

20 November 2009

[19-09]

PROPOSAL M1004

MAXIMUM RESIDUE LIMITS (September-December 2008, January-March 2009)

ASSESSMENT REPORT

Executive Summary

Purpose

The purpose of this Proposal is to consider incorporating limits for residues of agricultural and veterinary chemicals that may legitimately occur in food in the *Australia New Zealand Food Standards Code* (the Code). This includes maximum residue limits (MRLs) gazetted by the Australian Pesticides and Veterinary Medicines Authority (APVMA) from September 2008 to March 2009. This Proposal also includes consideration of limits requested by industry to further align the Code with international standards. This will permit the sale of foods containing legitimate residues and protect public health and safety by minimising residues in foods consistent with the effective control of pests and diseases.

This Proposal also includes consideration of some minor clarifications to Standard 1.4.2. The proposed edits are not intended to alter the intent or application of the Standard.

Food Standards Australia New Zealand's (FSANZ's) role in the regulation of agricultural and veterinary chemicals is to protect public health and safety by ensuring that any potential residues in food are within appropriate safety limits and to support industry and compliance agencies by maintaining limits in the Code that reflect legitimate residues in food.

Dietary exposure assessments indicate that in relation to current reference health standards, the proposed limits do not present any public health and safety concerns. This Proposal does not include consideration of any MRLs for antibiotic residues in food.

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

FSANZ will make a Sanitary and Phytosanitary notification to the World Trade Organization (WTO).

Submissions are now invited on this Report to assist FSANZ finalise the assessment.

This Proposal is being assessed under the General Procedure.

Assessing the Proposal

In assessing the Proposal and the subsequent development of food regulatory measures, FSANZ has had regard to its statutory objectives in section 18 and the following matters prescribed in section 59 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act):

- Whether costs that would arise from a food regulatory measure developed or varied as a result of the Proposal outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure
- There are no other measures that would be more cost-effective than a variation to Standard 1.4.2 that could achieve the same end
- Any relevant New Zealand standards
- Any other relevant matters

Preferred Approach

FSANZ recommends the proposed draft variations to Standard 1.4.2 – Maximum Residue Limits. The residues associated with the proposed variations do not present any public health and safety concerns and the proposed draft variations are necessary, cost-effective and will benefit consumers, Government and industry. The proposed draft variations will permit the sale of foods containing legitimate residues. The proposed minor amendments to the Standard will improve clarity and consistency of terminology.

Reasons for Preferred Approach

This Proposal has been assessed against the considerations provided for in section 59 of the FSANZ Act. FSANZ recommends the proposed draft variations to Standard 1.4.2 for the following reasons:

- MRLs serve to protect public health and safety by minimising residues in food consistent with the effective control of pests and diseases.
- Dietary exposure assessments indicate that the proposed variations do not present any public health and safety concerns.
- This approach ensures openness and transparency in relation to the residues that could reasonably occur in food.
- The proposed variations will benefit stakeholders by maintaining public health and safety while permitting the legal sale of food containing legitimate residues of agricultural and veterinary chemicals used to control pests and diseases and improve agricultural productivity.
- The APVMA has assessed appropriate residue, animal transfer, processing and metabolism studies, in accordance with *The Manual of Requirements and Guidelines – MORAG – for Agricultural and Veterinary Chemicals 1 July 2005* to support the use of chemicals on commodities as outlined in this Proposal.

- The Office of Chemical Safety (OCS) has undertaken a toxicological assessment of each chemical and has established an acceptable daily intake (ADI) and where appropriate an acute reference dose (ARfD).
- FSANZ has undertaken a preliminary regulation impact assessment and concluded that the proposed draft variations are necessary, cost-effective and beneficial.
- The proposed draft variations would remove inconsistencies between agricultural and food standards and provide certainty and consistency for producers, importers and Australian, State and Territory compliance agencies.
- The proposed changes are consistent with the FSANZ Act section 18 objectives.

Consultation

FSANZ is seeking public comment on this Assessment Report to assist in assessing the Proposal. Comments on, but not limited to, any impacts (costs/benefits) of the proposed variations, in particular the likely impacts on importation of food if the variations are advanced; any public health and safety considerations associated with the proposed limits; and any other affected parties would be welcome.

Invitation for Submissions

FSANZ invites public comment on this Report and the draft variations to the Code based on regulation impact principles for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in further considering this Proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed changes to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information, separate it from your submission and provide justification for treating it as confidential commercial material. Section 114 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked 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 using the Standards Development tab and then through Documents for Public Comment. Alternatively, you may email your submission directly to the Standards Management Officer at submissions@foodstandards.gov.au. There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 18 December 2009

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

Submissions received after this date will only be considered if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at standards.management@foodstandards.gov.au.

If you are unable to submit your submission electronically, 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
Tel (02) 6271 2222

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
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Introduction

Notifications were received from the Australian Pesticides and Veterinary Medicines Authority (APVMA) on 18 February, 8 April and 20 May 2009 seeking to vary the *Australia New Zealand Food Standards Code* (the Code). The proposed variations to the Code would align maximum residue limits (MRLs) in the Code for certain agricultural and veterinary chemicals with the APVMA MRLs listed in *The MRL Standard* and permit the sale of relevant foods legitimately treated during production.

This Proposal also includes consideration of varying MRLs for bifenthrin, boscalid, chlorpyrifos, cypermethrin, fenvalerate, flubendiamide, fludioxonil, lambda-cyhalothrin, myclobutanil, permethrin, pyraclostrobin, pyrimethanil and quinoxyfen for a range of foods in the Standard as a result of information provided by industry. Anomalies between the Code and international standards may have implications for trade in certain foods. The proposed variations to the Code would align limits in the Code with Codex and other standards internationally and permit the sale of relevant foods containing legitimate residues at levels that do not present health or safety concerns.

This Proposal also includes consideration of some minor clarifications to Standard 1.4.2. The proposed edits are not intended to alter the intent or application of the Standard.

In summary, this Proposal includes consideration of MRLs for abamectin, amitraz, bifenthrin, boscalid, bromoxynil, bupirimate, buprofezin, chlorantraniliprole (new chemical), chlorpyrifos, clothianidin, cypermethrin, cyprodinil, ethoxysulfuron, fenvalerate, flubendiamide, fludioxonil, imidacloprid, indoxacarb, iprodione, lambda-cyhalothrin (cyhalothrin), metalaxyl, methomyl, methoxyfenozide, metribuzin, myclobutanil, oxamyl, permethrin, phenmedipham, praziquantel, propiconazole, pymetrozine, pyraclostrobin, pyrimethanil, quinoxyfen, spinetoram (new chemical), spinosad, spirotetramat (new chemical), tebuconazole, thiacloprid and triadimenol; some clarifications to the Standard; and amendments to certain commodity names.

The draft variations to the Code are at **Attachment 1**. An explanatory statement of the proposed variations to the Standard and an outline of the recommended MRLs and dietary exposure assessments are at **Attachment 2**. The safety assessment methodology is outlined in **Attachment 3**; this includes an explanation of terminology.

FSANZ's role in the regulation of agricultural and veterinary chemicals is to protect public health and safety by ensuring that any potential residues in food are within appropriate safety limits and to support producers, importers and compliance agencies by maintaining limits in the Code that reflect legitimate residues in food.

In considering the issues associated with variations to limits in the Code for residues of agricultural and veterinary chemicals in food, it should be noted that the limit is the maximum level of a chemical that may be in a food, not the level that is usually present in a food. However, incorporating the limit into food legislation means that the residues of a chemical are minimised (i.e. must not exceed the MRL or other limit), irrespective of whether the dietary exposure assessment indicates that higher residues would not risk public health and safety.

Limits and variations to limits in the Code do not permit or prohibit the use of agricultural or veterinary chemicals. Other Australian Government, State and Territory legislation regulates use and control of agricultural and veterinary chemicals.

1. The Issue / Problem

Including limits for residues of agricultural and veterinary chemicals in foods in the Code has the effect of allowing the sale of food containing legitimate residues, where any residues do not exceed these limits. Variations in MRLs reflect the changing patterns of agricultural and veterinary chemicals available to chemical product users including food producers. These changes include both the development of new products and crop uses, and the withdrawal of older products following review. Where residues do not pose health or safety concerns, limits are also varied in line with international standards to reflect requirements for foods containing legitimate residues to be imported. Internationally, farmers face different pest and disease pressures and so agricultural and veterinary chemical use patterns may vary.

2. Current Standard

2.1 Background

Standard 1.4.2 lists the limits for agricultural and veterinary chemical residues which may occur in foods. If a limit is not listed for a particular agricultural or veterinary chemical/commodity 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.

Variations to the Code may be required to permit the sale of foods containing legitimate residues. A dietary exposure assessment is conducted before the Code is varied to ensure that proposed limits do not present any public health or safety concerns.

Further background information on MRLs, the regulatory framework for agricultural and veterinary chemicals and the FSANZ assessment process for incorporating limits, including MRLs for antibiotic substances, in the Code is provided at **Attachment 4**.

3. Objectives

In assessing this Proposal, FSANZ aims to ensure that approving the proposed draft variations does not present public health and safety concerns and that the sale of food containing legitimate residues is permitted.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are:

- the protection of public health and safety; and
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;

- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

For the reasons set out in this Report, the proposed draft variations to the Code are consistent with the FSANZ Act section 18 objectives.

4. Assessment Approach

FSANZ's primary role in developing food regulatory measures for agricultural and veterinary chemicals is to ensure that the potential residues in food are within reference health standards. FSANZ conducts and reviews dietary exposure assessments in accordance with internationally accepted practices and procedures.

In assessing the public health and safety implications of chemical residues, FSANZ considers the dietary exposure to chemical residues from potentially treated foods in the diet by comparing the dietary exposure with the relevant reference health standard. FSANZ will not approve variations to limits in the Code where dietary exposure to the residues of a chemical could risk public health and safety.

The steps undertaken in conducting a dietary exposure assessment are:

- determining the residues of a chemical in a treated food; and
- calculating the dietary exposure to a chemical from relevant foods, using food consumption data from national nutrition surveys and comparing this to the relevant reference health standard.

The estimated dietary exposure to a chemical is compared to the relevant reference health standard/s for that chemical in food (i.e. the acceptable daily intake (ADI) and/or the acute reference dose (ARfD)). FSANZ considers that dietary exposure to the residues of a chemical is acceptable where the best estimate of this exposure does not exceed the relevant standard/s.

The safety assessment methodology is further outlined in **Attachment 3**.

RISK ASSESSMENT

5. Risk Assessment Summary

FSANZ has reviewed the dietary exposure assessments submitted by the APVMA and conducted dietary exposure assessments to assess the limits requested by industry. Using the best available scientific data and internationally recognised risk assessment methodology, FSANZ concluded that in relation to current reference health standards, setting the limits as proposed does not present any public health and safety concerns.

The additional safety factors inherent in calculation of the ADI and ARfD mean that there is negligible risk to public health and safety when estimated exposures are below these reference health standards.

Risk Management

6. Options

After the submission period, the following options are available:

1. Option 1 – approve the draft variations
2. Option 2 – approve the draft variations subject to such amendments as FSANZ considers necessary
3. Option 3 – reject the draft variations

7. Impact Analysis

The impact analysis represents likely impacts based on available information. The impact analysis is designed to assist in the process of identifying affected parties and any alternative options consistent with the objective of the proposed changes. Information from public submissions is sought to further assess the proposed changes.

The draft variations may be amended and option 2 recommended for approval where the need is identified. For example, an MRL may be retained rather than reduced or deleted where the necessity for the MRL to allow for the importation and sale of safe food is identified through consultation. Further information to assist in identifying implications for imported foods is provided in section 9 of this Report and the requested variations are outlined in **Attachment 2**.

7.1 Affected Parties

The parties affected by proposed amendments include:

- consumers
- growers and producers
- importers of agricultural produce and food products
- the chemical industry
- Australian Government, State and Territory agencies involved in monitoring and regulating the use of agricultural and veterinary chemicals in food and the potential resulting residues

7.2 Benefit Cost Analysis

7.2.1 Option 1 – approve the draft variations

This option may contribute to community confidence that regulatory authorities are maintaining standards to minimise residues of agricultural and veterinary chemicals in the food supply. FSANZ does not consider there to be any dietary exposure implications associated with the proposed approval. The risk assessment has determined that there are no public health or safety concerns associated with the proposed variations. No additional costs to consumers have been identified.

Progressing this option benefits growers and producers as agricultural and food standards are further aligned. This means that foods produced in accordance with agricultural Standards and legislation may be sold under food legislation as MRL variations are incorporated in the Code. The proposed variations are unlikely to result in any costs for producers as changes in use patterns are made as required; current proper use results in compliance with the proposed variations already.

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. The proposed variations are unlikely to result in any costs for importers as no MRLs are being considered for reduction or deletion in this Proposal.

This option benefits Australian Government, State and Territory agencies in that it serves to further harmonise agricultural and food standards. This is of particular assistance to compliance agencies. Achieving further consistency between agricultural and food legislation would minimise compliance costs to primary producers and assist in efficient enforcement of regulations. This option is unlikely to result in discernable costs to Government agencies, although an awareness of changes in the standards for residues in food would be needed and there may be minimal impacts associated with slight changes to residue monitoring programs.

