FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

PROPOSAL M1004
MAXIMUM RESIDUE LIMITS (SEPTEMBER-DECEMBER 2008, JANUARY-MARCH 2009) EXPLANATORY STATEMENT

Executive Summary

Purpose

The purpose of this Proposal is to consider incorporating certain 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 approved 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 approved limits do not present any public health and safety concerns. This Proposal does not include 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 residues of 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 made a Sanitary and Phytosanitary notification to the World Trade Organization (WTO). The United States Government provided comments. FSANZ has addressed the issues raised in section 9 of this Report.

This Proposal has been assessed under the General Procedure.

Assessing the Proposal

In assessing the Proposal and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters as 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.

Decision

To approve the amended variations to Standard 1.4.2 – Maximum Residue Limits.

Reasons for Decision

This Proposal has been assessed against the considerations provided for in section 59 of the FSANZ Act. FSANZ has approved the amended 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 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 variations will benefit the community by maintaining public health and safety while permitting the legal sale of food with 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 and Environmental Health (OCSEH) 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 variations are necessary, cost-effective and beneficial.

- The variations remove inconsistencies between agricultural and food standards and provide certainty and consistency for producers, importers and Australian, State and Territory compliance agencies.

- The changes are consistent with the FSANZ Act section 18 objectives.

Consultation

FSANZ has now completed public consultation and further assessment of Proposal M1004. The Board has approved the amendments to the Code and this decision has been notified to the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council). If the Ministerial Council does not request that FSANZ review the amendments to the Code, an amendment to the Code will be published in the *Commonwealth Gazette* and the *New Zealand Gazette* and adopted by reference and without amendment under State and Territory food legislation.

Amendments following Public Consultation

FSANZ sought public comment on the draft variations shown at **Attachment 1B**. Taking into account comments received and further assessment, FSANZ amended the draft variations. The approved variations are provided at **Attachment 1A**.

The approved variations include the following:

- Inserting an MRL of 1.2 mg/kg for chlorantraniliprole residues in table grapes in the Code in addition to the MRL of 0.3 mg/kg for grapes proposed at Assessment. Consequently, the grape MRL excludes table grapes.

- Inserting MRLs of 5 mg/kg for myclobutanil, 2.5 mg/kg for pyraclostrobin and 0.7 mg/kg for quinoxyfen in cherries in the Code. These limits for residues that may occur in cherries are higher than those proposed at Assessment.

The variations were amended as residues may occur in foods at these levels following the controlled use of chemical products. No health or safety concerns were identified in relation to these changes. The amended variations minimise potential trade disruption and may benefit industry and consumers through greater choice and access to the relevant foods and food products. FSANZ's consideration of incorporating these MRLs in the Code is discussed in section 9.1.1 of this Report.

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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). These notifications include maximum residue limits (MRLs) gazetted by the APVMA from September 2008 to March 2009. The approved variations to the Code align 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 containing legitimate residues.

This Proposal also included consideration of MRLs for bifenthrin, boscalid, chlorantraniliprole, 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 approved variations to the Code would align limits in the Code with Codex or other standards and permit the sale of relevant foods containing legitimate residues at levels that do not present health or safety concerns in the context of the Australian diet.

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

In summary, this Proposal included 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. It also included consideration of some clarifications to the Standard and amendments to certain commodity names.

The variations to the Code are at **Attachments 1A** and **1B**. An explanatory statement of the approved variations is at **Attachment 2A**. An outline of these variations including the dietary exposure estimates is at **Attachment 2B**. A summary of comments received on the Assessment Report is provided at **Attachment 3**. The safety assessment methodology is outlined in **Attachment 4**; this includes an explanation of terms used in this Report.

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 the residues of a chemical that may be in a food, not the level that is usually present in a food. However, incorporating the limit in 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 use 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 with 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. Some limits are also listed in Standard 1.3.1 – Food Additives. If a limit is not listed for a particular agricultural or veterinary chemical/food combination, there must be no detectable residues of that chemical in that food. This general prohibition means that in the absence of the relevant limit in the Code, food may not be sold where there are detectable residues.

