

20 August 2015
[19–15]

Approval Report – Proposal M1012

Amendments to Standard 1.4.2

Food Standards Australia New Zealand (FSANZ) has assessed a proposal prepared by FSANZ to consider introducing certain temporary maximum residue limits (MRLs) for residues of agricultural and veterinary 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.

On 25 May 2015, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received three submissions.

FSANZ approved the draft variation on 12 August 2015. The Australia and New Zealand Ministerial Forum on Food Regulation¹ (Forum) was notified of FSANZ's decision on 19 August 2015.

This Report is provided pursuant to paragraph 63(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

¹ convening as the Australia and New Zealand Food Regulation Ministerial Council

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Supporting documents

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

SD1 MRLs for coumatetralyl and warfarin and dietary exposure estimates for the Australian population (at Approval).

Executive summary

FSANZ has approved a draft variation to Standard 1.4.2 to set temporary maximum residue limits (MRLs) in food for two agricultural and veterinary (agvet) chemicals - coumatetralyl and warfarin in pork commodities.

The approved draft variation aligns Standard 1.4.2 with the temporary MRLs set for these chemicals by the Australian Pesticides and Veterinary Medicines Authority (APVMA) in the APVMA's Agricultural and Veterinary Chemicals Code Instrument No.4 (MRL Standard).

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.

Dietary exposure assessments (DEAs) confirmed that the limits set by the approved draft variation to Standard 1.4.2 for coumatetralyl and warfarin do not present any public health and safety concerns in relation to relevant health-based guidance values (HBGVs).

Including the MRLs in the Code 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 made a notification under the World Trade Organization (WTO) Sanitary and Phytosanitary Agreement.

A revision of the Code via Proposal P1025 – Code Revision, will replace the existing Code on 1 March 2016. Proposal M1013 will amend the revised Code to ensure it contains the same MRLs that the approved draft variation inserts into the existing Code.

1 Introduction

1.1 The Proposal

The Proposal was prepared to consider introducing temporary MRLs in Standard 1.4.2 for residues of coumatetralyl and warfarin that may occur in certain pork commodities in order to align with the APVMA temporary MRLs for coumatetralyl and warfarin in pork commodities in the Agricultural and Veterinary Chemicals Code Instrument No.4 (MRL Standard²).

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

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 International Standards and 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: *0.01³ 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 agvet 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.

1.3 Reasons for preparing Proposal

The Proposal was prepared to consider adding temporary 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.

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>.

³ An asterisk indicates that the limit is at or about the limit of analytical quantification.

These amendments align Standard 1.4.2 with recent temporary MRL amendments gazetted by the APVMA. These MRLs were inserted into the APVMA MRL Standard in mid-April 2015. The APVMA will review these temporary MRLs in 2016.

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 was assessed under the General Procedure.

1.5 Decision

The draft variation as proposed following assessment was approved without change. The variation takes effect on gazettal.

The approved draft variation and the related explanatory statement is at Attachment A.

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

A revision of the Code via Proposal P1025 – Code Revision, will replace the existing Code on 1 March 2016. Proposal M1013 is being progressed by FSANZ to amend the revised Code to ensure it contains the same MRLs that the approved draft variation at Attachment A inserts into the existing Code.

2 Summary of the findings

2.1 Summary of issues raised in submissions

Table 1: Summary of issues

Issue	Raised by	FSANZ response
<p>Support progression of the Proposal</p> <p>Specific issues raised:</p> <p>FSANZ should seek guidance from the Therapeutic Goods Administration on pharmacological risks of the proposed MRLs</p>	<p>NSW Food Authority (and the NSW Department of Primary Industries)</p> <p>Victorian Depts of Health and Human Services, Economic Development, Jobs, Transport and Resources and PrimeSafe (the Departments)</p>	<p>FSANZ notes the variation is supported.</p> <p>Coumatetralyl and warfarin have a common mode of pharmacological action. The levels of residues on food are so low that there will be no impact on the therapeutic dose for people taking warfarin medication. It is also noted that the respective DEAs based on consumption of pork do not exceed the relevant tolerable daily intake (TDI).</p>
<p>Support proposed inclusion on basis that more information is provided about the risk assessment to address concerns about public health; and that the MRLs are temporary in nature.</p>	<p>Queensland Department of Agriculture and Fisheries (DAF), Safe Food Production Queensland (SFPQ) and Queensland Department of Health⁵.</p>	<p>FSANZ determined that there are no public health and safety issues associated with inclusion of the proposed temporary MRLs.</p>

⁵ This submission does not represent a whole of Queensland Government position.