Interested parties are invited to comment on any impacts of the proposed variations during the public consultation period. This is to ensure that any adverse consequences of the proposed variations can be addressed. Imported foods and Codex MRLs are addressed in section 9 of this Report.

7.2.2 Option 2 –approve the draft variations subject to such amendments as FSANZ considers necessary

FSANZ will consider any comments received and may amend the draft variations following further assessment.

7.2.3 Option 3 – reject the draft variations

This option would allow inconsistencies between agricultural and food legislation to perpetuate as the Code would not reflect legitimate use of chemical products in Australia as determined by the APVMA. This may result in foods legitimately treated during production not being permitted for sale. Producers would incur significant costs. This may also create uncertainty, inefficiency and confusion in the enforcement of regulations. In addition, the anomalies between the Code and international standards identified by industry would perpetuate and may have implications for trade in certain foods. This would impact negatively on all affected parties and producers, industry and compliance agencies in particular.

Importers and consequently consumers may be disadvantaged where proposed additional or increased MRLs are not progressed as this may unnecessarily limit sources of certain foods.

7.2.4 Summary

FSANZ conducted a Best Practice Regulation Preliminary Assessment and concluded that 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.

FSANZ consulted with the Office of Best Practice Regulation (OBPR) on the need for the preparation of a regulation impact statement (RIS) under the Council of Australian Governments' requirements. The OBPR concluded that the proposed changes are minor and do not substantially alter existing arrangements. The OBPR advised that a RIS is therefore not required.

7.3 Comparison of Options

In assessing proposed variations to the Code, FSANZ considers the impact of various regulatory and non-regulatory options on all sectors of the community, including consumers, food industries and governments in Australia.

FSANZ recommends approving option 1 – approve the draft variations for the following reasons:

- There are no public health and safety concerns associated with the proposed variations.
- This approach ensures openness and transparency in relation to the residues that could reasonably occur in food.
- The changes would minimise potential costs to primary producers, rural and regional communities and importers in terms of permitting the sale of food containing legitimate residues.
- The changes would minimise residues in food consistent with the effective use of agricultural and veterinary chemicals to control pests and diseases.
- The changes would further align the Code with international standards.
- The changes would remove inconsistencies between agricultural and food standards and assist compliance agencies.

Option 2 may be recommended at the Approval stage subject to the need for any required amendments being identified through consultation and further assessment.

Option 3 is an undesirable option because potential substantial costs to primary producers may result. Additional costs may impact negatively on their viability and in turn the viability of the rural and regional communities that depend upon the sale of agricultural produce. This option may restrict the opportunity for importers to source safe produce or foods internationally and potentially impact consumers through higher food prices and limited choice. Also, consequent inconsistencies between agricultural and food legislation could have negative impacts on compliance costs for producers, perception problems in export markets and undermine the efficient enforcement of standards for chemical residues.

The benefits of progressing option 1 outweigh any associated costs.

Communication and Consultation Strategy

8. Communication

FSANZ consideration of amending limits in the Code for residues of agricultural or veterinary chemicals in food does not normally generate public interest.

FSANZ adopts a basic communication strategy, with a focus on alerting the community that a change to the Code is being contemplated.

FSANZ publishes the details of proposed changes and subsequent assessment reports on its website, notifies the community of the period of public consultation through newspaper advertisements, and issues media releases drawing attention to proposed Code amendments. Once the Code has been amended, FSANZ incorporates the changes in the website version of the Code and, through its email and telephone information service, responds to industry enquiries.

Should the media show an interest in any of the chemicals being assessed, FSANZ or the APVMA can provide background information as required.

9. Consultation

FSANZ is seeking public comment on the proposed changes to the Code outlined in this Report to assist in finalising the assessment. Comments on, but not limited to, any impacts (costs/benefits) of the proposed variations, in particular the likely impacts on importation of food if specific variations are advanced; any public health and safety considerations associated with the proposed changes; and any other affected parties would be useful.

9.1 World Trade Organization (WTO)

As a member of the World Trade Organization (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.

Limits prescribed in the Code constitute a mandatory requirement applying 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 Proposal includes consideration of varying limits in the Code for residues of agricultural and veterinary chemicals in food that are addressed in the international Codex standard. Limits in the Proposal relate to chemical residues that may occur in heavily traded agricultural commodities that may indirectly have a significant effect on trade of derivative food products between WTO members.

This Proposal will be notified as a Sanitary and Phytosanitary (SPS) measure in accordance with the WTO Agreement on the Application of SPS Measures as the primary objective of the measure is to support the regulation of the use of agricultural and veterinary chemical products to protect human, animal and plant health and the environment.

9.2 Codex Alimentarius Commission Standards

Codex standards are used as the relevant international standard or basis as to whether a new or changed standard requires a WTO notification.

FSANZ may consider varying limits for residues of agricultural or veterinary chemicals in food in a Proposal where interested parties have identified anomalies between the Code and international standards that may result in adverse impacts. FSANZ must have regard to its WTO obligations, the promotion of consistency between domestic and international food standards; and the promotion of fair trading in food.

These matters encompass a consideration of international standards and trade issues. The assessment gives careful consideration to public health and safety.

Industry provided information that discrepancies between the Code and international standards may present barriers to trade in certain foods. This Proposal includes proposed limits for bifenthrin, boscalid, chlorpyrifos, cypermethrin, fenvalerate, flubendiamide, fludioxonil, lambda-cyhalothrin (cyhalothrin), myclobutanil, permethrin, pyraclostrobin, pyrimethanil and quinoxifen to address these discrepancies. Further detail is provided at **Attachment 2**. The proposed variations to the Code would align limits in the Code with international standards and permit the sale of relevant foods containing legitimate residues that do not present health or safety concerns.

The following table lists proposed limits where there is a corresponding Codex limit.

Chemical Food	Proposed limit^{††} mg/kg	Codex limit mg/kg
Abamectin Melons, except watermelon Peppers Watermelon	T0.02 T0.02 T0.02	*0.01 Peppers, Sweet 0.02 *0.01
Amitraz Edible offal (mammalian) Meat (mammalian)	0.5 0.1	Edible offal of cattle, pigs and sheep 0.2 Cattle meat 0.05 Pig meat 0.05 Sheep meat 0.1
Boscalid Stone fruits	1.7	3
Chlorantraniliprole Celery Cotton seed Edible offal (mammalian) Eggs Fruiting vegetables, cucurbits Fruiting vegetables, other than cucurbits [except peppers, chilli] Grapes Leafy vegetables [except lettuce, head; rucola] Lettuce, head Rucola (rocket) Meat (mammalian) (in the fat) Milks Peppers, Chili Pome fruits Potato Poultry, edible offal of Poultry meat (in the fat) Stone fruits	5 0.3 *0.01 0.03 0.2 0.3 0.3 15 3 T20 *0.01 *0.01 1 0.3 *0.01 *0.01 1	7 0.3 *0.01 *0.01 0.3 Fruiting vegetables, other than cucurbits, except mushrooms and sweet corn 0.6 1 Leafy vegetables 20 Meat (from mammals other than marine mammals) (fat) *0.01 *0.01 Milk fats 0.1 Chilli peppers (dry) 5 0.4 Root and tuber vegetables 0.02 *0.01 *0.01 1
Chlorpyrifos Peppers, Chili (dry) Tea, green, black	20 2	Chilli peppers (dry) 20 2
Cypermethrin Tea, green, black	0.5	20

Chemical Food	Proposed limit^{†‡} mg/kg	Codex limit mg/kg
Cyprodinil Egg plant	T0.2	0.2
Fludioxonil Egg plant	T0.2	0.3
Metalaxyl Peppers	T1	1
Methoxyfenozide Dried grapes	6	Dried grapes (=currants, raisins and sultanas) 3
Fruiting vegetables, other than cucurbits	3	Peppers 2
Grapes	2	Sweet corn (corn-on-the-cob) *0.02
Macadamia nuts	0.05	Tomato 2
Pome fruits	0.5	1
		Tree nuts 0.1
		2
Myclobutanil Stone fruits [except plums]	2	2
Permethrin Cherries	4	Stone fruits 2
Pyraclostrobin Broccoli, Chinese	T1	Flowerhead brassicas 0.1
Brassica leafy vegetables	T3	Kale 1
Stone fruits	0.9	1
Pyrimethanil Pome fruits	7	7
Stone fruits	10	Apricot 3
		Cherries 4
		Nectarine 4
		Peach 4
		Plums (including prunes) 2
Quinoxifen Cherries	0.4	0.4
Spinetoram Edible offal (mammalian)	*0.01	*0.01
Meat (mammalian) (in the fat)	*0.01	Meat (from mammals other than marine mammals) (fat) 0.2
Milks	*0.01	*0.01
Milk fats	*0.01	0.1
Pome fruits	0.1	0.05
Spinosad Edible offal (mammalian)	0.5	Cattle kidney 1
		Cattle liver 2
		Edible offal (except cattle) 0.5
		Cattle meat 1
Meat (mammalian) (in the fat)	2	Meat (from mammals other than marine mammals) (fat) except cattle
		2

Chemical Food	Proposed limit^{†‡} mg/kg	Codex limit mg/kg
Spirotetramat Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas [except Brussels sprouts] Brussels sprouts Citrus fruits Edible offal (mammalian) Fruiting vegetables, cucurbits Lettuce, head Lettuce, leaf Meat (mammalian) Milks Peppers, Sweet Tomato	T7 T1 T1 T0.05 T2 T*0.01 T*0.005 T5 T7	Cabbages, Head 2 Flowerhead brassicas 1 0.5 0.03 0.2 Leafy vegetables 7 Meat (from mammals other than marine mammals) *0.01 *0.005 Fruiting vegetables, other than cucurbits, except mushrooms and sweet corn 1
Thiacloprid Cotton seed	T0.1	*0.02
Triadimenol Egg plant	T1	Fruiting vegetables, other than cucurbits, except fungi and sweet corn 1

[†] Note that a 'T' indicates that the limit is temporary.

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

FSANZ invites comment on any possible ramifications of approving the proposed MRLs.

9.3 New Zealand Standards

All imported and domestically produced food sold in New Zealand (except for food imported from Australia) must comply with the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2009 and amendments (the New Zealand MRL Standards).

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. If the food is imported, it may comply with Codex MRLs. Further information about the New Zealand MRL Standards is available on the New Zealand Food Safety Authority website at: <http://www.nzfsa.govt.nz/acvm/registers-lists/nz-mrl/index.htm>

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.

The following table lists the proposed variations to MRLs and includes the corresponding MRL in the New Zealand MRL Standards.

Chemical Food	Proposed MRL[†] mg/kg	NZ MRL[‡] mg/kg
Boscalid Stone fruits	1.7	0.05(*)
Chlorantraniliprole Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas Pome fruits	0.3 0.3	Brassica vegetables 0.3 0.3
Cyprodinil Strawberry	T5	1
Fludioxonil Strawberry	T5	1
Metalaxyl Peppers	T1	Fruiting vegetables (except tomatoes) 0.2
Methoxyfenozide Kiwifruit Pome fruits	2 0.5	0.5 0.5
Pyraclostrobin Stone fruits	0.9	0.02(*)
Spinetoram Pome fruits	0.1	Apples 0.05 Pears 0.05
Spinosad Edible offal (mammalian) Meat (mammalian) (in the fat)	0.5 2	Sheep fat 2 Sheep kidney 0.5 Sheep liver 0.5 Sheep meat 0.05

[†] Note that a 'T' indicates that the limit is temporary.

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

FSANZ requests comment on the proposed MRLs in relation to the corresponding New Zealand MRLs.

9.4 Imported foods

Internationally, countries set MRLs according to good agricultural practice (GAP) or good veterinary practice (GVP). Agricultural and veterinary chemicals are used differently in different countries around the world as pests, diseases and environmental factors differ and because product use patterns differ. This means that residues in imported foods may be legitimately different from those in domestically produced foods.

Deletions or reductions of MRLs may impact imported foods that may comply with existing MRLs even though these existing MRLs are no longer required for domestically produced food. This is because imported foods may contain residues consistent with the MRLs proposed for deletion or reduction.

FSANZ is committed to ensuring that the implications of MRL variations are considered. Under the current process for considering variations to the Code, FSANZ encourages submissions including specific data demonstrating a need for certain MRLs to be retained or varied. FSANZ will consider retaining MRLs proposed for deletion or reduction where these MRLs are necessary to continue to allow the sale of safe food; and where the MRLs are supported by adequate data or information demonstrating that the residues associated with these MRLs do not raise any public health or safety concerns. Further information on data requirements may be obtained from FSANZ.

No MRLs are being considered for reduction or deletion in this Proposal. The proposed variations to the Code are at **Attachment 1** and the recommended changes are outlined in **Attachment 2**.

FSANZ requests comment on any possible ramifications for imported foods of the proposed MRLs.

Conclusion

10. Conclusion and Preferred Option

This Proposal has been assessed against the considerations provided for in section 59 of the FSANZ Act.

