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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By New Zealand Food Safety

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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 **3 April 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

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.

2.2 SUMMARY OF PROPOSED AMENDMENTS

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.

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

New Zealand Food Safety proposes to add a new exemption for glycerol in Schedule 3 of the Food Notice, for which compliance with a maximum residue level is not required. This compound is commonly used on udders of dairy animals as an emollient and skin conditioner in teat sanitisers.

New Zealand Food Safety also proposes to add a new exemption for sorbitol in Schedule 3 of the Food Notice, for which compliance with a maximum residue level is not required. Like glycerine this compound is commonly used as an emollient and skin conditioner on dairy animals, and can be used with glycerine in a single teat sanitiser compound.

3 Proposals

3.1 PROPOSAL TO EXEMPT GLYCEROL FROM COMPLIANCE WITH A MRL

It is proposed that glycerine, when used as an emollient and skin conditioner in teat sanitisers applied to lactating dairy animals, be exempt from compliance with an MRL by addition to Schedule 3 of the Notice. Glycerol, also called glycerine or glycerin, is a polyol compound used as a food additive and in pharmaceutical preparations. In veterinary medicines, glycerol is used as a solvent and stabiliser excipient in liquid formulations, and as an emollient and skin conditioner in teat sanitisers. Glycerol is generally recognised as safe as a food additive and humectant when used in accordance with good manufacturing practice in food manufacture and with good agricultural practice for veterinary use.

The quantity of glycerol in milk would be limited given that teat sanitisers are diluted prior to use and are generally administered to dairy animals as a topical post-milking treatment in New Zealand. Due to this, and the recognition that the compound is internationally considered safe for other food-related uses, an exemption with conditions is being proposed to ensure good agricultural practice without the need to apply residue limits.

The proposed entry in Schedule 3 will read as follows:

Substance	CAS#	Condition
Glycerol (glycerine)	56-81-5	When used topically as a skin conditioner or as an active ingredient in a teat sanitiser

3.2 PROPOSAL TO EXEMPT SORBITOL FROM COMPLIANCE WITH A MRL

Sorbitol is also a polyol compound used in a similar manner to glycerol in veterinary medicines, particularly its use in dairy teat sanitisers as a skin conditioner. Sorbitol is also generally recognised as safe, though it is known to have gastrointestinal effects at high doses. Its presence in milk through the application of teat sanitisers would be limited due to the way sanitisers are used in New Zealand. As per glycerol, an exemption for sorbitol allows for assurance of the good agricultural practice of its use in teat sanitisers without the need for residue limits.

The proposed entry in Schedule 3 will read as follows:

Substance	CAS#	Condition
Sorbitol	50-70-4	When used topically as a skin conditioner or as an active ingredient in a teat sanitiser