1 Request for submissions

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

For **each compound** you are commenting on, please clearly answer the following questions.

Do you agree or disagree with the proposed addition, amendment or deletion?

For compounds listed in Schedule 1, do you agree or disagree with the proposed MRL(s)?

For compounds listed in Schedules 2 or 3, do you agree or disagree with the listing or the conditions?

Please feel free to include with your answers above, any supporting discussion, data or examples that you feel is relevant.

Submissions close at 5pm on **XX XXX 2023**. 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. The Ministry for Primary Industries will take such indications into account when determining whether to release information. Any decision to withhold information requested under the OIA may be reviewed by the Ombudsman.

2 Introduction

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

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

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

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

2.1 ESTABLISHING MAXIMUM RESIDUE LEVELS

2.1.1 Regulatory Structure

MRLs are the maximum legal levels of agricultural compound residues permitted in food for sale in New Zealand and are set out in the Notice. The Notice is updated up to four times a year to reflect changes in the use of agricultural compounds in the production of food. The Notice is available from the Ministry for Primary Industries (MPI) New Zealand Food Safety website at: https://www.mpi.govt.nz/dmsdocument/19550-maximum-residue-levels-for-agricultural-compounds.

New Zealand Food Safety administers the Notice, with the final decision on any changes to the Notice resting with the Director-General of MPI. The Notice is issued under section 405 of the Food Act 2014. When setting or amending MRLs, the Director-General must follow, as far as practicable, international best practice on dietary intake assessment and setting of maximum residue levels. The requirements for the content of the Notice are set out in Part 6 of the Food Regulations 2015 (the Food Regulations), allowing for the setting of MRLs for agricultural compounds as well as specifying compounds to which no MRL applies.

In addition to establishing the requirements for domestically produced foods, Part 6 of the Food Regulations also outlines the residue level compliance requirements for imported foods. Regulation 144 states that food must not contain residues of agricultural compounds unless the residue level does not exceed:

- the MRLs specified for that food in a notice set under the Food Act 2014 (regulation 144(1)(a)); or
- the default MRL of 0.1 mg/kg (regulation 144(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) (regulation 144(1)(d)).

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

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

2.1.2 Determining Maximum Residue Levels

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

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

Where it has been determined that MRLs can be set, those MRLs are proposed for inclusion in the Notice for approved or proposed agricultural compound uses. For veterinary medicines, MRLs may be proposed for animal products from a specific species (e.g., cattle, chicken) or a species group (e.g., mammalian, poultry) depending on the residue and metabolism profile of the agricultural compound being considered. Similarly, for agricultural chemicals, an MRL may be set for an individual crop or crop product (e.g., avocados, wheat grains) or for a crop grouping (e.g., pome fruits). When it has been determined that assigning an MRL to a crop grouping is appropriate, the grouping used aligns with the Codex classifications of foods and animal feeds.

For agricultural chemicals used on a crop from which both food and animal feed commodities are derived, MRLs are proposed for both the food commodities intended for human consumption from the treated crop, and animal commodities for the species or species group to which the feed commodity is fed. If the compound for which the MRLs are set is also used as a veterinary medicine, all approved veterinary and agricultural chemical uses are

considered when setting the animal commodity MRLs. If an agricultural chemical is used on a crop from which only animal feed is harvested (e.g., pasture, fodder crops), only animal commodity MRLs will be proposed.

2.1.3 Estimating Chronic Dietary Exposure

National estimated daily intake

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

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

Health Based Guidance Values

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

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

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

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

2.1.4 International MRLs and Trade

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

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

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

2.1.5 Agricultural Compounds for Which No Maximum Residue Level Applies

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

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

Where New Zealand Food Safety has determined that an MRL is not required, the compound is proposed for listing in Schedule 2 (for agricultural chemicals) or Schedule 3 (for veterinary medicines) with conditions on their use to ensure the listing applies only to those situations that have been evaluated. If a compound listed in Schedule 2 or 3 is used in a way that does not meet the specified condition, the default MRL of 0.1 mg/kg will apply to food derived from treated plants or animals. Each proposal for inclusion in Schedule 2 or 3 includes a discussion of the rationale behind the considerations for listing, and a discussion of the assessed risks and proposed conditions.