The preferred approach is to adopt option 1 to approve the draft variations.

Preferred Approach

FSANZ recommends the proposed draft variations to Standard 1.4.2 – Maximum Residue Limits. The residues associated with the proposed variations do not present any public health and safety concerns and the proposed draft variations are necessary, cost-effective and will benefit consumers, Government and industry. The proposed draft variations will permit the sale of foods containing legitimate residues. The proposed minor amendments to the Standard will improve clarity and consistency of terminology.

10.1 Reasons for Preferred Approach

FSANZ recommends the proposed draft variations to Standard 1.4.2 for the following reasons:

- MRLs serve to protect public health and safety by minimising residues in food consistent with the effective control of pests and diseases.
- Dietary exposure assessments indicate that the proposed variations do not present any public health and safety concerns.
- This approach ensures openness and transparency in relation to the residues that could reasonably occur in food.
- The proposed variations will benefit stakeholders by maintaining public health and safety while permitting the legal sale of food containing legitimate residues of agricultural and veterinary chemicals used to control pests and diseases and improve agricultural productivity.
- The APVMA has assessed appropriate residue, animal transfer, processing and metabolism studies, in accordance with *The Manual of Requirements and Guidelines – MORAG – for Agricultural and Veterinary Chemicals 1 July 2005* to support the use of chemicals on commodities as outlined in this Proposal.
- The Office of Chemical Safety (OCS) has undertaken a toxicological assessment of each chemical and has established an ADI and where appropriate an ARfD.

- FSANZ has undertaken a preliminary regulation impact assessment and concluded that the proposed draft variations are necessary, cost-effective and beneficial.
- The proposed draft variations would remove inconsistencies between agricultural and food standards and provide certainty and consistency for producers, importers and Australian, State and Territory compliance agencies.
- The proposed changes are consistent with the FSANZ Act section 18 objectives.

11. Implementation and Review

The use of chemical products and MRLs are under constant review as part of the APVMA Chemical Review Program. In addition, regulatory agencies continue to monitor health, agricultural and environmental issues associated with chemical product use. Residues in food are also monitored through:

- State and Territory residue monitoring programs;
- Australian Government programs such as the National Residue Survey; and
- dietary exposure studies such as the Australian Total Diet Study.

These monitoring programs and the continual review of the use of agricultural and veterinary chemicals mean that there is considerable scope to review limits in the Code.

It is proposed that the variations in this Proposal should take effect on gazettal and that the limits be subject to existing monitoring arrangements.

ATTACHMENTS

1. Draft variations to the *Australia New Zealand Food Standards Code*
2. Explanatory Statement of Amendments to Standard 1.4.2 and a Summary of Limits under Consideration in Proposal M1004
3. Safety Assessment Methodology
4. Background Information

Draft variations to the *Australia New Zealand Food Standards Code*

Section 94 of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunseting

To commence: on gazettal

[1] **Standard 1.4.2** of the *Australia New Zealand Food Standards Code* is varied by –

[1.1] *omitting from subclause 1(2) –*

asterix

substituting –

asterisk

[1.2] *omitting the definition of extraneous residue limit (ERL) in subclause 1(6), substituting –*

extraneous residue limit (ERL) means the maximum level of a residue of a chemical –

- (a) permitted to present to be present in a food; and
- (b) which arises from environmental sources other than the use of a chemical directly or indirectly on the food.

[1.3] *omitting the definition of maximum residue limit (MRL) in subclause 1(6), substituting –*

maximum residue limit (MRL) means the maximum level of a residue of a chemical which is permitted to be present in a food.

[1.4] *omitting from the definition of residue definition in subclause 1(6) the word compound*

[1.5] *inserting in clause 1 –*

(7) To avoid doubt, the express mention of a particular chemical in the residue definition for a chemical does not exclude other metabolites, degradates or impurities of that chemical.

[1.6] *omitting subclause 2(1), substituting –*

(1) The permitted MRL for a residue of a chemical in food is listed in Schedule 1, and is expressed in milligrams per kilogram of food.

[1.7] *omitting subclause 3(1), substituting –*

(1) The permitted ERL for a residue of a chemical in food is listed in Schedule 2, and is expressed in milligrams per kilogram of food.

[1.8] *omitting from subclause 3(2) the word agricultural.*

[1.9] *omitting wherever occurring in Schedule 1 the text in Column 1 of the Table to this*

sub-item, substituting the text in Column 2.

Table to sub-item 1.9

Column 1 Omit ...	Column 2 Substitute ...
COMMON BEAN (DRY)	COMMON BEAN (DRY) (NAVY BEAN)
COTTONSEED	COTTON SEED
MELONS [EXCEPT WATERMELON]	MELONS, EXCEPT WATERMELON
PEPPERS, SWEET	PEPPERS, SWEET
RAPE SEED	RAPE SEED (CANOLA)
SILVERBEET	SILVER BEET

[1.10] omitting from Schedule 1 the chemical residue definition for the chemical appearing in Column 1 of the Table to this sub-item, substituting the chemical residue definition appearing in Column 2 –

COLUMN 1	COLUMN 2
AMITRAZ	SUM OF AMITRAZ AND <i>N</i> -(2,4-DIMETHYLPHENYL)- <i>N</i> '-METHYLFORMAMIDINE, EXPRESSED AS <i>N</i> -(2,4-DIMETHYLPHENYL)- <i>N</i> '-METHYLFORMAMIDINE

[1.11] inserting in Schedule 1 –

CHLORANTRANILIPROLE	
<i>PLANT COMMODITIES AND ANIMAL COMMODITIES OTHER THAN MILK: CHLORANTRANILIPROLE</i>	
<i>MILK: SUM OF CHLORANTRANILIPROLE, 3-BROMO-<i>N</i>-[4-CHLORO-2-(HYDROXYMETHYL)-6-[(METHYLAMINO)CARBONYL]PHENYL]-1-(3-CHLORO-2-PYRIDINYL)-1<i>H</i>-PYRAZOLE-5-CARBOXAMIDE, AND 3-BROMO-<i>N</i>-[4-CHLORO-2-(HYDROXYMETHYL)-6-[[[(HYDROXYMETHYL)AMINO)CARBONYL]PHENYL]-1-(3-CHLORO-2-PYRIDINYL)-1<i>H</i>-PYRAZOLE-5-CARBOXAMIDE, EXPRESSED AS CHLORANTRANILIPROLE</i>	
ALL OTHER FOODS	*0.01
BRASSICA (COLE OR CABBAGE) VEGETABLES, HEAD CABBAGES, FLOWERHEAD BRASSICAS	0.3
CELERY	5
COTTON SEED	0.3
CORIANDER (LEAVES, STEM, ROOTS)	T20
DRIED FRUITS	2
EDIBLE OFFAL (MAMMALIAN)	*0.01
EGGS	0.03
FRUITING VEGETABLES, CUCURBITS	0.2
FRUITING VEGETABLES, OTHER THAN CUCURBITS [EXCEPT PEPPERS, CHILI]	0.3
GRAPES	0.3
HERBS	T20

LEAFY VEGETABLES [EXCEPT LETTUCE, HEAD; RUCOLA]	15
LETTUCE, HEAD	3
MEAT (MAMMALIAN) (IN THE FAT)	*0.01
MEXICAN TARRAGON	T20
MILKS	*0.01
PEPPERS, CHILI	1
POME FRUITS	0.3
POTATO	*0.01
POULTRY, EDIBLE OFFAL OF	*0.01
POULTRY MEAT (IN THE FAT)	*0.01
RHUBARB	5
RUCOLA (ROCKET)	T20
STONE FRUITS	1
SPINETORAM	
SUM OF ETHYL-SPINOSYN-J AND ETHYL- SPINOSYN-L	
EDIBLE OFFAL (MAMMALIAN)	*0.01
EGGS	*0.01
MEAT (MAMMALIAN) (IN THE FAT)	*0.01
MILKS	*0.01
MILK FATS	*0.01
POULTRY, EDIBLE OFFAL OF	*0.01
POULTRY MEAT (IN THE FAT)	*0.01
POME FRUITS	0.1
STONE FRUITS	0.2
SPIROTETRAMAT	
SUM OF SPIROTETRAMAT, AND CIS-3-(2,5- DIMETHYLPHENYL)-4-HYDROXY-8-METHOXY-1- AZASPIRO[4.5]DEC-3-EN-2-ONE, EXPRESSED AS SPIROTETRAMAT	
BRASSICA (COLE OR CABBAGE) VEGETABLES, HEAD CABBAGES, FLOWERHEAD BRASSICAS [EXCEPT BRUSSELS SPROUTS]	T7
BRUSSELS SPROUTS	T1
CITRUS FRUITS	T1
COTTON SEED	T1
EDIBLE OFFAL (MAMMALIAN)	T0.05
FRUITING VEGETABLES, CUCURBITS	T2
LETTUCE, HEAD	T5
LETTUCE, LEAF	T10
MANGO	T0.3
MEAT (MAMMALIAN)	T*0.01
MILKS	T*0.005
ONION, BULB	T0.5
PEPPERS, SWEET	T5
TOMATO	T7

[1.12] omitting from Schedule 1 the foods and associated MRLs for each of the following chemicals –

ABAMECTIN	
SUM OF AVERMECTIN B1A, AVERMECTIN B1B AND (Z)-8,9 AVERMECTIN B1A, AND (Z)-8,9 AVERMECTIN B1B	
PEPPERS, SWEET	0.02
AMITRAZ	
SUM OF AMITRAZ AND N-(2,4-DIMETHYLPHENYL)-N'-METHYLFORMAMIDINE, EXPRESSED AS AMITRAZ	
EDIBLE OFFAL OF CATTLE, PIGS AND SHEEP	0.5
MEAT OF CATTLE, PIGS AND SHEEP	0.1
BROMOXYNIL	
BROMOXYNIL	
MEAT (MAMMALIAN)	*0.02
CHLORPYRIFOS	
CHLORPYRIFOS	
VEGETABLES [EXCEPT ASPARAGUS; BRASSICA VEGETABLES; CASSAVA; CELERY; LEEK; PEPPERS, SWEET; POTATO; SWEDE; SWEET POTATO; TARO AND TOMATO]	T*0.01
INDOXACARB	
SUM OF INDOXACARB AND ITS R-ISOMER	
LEAFY VEGETABLES [EXCEPT LETTUCE, HEAD]	5
METALAXYL	
METALAXYL	
VEGETABLES [EXCEPT AS OTHERWISE LISTED UNDER THIS CHEMICAL]	0.1
METHOXYFENOZIDE	
METHOXYFENOZIDE	
TOMATO	3

[1.13] inserting in alphabetical order in Schedule 1, the foods and associated MRLs for each of the following chemicals –

ABAMECTIN	
SUM OF AVERMECTIN B1A, AVERMECTIN B1B AND (Z)-8,9 AVERMECTIN B1A, AND (Z)-8,9 AVERMECTIN B1B	
MELONS, EXCEPT WATERMELON	T0.02
PEPPERS	T0.02
WATERMELON	T0.02
AMITRAZ	
SUM OF AMITRAZ AND N-(2,4-DIMETHYLPHENYL)-N'-METHYLFORMAMIDINE, EXPRESSED AS AMITRAZ	
EDIBLE OFFAL (MAMMALIAN)	0.5

MEAT (MAMMALIAN)	0.1
BIFENTHRIN BIFENTHRIN	
TEA, GREEN, BLACK	5
BOSCALID COMMODITIES OF PLANT ORIGIN: BOSCALID COMMODITIES OF ANIMAL ORIGIN: SUM OF BOSCALID, 2-CHLORO-N-(4'-CHLORO-5- HYDROXYBIPHENYL-2-YL) NICOTINAMIDE AND THE GLUCURONIDE CONJUGATE OF 2-CHLORO-N-(4'- CHLORO-5-HYDROXYBIPHENYL-2-YL) NICOTINAMIDE, EXPRESSED AS BOSCALID EQUIVALENTS	
STONE FRUITS	1.7
BROMOXYNIL BROMOXYNIL	
MEAT (MAMMALIAN) (IN THE FAT)	T0.05
BUPIRIMATE BUPIRIMATE	
EGG PLANT	T1
BUPROFEZIN BUPROFEZIN	
CELERY	T1
CHLORPYRIFOS CHLORPYRIFOS	
PEPPERS, CHILI (DRY)	20
TEA, GREEN, BLACK	2
VEGETABLES [EXCEPT ASPARAGUS; BRASSICA VEGETABLES; CASSAVA; CELERY; LEEK; PEPPERS, CHILI (DRY); PEPPERS, SWEET; POTATO; SWEDE; SWEET POTATO; TARO AND TOMATO]	T*0.01
CLOTHIANIDIN CLOTHIANIDIN	
SUGAR CANE	T0.2
CYHALOTHRIN CYHALOTHRIN, SUM OF ISOMERS	
TEA, GREEN, BLACK	1
CYPERMETHRIN CYPERMETHRIN, SUM OF ISOMERS	
TEA, GREEN, BLACK	0.5
CYPRODINIL CYPRODINIL	
EGG PLANT	T0.2
STRAWBERRY	T5