Issue	Raised by	FSANZ response
<p>Specific issues raised:</p> <p>Inconsistent approach regarding inclusion of rodenticide residues in food and with proposed criteria for low level MRLs in P1027⁴</p> <p>Residues may occur through normal lawful use of rodenticides, proposed MRLs provide <i>de facto</i> permission for the misapplication of rodenticides, and current labelling directions are adequate</p> <p>Dietary risk assessment conforms to accepted international methodology</p> <p>Sub-populations are considered, and acute dietary risk is addressed</p> <p>Dietary risk assessment is transparent</p> <p>Temporary MRLs are not longer than 12 months</p>		<p>These are the only cases of inadvertent residues arising from the use of rodenticides of which FSANZ is aware. FSANZ is considering management of low level MRLs only for chemicals that are currently listed in Standard 1.4.2 though P1027. Rodenticides are not within the scope of P1027 as they are not currently listed in Standard 1.4.2.</p> <p>Standard 1.4.2 is not a control-of-use standard. Control of use is managed through the APVMA MRL Standard. This proposal is intended to align residues with the APVMA temporary provisions for relevant foods inadvertently containing legitimate residues of coumatetralyl and warfarin that do not present any health and safety concerns. It is understood that the chemical products containing coumatetralyl and warfarin have been used according to label directions.</p> <p>FSANZ conducts and reviews DEAs for MRLs using the best available scientific data and internationally recognised risk assessment methodologies⁶. These are set out in detail in Section 5.4 of the FSANZ document <i>Principles and Practice of Dietary Exposure Assessment for Food Regulatory Purposes</i>⁷.</p> <p>The HBGVs take into consideration all sub-populations that may be adversely affected. An acute DEA using an acute reference dose (ARfD) is not considered necessary to assess coumatetralyl or warfarin as no acute hazard has been identified for either rodenticide.</p> <p>The mean and 90th percentile estimated dietary exposures to coumatetralyl and warfarin for general population are provided in Table 2.</p> <p>The MRLs for coumatetralyl and warfarin in pork commodities in the APVMA MRL Standard are temporary and will be reviewed by the APVMA in 2016. FSANZ will amend the MRLs in Standard 1.4.2 in light of the APVMA's review.</p>

⁴ Details on this proposal are on the FSANZ website here:

<http://www.foodstandards.gov.au/code/proposals/Pages/P1027.aspx>

⁶ FAO/WHO (2009) *Environmental Health Criteria 240: Principles and Methods for the Risk Assessment of Chemicals in Food*. World Health Organization.

⁷ FSANZ (2009) *Principles and Practice of Dietary Exposure Assessment for Food Regulatory Purposes*, http://www.foodstandards.gov.au/science/exposure/Documents/Principles%20_%20practices%20exposure%20assessment%202009.pdf

Issue	Raised by	FSANZ response
Involvement of the Meat Implementation Working Group (MIWG)		State and federal government agencies are currently working with industry to minimise any residues of coumatetralyl and warfarin in food and to ensure that the use of rodenticides in and around piggeries remains appropriate. The MIWG has introduced guidance including a clearance protocol for piggeries affected by rodenticides. This guidance will assist managing the release for sale of any pork commodities containing trace amounts of coumatetralyl or warfarin.

2.2 Risk assessment

To assess the public health and safety implications of agvet chemical residues in food, FSANZ estimates the dietary exposure and compares it against the relevant HBGV. The HBGVs reflect the level of an agvet chemical that can be ingested over a defined time period without appreciable health risk. Commonly used HBGVs are the acceptable daily intake (ADI), ARfD and the TDI.

An ADI is usually only established for agvet chemicals which are intentionally used in food producing crops, animals or crops used for stock feed. As rodenticides are not intentionally administered to food producing animals, a TDI is considered to be the appropriate HBGV for the DEA for both coumatetralyl and warfarin.

FSANZ conducts and reviews DEAs for MRLs using the best available scientific data and internationally recognised risk assessment methodologies⁶. 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 for a chemical that is not intentionally used are:

- determining the residues of a chemical in foods of interest
- 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 these residues in food. The DEA used the temporary MRLs gazetted by the APVMA in their MRL Standard as the concentration level and consumption data for the Australian population aged 2 years and above, 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 consuming pork and liver (all types) was similar to the proportion consuming these foods in 1995.

