25 May 2015
[09–15]

Call for submissions – Proposal M1012

Amendments to Standard 1.4.2

FSANZ has assessed a proposal prepared to consider including maximum residue limits (MRLs) for coumatetralyl and warfarin in the *Australia New Zealand Food Standards Code* (the Code) and has prepared a draft food regulatory measure. Pursuant to section 61 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at information for submitters.

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at information for submitters.

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on documents for public comment. You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 22 June 2015

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
CANBERRA BC ACT 2610
AUSTRALIA
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Supporting document

The following document which informed the assessment of this Proposal is available on the FSANZ website at http://www.foodstandards.gov.au/code/proposals/Pages/M1012-MRLs.aspx

SD1 MRLs proposed for coumatetralyl and warfarin and dietary exposure estimates for the Australian population

Executive summary

The purpose of this Proposal is to consider incorporating temporary maximum residue limits (MRLs) for the agricultural and veterinary (agvet) chemicals coumatetralyl and warfarin. The changes would align with the temporary MRLs that have been set by the APVMA. Low levels of these agvet chemicals, which are rodenticides, may inadvertently occur in pork commodities. MRLs will be listed in Standard 1.4.2 in the *Australia New Zealand Food Standards Code* (the Code).

Standard 1.4.2 lists the MRLs for agvet chemical residues. Maximum limits prescribed in the Code are a mandatory requirement applying to all food products of a particular class whether produced domestically or imported.

The Proposal includes consideration of MRLs gazetted by the Australian Pesticides and Veterinary Medicines Authority (APVMA) and aligns Standard 1.4.2 with the APVMA's Agricultural and Veterinary Chemicals Code Instrument No.4 (MRL Standard). The MRLs considered in this Proposal are for the agvet chemicals coumatetralyl and warfarin in pork commodities.

Dietary exposure assessments (DEAs) indicate that the proposed limits for the agvet chemical residues of interest do not present any public health and safety concerns in relation to relevant health-based guidance values (HBGVs).

Including the MRLs in the Code as proposed will permit the sale of foods containing legitimate residues, protect public health and safety and minimise residues in foods consistent with the effective control of pests and diseases.

The *Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System* (the Treaty) excludes MRLs for agvet chemicals in food from the system setting joint food standards.

FSANZ has made a sanitary and phytosanitary notification to the World Trade Organization (WTO).

1 Introduction

1.1 The Proposal

The Proposal was prepared to consider introducing certain temporary MRLs for residues of agvet chemicals that may occur in food, in order to align standards with the APVMA temporary MRLs for coumatetralyl and warfarin in pork commodities.

1.2 The current Standard

Standard 1.4.2 lists the limits for agvet chemical residues which may occur in foods. These limits are mandatory and apply to all food products of a particular class whether produced domestically or imported. Food products with residues exceeding the relevant limit listed in the Code cannot legally be supplied in Australia. This ensures that residues of agvet chemicals are kept as low as possible and are consistent with the approved use of chemical products to control pests and diseases of plants and animals.

1.2.1 Codex Alimentarius Commission Standards

Codex standards are used as the relevant international standard to determine whether a new or changed standard requires a WTO notification. Codex has not established MRLs for coumatetralyl or warfarin. MRLs for coumatetralyl and warfarin are not specifically established by other regulatory authorities, however some international pesticide databases list default MRLs that apply to any chemical/food combination, including coumatetralyl and warfarin. Examples include: *0.01[1] mg/kg by the European Union, 0.001 mg/kg in Japan and 0.1 mg/kg in New Zealand.

FSANZ may consider varying limits for residues of agricultural or veterinary chemicals in food in a proposal when there are differences between the Code and international standards that may negatively impact on trade. In some cases, the Australian MRL may exceed a Codex MRL due to different use patterns from those considered at the time the Codex MRL was set. In these cases, as for the consideration for any MRL, the assessment process ensures that the levels of residues in food are safe for the Australian population.

The proposed variations to the Code would permit the sale in Australia of relevant foods containing legitimate residues of coumatetralyl or warfarin that do not present health or safety concerns.

1.3 Reasons for preparing the Proposal

The Proposal was prepared to consider adding MRLs in pork commodities into Standard 1.4.2 for the rodenticides coumatetralyl and warfarin. Currently, if there is no MRL in the Code for a given chemical/commodity combination, there is a zero tolerance approach to enforcement by the jurisdictions. This means that foods with low level residues of agvet chemicals that do not have MRLs listed in Standard 1.4.2 are in technical violation of the Code and are illegal for sale. Introducing MRLs for coumatetralyl and warfarin will allow certain pork commodities that inadvertently contain residues at low levels to be legally sold in Australia.