FENVALERATE	
FENVALERATE, SUM OF ISOMERS	
TEA, GREEN, BLACK	0.05
FLUBENDIAMIDE	
<i>COMMODITIES OF PLANT ORIGIN: FLUBENDIAMIDE</i>	
<i>COMMODITIES OF ANIMAL ORIGIN: SUM OF FLUBENDIAMIDE AND 3-iodo-N-(2-methyl-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl)phthalimide, expressed as flubendiamide</i>	
COTTON SEED	T0.5
STONE FRUITS	1.6
FLUDIOXONIL	
<i>COMMODITIES OF ANIMAL ORIGIN: SUM OF FLUDIOXONIL AND OXIDISABLE METABOLITES, EXPRESSED AS FLUDIOXONIL</i>	
<i>COMMODITIES OF PLANT ORIGIN: FLUDIOXONIL</i>	
EGG PLANT	T0.2
POMEGRANATE	5
STRAWBERRY	T5
IMIDACLOPRID	
SUM OF IMIDACLOPRID AND METABOLITES CONTAINING THE 6-CHLOROPYRIDINYLMETHYLENE MOIETY, EXPRESSED AS IMIDACLOPRID	
COMMON BEAN (DRY) (NAVY BEAN)	T1
INDOXACARB	
SUM OF INDOXACARB AND ITS <i>R</i> -ISOMER	
CORIANDER (LEAVES, STEM, ROOTS)	T20
HERBS	T20
LEAFY VEGETABLES [EXCEPT LETTUCE, HEAD; RUCOLA]	5
MEXICAN TARRAGON	T20
RUCOLA (ROCKET)	T20
IPRODIONE	
IPRODIONE	
EGG PLANT	T7
METALAXYL	
METALAXYL	
PEPPERS	T1
VEGETABLES [EXCEPT BULB VEGETABLES; FRUITING VEGETABLES, CUCURBITS; LEAFY VEGETABLES; PEPPERS; PODDED PEA (YOUNG PODS) (SNOW AND SUGAR SNAP)]	T0.1
METHOMYL	
SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OXIME'), EXPRESSED AS METHOMYL <i>SEE ALSO THIODICARB</i>	
SWEET POTATO	T1

METHOXYFENOZIDE	
METHOXYFENOZIDE	
AVOCADO	0.5
BLUEBERRIES	2
CITRUS FRUITS	1
COFFEE BEANS	0.2
CUSTARD APPLE	0.3
DRIED GRAPES	6
FRUITING VEGETABLES, OTHER THAN CUCURBITS	3
GRAPES	2
KIWIFRUIT	2
LITCHI	2
LONGAN	2
MACADAMIA NUTS	0.05
POME FRUITS	0.5
METRIBUZIN	
METRIBUZIN	
RAPE SEED (CANOLA)	*0.02
MYCLOBUTANIL	
MYCLOBUTANIL	
STONE FRUITS [EXCEPT PLUMS]	2
OXAMYL	
SUM OF OXAMYL AND 2-HYDROXYIMINO-N,N- DIMETHYL-2-(METHYLTHIO)-ACETAMIDE, EXPRESSED AS OXAMYL	
SWEET POTATO	T0.5
PERMETHRIN	
PERMETHRIN, SUM OF ISOMERS	
CHERRIES	4
PHENMEDIPHAM	
PHENMEDIPHAM	
CHARD (SILVER BEET)	T0.2
CHICORY LEAVES	T0.2
ENDIVE	T0.2
RADICCHIO	T0.2
SPINACH	T0.2
PRAZQUANTEL	
PRAZQUANTEL	
FISH MUSCLE/SKIN	T*0.01
PROPICONAZOLE	
PROPICONAZOLE	
SUNFLOWER SEED	T2
PYMETROZINE	
PYMETROZINE	
LEAFY HERBS	T10

PYRACLOSTROBIN	
<i>COMMODITIES OF PLANT ORIGIN:</i> PYRACLOSTROBIN	
<i>COMMODITIES OF ANIMAL ORIGIN:</i> SUM OF PYRACLOSTROBIN AND METABOLITES HYDROLYSED TO 1-(4-CHLORO-PHENYL)-1H-PYRAZOL-3-OL, EXPRESSED AS PYRACLOSTROBIN	
BROCCOLI, CHINESE	T1
BRASSICA LEAFY VEGETABLES	T3
STONE FRUITS	0.9
PYRIMETHANIL	
PYRIMETHANIL	
STONE FRUITS	10
QUINOXYFEN	
QUINOXYFEN	
CHERRIES	0.4
TEBUCONAZOLE	
TEBUCONAZOLE	
SOYA BEAN (DRY)	T0.1
THIACLOPRID	
THIACLOPRID	
COTTON SEED	T0.1
TRIADIMENOL	
TRIADIMENOL SEE ALSO TRIADIMEFON	
EGG PLANT	T1

[1.14] omitting from Schedule 1, under the entries for the following chemicals, the *Maximum Residue Limit for the food*, substituting –

BROMOXYNIL	
BROMOXYNIL	
EDIBLE OFFAL (MAMMALIAN)	T0.5
ETHOXSULFURON	
<i>COMMODITIES OF PLANT ORIGIN:</i> ETHOXSULFURON	
<i>COMMODITIES OF ANIMAL ORIGIN:</i> 2-AMINO-4,6- DIMETHOXPYRIMIDINE, EXPRESSED AS ETHOXSULFURON	
EDIBLE OFFAL (MAMMALIAN)	*0.05
MEAT (MAMMALIAN)	*0.05
MILKS	*0.01
SUGAR CANE	*0.01
PYRIMETHANIL	
PYRIMETHANIL	
POME FRUITS	7
SPINOSAD	
SUM OF SPINOSYN A AND SPINOSYN D	
EDIBLE OFFAL (MAMMALIAN)	0.5
MEAT (MAMMALIAN) (IN THE FAT)	2

|_____|

[1.15] *arranging the entries in Schedule 1 under the chemical Fludioxonil in alphabetical order*

Attachment 2

Explanatory Statement of Amendments to Standard 1.4.2 and a Summary of Limits under Consideration in Proposal M1004

EXPLANATORY STATEMENT OF PROPOSED AMENDMENTS TO STANDARD 1.4.2

Item 1.1

The proposed editorial amendment to subclause 1(3) is to correct a typographical error.

Item 1.2

The proposed amendment to the definition of 'extraneous residue limit' under subclause 1(6) is to improve consistency of use of terminology, particularly use of 'chemical' rather than 'pesticide' (a definition of chemical is provided in clause 1). The proposed change will remove reference to the units in which limits are expressed. The units, (mg/kg), are more properly included in subclause 3(1) than in the definition of extraneous residue limit.

Item 1.3

The proposed amendment to the definition of 'maximum residue limit' under subclause 1(6) is to improve consistency of use of terminology and provide clarity that the MRL refers to the residues of the relevant chemical. It is proposed to remove the wording 'unless otherwise stated' as there are no exceptions to this definition in the Standard. The proposed change will also remove reference to the units in which limits are expressed. The units, (mg/kg), are more properly included in subclause 2(1) than in the definition of maximum residue limit.

Item 1.4

This item omits the word 'compound' from the definition of 'residue definition', so that the definition of 'residue definition' refers to 'chemical' which is defined in clause 1. The amendment is proposed to improve consistency of use of terminology.

Item 1.5

This item inserts a new subclause (7) which is intended to provide clarity that residue definitions in this Standard are not intended to include every substance that may be present.

Item 1.6

This item omits subclause 2(1), and substitutes a new subclause which improves consistency of terminology for maximum residue limits. It also clarifies that the MRL applies to residues of a chemical. Furthermore, the new subclause 2(1) provides that the limits in Schedule 1 are expressed in mg/kg.

Item 1.7

This item makes similar amendments to those described for Item 1.6, but for extraneous residue limits.

Item 1.8

This item proposes the deletion of the word 'agricultural' from subclause 3(2). The use of this word is redundant in this subclause as the definition of 'chemical' is provided in subclause 1(6). The definition of 'chemical' in this Standard includes 'agricultural' and 'veterinary'. The proposed change clarifies that subclause (2) is not intended to exclude veterinary chemicals.

Items 1.9 to 1.14

These items propose a series of amendments to the substantive provisions in Schedule 1 of Standard 1.4.2. The rationale for those changes is described in the Assessment Report.

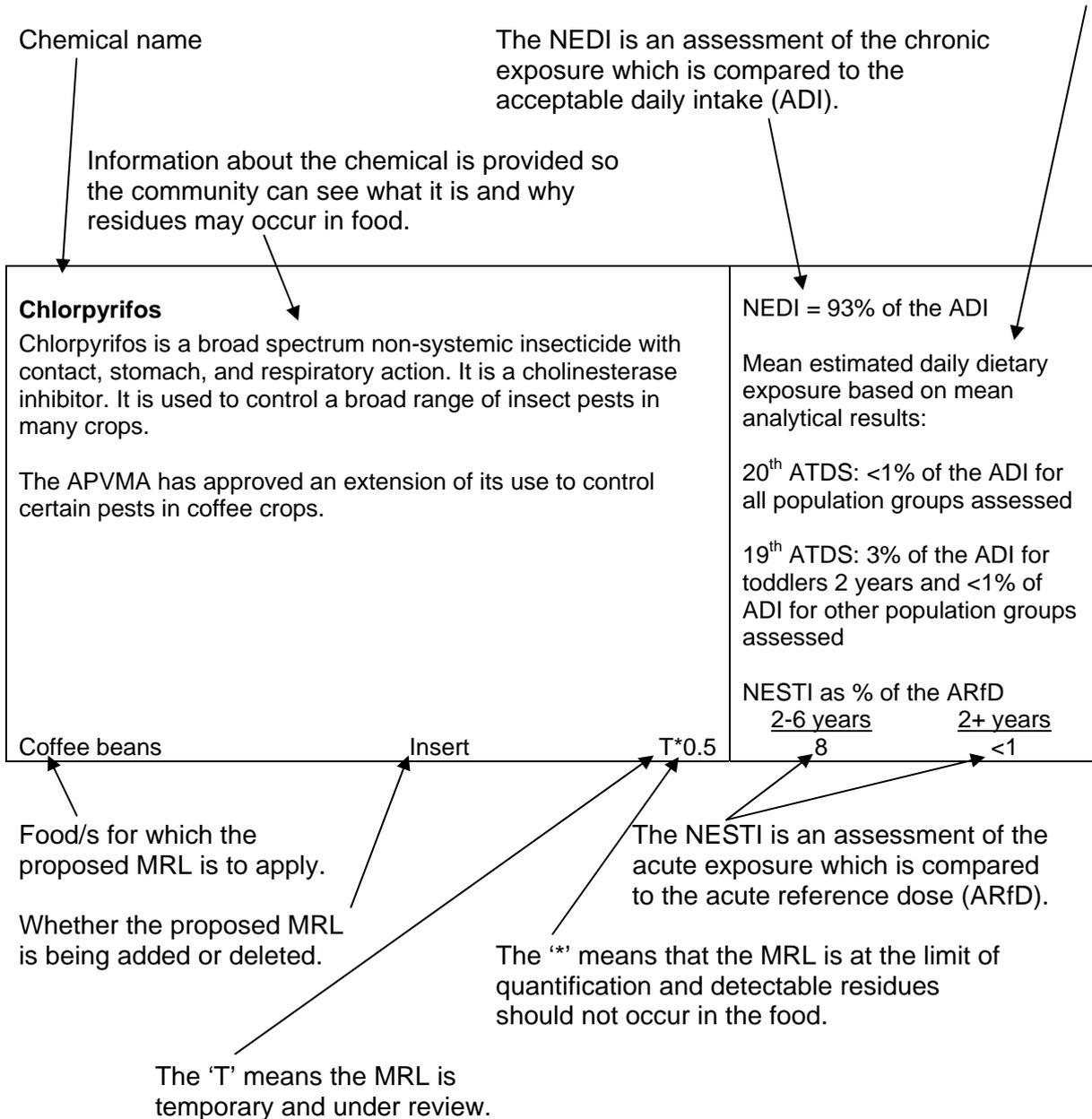
Item 1.15

This item ensures that the existing entries for each food and the relevant limit in Schedule 1 under the chemical 'Fludioxonil' are listed in alphabetical order consistent with formatting under other chemicals in the Schedules to the Standard.

INTERPRETIVE GUIDE TO THE SUMMARY TABLE OF MRLS UNDER CONSIDERATION

The following is an example of an entry and the proposed MRL is not being considered in this Proposal. Further information on calculating dietary exposure is provided at **Attachment 3**.

Data from the 19th and 20th ATDS are provided when available because they provide an indication of the typical exposure to chemicals in table ready foods. The ATDS results are more realistic because analysed concentrations of the chemical in foods as consumed are used. The National Estimated Daily Intake (NEDI) and National Estimated Short Term Intake (NESTI) calculations are theoretical calculations that protectively overestimate exposure. Small variations may be noted in the exposure assessment between different ATDSs. These variations are minor and are typically due to the different range of foods in the individual studies.



