New Zealand Food Safety
Haumaru Kai Aotearoa

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

New Zealand Food Safety Discussion Paper No: 2020/03

Prepared for public consultation
By New Zealand Food Safety

ISBN No: 978-1-99-001769-8 (online)
ISSN No: 2624-0157 (online)

April 2020

New Zealand Government

Ministry for Primary Industries
Manatū Ahu Matua

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1 Submissions

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

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

On balance, do you oppose any of the details of the exemption as proposed (substance or condition of exemption)?

Do you oppose an exemption being set <u>at all</u> for this compound for the commodity? If so, why do you oppose it?

Submissions close at 5pm on **16 June 2020**. Your comments should be sent to:

MRL Amendments
New Zealand Food Safety
Ministry for Primary Industries
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

Agricultural compounds are natural or synthetic substances used in the management of plants and animals, and include veterinary medicines, fertilisers, and pesticides (fungicides, herbicides and insecticides). Growers and farmers use agricultural compounds to manage disease in animals and crops, protect the food supply, and maximise the quantity and quality of the food they grow.

Use of these agricultural compounds can leave residues in the food from those crops and animals that must be managed. To ensure only the appropriate amount of agricultural compounds are used to achieve their intended purpose, a set of principles and methods known as good agricultural practice (GAP) are utilised. GAP covers the production of safe and good quality horticultural and animal products.

GAP is established for each agricultural compound by evaluating public health, crop safety, animal health and safety, and occupational and environmental safety considerations for the range of treatments and use patterns. This involves determining the administration and application rates and ranges necessary for an agricultural compound to achieve its intended effects, while leaving the smallest amount of residue practicable without compromising that efficacy.

Once the GAP has been established for a use for an agricultural compound, the residues resulting from its use up to the highest authorised dose or application rate is then used to establish maximum residue levels (MRLs) in food commodities from crops and animals associated with that use. The MRLs are then compared against the health based guidance value in an evaluation commonly referred to as the dietary exposure (or dietary risk) assessment. This is explained in more detail below.

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

To meet New Zealand's obligations under the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) the proposed 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.

2.1 BACKGROUND

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

New Zealand Food Safety administers the MRL Food Notice, with the final decision on any changes to the Notice resting with the Director-General of MPI. The Food Notice is issued under section 405 of the Food Act 2014. When setting or amending MRLs, the Director-General must take into account:

- the need to protect public health;
- the desirability of avoiding unnecessary restrictions on trade;

- the desirability of maintaining consistency between New Zealand's food standards and those standards that apply internationally;
- New Zealand's obligations under any relevant international treaty, agreement, convention, or protocol, and, in particular, under the Australia-New Zealand Joint Food Standards Agreement; and
- such other matters as appropriate.

The requirements for the content of the MRL Food Notice are set out in Part 6 of the Food Regulations 2015, allowing for the promulgation of MRLs for agricultural compounds as well as the promulgation of exemptions from compliance with MRLs. In addition to establishing the requirements on domestically produced foods, Part 6 of the Food Regulations also outlines the residue level compliance requirements for imported foods. Clause 144 states that food must contain residues of agricultural compounds:

- no greater than the MRLs specified for that food in a notice set under the Food Act 2014 (section (1)(a)); or
- the default MRL of 0.1 mg/kg (section (1)(c)); or
- for imported food, the current editions of either the Maximum Residue Limits (MRLs) and Extraneous Maximum Residue Limits (EMRLs) for Pesticides (Codex Pesticides Residues in Food Online Database), or the Maximum Residue Limits for Veterinary Drugs in Food (Codex Veterinary Drug Residue in Food Online Database) (section (1)(d)).

As imported food commodities can comply with either a Codex MRL or a MRL established in the MRL Food Notice, New Zealand's obligations under the SPS Agreement are met.

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

2.1.1 National Estimated Dietary Intake

The chronic dietary exposure to a substance is estimated by the NEDI calculation, encompassing all authorised uses of the agricultural compound, and using food consumption data based upon the 1997 National Nutritional Survey for adults and the 1995 National Nutrition Survey of Australia, for children. The NEDI calculation is made in accordance with Guidelines for predicting dietary intake of pesticide residues (revised) [World Health Organization, 1997]. The NEDI calculation provides an estimation of the potential chronic exposure to toxicologically relevant residues in all food derived from crops/livestock treated with the agricultural compound according to the authorised GAP use.