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 5**.

3. Objectives

In assessing this Proposal, FSANZ ensured that approving the variations to the Code did 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 Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council).

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 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/s (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 4**.

RISK ASSESSMENT

5. Risk Assessment Summary

FSANZ has reviewed the dietary exposure assessments conducted by the APVMA and conducted dietary exposure assessments to assess the limits requested by other parties. Using the best available scientific data and internationally recognised risk assessment methodology, FSANZ concluded that in relation to current reference health standards, the approved limits do 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

The following options were consulted on in the assessment of this Proposal.

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 changes. FSANZ sought public comment on the draft variations, and considered the issues raised in further assessment of the proposed changes.

7.1 Affected Parties

The sectors of the community potentially affected by the approved amendments include:

- consumers
- growers and producers
- importers of agricultural produce and food products
- the chemical industry
- Australian Government and 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. The risk assessment has determined that there are no public health or safety concerns associated with this option. No additional costs to consumers were identified.

This option benefits growers and producers in Australia 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 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 these variations already.

Importers may benefit by the approval of the variations. Additional or increased MRLs may benefit importers and, consequently, consumers in that this may extend the options to source safe foods. The variations are unlikely to result in any costs for importers as no MRLs were considered for reduction or deletion in this Proposal. Nevertheless, MRL variations have the potential to restrict importation of foods and could potentially result in higher food prices and a reduced product range available to consumers.

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 were invited to comment on any impacts of the proposed variations during the public consultation period. This was to ensure that any adverse consequences of the proposed variations could 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

This option has similar costs and benefits to option 1. FSANZ considered the comments received and amended the draft variations. This is discussed in section 9.1.1 of this Report. The approved variations are provided at **Attachment 1A** and the draft variations consulted on at Assessment are at **Attachment 1B**.

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 residues that may be present in foods following 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. Importers and consequently consumers may be disadvantaged where proposed MRL variations are not progressed as this may unnecessarily limit sources of certain foods.

In addition, the anomalies between the Code and international standards identified by industry and other interested parties 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.

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.

For the following reasons, FSANZ approved option 2 – approve the draft variations subject to such amendments as FSANZ considers necessary:

- 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.

- The necessity to amend the proposed variations to allow for the importation and sale of certain foods was identified through consultation and further assessment.

Option 1 was not recommended at the Approval stage as the need to amend the proposed draft variations was identified through consultation and further assessment. This is discussed in section 9.1.1 of this Report.

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 certain produce or foods internationally and potentially impact consumers through higher food prices and limited choice. Also, consequential 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 2 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 changes to the Code are being contemplated.

FSANZ publishes the details of proposed changes and subsequent reports on its website (www.foodstandards.gov.au), 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 community 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

Public comment was sought to assist in finalising the assessment of the changes to the Code proposed in the Assessment Report. The changes proposed at Assessment are provided at **Attachment 1B** to this Report. Comments were invited 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 to this Proposal.

Submissions were received from the California Grape and Tree Fruit League (CGTFL), the California Table Grape Commission (CTGC), the Food and Beverage Importers Association (FBIA), the Food Technology Association of Australia (FTAA), the United States Northwest Horticultural Council (NHC), the NSW Food Authority, the Queensland Government, Unilever Australasia (Unilever) and the Victorian Government.

FSANZ notified this Proposal to the World Trade Organization (WTO) and received comments from the United States.

Submissions from the FBIA, FTAA, the NSW Food Authority, the Queensland Government, Unilever and the Victorian Government support approving the proposed draft variations.

FSANZ thanks all submitters for their comments. There is a summary of comments provided at **Attachment 3**.

9.1 Issues raised in submissions

The CTGC and the United States Government requested that FSANZ consider harmonising with the United States or Codex chlorantraniliprole MRL for table grapes to avoid potential trade disruption. The NHC raised concern that a number of proposed stone fruit and pome fruit MRLs are lower than the corresponding United States MRLs. The NHC and United States Government also raised a trade concern in relation to cherries and the proposed pyraclostrobin MRL. The CGTFL and NHC requested that FSANZ consider harmonising with a number of United States stone fruit and cherry MRLs in future.