Estimates of exposure were compared to the relevant HBGVs for coumatetralyl⁸ and warfarin⁹.

⁸ Coumatetralyl – TDI: 0.000003 mg/kg bw/day

⁹ Warfarin – TDI: 0.0003 mg/kg bw/day

The DEA indicates that for estimated mean and high (90th percentile) all respondent dietary exposures to coumatetralyl and warfarin for the Australian population aged 2 years and above, at the proposed MRLs, are well below their respective HBGVs (refer to **Table 2**). The proposed temporary MRLs for inclusion in Standard 1.4.2 are protective of public health and safety.

Table 2: Mean and 90th percentile estimated dietary exposure to warfarin and coumatetralyl in pig products (meat, fat, offal) for all respondents aged 2 years and above, based on 1995 National Nutrition Survey raw commodity consumption data⁺

<i>Estimated respondent dietary exposure</i>		<i>Warfarin</i>	<i>Coumatetralyl</i>
Mean	No. consumers*	8,857	8,857
	mg/day	0.00036	0.00005
	% TDI	2 [^]	28 [~]
P90	mg/day	0.001	0.00014
	% TDI	5 [^]	78 [~]

⁺ derived using FSANZ's custom build dietary exposure assessment program, Harvest, using total pig product consumption from all sources (i.e. reported as consumed (e.g. pork chop, fried liver) and where present in recipes (e.g. pork stir fry, liver pate)) and proposed M1012 MRL chemical concentrations. Modelling assumes that the chemical is present in all specified foods at the proposed concentrations, representing a conservative, worst case scenario.

* Number of respondents for the 1995 NNS = 13,858

[^] Warfarin – TDI: 0.0003 mg/kg bw/day

[~] Coumatetralyl – TDI: 0.000003 mg/kg bw/day

A summary of the mean dietary exposure estimates for coumatetralyl and warfarin is provided in **SD1**¹⁰.

2.3 Risk management

FSANZ is committed to maintaining MRLs in the Code that reflect good agricultural practice 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 to the agvet chemical 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 safe levels.

2.4 Risk communication

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

¹⁰ SD1 has been slightly amended since the Call for Submission report, to provide further detail regarding the acronyms (NEDI and NESTI). Also the dietary exposure estimate differs slightly from the estimate provided in the M1012 Call for Submissions SD1. The previous estimate was derived using FSANZ's standard deterministic MRL methodology based on summary 1995 NNS raw commodity consumption data. The updated estimate was derived from Harvest, which is based on individual dietary records.

FSANZ called for public comment on the proposed changes to the Code outlined in this consultation document to help finalise the assessment. Comments received are summarised in section 2.1 above.

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 are notified at each stage of the assessment.

2.4.1 Consultation

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

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

2.4.2 World Trade Organization (WTO)

As members of the WTO, Australia is obligated to notify WTO member nations 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 made a notification to the WTO for this Proposal in accordance with the WTO Agreement on the Application of Sanitary and Phytosanitary Measures. No member nation provided comment on this Proposal.

2.5 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:

2.5.1 Section 59

2.5.1.1 Cost benefit analysis

FSANZ is required to have regard to whether the direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the proposal will outweigh the costs to the community, Government or industry that would arise from the development or variation of the food regulatory measure.

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. Consumer safety is also preserved.

2.5.1.2 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.

2.5.1.3 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.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2 Subsection 18(1)

FSANZ had regard to the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.5.2.1 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.

2.5.2.2 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.

2.5.2.3 The prevention of misleading or deceptive conduct

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

2.5.3 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 HBGVs. 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 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**

Not applicable.

- **any written policy guidelines formulated by the Ministerial Council**¹¹

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).

Attachments

- A. Approved draft variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement

¹¹ Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

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



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

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

”

Attachment B – 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.

The Authority 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 variation.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation¹², section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislative Instruments Act 2003*.

2. Purpose

The approved draft variation to Standard 1.4.2 includes temporary MRLs for residues in pork commodities of the agvet chemicals coumatetralyl and warfarin.

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.

¹² convening as the Australia and New Zealand Food Regulation Ministerial Council

4. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal M1012 included 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 public 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.