The possible implications for consumer health are considered during the toxicological and dietary risk assessments, by comparing the NEDI with a Health Based Guidance Value (HBGV). Provided the estimated dietary exposure of all toxicologically relevant residue components in all fresh and processed food is less than the HBGV, the use of an agricultural compound according to GAP is unlikely to pose a health risk to consumers.

2.1.2 Health Based Guidance Values

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

A $PDE_{(food)}$ is a value determined by a toxicological evaluation by the New Zealand Environmental Protection Authority (EPA) as part of its responsibility for managing public health under the Hazardous Substances and New Organisms Act 1996 (the HSNO Act). A

$PDE_{(food)}$ gives the potential daily exposure a person may be subject to from a substance, via food.

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

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

2.1.3 International MRLs and Trade

Where MRLs are being set, the “Relevant International MRLs” table listed in each entry is a summary of the MRLs set by Codex and a selection of other international regulatory bodies reviewed to evaluate trade risk. For animal commodities, the MRLs set by Australia, Canada, China, Codex, the European Union, Japan, and the USA are reviewed and compared; for horticultural commodities, MRLs set by Codex and Australia are reviewed and compared. Other international MRLs are reviewed and reported in the table if there is a particular trade risk to be considered for those regions. If a particular international body or regulator does not have MRLs set for the species or crop for which a New Zealand MRL is being proposed, that international body or regulator is omitted from the “other international MRLs” section of the proposal entry.

Where MRL exemptions are proposed, the proposed exemptions from compliance with a MRL have been thoroughly assessed in accordance with international methodologies published by the Organisation for Economic Cooperation and Development (OECD), International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH), or FAO. Each proposal includes a discussion of the rationale behind the considerations for exemption, and a discussion of the assessed risks. New Zealand Food Safety has evaluated the potential food safety and dietary intake risks associated with promulgating an exemption, and determined that MRLs are not required to manage compliance to GAP or food safety risk.

2.2 SUMMARY OF PROPOSED AMENDMENTS

2.2.1 Amendment to Schedule 2: Amendment of an Exemption from Maximum Residue Levels for Agricultural Chemicals

New Zealand Food Safety proposes to amend the existing exemption Plant Extracts (unrefined) in Schedule 2 of the Food Notice, for which compliance with a maximum residue level is not required for agricultural chemical compounds. This amendment will add an additional plant species, *Clitorea ternatea* (Butterfly Pea), to allow extracts from this plant to be used as an agricultural compound as an insecticide in fruit and vegetable crops without the need for compliance with a MRL.

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

New Zealand Food Safety also proposes to add a new exemption for medium chain fatty acids and their mono-, di-, and triglycerides in Schedule 3 of the Food Notice, for which compliance with a maximum residue level is not required for veterinary medicine compounds. These fatty acids are used as antimicrobials in teat sanitisers for the prevention of mastitis in dairy animals.

3 Proposals

3.1 PROPOSAL TO AMEND THE EXEMPTION FOR PLANT EXTRACTS (UNREFINED) FROM COMPLIANCE WITH A MRL

It is proposed that the current list of plant species in the Plant Extracts (unrefined) exemption is amended to include extracts derived from *Clitorea ternatea* (Butterfly pea). The *Clitorea ternatea* extract will be used as an insecticide for whitefly, thrips, aphids, scale and other sucking insects in a range of food and non-food producing crops. The main extract components, flavonoids and cyclotides, are the same or closely similar to those commonly found in food.

When used according to GAP, residues from the *Clitoria ternatea* extract will not occur in foods and animal feeds above background levels of these or similar compounds. The compounds in the extract are therefore not expected to produce any toxic effects from dietary exposure.

The entry in Schedule 2 is proposed to be amended as follows:

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

3.2 PROPOSAL TO EXEMPT MEDIUM CHAIN FATTY ACIDS AND THEIR MONO-, DI-, AND TRIGLYCERIDES FROM COMPLIANCE WITH A MRL

Medium chain fatty acids and their mono-, di-, and triglycerides, such as lactic, capric, caprylic, lauric, and myristic acids, are used as antimicrobial active ingredients in some teat sanitisers. These compounds are generally recognised as safe (GRAS) for human consumption when used as food additives; when used according to GAP, the residues resulting from their use as teat sanitisers can be expected to be low in milk and dairy products and comparable to GRAS food additive levels.

The promulgation of an exemption for these medium chain fatty acids will allow for assurance of their good agricultural practice use in teat sanitisers without the need to establish maximum residue levels.

The proposed entry in Schedule 3 will read as follows:

Substance	CAS#	Condition
Medium chain fatty acids (C6-C12) and their mono-, di-, and triglycerides	n/a	When used as a teat sanitiser