**SUMMARY OF MRLS UNDER CONSIDERATION IN PROPOSAL M1004
APVMA MRLS – SEPTEMBER 2008 – MARCH 2009 AND INDUSTRY REQUESTS**

Requested MRLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment		
<p>Abamectin Abamectin is an insecticide and acaricide with contact and stomach action. It inhibits stimulation of neurons by binding to gamma-aminobutyric acid regulated chloride channels and allowing free passage of chloride ions into the neuron. It is used to control mites on cotton and various fruits and vegetables.</p> <p>The APVMA has issued permits for its use to control two spotted mite (<i>Tetranychus urticae</i>) and western flower thrip (<i>Frankliniella occidentalis</i>) on chillies and paprika (capsicum); and two spotted mite on melons.</p>			NEDI: 78% of the ADI		
Melons, except watermelon	Insert	T0.02	NESTI as % of the ARfD		
Peppers	Insert	T0.02	<u>2-6 years</u>		<u>2+ years</u>
Peppers, sweet	Omit	0.02	24	9	
Watermelon	Insert	T0.02	1	Chilli	<1
			4	Capsicum	2
			24		25
<p>Amitraz Amitraz is a non-systemic amidine acaricide and insecticide. It interacts with the octopamine receptors in the tick nervous system resulting in an increase in neuronal activity, tick detachment and death. It is used to control ticks on cattle; mange on cattle and pigs; and cattle tick on sheep, goats, deer and certain edible exotic animals. The use pattern has been approved for over 30 years.</p> <p>The APVMA has recommended extending the existing MRLs to cover all relevant species.</p> <p>Amendment to residue definition</p> <p>Omit: Sum of amitraz and N-(2,4-dimethylphenyl)-N'-methylformamide, expressed as amitraz</p> <p>Substitute: Sum of amitraz and N-(2,4-dimethylphenyl)-N'-methylformamide, expressed as N-(2,4-dimethylphenyl)-N'-methylformamide</p>			NEDI: 84% of the ADI		
Edible offal of cattle, pigs and sheep	Omit	0.5	<u>2-6 years</u>		<u>2+ years</u>
Edible offal (mammalian)	Insert	0.5	4		15
Meat of cattle, pigs and sheep	Omit	0.1			
Meat (mammalian)	Insert	0.1	14		8

Requested MRLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)	Dietary Exposure Assessment															
<p>Bromoxynil Bromoxynil is a selective contact herbicide. It inhibits photosynthetic electron transport and also uncouples oxidative phosphorylation. It is used to control annual broad leaf weeds in various cereal crops and horticultural situations.</p> <p>The APVMA has issued a permit for its use to control weeds in sorghum. The APVMA has advised that while residues in feeds are expected to be <0.1 mg/kg, animal transfer studies indicate the possibility of detectable residues in offal and fat.</p> <table border="0" data-bbox="177 593 983 714"> <tr> <td>Edible offal (mammalian)</td> <td>Omit</td> <td>*0.02</td> </tr> <tr> <td></td> <td>Substitute</td> <td>T0.5</td> </tr> <tr> <td>Meat (mammalian)</td> <td>Omit</td> <td>*0.02</td> </tr> <tr> <td>Meat (mammalian) (in the fat)</td> <td>Insert</td> <td>T0.05</td> </tr> </table>	Edible offal (mammalian)	Omit	*0.02		Substitute	T0.5	Meat (mammalian)	Omit	*0.02	Meat (mammalian) (in the fat)	Insert	T0.05	<p>NEDI: 25% of the ADI</p>			
Edible offal (mammalian)	Omit	*0.02														
	Substitute	T0.5														
Meat (mammalian)	Omit	*0.02														
Meat (mammalian) (in the fat)	Insert	T0.05														
<p>Bupirimate Bupirimate is a systemic fungicide with protective and curative action. It is absorbed by the leaves, with translocation in the xylem and translaminar action. It inhibits sporulation. It is used to control powdery mildews of fruits, cucurbits and other vegetables.</p> <p>The APVMA has issued a permit for its use to control powdery mildew on eggplant.</p> <table border="0" data-bbox="177 990 983 1021"> <tr> <td>Egg plant</td> <td>Insert</td> <td>T1</td> </tr> </table>	Egg plant	Insert	T1	<p>NEDI: 3% of the ADI</p> <p>20th ATDS: not detected in any foods sampled</p> <p>19th ATDS: not detected in any foods sampled</p>												
Egg plant	Insert	T1														
<p>Buprofezin Buprofezin is an insecticide and acaricide with contact and stomach action. It inhibits the moulting of nymphs and larvae by suppressing ecdysis. It is used to control various pests in cotton, fruit and vegetable situations.</p> <p>The APVMA has issued a permit for its use to control whitefly (<i>Trialeurodes</i> spp.) in celery.</p> <table border="0" data-bbox="177 1294 983 1352"> <tr> <td>Celery</td> <td>Insert</td> <td>T1</td> </tr> </table>	Celery	Insert	T1	<p>NEDI: 23% of the ADI</p> <p>NESTI as % of the ARfD</p> <table border="0" data-bbox="983 1265 1388 1352"> <tr> <td></td> <td><u>2-6 years</u></td> <td></td> <td><u>2+ years</u></td> </tr> <tr> <td></td> <td>3</td> <td>Celery</td> <td><1</td> </tr> <tr> <td></td> <td>3</td> <td>Celery, raw</td> <td><1</td> </tr> </table>		<u>2-6 years</u>		<u>2+ years</u>		3	Celery	<1		3	Celery, raw	<1
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Requested MRLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)	Dietary Exposure Assessment																																																																											
<p>Chlorantraniliprole</p> <p>Chlorantraniliprole is an insecticide. It acts through unregulated activation of the ryanodine receptor channels in the larvae and some adults of most lepidopteran species of insect, leading to depletion of internal calcium stores. This impairs muscle contraction. Affected insects exhibit general lethargy and paralysis followed by death. It is used to control insect pests in cotton and various fruit and vegetable situations. Some of the recommended MRLs are at the limit of quantification (LOQ).</p> <p>The APVMA has issued a permit for its use to control native budworm (<i>Helicoverpa</i> spp.) and cluster caterpillar (<i>Spodoptera litura</i>) on culinary herbs.</p> <p>New chemical</p> <p>Insert residue definition:</p> <p><i>Plant commodities and animal commodities other than milk:</i> Chlorantraniliprole <i>Milk:</i> Sum of chlorantraniliprole, 3-bromo-<i>N</i>-[4-chloro-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1<i>H</i>-pyrazole-5-carboxamide, and 3-bromo-<i>N</i>-[4-chloro-2-(hydroxymethyl)-6-[[[(hydroxymethyl)amino]carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1<i>H</i>-pyrazole-5-carboxamide, expressed as chlorantraniliprole</p> <table border="0" data-bbox="177 1075 983 1962"> <tr><td>All other foods</td><td>Insert</td><td>*0.01</td></tr> <tr><td>Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas</td><td>Insert</td><td>0.3</td></tr> <tr><td>Celery</td><td>Insert</td><td>5</td></tr> <tr><td>Cotton seed</td><td>Insert</td><td>0.3</td></tr> <tr><td>Coriander (leaves, stem, roots)</td><td>Insert</td><td>T20</td></tr> <tr><td>Dried fruits</td><td>Insert</td><td>2</td></tr> <tr><td>Edible offal (mammalian)</td><td>Insert</td><td>*0.01</td></tr> <tr><td>Eggs</td><td>Insert</td><td>0.03</td></tr> <tr><td>Fruiting vegetables, cucurbits</td><td>Insert</td><td>0.2</td></tr> <tr><td>Fruiting vegetables, other than cucurbits [except peppers, chili]</td><td>Insert</td><td>0.3</td></tr> <tr><td>Grapes</td><td>Insert</td><td>0.3</td></tr> <tr><td>Herbs</td><td>Insert</td><td>T20</td></tr> <tr><td>Leafy vegetables [except lettuce, head; rucola]</td><td>Insert</td><td>15</td></tr> <tr><td>Lettuce, head</td><td>Insert</td><td>3</td></tr> <tr><td>Meat (mammalian) (in the fat)</td><td>Insert</td><td>*0.01</td></tr> <tr><td>Mexican tarragon</td><td>Insert</td><td>T20</td></tr> <tr><td>Milks</td><td>Insert</td><td>*0.01</td></tr> <tr><td>Peppers, Chili</td><td>Insert</td><td>1</td></tr> <tr><td>Pome fruits</td><td>Insert</td><td>0.3</td></tr> <tr><td>Potato</td><td>Insert</td><td>*0.01</td></tr> <tr><td>Poultry, edible offal of</td><td>Insert</td><td>*0.01</td></tr> <tr><td>Poultry meat (in the fat)</td><td>Insert</td><td>*0.01</td></tr> <tr><td>Rhubarb</td><td>Insert</td><td>5</td></tr> <tr><td>Rucola (rocket)</td><td>Insert</td><td>T20</td></tr> <tr><td>Stone fruits</td><td>Insert</td><td>1</td></tr> </table>	All other foods	Insert	*0.01	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	Insert	0.3	Celery	Insert	5	Cotton seed	Insert	0.3	Coriander (leaves, stem, roots)	Insert	T20	Dried fruits	Insert	2	Edible offal (mammalian)	Insert	*0.01	Eggs	Insert	0.03	Fruiting vegetables, cucurbits	Insert	0.2	Fruiting vegetables, other than cucurbits [except peppers, chili]	Insert	0.3	Grapes	Insert	0.3	Herbs	Insert	T20	Leafy vegetables [except lettuce, head; rucola]	Insert	15	Lettuce, head	Insert	3	Meat (mammalian) (in the fat)	Insert	*0.01	Mexican tarragon	Insert	T20	Milks	Insert	*0.01	Peppers, Chili	Insert	1	Pome fruits	Insert	0.3	Potato	Insert	*0.01	Poultry, edible offal of	Insert	*0.01	Poultry meat (in the fat)	Insert	*0.01	Rhubarb	Insert	5	Rucola (rocket)	Insert	T20	Stone fruits	Insert	1	<p>NEDI: <1% of the ADI</p>
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<p>Chlorpyrifos</p> <p>Chlorpyrifos is a broad spectrum non-systemic insecticide with contact, stomach, and respiratory action. It is a cholinesterase inhibitor. It is used to control a broad range of insect pests in many crops including cotton, sugarcane, vegetables, pome and stone fruit, pastures, turf and ornamental crops.</p> <p>Unilever Australasia requested that FSANZ consider including a chlorpyrifos MRL for tea in the Code based on the Codex MRL. Unilever made the request based on the Tea Global Plant Protection Initiative principle of progressing toward ensuring that tea is produced and traded in a compliant manner across international boundaries. Unilever provided information that chlorpyrifos is used in tea production in India and Kenya to control a wide range of pests including termites, cockchafer grubs, crickets and thrips. Legitimate chlorpyrifos residues may occur in tea imported to Australia from these countries. The Food and Beverages Importers Association (FBIA) requested that FSANZ consider incorporating the Codex chlorpyrifos MRL for dry chilli peppers in the Code. Chillies are imported to Australia from a range of countries and legitimate residues may occur.</p> <p>Chlorpyrifos is currently under review by the APVMA. FSANZ notes that the conclusion of the review is imminent and that upon finalisation, the APVMA may vary chlorpyrifos MRLs. Following the anticipated recommended changes to use patterns, the NEDI is likely to be approximately 60% of the ADI and the highest NESTI among relevant commodities is likely to be approximately 58% of the ARfD. The estimated dietary exposures will be reassessed following notification of the MRL variations to FSANZ. The Chlorpyrifos Preliminary Review Findings Report On Additional Residues Data is available on the APVMA website at: http://www.apvma.gov.au/chemrev/chlorpyrifos.shtm</p> <p>FSANZ noted the anomalies in the Code in relation to Codex standards for residues in tea and chillies and that there may be implications for trade as a consequence. MRLs harmonised with Codex limits are proposed for inclusion in the Code.</p> <p>The commodity name 'Peppers, Chili (dry)' is used for dried chillies in line with the Codex classification of foods and animal feeds.</p> <table border="0" data-bbox="177 1568 983 1930"> <tr> <td>Peppers, Chili (dry)</td> <td>Insert</td> <td>20</td> </tr> <tr> <td>Tea, green, black</td> <td>Insert</td> <td>2</td> </tr> <tr> <td>Vegetables [except asparagus; brassica vegetables; cassava; celery; leek; peppers, chili (dry); peppers, sweet; potato; swede; sweet potato; taro and tomato]</td> <td>Insert</td> <td>T*0.01</td> </tr> <tr> <td>Vegetables [except except asparagus; brassica vegetables; cassava; celery; leek; peppers, sweet; potato; swede; sweet potato; taro and tomato]</td> <td>Omit</td> <td>T*0.01</td> </tr> </table>	Peppers, Chili (dry)	Insert	20	Tea, green, black	Insert	2	Vegetables [except asparagus; brassica vegetables; cassava; celery; leek; peppers, chili (dry); peppers, sweet; potato; swede; sweet potato; taro and tomato]	Insert	T*0.01	Vegetables [except except asparagus; brassica vegetables; cassava; celery; leek; peppers, sweet; potato; swede; sweet potato; taro and tomato]	Omit	T*0.01	<p>NEDI: 94% of the ADI</p> <p>Mean estimated daily dietary exposure based on mean analytical results:</p> <p>20th ATDS: <1% of the ADI for all population groups assessed</p> <p>19th ATDS: 3% of the ADI for toddlers 2 years, 1% of the ADI for boys 12 years and <1% of the ADI for other population groups assessed</p> <table border="0" data-bbox="983 1500 1391 1635"> <tr> <td colspan="4">NESTI as % of the ARfD</td> </tr> <tr> <td></td> <td><u>2-6 years</u></td> <td></td> <td><u>2+ years</u></td> </tr> <tr> <td></td> <td>58</td> <td></td> <td>8</td> </tr> <tr> <td></td> <td><1</td> <td>Dried tea</td> <td><1</td> </tr> </table>	NESTI as % of the ARfD					<u>2-6 years</u>		<u>2+ years</u>		58		8		<1	Dried tea	<1
Peppers, Chili (dry)	Insert	20																											
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Requested MRLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)	Dietary Exposure Assessment																																							
<p>Ethoxysulfuron Ethoxysulfuron is a selective herbicide. It inhibits biosynthesis of essential amino acids valine and isoleucine leading to preventing cell division and plant growth. It is used to control nutgrass and certain broad leaf weeds in sugarcane.</p> <p>The APVMA has advised that residue trials were undertaken on sugarcane crops. The data indicate that the existing limits remain appropriate. The data are sufficient to remove the temporary status of the MRLs. Livestock consuming tops from mature cane crops will be exposed to negligible amounts of ethoxysulfuron.</p> <table border="0" data-bbox="177 622 983 864"> <tr> <td>Edible offal (mammalian)</td> <td>Omit</td> <td>T*0.05</td> </tr> <tr> <td></td> <td>Substitute</td> <td>*0.05</td> </tr> <tr> <td>Meat (mammalian)</td> <td>Omit</td> <td>T*0.05</td> </tr> <tr> <td></td> <td>Substitute</td> <td>*0.05</td> </tr> <tr> <td>Milks</td> <td>Omit</td> <td>T*0.01</td> </tr> <tr> <td></td> <td>Substitute</td> <td>*0.01</td> </tr> <tr> <td>Sugar cane</td> <td>Omit</td> <td>T*0.01</td> </tr> <tr> <td></td> <td>Substitute</td> <td>*0.01</td> </tr> </table>	Edible offal (mammalian)	Omit	T*0.05		Substitute	*0.05	Meat (mammalian)	Omit	T*0.05		Substitute	*0.05	Milks	Omit	T*0.01		Substitute	*0.01	Sugar cane	Omit	T*0.01		Substitute	*0.01	<p>NEDI: <1% of the ADI</p> <p>NESTI as % of the ARfD</p> <table border="0" data-bbox="991 562 1372 864"> <thead> <tr> <th></th> <th><u>2-6 years</u></th> <th><u>2+ years</u></th> </tr> </thead> <tbody> <tr> <td></td> <td><1</td> <td><1</td> </tr> </tbody> </table>		<u>2-6 years</u>	<u>2+ years</u>		<1	<1		<1	<1		<1	<1		<1	<1
Edible offal (mammalian)	Omit	T*0.05																																						
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<p>Fenvalerate Fenvalerate is a pyrethroid, non-systemic insecticide with contact and stomach action. It acts on the nervous system of insects and disrupts the function of neurons by interaction with the sodium channel. Internationally, it is used to control a wide range of chewing, sucking and boring insects in fruits, vines, hops, nuts, vegetables, oilseeds, cereals, tobacco, sugar cane, ornamentals and forestry; flying and crawling insects in public health and animal housing situations; and as an animal ectoparasiticide.</p> <p>Unilever Australasia requested that FSANZ consider including a fenvalerate MRL for tea in the Code harmonised with the European Union MRL of 0.05 mg/kg. Unilever made the request based on the Tea Global Plant Protection Initiative principle of progressing toward ensuring that tea is produced and traded in a compliant manner across international boundaries. Unilever provided information that fenvalerate is used in tea production in China, Indonesia and India to control lepidopterous larvae, shot hole borer, tea mosquito, mosquito bug, thrips and tea jassid. Legitimate residues may occur in tea imported to Australia from these countries. FSANZ has noted that without an MRL, there may be implications for trade in tea where no safety concerns have been identified. The proposed MRL would harmonise with applicable standards in other tea importing countries.</p> <table border="0" data-bbox="177 1630 983 1648"> <tr> <td>Tea, green, black</td> <td>Insert</td> <td>0.05</td> </tr> </table>	Tea, green, black	Insert	0.05	<p>NEDI: 47% of the ADI</p> <p>Mean estimated daily dietary exposure based on mean analytical results:</p> <p>20th ATDS: not detected in any foods sampled</p> <p>19th ATDS: <1% of the ADI for all population groups assessed</p>																																				
Tea, green, black	Insert	0.05																																						