[1] An asterisk indicates that the limit is at or about the limit of analytical quantification.

These amendments will align Standard 1.4.2 with recent temporary MRL amendments gazetted by the APVMA. These MRLs were inserted into the Agricultural and Veterinary Chemicals Code Instrument No.4 (MRL Standard[2]) in mid-April 2015.

MRLs are usually established according to principles of good agricultural practice (GAP) or good veterinary practice (GVP). The proposed MRLs will permit the sale of foods containing legitimate residues, protect health and safety and minimise residues in foods consistent with the effective control of pests and diseases.

The limits may minimise potential trade disruption and extend consumer choice.

1.4 Procedure for assessment

The Proposal is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Risk assessment

To assess the public health and safety implications of chemical residues in food, FSANZ estimates the dietary exposure to chemical residues from potentially treated foods and compares the dietary exposure with the relevant HBGV. Commonly used HBGVs are the acceptable daily intake (ADI), the acute reference dose (ARfD) or the tolerable daily intake (TDI). An ADI is usually only established for pesticides which are intentionally used in food producing crops, animals or crops used for stock feed. Chemicals which are not used in this way but for which there may be the potential for substantial human exposure are assigned a TDI or Tolerable Weekly Intake. Both ADIs and TDIs are calculated in a similar way.

FSANZ conducts and reviews DEAs for MRLs using the best available scientific data and internationally recognised risk assessment methodology. Variations to MRLs in the Code will not be supported where estimated dietary exposures to the residues of a chemical indicate a potential public health and safety risk for the population or a population sub group.

The steps undertaken in conducting a DEA are:

- determining the residues of a chemical in a treated food
- calculating dietary exposure to a chemical from relevant foods, using residue data and food consumption data from Australian national nutrition surveys
- completing a risk characterisation where estimated dietary exposures are compared to the relevant HBGV.

FSANZ has used a standard chronic DEA methodology to assess the safety of residues of the two chemicals in food. The DEA used the MRLs gazetted by the APVMA in their MRL Standard and consumption data for the Australian population derived from the 1995 National Nutrition Survey (NNS). The 1995 NNS data were compared with the most recent 2011–12 National Nutrition and Physical Activity Survey, which indicated the proportion of the population consuming bacon and ham has decreased slightly, while the proportion of consumers of pork and liver (all types) is similar to the proportions consuming these foods in 1995.

[2] The Agricultural and Veterinary Chemicals Code Instrument 4 (MRL Standard) sets MRLs for agvet chemicals in agricultural produce particularly produce entering the food chain. This can be accessed via the APVMA website at http://apvma.gov.au/node/10806.

Estimates of exposure were compared to the relevant HBGVs for coumatetralyl[3] and warfarin[4].

The DEA indicates that estimated dietary exposures to coumatetralyl and warfarin at the proposed MRLs are well below their respective HBGVs. The proposed temporary MRLs for inclusion in Standard 1.4.2 are protective of public health and safety.

A summary of the dietary exposure estimates for coumatetralyl and warfarin is provided in **SD1**.

2.2 Risk management

FSANZ is committed to maintaining MRLs in the Code that reflect GAP and that may safely occur in food; this ensures that such food may be sold. The safety of the residues in the context of the Australian diet is a key consideration. FSANZ will only approve variations to MRLs in the Code where the risk assessment concludes that estimated dietary exposure is within HBGVs.

Currently there are no MRLs established for rodenticides in the Code. As there are no MRLs for coumatetralyl or warfarin in the Code, the proposed temporary risk management measures will facilitate trade in certain pork commodities that inadvertently contain residues at low levels.

2.3 Risk communication

FSANZ has adopted a basic communication strategy for this Proposal, with a focus on alerting the community that changes to the Code are being contemplated.

FSANZ is seeking public comment on the proposed changes to the Code outlined in this consultation document to help finalise the assessment. All comments are welcome. However, FSANZ is particularly interested in comments on any impacts (costs/benefits) of the proposed variations, in particular, likely impacts on importation of food if specific variations are advanced and any public health and safety considerations associated with the proposed changes.

FSANZ publishes details about proposed changes, submissions and subsequent reports on its website and issues a Notification Circular and media releases drawing attention to proposed Code amendments and calls for comment. Email alerts are sent to more than 5000 subscribers. Social media and FSANZ publications are also used to communicate calls for submissions.

