

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

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Contents

Page

1	Request for submissions	1
2	Introduction	2
2.1	Establishing Maximum Residue Levels	2
2.2	Summary of Proposed Amendments	5
3	PROPOSALS	7
3.1	Proposal to amend the MRLs for pydiflumetofen	7
3.2	Proposal to delete the Notice entry for warfarin	9
3.3	Proposal to set an entry for diatomaceous earth in Schedule 3	9
3.4	Proposal to set an entry for gonadorelin in Schedule 3	10
3.5	Proposal to set an entry for sepiolite in Schedule 3	10

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 are relevant.

Submissions close at 5pm on **13 February 2024**. 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 lowest amount of an agricultural compound is used to consistently achieve its intended purpose. This will 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 efficacy, crop safety, and animal health and safety 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 the 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 **pydiflumetofen**, to set MRLs at 0.2 mg/kg for barley grain, 0.01(*) mg/kg for eggs, 0.01(*) mg/kg for milk, 0.01(*) mg/kg for poultry fat, 0.01(*) mg/kg for poultry meat, and 0.01(*) mg/kg for poultry offal; and
- The removal of the Notice entry for **warfarin**.

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

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

MPI proposes to make the following changes to Schedule 3 of the Notice:

- The addition of a new entry for **diatomaceous earth**, when used as a veterinary medicine;
- The addition of a new entry for **gonadorelin**, when used to manage reproduction in ruminants; and
- The addition of a new entry for **sepiolite**, when used as a mycotoxin binder.

3 PROPOSALS

3.1 Proposal to amend the MRLs for pydiflumetofen

It is proposed that the MRLs for pydiflumetofen are amended to support the GAP use of the compound in barley.

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)
Pydiflumetofen	1228284-64-7	Pydiflumetofen	Barley grain	0.2
			Eggs	0.01(*)
			Grapes	0.2
			Mammalian fat	0.03
			Mammalian meat	0.01(*)
			Mammalian offal	0.03
			Milk	0.01(*)
			Potatoes	0.01(*)
			Poultry fat	0.01(*)
			Poultry meat	0.01(*)
			Poultry offal	0.01(*)

3.1.1 Amendment Rationale

The proposed MRLs are to support a new use to control *Ramularia* and scald in barley when used in accordance with the use pattern and withholding periods proposed as GAP in New Zealand. Pydiflumetofen is currently approved for use in New Zealand in grapes for powdery mildew and *Botrytis* control, with animal commodity MRLs set to manage the potential for residue transfer to animal commodities resulting from the practice of introducing sheep for leaf plucking and grazing in vineyards. With the introduction of use on a cereal crop that may be used as feed in food producing animals, new and revised animal commodity MRLs are also being proposed.

3.1.2 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 proposed new use pattern is up to two applications of 75 gai/ha in barley for the control of *Ramularia* and scald as preventative sprays when conditions favour disease. These applications must be made in mixture with another approved non-cross-resistant fungicide, with the first application typically at BBCH 31-32 and the second application between BBCH 39-45 (flag leaf) and BBCH 69 (end of flowering). This use will attract a pre-harvest interval of 42 days for barley grain, and an interval of 28 days between treatment and use of green feed or silage for animal consumption.

3.1.3 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 barley grain. The residue definition of 'pydiflumetofen' remains appropriate to manage both GAP compliance and dietary intake in plant commodities.

Animal metabolism and feeding study data characterising the residue transfer potential to animal commodities following exposure to pydiflumetofen were sufficient to inform a review of the animal commodity MRLs. Because treated barley and products from barley crops may be used as animal feed beyond the previously considered vineyard uses, poultry MRLs have been

proposed. In addition, the milk MRL has been revised to represent the expected feed burden for ruminant species when both barley and vineyard uses are considered. When pydiflumetofen is used according with New Zealand GAP and all pre-harvest and pre-grazing intervals are observed, residues in animal commodities can be expected to conform to the established and new animal commodity MRLs. Controls applied to the use of pydiflumetofen in vineyards with respect to grazing sheep remain appropriate to manage GAP compliance and residues for that use.