Requested MRLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)	Dietary Exposure Assessment									
<p>Flubendiamide Flubendiamide is an insecticide. It is a ryanodine receptor agonist. It is used to control diamondback moth, cabbage white butterfly, cluster caterpillar, heliothis (<i>Helicoverpa</i> spp.), and soybean looper in various horticultural situations.</p> <p>The APVMA has issued a permit for its use to control heliothis and sucking pests on cotton.</p> <p>The NHC requested that FSANZ consider including flubendiamide MRLs in the Code for pome and stone fruits. The NHC provided information that the United States pome fruit industry does not have access to the Australian market. FSANZ understands that market access is some time away and on this basis considers that the requested MRL for pome fruits is not required in the Code at this stage. Cherries are imported from the United States and may legitimately contain flubendiamide residues. Including the proposed stone fruits MRL harmonised with the United States MRL in the Code may minimise potential trade disruption and extend consumer choice.</p> <table border="0" data-bbox="188 898 975 958"> <tr> <td>Cotton seed</td> <td>Insert</td> <td>T0.5</td> </tr> <tr> <td>Stone fruits</td> <td>Insert</td> <td>1.6</td> </tr> </table>	Cotton seed	Insert	T0.5	Stone fruits	Insert	1.6	<p>NEDI: 38% of the ADI</p>			
Cotton seed	Insert	T0.5								
Stone fruits	Insert	1.6								
<p>Fludioxonil Fludioxonil is a non-systemic fungicide. It inhibits mainly the germination of conidia and, to a lesser extent, the germ tube and mycelial growth. It inhibits kinase in osmotic signal transduction. It is used to control moulds in various field crop and horticultural situations.</p> <p>The APVMA has issued permits for its use to control grey mould (<i>Botrytis cinerea</i>) on eggplant and stem end rot and leaf blotch (<i>Gnomonia comari</i>) in strawberry.</p> <p>Corrs Chambers Westgarth requested on behalf of its client Roll Corporation (California) that FSANZ consider including a fludioxonil MRL for pomegranate in the Code harmonised with the United States MRL of 5 mg/kg. Information was provided that fludioxonil is used as a post harvest treatment in pomegranate production in the United States to control grey mould; pomegranates and pomegranate food products are exported from the United States to Australia; and these foods may legitimately contain fludioxonil residues. Including the proposed pomegranate MRL harmonised with the United States MRL in the Code may minimise potential trade disruption and extend consumer choice.</p> <table border="0" data-bbox="188 1664 975 1753"> <tr> <td>Egg plant</td> <td>Insert</td> <td>T0.2</td> </tr> <tr> <td>Pomegranate</td> <td>Insert</td> <td>5</td> </tr> <tr> <td>Strawberry</td> <td>Insert</td> <td>T5</td> </tr> </table>	Egg plant	Insert	T0.2	Pomegranate	Insert	5	Strawberry	Insert	T5	<p>NEDI: 22% of the ADI</p>
Egg plant	Insert	T0.2								
Pomegranate	Insert	5								
Strawberry	Insert	T5								

Requested MRLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)	Dietary Exposure Assessment
<p>Imidacloprid Imidacloprid is a systemic insecticide with contact and stomach action. It acts on the central nervous system of insects causing blockage of postsynaptic nicotinic acetylcholine receptors. It is used as a seed dressing, or soil or foliar treatment to control sucking insects including aphids, thrips and whitefly in cereals, oilseeds, fruits and vegetables.</p> <p>The APVMA has issued a permit for its use to control silverleaf whitefly (<i>Bemisia tabaci</i>) on navy beans.</p> <p>Common bean (dry) (navy bean) Insert T1</p>	<p>NEDI: 18% of the ADI</p> <p>NESTI as % of the ARfD <u>2-6 years</u> <u>2+ years</u> 2 <1</p>
<p>Indoxacarb Indoxacarb is an insecticide. It is active by contact and ingestion. It blocks sodium ion channels in nerve cells causing cessation of feeding, poor coordination, paralysis and ultimately death. It is used to control Lepidoptera in cotton, fruit and vegetables.</p> <p>The APVMA has issued a permit for its use to control native budworm (<i>Helicoverpa</i> spp.) and cluster caterpillar (<i>Spodoptera litura</i>) on protected and field grown culinary herbs.</p> <p>Coriander (leaves, stem, roots) Insert T20 Herbs Insert T20 Leafy vegetables [except lettuce, head] Omit 5 Leafy vegetables [except lettuce, head; rucola] Insert 5 Mexican tarragon Insert T20 Rucola (rocket) Insert T20</p>	<p>NEDI: 15% of the ADI</p> <p>NESTI as % of the ARfD <u>2-6 years</u> <u>2+ years</u> 10 5</p> <p>61 45</p>
<p>Iprodione Iprodione is a contact fungicide with protective and curative action. It inhibits spore germination and growth of fungal mycelium. It is used to control various moulds and rots including Sclerotinia (<i>Sclerotinia sclerotiorum</i>), grey mould (<i>Botrytis cinerea</i>) and Alternaria leaf spot (<i>Alternaria brassicae</i>) in cereals, oilseeds, pulses, nuts, fruits and vegetables.</p> <p>The APVMA has issued a permit for its use to control grey mould on eggplant in protected cropping situations.</p> <p>Egg plant Insert T7</p>	<p>NEDI: 44% of the ADI</p> <p>Mean estimated daily dietary exposure based on mean analytical results:</p> <p>20th ATDS – 1% of the ADI for adult males 25 – 34 years and toddlers 2 years and <1% of the ADI for other population groups assessed</p> <p>19th ATDS – 1% of the ADI for toddlers 2 years and <1% of the ADI for other population groups assessed</p>