Individuals and organisations making submissions on this Proposal will be notified at each stage of the assessment. If the FSANZ Board approves the draft variations to the Code, FSANZ will notify its decision to the Australia and New Zealand Ministerial Forum on Food Regulation. FSANZ will notify the gazetted changes to the Code in the national press and on the FSANZ website.

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ's consideration of M1012 will include one round of public consultation following an assessment and the preparation of a draft variation to Standard 1.4.2 and associated report.

[3] Coumatetralyl – TDI: 0.000003 mg/kg bw/day
[4] Warfarin – TDI: 0.0003 mg/kg bw/day

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Proposal. Every submission on a proposal will be considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

FSANZ considers that the proposed measure of amending MRLs in Standard 1.4.2 will not have a significant impact on trade. However, a notification to the WTO under Australia's obligations under the WTO Application of Sanitary and Phytosanitary Measures Agreement has been made to enable other WTO members to comment on the proposed amendments.

2.4 FSANZ Act assessment requirements

When assessing this Proposal and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 59 of the FSANZ Act:

2.4.1 Section 59

2.4.1.1 Cost benefit analysis

A Regulation Impact Statement is not required because the proposed variations to Standard 1.4.2 are minor and do not substantially alter existing arrangements. In 2010, the Office of Best Practice Regulation provided a standing exemption from the need to assess if a Regulation Impact Statement is required for applications relating to MRLs as they are machinery in nature and their use is voluntary.

A limited impact analysis on different stakeholders is provided below. This indicates that the direct and indirect benefits that would arise from the proposed MRL variations outweigh the costs to the community, government or industry that would arise from their development or making.

The proposed MRL variations benefit Australian Government, state and territory agencies, growers and producers, in that they serve to further harmonise agricultural and food standards. Achieving further consistency between agricultural and food legislation will minimise compliance costs to primary producers and assist in efficient enforcement of regulations.

Importers may benefit by the approval of the proposed draft variations. Additional or increased MRLs may benefit importers and consequently consumers in that this may extend the options to source safe foods.

2.4.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the Proposal.

2.4.1.3 Any relevant New Zealand standards

The *Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System* (the Treaty) excludes MRLs for agvet chemicals in food from the system setting joint food standards. Australia and New Zealand independently and separately develop MRLs for agvet chemicals in food.

All domestically produced food sold in New Zealand must comply with the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2012 and any amendments (the New Zealand MRL Standards). If food is imported into New Zealand, such food must comply either with the New Zealand MRL Standards or with Codex MRLs (except for food imported from Australia).

Under the New Zealand MRL Standards, agricultural chemical residues in food must comply with the specific MRLs listed in the Standards. The New Zealand MRL Standards also include a provision for residues of up to 0.1 mg/kg for agricultural chemical/commodity combinations not specifically listed.

Further information about the New Zealand MRL Standards is available on the New Zealand Ministry for Primary Industries website at http://www.foodsafety.govt.nz/industry/sectors/plant-products/pesticide-mrl/.

Limits in the Code and in the New Zealand MRL Standards may differ for a number of legitimate reasons including differing use patterns for chemical products as a result of varying pest and disease pressures and varying climatic conditions.

2.4.1.4 Any other relevant matters

There are no other relevant matters.

2.4.2 Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.4.2.1 Protection of public health and safety

FSANZ has undertaken a DEA based on the temporary MRLs recently gazetted by the APVMA. Using the best available scientific data and internationally recognised risk assessment methodology, FSANZ concluded that the proposed MRLs for coumatetralyl and warfarin do not present any public health and safety concerns.

2.4.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

This objective is not relevant to matters under consideration in the Proposal.

2.4.2.3 The prevention of misleading or deceptive conduct

This objective is not relevant to matters under consideration in the Proposal.

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ's primary role in developing food regulatory measures for residues of agvet chemicals in food is to ensure that estimated dietary exposures to potential residues are within HBGV's. As described in Section 2.4.2.1, FSANZ conducts and reviews DEA's using the best available scientific data and internationally recognised risk assessment methodology.

- **the promotion of consistency between domestic and international food standards**

The proposed changes will better align the Agricultural and Veterinary Chemicals Code Instrument No.4 (MRL Standard), which relates to foods that are produced domestically, and Standard 1.4.2 which applies to both foods that are produced domestically and foods that are imported into Australia.

- **the desirability of an efficient and internationally competitive food industry**

The proposed MRL variations ensure an open and transparent process has been followed in relation to the residues that could reasonably occur in food.