The existing residue definitions for animal commodities remain appropriate: 'pydiflumetofen' for GAP compliance, and the following for dietary intake estimation –

- *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.*

3.1.4 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 exposed to pydiflumetofen, the NEDI is estimated to total less than 1% 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.

3.1.5 Relevant International MRLs for Pydiflumetofen

Authority	Food	Maximum Residue Level (mg/kg)
Australia	Cereal grains [except Maize and Popcorn]	3
	Edible offal (mammalian)	0.02
	Eggs	0.01
	Meat (mammalian) [in the fat]	0.02
	Milks	0.01
	Poultry meat	0.01
	Poultry, edible offal of	0.01
Codex	Barley, similar grains, and pseudocereals with husks (subgroup)	3
	Edible offal (mammalian)	0.1
	Eggs	0.02
	Mammalian fats (except milk fats)	0.1
	Meat (from mammals other than marine mammals)	0.1
	Milks	0.01
	Poultry fats	0.01
	Poultry meat	0.01
Canada	Poultry, edible offal of	0.01
	Eggs	0.01
	Fat of cattle, goats, horses, and sheep	0.03
	Fat of hogs and poultry	0.01
	Meat byproducts of cattle, goats, horses, and sheep	0.03
	Meat byproducts of hogs and poultry	0.01
	Meat of cattle, goats, hogs, horses, poultry, and sheep	0.01
	Milk	0.03

Authority	Food	Maximum Residue Level (mg/kg)
Japan	Mammalian muscle	0.01
	Mammalian fat	0.03
	Mammalian liver	0.03
	Mammalian kidney	0.03
	Mammalian edible offal	0.03
	Milk	0.03
United States	Cattle, horse, and sheep by-products	0.03
	Cattle, horse, and sheep fat	0.03
	Cattle, horse, and sheep kidney	0.03
	Cattle, horse, and sheep liver	0.03
	Cattle, horse, and sheep meat	0.01
	Milk	0.03

3.2 Proposal to delete the Notice entry for warfarin

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)
Warfarin	81-81-2	Warfarin	Any food	0.001(*)

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

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 warfarin de-registered in 2005. Warfarin MRLs are therefore no longer required to manage the use of the compound in New Zealand.

3.3 Proposal to set an entry for diatomaceous earth in Schedule 3

It is proposed that diatomaceous earth is added to Schedule 3 of the Notice to identify it as a veterinary medicine to which no MRL applies when the compound is used as a veterinary medicine.

Diatomaceous earth is a naturally occurring soft, siliceous sedimentary rock composed of the fossilised remains of diatoms, a type of hard-shelled microalgae. Diatomaceous earth is not pharmacologically active, with its efficacy as an adsorbent and anti-parasitic arising from its porous physical form. It is not systemically absorbed and consequently residues are not expected to be present in animal commodities following its use as a veterinary medicine.

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

Substance	CAS#	Condition
Diatomaceous earth	n/a	When used as a veterinary medicine

3.4 Proposal to set an entry for gonadorelin in Schedule 3

It is proposed that gonadorelin is added to Schedule 3 of the Notice to identify it as a veterinary medicine to which no MRL applies. Gonadorelin is a synthetic agonist of gonadotropin-releasing hormone used in food-producing animals to manage fertility status. When administered to ruminants as a veterinary medicine, gonadorelin is rapidly absorbed, metabolised, and excreted, leaving no residues in animal commodities or at the injection site within 24 hours of treatment. As such, MRLs are not required to manage residues or food safety.

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

Substance	CAS#	Condition
Gonadorelin	33515-09-2	When used to manage reproduction

3.5 Proposal to set an entry for sepiolite in Schedule 3

It is proposed that sepiolite is added to Schedule 3 of the Notice to identify it as a veterinary medicine to which no MRL applies. Sepiolite is a naturally occurring fibrous phyllosilicate clay mineral of sedimentary origin composed of hydrated magnesium silicate. Sepiolite is not pharmacologically active, with its efficacy as a mycotoxin binder arising from its highly porous physical form. It is not systemically absorbed and consequently residues are not expected to be present in the produce of animals.

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

Substance	CAS#	Condition
Sepiolite	n/a	When used as an orally administered mycotoxin binder