Requested MRLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)	Dietary Exposure Assessment																																																																																							
<p>Methoxyfenozone Methoxyfenozone is an insecticide. It is a second generation ecdysone agonist. It causes cessation of feeding and premature lethal moult. It is primarily active by ingestion, but also with contact and ovicidal activity. It does not have translaminar or phloem-systemic properties. It is used to control various insect pests in cotton and tomato.</p> <p>The APVMA has approved an extension of its use to control various insect pests in apples, pears, citrus, grapevines, avocado, custard apple, kiwifruit, longan, lychee, macadamia, coffee, blueberries, eggplant, capsicum and chillies.</p> <table border="0"> <tr> <td>Avocado</td> <td>Insert</td> <td>0.5</td> </tr> <tr> <td>Blueberries</td> <td>Insert</td> <td>2</td> </tr> <tr> <td>Citrus fruits</td> <td>Insert</td> <td>1</td> </tr> <tr> <td>Coffee beans</td> <td>Insert</td> <td>0.2</td> </tr> <tr> <td>Custard apple</td> <td>Insert</td> <td>0.3</td> </tr> <tr> <td>Dried grapes</td> <td>Insert</td> <td>6</td> </tr> <tr> <td>Fruiting vegetables, other than cucurbits</td> <td>Insert</td> <td>3</td> </tr> <tr> <td>Grapes</td> <td>Insert</td> <td>2</td> </tr> <tr> <td>Kiwifruit</td> <td>Insert</td> <td>2</td> </tr> <tr> <td>Litchi</td> <td>Insert</td> <td>2</td> </tr> <tr> <td>Longan</td> <td>Insert</td> <td>2</td> </tr> <tr> <td>Macadamia nuts</td> <td>Insert</td> <td>0.05</td> </tr> <tr> <td>Pome fruits</td> <td>Insert</td> <td>0.5</td> </tr> <tr> <td>Tomato</td> <td>Omit</td> <td>3</td> </tr> </table>	Avocado	Insert	0.5	Blueberries	Insert	2	Citrus fruits	Insert	1	Coffee beans	Insert	0.2	Custard apple	Insert	0.3	Dried grapes	Insert	6	Fruiting vegetables, other than cucurbits	Insert	3	Grapes	Insert	2	Kiwifruit	Insert	2	Litchi	Insert	2	Longan	Insert	2	Macadamia nuts	Insert	0.05	Pome fruits	Insert	0.5	Tomato	Omit	3	<p>NEDI: 8% of the ADI</p> <p>NESTI as % of the ARfD</p> <table border="0"> <tr> <td></td> <td><u>2-6 years</u></td> <td><u>2+ years</u></td> </tr> <tr> <td></td> <td><1</td> <td><1</td> </tr> <tr> <td></td> <td>5</td> <td><1</td> </tr> <tr> <td></td> <td>8</td> <td>3</td> </tr> <tr> <td></td> <td><1</td> <td><1</td> </tr> <tr> <td></td> <td>2</td> <td><1</td> </tr> <tr> <td></td> <td>2</td> <td><1</td> </tr> <tr> <td></td> <td>8</td> <td>3</td> </tr> <tr> <td></td> <td>4</td> <td>2</td> </tr> <tr> <td></td> <td><1</td> <td>4</td> </tr> <tr> <td></td> <td>4</td> <td>1</td> </tr> <tr> <td></td> <td>8</td> <td>2</td> </tr> <tr> <td></td> <td>8</td> <td>2</td> </tr> <tr> <td></td> <td><1</td> <td><1</td> </tr> <tr> <td></td> <td>4</td> <td><1</td> </tr> </table> <p>Excluding wine 2 Wine only 4</p>		<u>2-6 years</u>	<u>2+ years</u>		<1	<1		5	<1		8	3		<1	<1		2	<1		2	<1		8	3		4	2		<1	4		4	1		8	2		8	2		<1	<1		4	<1
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<p>Metribuzin Metribuzin is a selective systemic herbicide. It acts as a photosynthetic electron transport inhibitor at the photosystem II receptor site of weeds. It is used for pre- and post-emergence control of many grass and broad leaf weeds in cereal, sugarcane and vegetable crops.</p> <p>The APVMA has approved an extension of its use to control weeds in canola. The recommended MRL is at the LOQ.</p> <table border="0"> <tr> <td>Rape seed (canola)</td> <td>Insert</td> <td>*0.02</td> </tr> </table>	Rape seed (canola)	Insert	*0.02	<p>NEDI: 5% of the ADI</p> <p>NESTI as % of the ARfD</p> <table border="0"> <tr> <td></td> <td><u>2-6 years</u></td> <td><u>2-6 years</u></td> </tr> <tr> <td></td> <td><1</td> <td>Edible oil <1</td> </tr> </table>		<u>2-6 years</u>	<u>2-6 years</u>		<1	Edible oil <1																																																																														
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<p>Myclobutanil Myclobutanil is a systemic fungicide with protective and curative action. It is translocated within the plant. It inhibits ergosterol biosynthesis. It is used in Australia to control powdery mildew on grape vines, pome fruits and strawberries.</p> <p>Dow AgroSciences requested that FSANZ include an MRL in the Code for myclobutanil residues in cherries harmonised with the Codex MRL. Dow provided information that myclobutanil is registered to control fungal diseases in cherry production in the United States and other countries and that residues consistent with the Codex MRL may occur in cherries exported to Australia. An MRL harmonised with the Codex limit is proposed for inclusion in the Code. This may minimise potential trade disruption and extend consumer choice.</p> <table border="0"> <tr> <td>Stone fruits [except plums]</td> <td>Insert</td> <td>2</td> </tr> </table>	Stone fruits [except plums]	Insert	2	<p>NEDI: 6% of the ADI</p> <p>20th ATDS: not detected in any foods sampled</p> <p>19th ATDS: not detected in any foods sampled</p>																																																																																				
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<p>Pyraclostrobin Pyraclostrobin is a fungicide. It inhibits mitochondrial respiration by blocking electron transfer at the cytochrome bc1 complex. It is used to control fungal diseases in fruit and vegetables.</p> <p>The APVMA has issued a permit for its use to control white blister rust (<i>Albugo candida</i>) in certain brassica vegetables.</p> <p>The NHC requested that FSANZ consider extending the apple pyraclostrobin MRL to pome fruits to include pear and to stone fruits to include cherries. The NHC provided information that the United States pome fruit industry does not have access to the Australian market. FSANZ understands that market access is some time away and on this basis considers that the requested MRL for pears is not required in the Code at this stage. Cherries are imported from the United States and may legitimately contain pyraclostrobin residues. Including the proposed MRL harmonised with the United States pyraclostrobin MRL for stone fruit in the Code may minimise potential trade disruption and extend consumer choice.</p> <table border="0" data-bbox="177 896 983 1084"> <tr> <td>Broccoli, Chinese</td> <td>Insert</td> <td>T1</td> </tr> <tr> <td>Brassica leafy vegetables</td> <td>Insert</td> <td>T3</td> </tr> <tr> <td>Stone fruits</td> <td>Insert</td> <td>0.9</td> </tr> </table>	Broccoli, Chinese	Insert	T1	Brassica leafy vegetables	Insert	T3	Stone fruits	Insert	0.9	<p>NEDI: 3% of the ADI</p> <p>NESTI as % of the ARfD</p> <table border="0" data-bbox="983 851 1390 1084"> <thead> <tr> <th></th> <th><u>2-6 years</u></th> <th><u>2+ years</u></th> </tr> </thead> <tbody> <tr> <td></td> <td>53</td> <td>17</td> </tr> <tr> <td></td> <td>55</td> <td>71</td> </tr> <tr> <td>26 Chinese cabbage, pak choi</td> <td></td> <td>71</td> </tr> <tr> <td>36 Komatsuma, mustard spinach</td> <td></td> <td>40</td> </tr> <tr> <td>2</td> <td></td> <td>1</td> </tr> </tbody> </table>		<u>2-6 years</u>	<u>2+ years</u>		53	17		55	71	26 Chinese cabbage, pak choi		71	36 Komatsuma, mustard spinach		40	2		1			
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<p>Pyrimethanil Pyrimethanil is a fungicide with protectant action. It inhibits fungal enzymes necessary for infection. It is used to control fungal diseases in a range of horticultural situations.</p> <p>DeGroot Technical Services requested on behalf of its client Janssen-Cilag Pty Limited that FSANZ consider harmonising with the Codex MRL for pome fruits of 7 mg/kg and the United States MRL for stone fruits of 10 mg/kg for pyrimethanil residues that may occur in these fruits. Information was provided that pyrimethanil is registered for post-harvest use on pome and stone fruits in Asian, European and American countries that may export these fruits to Australia. Pome fruits may be imported from Asia and cherries may be imported from the United States. These fruits may legitimately contain pyrimethanil residues. Including the proposed MRLs in the Code may minimise potential trade disruption and extend consumer choice.</p> <table border="0" data-bbox="177 1635 983 1937"> <tr> <td>Pome fruits</td> <td>Omit Substitute</td> <td>0.05 7</td> </tr> <tr> <td>Stone fruits</td> <td>Insert</td> <td>10</td> </tr> </table>	Pome fruits	Omit Substitute	0.05 7	Stone fruits	Insert	10	<p>NEDI: 14% of the ADI</p> <p>Mean estimated daily dietary exposure based on mean analytical results:</p> <p>20th ATDS: <1% of the ADI for all population groups assessed</p> <p>NESTI as % of the ARfD</p> <table border="0" data-bbox="983 1590 1390 1937"> <thead> <tr> <th></th> <th><u>2-6 years</u></th> <th><u>2+ years</u></th> </tr> </thead> <tbody> <tr> <td>50 Apple</td> <td></td> <td>12</td> </tr> <tr> <td>32 Pear</td> <td></td> <td>9</td> </tr> <tr> <td>32 Apricot</td> <td></td> <td>7</td> </tr> <tr> <td>20 Cherries</td> <td></td> <td>2</td> </tr> <tr> <td>35 Nectarine</td> <td></td> <td>15</td> </tr> <tr> <td>38 Peach</td> <td></td> <td>13</td> </tr> <tr> <td>36 Plums (including prunes)</td> <td></td> <td>10</td> </tr> </tbody> </table>		<u>2-6 years</u>	<u>2+ years</u>	50 Apple		12	32 Pear		9	32 Apricot		7	20 Cherries		2	35 Nectarine		15	38 Peach		13	36 Plums (including prunes)		10
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<p>Spirotetramat Spirotetramat is a cyclic ketoenole insecticide. It is a tetramic acid derivative. It inhibits acetyl CoA carboxylase, a key enzyme in fatty acid biosynthesis. It is active against a wide spectrum of sucking insects including aphids, scales, mealybugs, whiteflies, psyllids and certain thrips.</p> <p>The APVMA has approved its use to control silverleaf whitefly and various aphid, scale and thrip pests in certain fruit and vegetable crops. The recommended meat and milk MRLs are at the LOQ.</p> <p>The APVMA has issued a permit for its use to control certain pests on citrus fruits and mango.</p> <p>New chemical</p> <p>Insert residue definition: Sum of spirotetramat, and cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, expressed as spirotetramat.</p> <table border="0" data-bbox="177 958 986 1541"> <tr> <td>Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas [except Brussels sprouts]</td> <td>Insert</td> <td>T7</td> </tr> <tr> <td>Brussels sprouts</td> <td>Insert</td> <td>T1</td> </tr> <tr> <td>Citrus fruits</td> <td>Insert</td> <td>T1</td> </tr> <tr> <td>Cotton seed</td> <td>Insert</td> <td>T1</td> </tr> <tr> <td>Edible offal (mammalian)</td> <td>Insert</td> <td>T0.05</td> </tr> <tr> <td>Fruiting vegetables, cucurbits</td> <td>Insert</td> <td>T2</td> </tr> <tr> <td>Lettuce, head</td> <td>Insert</td> <td>T5</td> </tr> <tr> <td>Lettuce, leaf</td> <td>Insert</td> <td>T10</td> </tr> <tr> <td>Mango</td> <td>Insert</td> <td>T0.3</td> </tr> <tr> <td>Meat (mammalian)</td> <td>Insert</td> <td>T*0.01</td> </tr> <tr> <td>Milks</td> <td>Insert</td> <td>T*0.005</td> </tr> <tr> <td>Onion, bulb</td> <td>Insert</td> <td>T0.5</td> </tr> <tr> <td>Peppers, Sweet</td> <td>Insert</td> <td>T5</td> </tr> <tr> <td>Tomato</td> <td>Insert</td> <td>T7</td> </tr> </table>	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas [except Brussels sprouts]	Insert	T7	Brussels sprouts	Insert	T1	Citrus fruits	Insert	T1	Cotton seed	Insert	T1	Edible offal (mammalian)	Insert	T0.05	Fruiting vegetables, cucurbits	Insert	T2	Lettuce, head	Insert	T5	Lettuce, leaf	Insert	T10	Mango	Insert	T0.3	Meat (mammalian)	Insert	T*0.01	Milks	Insert	T*0.005	Onion, bulb	Insert	T0.5	Peppers, Sweet	Insert	T5	Tomato	Insert	T7	<p>NEDI: 15% of the ADI</p> <p>NESTI as % of the ARfD</p> <table border="0" data-bbox="994 927 1372 1541"> <thead> <tr> <th colspan="2"></th> <th><u>2-6 years</u></th> <th><u>2+ years</u></th> </tr> </thead> <tbody> <tr> <td>10</td> <td>Broccoli</td> <td>3</td> <td></td> </tr> <tr> <td>5</td> <td>Cabbage</td> <td>4</td> <td></td> </tr> <tr> <td>15</td> <td>Cauliflower</td> <td>6</td> <td></td> </tr> <tr> <td><1</td> <td></td> <td></td> <td><1</td> </tr> <tr> <td>4</td> <td></td> <td></td> <td>1</td> </tr> <tr> <td><1</td> <td></td> <td></td> <td><1</td> </tr> <tr> <td><1</td> <td></td> <td></td> <td><1</td> </tr> <tr> <td><</td> <td>Cucumber</td> <td><1</td> <td></td> </tr> <tr> <td>1</td> <td>Melon</td> <td><1</td> <td></td> </tr> <tr> <td>3</td> <td>Zucchini</td> <td><1</td> <td></td> </tr> <tr> <td>2</td> <td></td> <td>1</td> <td></td> </tr> <tr> <td>5</td> <td></td> <td>3</td> <td></td> </tr> <tr> <td>1</td> <td></td> <td><1</td> <td></td> </tr> <tr> <td><1</td> <td></td> <td><1</td> <td></td> </tr> <tr> <td><1</td> <td></td> <td><1</td> <td></td> </tr> <tr> <td><1</td> <td></td> <td><1</td> <td></td> </tr> <tr> <td>1</td> <td></td> <td><1</td> <td></td> </tr> <tr> <td>10</td> <td></td> <td>4</td> <td></td> </tr> </tbody> </table>			<u>2-6 years</u>	<u>2+ years</u>	10	Broccoli	3		5	Cabbage	4		15	Cauliflower	6		<1			<1	4			1	<1			<1	<1			<1	<	Cucumber	<1		1	Melon	<1		3	Zucchini	<1		2		1		5		3		1		<1		<1		<1		<1		<1		<1		<1		1		<1		10		4	
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<p>Tebuconazole Tebuconazole is a triazole fungicide. It is a non-systemic foliar fungicide with protective action. Tebuconazole It inhibits steroid demethylation leading to inhibition of ergosterol biosynthesis. It is used to control various fungal diseases in many crops.</p> <p>The APVMA has issued a permit for its use to control soybean rust (<i>Phakospora phachyrhizi</i>) in soybeans.</p> <p>Soya bean (dry) Insert T0.1</p>	<p>NEDI: 18% of the ADI</p> <p>20th ATDS: not detected in any foods sampled</p>																																																																																																																						

Safety Assessment Methodology

1.1 Determining the Residues of a Chemical in a Treated Food

The APVMA assesses a range of data when considering the proposed use of a chemical product on a food. These data enable the APVMA to determine what the likely residues of a chemical will be on a treated food. These data also enable the APVMA to determine what the maximum residues will be on a treated food if the chemical product is used as proposed and from this, the APVMA determines an MRL.