The changes will minimise potential costs to primary producers, rural and regional communities and importers in terms of permitting the sale of food containing legitimate residues.

- **the promotion of fair trading in food**

Section 2.4.1.1 lists a number of considerations that address fair trading with respect to variations to MRLs in this proposal.

- **any written policy guidelines formulated by the Ministerial Council**[5]

The proposal has regard to the Ministerial Council policy guideline on the regulation of residues of agvet chemicals in food, in particular the specific policy principles to: be consistent with the effective regulation of the registration, permission and use of agvet chemicals; promote a consistent approach to MRLs for both domestic and imported foods, where appropriate; and be consistent with Australia's obligations under the WTO Sanitary and Phytosanitary Agreement (SPS Agreement).

3 Draft variation

The draft variation to the Standard 1.4.2 of the current Code and related draft explanatory statement are at Attachment A. The variation is intended to take effect on gazettal.

An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislative Instruments (FRLI).

[5] Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

3.1 Transitional arrangements

3.1.1 Transitional arrangements for Code Revision

FSANZ has completed a review of the Code undertaken under Proposal P1025[6] in order to improve its clarity and legal efficacy. Following approval of the revision and Ministerial consideration, the new Code will commence on 1 March 2016 (following gazettal 10 April 2015 and registration on the Federal Register of Legislative Instruments). The current Code will also be repealed on this date. The approved variation at Attachment A will be included in a Code maintenance proposal on MRLs to be prepared and finalised before the end of 2015 to enable an updated Schedule 20 in the revised Code to take effect on 1 March 2016.

Attachment

A. Draft variation to the *Australia New Zealand Food Standards Code* and related Draft Explanatory Statement

[6] http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx

Attachment A – Draft variation to the *Australia New Zealand Food Standards Code*

Food Standards (Proposal M1012 – Amendments to Standard 1.4.2) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the Food Standards Australia New Zealand Act 1991. The Standard commences on the date specified in clause 3 of this variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Proposal M1012 – Amendments to Standard 1.4.2) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies a Standard in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

SCHEDULE

[1] **Standard 1.4.2** is varied by inserting in alphabetical order in Schedule 1

“

Coumatetralyl Coumatetralyl	
Pig, edible offal of [except liver]	T0.003
Pig fat	T*0.001
Pig liver	T0.004
Pig meat	T*0.001

”

“

Warfarin Warfarin	
Pig, edible offal [except liver]	T0.007
Pig fat	T0.007
Pig liver	T0.04
Pig meat	T0.007

”

Draft Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

FSANZ prepared Proposal M1012 to consider introducing certain temporary maximum residue limits (MRLs) for residues of agricultural and veterinary (agvet) chemicals that may occur in food, in order to align standards with the Australian Pesticides and Veterinary Medicines Authority (APVMA) temporary MRLs for coumatetralyl and warfarin in pork commodities. The Authority considered the Proposal in accordance with Division 2 of Part 3 and has approved a draft Standard.

2. Purpose

The purpose of the proposed variation to Standard 1.4.2 is to include temporary MRLs for residues of the agvet chemicals coumatetralyl and warfarin in pork commodities.

Standard 1.4.2 lists the limits for agvet chemical residues which may occur in foods. If a limit is not listed for a particular agricultural or veterinary chemical/food combination, there must be no detectable residues of that chemical in that food. This general prohibition means that, in the absence of the relevant limit in the Code, food may not be sold where there are detectable residues.

MRL variations may be required to permit the sale of foods containing legitimate residues. These are technical amendments that align Standard 1.4.2 with the APVMA's Agricultural and Veterinary Chemicals Code Instrument No.4 (MRL Standard).

A dietary exposure assessment is conducted before MRLs are varied to ensure that proposed limits do not present any public health or safety concerns.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal M1012 will include one round of public consultation following an assessment and the preparation of a draft Standard and associated report. Submissions were called for on 25 May 2015 for a four-week consultation period.

A Regulation Impact Statement was not required because the proposed variations to Standard 1.4.2 are minor and do not substantially alter existing arrangements.

Business compliance costs and other impacts on business, individuals, regulatory agencies and the economy are low or nil. The regulatory proposal does not impose impacts on business, individuals, regulatory agencies or the economy that warrant further analysis. The changes to regulation are machinery in nature involving technical variations to the Standard, which will not have appreciable impacts and are consistent with existing policy.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

Item 1 inserts new entries for the chemicals listed. The entries include the chemical name, residue definition, foods and associated MRLs. This item incorporates the new entries in alphabetical order among the chemicals listed in the Schedule.