2.2 SUMMARY OF PROPOSED AMENDMENTS

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

- the new or amended entry proposed for inclusion in the Notice;
- the rationale for the new entry or amendment being proposed;
- New Zealand good agricultural practice for the compound and target crop or species;
- the relevant residues information used in determining the proposed MRLs;
- a summary of the dietary risk and public health assessment; and
- the MRLs set by Codex and other authorities that are relevant to the new or amended entry.

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

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

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

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

- An amendment to the entry for triclabendazole, to set an MRL of 0.005 (*) mg/kg in milk, and 0.1 mg/kg in goat fat, meat and offal; and

- Removal of the entry for pirlimycin.

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

- The addition of a new entry for S-abscisic acid, when used as a plant growth regulator.

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

- The addition of a new entry for alfalfa extract, when used as an aid in the management of gastric ulcers in horses.

3 Proposals

3.1 PROPOSAL TO AMEND THE MRLS FOR TRICLABENDAZOLE

It is proposed that MRLs for triclabendazole are amended to better support the GAP use of the compound in cattle and goats.

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

Compound Common Name	CAS#	Residue to which the maximum residue level applies	Food	Maximum Residue Level (mg/kg)
Triclabendazole	68786-66-3	Sum of: Triclabendazole, triclabendazole sulphoxide, and triclabendazole sulphone Expressed as: Triclabendazole	Cattle fat Cattle meat ~~Edible offal of cattle~~ **Cattle offal** **Goat fat** **Goat meat** **Goat offal** ~~Edible offal of sheep~~ **Sheep offal** **Milk** Sheep fat Sheep meat	0.1 0.2 0.3 **0.1** **0.1** **0.1** 0.1 **0.005(*)** 0.1 0.1

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

3.1.1 Amendment Rationale

Triclabendazole has been approved for use in ruminants in New Zealand for parasite control since 1986, with fat, meat, and offal commodities attracting set withholding periods. The use of the compound is however excluded from use in lactating cattle, with milk withholding periods set to enforce this exclusion as GAP. The proposed revised entry will better reflect the GAP use of triclabendazole in ruminants, with the setting of a milk MRL at the limit of analytical quantification and the setting of MRLs for goat commodities.

Amendment of the food identifiers for cattle and sheep offal is also proposed to align with the terminology used in other entries. The target animal product, and the MRLs that apply to them, remain unchanged.

3.1.2 Good Agricultural Practice

Triclabendazole is a halogenated benzimidazole fasciolicide which acts by inhibiting microtubule formation in the target parasite. It is used in veterinary medicine as a treatment for *Fasciola hepatica* in cattle, sheep, and goats at a dose range of 10-30 mg/kg, either alone or in combination with abamectin, oxfendazole, and/or levamisole. The lower dose rates are approved for oral administration, while the higher dose rates are administered in topical formulations. Use of this triclabendazole alone or in combination attracts a meat withholding period of between 28 and 91 days depending on the use pattern, formulation details, and administration route. All registered products also attract milk withholding periods of at least 35 days to ensure the product is only used in non-lactating dairy animals as per New Zealand GAP.

3.1.3 Residue Information

The proposed MRLs for goat-derived commodities are supported by species-specific metabolism and residue data that confirm residues in all commodities will conform to 0.1 mg/kg when used according to GAP and the withholding periods are observed. Because the

compound is not permitted for use in lactating dairy animals, the proposed milk MRL will be set to ensure a lack of residues in milk rather than a level conforming to GAP use. As such, it was not necessary to evaluate milk residue data for triclabendazole.

The MRLs for other animal commodities will remain unchanged.