The MRL is the maximum level of a chemical that may be in a food and it is not the level that is usually present in a treated food. However, incorporating the MRL into food legislation means that the residues of a chemical are minimised (i.e. must not exceed the MRL), irrespective of whether the dietary exposure assessment indicates that higher residues would not risk public health and safety.

1.2 Determining the Acceptable Reference Health Standard for a Chemical in Food

The Office of Chemical Safety (OCS) assesses the toxicology of agricultural and veterinary chemicals and establishes the acceptable daily intake (ADI) and where appropriate, the acute reference dose (ARfD) for a chemical. In the case that an Australian ADI or ARfD has not been established, a Joint Food and Agriculture Organization / World Health Organization Meeting on Pesticide Residues (JMPR) ADI or ARfD may be used for risk assessment purposes if the OCS advises this is appropriate.

Both the APVMA and FSANZ use these reference health standards in dietary exposure assessments.

The ADI is the daily intake of an agricultural or veterinary chemical, which, during the consumer's entire lifetime, appears to be without appreciable risk to the health of the consumer. This is on the basis of all the known facts at the time of the evaluation of the chemical. It is expressed in milligrams of the chemical per kilogram of body weight.

The ARfD of a chemical is the estimate of the amount of a substance in food, expressed on a body weight basis that can be ingested over a short period of time, usually during one meal or one day, without appreciable health risk to the consumer, on the basis of all the known facts at the time of evaluation.

1.3 Calculating Dietary Exposure

The APVMA and FSANZ undertake chronic dietary exposure assessments for all agricultural and veterinary chemicals and undertake acute dietary exposure assessments where either the OCS or JMPR has established an ARfD.

The APVMA and FSANZ have agreed that all dietary exposure assessments for agricultural and veterinary chemicals undertaken by the APVMA will be based on food consumption data for raw commodities, derived from individual dietary records from the latest National Nutrition Survey (NNS) and chemical residue data provided by the APVMA or FSANZ. The Australian Bureau of Statistics with the then Australian Government Department of Health and Aged Care undertook the latest NNS over a 13-month period (1995 to early 1996).

The sample of 13,858 respondents aged 2 years and older was a representative sample of the Australian population and, as such, a diversity of food consumption patterns was reported.

1.3.1 *Chronic Dietary Exposure Assessment*

The National Estimated Daily Intake (NEDI) represents an estimate of chronic dietary exposure. Chemical residue data, as opposed to the MRL, are the preferred concentration data to use if they are available, as they provide a more realistic estimate of dietary exposure. The NEDI calculation may incorporate more specific data including food consumption data for particular sub-groups of the population. The NEDI calculation may take into account such factors as the proportion of the crop or commodity treated; residues in edible portions and the effects of processing and cooking on residue levels; and may use median residue levels from supervised trials rather than the MRL to represent pesticide residue levels. Monitoring and surveillance data or data from total diet studies may also be used, such as the 19th and 20th Australian Total Diet Surveys (ATDS).

FSANZ is currently undertaking the 23rd ATDS (now the Australian Total Diet Study). The study will analyse the levels of various agricultural and veterinary chemicals in food and estimate the potential dietary exposure of population groups in Australia to those chemicals.

In conducting chronic dietary exposure assessments, the APVMA and FSANZ consider the residues in foods that could result from the permitted uses of a chemical product. Where data are not available on the specific residues in a food then a cautious approach is taken and the MRL is used. The use of the MRL in dietary exposure estimates may result in considerable overestimates of exposure because it assumes that the chemical will be used on all crops for which there is a registered use or an approved permit; treatment occurs at the maximum application rate; the maximum number of permitted treatments have been applied; the minimum withholding period applies; and that the entire national crop contains residues equivalent to the MRL. In agriculture and animal husbandry this is not the case, but for the purposes of undertaking a risk assessment, it is important to be conservative in the absence of reliable data to refine the dietary exposure estimates further. In reality, only a portion of a specific crop is treated with a pesticide; most treated crops contain residues well below the MRL at harvest; and residues are usually reduced during storage, preparation, commercial processing and cooking. It is also unlikely that every food for which an MRL is proposed will have been treated with the same pesticide over the lifetime of consumers.

The residues that are likely to occur in all foods are multiplied by the mean daily consumption of these foods derived from individual dietary records from the latest NNS for all survey respondents regardless of whether they consumed the food or not. These calculations provide information on the level of a chemical that is consumed for each food and take into account the consumption of processed foods e.g. apple pie and bread. The estimated exposure for each food is added together to provide the total mean dietary exposure to a chemical from all foods with MRLs.

The estimated mean dietary exposure is then divided by the average Australian's bodyweight to provide the amount of chemical consumed per day per kg of human bodyweight.

1.3.2 *Acute Dietary Exposure Assessment*

The National Estimated Short Term Intake (NESTI) is used to estimate acute dietary exposure. Acute (short term) dietary exposure assessments are undertaken where the OCS has determined an ARfD for a chemical or advised that a JMPR ARfD is appropriate.

Acute dietary exposures are normally only estimated for raw unprocessed commodities (fruit and vegetables) but may include consideration of meat, offal, cereal, milk or dairy product consumption on a case-by-case basis.

The NESTI is calculated in a similar way to the chronic dietary exposure. Generally, the residues of a chemical in a specific food are multiplied by the 97.5th percentile food consumption of that food based on consumers only, if appropriate the exposure is divided by a mean body weight for the population group being assessed and this result is compared to the ARfD. The exact equations for calculating the NESTIs differ depending on the type or size of the commodity. These equations are set and used internationally. NESTIs are calculated from ARfDs set by the OCS or JMPR, consumption data from the 1995 NNS and the MRL when the data on the actual residues in foods are not available.

The NESTI calculation incorporates the large portion (97.5th percentile) food consumption data and can take into account such factors as the highest residue on a composite sample of an edible portion; the supervised trials median residue (STMR), representing typical residue in an edible portion resulting from the maximum permitted pesticide use pattern; processing factors which affect changes from the raw commodity to the consumed food and the variability factor where appropriate.

1.3.3 *Risk Characterisation*

The estimated mean chronic dietary exposure is compared to the ADI to characterise risk to the Australian population. FSANZ considers that the chronic and acute dietary exposure to the residues of a chemical is acceptable where the best estimates of mean chronic and acute dietary exposure do not exceed the ADI or ARfD.

Background Information

1.1 Maximum Residue Limits

The MRL is the highest concentration of a chemical residue that is legally permitted or accepted in a food. The MRL does not indicate the amount of chemical that is always present in a treated food but it does indicate the highest residue that could possibly result from the registered conditions of use. The concentration is expressed in milligrams of the chemical per kilogram (mg/kg) of the food.

MRLs in the Code apply in relation to the sale of food under State and Territory food legislation and the inspection of imported foods by the Australian Quarantine and Inspection Service. MRLs assist in indicating whether an agricultural or veterinary chemical product has been used according to its registered use and if the MRL is exceeded then this indicates a likely misuse of the chemical product. MRLs are also used as standards for international trade in food. In addition, MRLs, while not direct public health limits, act to protect public health and safety by minimising residues in food consistent with the effective control of pests and diseases.

Some of the proposed MRLs in this Proposal are at the limit of quantification (LOQ) and are indicated by an * in front of the MRL. The LOQ is the lowest concentration of an agricultural or veterinary chemical residue that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis. MRLs at the LOQ mean that no detectable residues of the relevant chemical should occur. FSANZ incorporates MRLs at the LOQ in the Code to assist in identifying a practical benchmark for enforcement. Future developments in methods of detection may lead to lowering these limits.

Some of the proposed MRLs in this Application are temporary and are indicated by a 'T' in front of the MRL. These MRLs may include uses associated with the APVMA minor use program; off-label permits for minor and emergency uses; or trial permits for research.

FSANZ does not issue permits or grant permission for the temporary use of agricultural and veterinary chemicals. Further information on permits for the use of agricultural and veterinary chemicals can be found on the APVMA website at www.apvma.gov.au or by contacting the APVMA on +61 2 6210 4700.

1.2 Use of Agricultural and Veterinary Chemicals

In Australia, the APVMA is responsible for assessing and registering agricultural and veterinary chemical products, and regulating them up to the point of sale. Following the sale of such products, the use of the chemicals is regulated by State and Territory 'control of use' legislation.

Before registering a product, the APVMA independently evaluates its safety and performance, making sure that the health and safety of consumers, those handling or applying the chemical, animals, crops and the environment are protected. This evaluation includes a dietary exposure assessment where appropriate. When a chemical product is registered for use or a permit for use approved, the APVMA includes MRLs in The MRL Standard.

MRLs assist States and Territories in regulating the use of agricultural and veterinary chemicals.

1.3 Maximum Residue Limit Notifications and Submissions

After registering agricultural or veterinary chemical products or conducting a review based on scientific evaluations, the APVMA notifies FSANZ to incorporate the MRL variations in Standard 1.4.2 of the Code.

Appropriate toxicology, residue, animal transfer, processing and metabolism studies are provided to the APVMA in accordance with *The Manual of Requirements and Guidelines – MORAG – for Agricultural and Veterinary Chemicals 1 July 2005* to support the requested MRLs.

Reports for individual chemicals are available on request from the relevant Project Coordinator at FSANZ on +61 2 6271 2222.

FSANZ is committed to ensuring that the implications of MRL variations are considered. Under the current process for considering variations to the Code, FSANZ encourages submissions including specific data demonstrating a need for certain MRLs to be retained or varied. FSANZ will consider retaining MRLs proposed for deletion or reduction where these MRLs are necessary to continue to allow the sale of safe food; and where the MRLs are supported by adequate data or information demonstrating that the residues associated with these MRLs do not raise any public health or safety concerns. Further information on data requirements may be obtained from FSANZ.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection.

FSANZ may also consider varying limits for residues of agricultural or veterinary chemicals in food in a Proposal where interested parties have identified anomalies between the Code and international standards that may result in adverse impacts. FSANZ must have regard to its WTO obligations, the promotion of consistency between domestic and international food standards; and the promotion of fair trading in food. These matters encompass a consideration of international standards and trade issues. The assessment gives careful consideration to public health and safety and includes public consultation.

FSANZ reviews the information provided and validates whether the estimated dietary exposure is within appropriate safety limits. If satisfied that the residues are within safety limits and subject to adequate resolution of any issues raised during public consultation, FSANZ will agree to incorporate the proposed limits in the Code.

FSANZ notifies the Ministerial Council when variations to the Code are approved. If the Ministerial Council does not request a review of the draft variations, the changes are gazetted and automatically adopted by reference into the food laws of the Australian States and Territories.

1.4 Antibiotics

Applicants seeking to register antibiotics for veterinary uses are required to provide suitable data to the Office of Chemical Safety to permit establishment of an ADI based on a microbiological endpoint as well as a toxicological one. The ADI is based on whichever is the most sensitive. This ensures that any antibiotic residues which may be present in food will not facilitate the development of antibiotic resistance in the microflora of the colon when ingested.

The National Health and Medical Research Council (NHMRC), with reference to the former Expert Advisory Group on Antimicrobial Resistance (EAGAR), has developed the principles by which government and regulatory agencies conduct assessments on antimicrobial resistance issues and measures designed to reduce the risk of antimicrobial resistance developing.

As part of its registration and chemical review processes, the APVMA conducts rigorous risk assessments for new antibiotics and extensions of indications, applying the NHMRC/EAGAR principles, to determine the likely impact on the efficacy of antibiotics that are essential for human therapeutics. If the risk of antimicrobial resistance associated with a proposed use pattern can not be adequately managed, the APVMA will not grant registration for that use pattern.

The APVMA consults with the NHMRC and other independent experts on risk assessments for antibiotics. Formerly the NHMRC provided advice on antimicrobial resistance issues via EAGAR. EAGAR's term of appointment expired on 31 December 2007 and the Committee has not been reappointed. Currently the NHMRC draws on members of its Expert Panel on Health Advice in regard to provision of advice to agencies on antimicrobial resistance.

1.5 Australia and New Zealand Joint Food 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 agricultural and veterinary chemicals in food from the system setting joint food standards. Australia and New Zealand independently and separately develop MRLs for agricultural and veterinary chemicals in food.

The Trans Tasman Mutual Recognition Arrangement (TTMRA) between Australia and New Zealand commenced on 1 May 1998. The following provisions apply under the TTMRA.

- Food produced or imported into Australia that complies with Standard 1.4.2 of the Code can be legally sold in New Zealand.
- Food produced or imported into New Zealand that complies with the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2008 (and amendments) can be legally sold in Australia.