3.1.4 Dietary Risk Assessment

The HBGV of 0.0015 mg/kg bw/d was considered appropriate for use in the assessment. Based on the residue profile expected in food from animals treated with triclabendazole when used according to GAP, the NEDI is estimated to total less than 29% of the HBGV.

New Zealand Food Safety has therefore determined that the use of triclabendazole according to the GAP specified above and complying with the revised MRLs, is unlikely to pose any health risks from authorised use.

3.1.5 Relevant International MRLs

Authority	Food	Maximum Residue Level (mg/kg)
Australia	Fat (mammalian) Kidney (mammalian) Liver (mammalian) Meat (mammalian) Milks	1 1 2 0.5 0.01
European Union	Muscle, all ruminants Fat, all ruminants Liver, all ruminants Kidney, all ruminants Milk	0.225 0.1 0.25 0.15 0.01
Japan	Other terrestrial mammals, muscle Other terrestrial mammals, fat Other terrestrial mammals, liver Other terrestrial mammals, kidney Other terrestrial mammals, edible offal	0.2 0.1 0.3 0.2 0.3

3.2 PROPOSAL TO DELETE THE NOTICE ENTRY FOR PIRLIMYCIN

It is proposed that the following entry is deleted from Schedule 1 of the Notice:

Compound Common Name	CAS#	Residue to which the maximum residue level applies	Food	Maximum Residue Level (mg/kg)
~~Pirlimycin~~	~~78822-40-9~~	~~Sum of: Pirlimycin, pirlimycin sulphoxide, and pirlimycin sulphone~~	~~Cattle fat~~ ~~Cattle kidney~~ ~~Cattle liver~~ ~~Cattle meat~~ ~~Cattle milk~~	~~0.05~~ ~~0.1~~ ~~0.5~~ ~~0.05~~ ~~0.1~~

3.2.1 Amendment Rationale

The deletion is being proposed because the compound is no longer used as an agricultural compound in New Zealand, with the last registered agricultural compound containing pirlimycin de-registered in 2015. Prior to this, pirlimycin was used as an antibiotic to treat mastitis in cattle. MRLs are therefore no longer required to manage the use of pirlimycin as an agricultural compound in New Zealand.

3.3 PROPOSAL TO SET AN ENTRY FOR S-ABSCISIC ACID IN SCHEDULE 2

It is proposed that S-abscisic acid is added to Schedule 2 of the Notice to identify it as an agricultural chemical to which no MRL applies. S-abscisic acid is a naturally occurring plant growth regulator and plays roles in stress resistance, fruit set, ripening and senescence. When used as an agricultural chemical to regulate plant growth, the additional amount present is negligible compared to naturally occurring amounts and unlikely to present an additional hazard for use in food, or if treated crops or orchards are used for animal feed. It is therefore considered that residues do not need to be managed through the application on an MRL when the compound is used as a plant growth regulator.

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

Substance	CAS#	Condition
S-Abscisic acid	**21293-29-8**	**When used as a plant growth regulator**

3.4 PROPOSAL TO SET AN ENTRY FOR ALFAFA EXTRACT IN SCHEDULE 3

It is proposed that alfalfa extract is added to Schedule 3 of the Notice to identify it as a veterinary medicine to which no MRL applies. The process by which the alfalfa extract is produced is similar to that used to produce silage feed. When the alfalfa extract is then fed to horses as either a supplemental feed or total ration, it can act as a veterinary medicine by aiding in the prevention and healing of gastric ulcers in affected animals.

The fermentation process used to produce the alfalfa extract, and the use of that extract as an agricultural compound, does not present a hazard with respect to its use in horses that would require management through the application of an MRL. As such, an MRL does not need to apply to its use in the prevention and treatment of gastric ulcers.

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

Substance	CAS#	Condition
Alfalfa extract	**84082-36-0**	**When used to aid in treatment or prevention of gastric ulceration in horses**