The FBIA endorsed certain proposed MRLs that align with Codex and other standards in recognition of residues that may occur in imported foods. Unilever supports consideration of MRLs for a wider range of imported foods where supporting information is provided. The FTAA expressed the view that the Code should recognise APVMA MRLs by reference. The FTAA and Victorian Government noted that a cypermethrin MRL of 0.5 mg/kg was proposed at Assessment for tea while the corresponding Codex MRL is 20 mg/kg.

9.1.1 Higher MRLs required for residues in grapes and cherries

The CTGC and the United States Government requested that FSANZ consider harmonising the chlorantraniliprole MRL for table grapes with the United States (1.2 mg/kg) or Codex (1 mg/kg) limit on the basis that the lower MRL of 0.3 mg/kg proposed at Assessment could become an impediment to trade in table grapes.

The NHC raised concern in relation to cherries and proposed myclobutanil, pyraclostrobin and quinoxyfen MRLs that are lower than corresponding United States MRLs. Where growers use products in accordance with approved label conditions in the United States, residues on cherries may be higher than the proposed MRL where the United States MRL is higher. Cherries are exported to Australia and trade may be disrupted. The NHC and CGTFL noted that the United States pyraclostrobin MRL for stone fruit was recently increased from 0.9 mg/kg to 2.5 mg/kg. The United States Government also raised concern that the proposed MRL for pyraclostrobin on cherries may result in a significant impact on trade.

9.1.1.1 FSANZ evaluation

FSANZ consulted on including an MRL of 0.3 mg/kg for chlorantraniliprole residues that may occur in grapes in the Code. FSANZ noted that the corresponding Codex MRL is 1 mg/kg. The proposed MRL was requested by the APVMA and as such relates to residues that may be expected to occur in grapes following the approved conditions of use of chlorantraniliprole in grape production in Australia.

FSANZ also consulted on including MRLs of 2 mg/kg for myclobutanil, 0.9 mg/kg for pyraclostrobin and 0.4 mg/kg for quinoxyfen in the Code for residues that may occur in cherries. FSANZ noted that the corresponding Codex pyraclostrobin MRL is 1 mg/kg. The pyraclostrobin MRL was requested by the NHC and the myclobutanil and quinoxyfen MRLs were requested by Dow AgroSciences. These chemicals are registered to control fungal diseases in cherry production in other countries including the United States. The pyraclostrobin MRL proposed at Assessment harmonised with the then corresponding United States MRL and the proposed myclobutanil and quinoxyfen MRLs harmonised with Codex limits.

Submitters identified that trade could potentially be disrupted as a result of the proposed changes and provided information substantiating that higher MRLs may be required for residues of these chemicals that may occur in grapes and cherries imported to Australia.

In the development or variation of food regulatory measures, FSANZ must have regard to the promotion of consistency between domestic and international food standards; and the promotion of fair trading in food. There are MRLs listed in United States food standards of 1.2 mg/kg for chlorantraniliprole in table grapes and 5 mg/kg for myclobutanil, 2.5 mg/kg for pyraclostrobin and 0.7 mg/kg for quinoxyfen in cherries. These MRLs relate to the registered use of these chemicals in the production of grapes and cherries there. These foods may be imported to Australia from the United States and could legitimately contain residues consistent with these limits.

FSANZ notes that Australia is an important market for United States grapes and cherries and that harmonised standards reduce the potential for trade disruption.

FSANZ conducted assessments of potential dietary exposure to residues of chlorantraniliprole, myclobutanil, pyraclostrobin and quinoxyfen encompassing all foods in which these residues may occur.

FSANZ concluded that MRLs of 1.2 mg/kg for chlorantraniliprole in table grapes and 5 mg/kg for myclobutanil, 2.5 mg/kg for pyraclostrobin and 0.7 mg/kg for quinoxyfen in cherries do not present any public health or safety concerns. The estimated dietary exposure to residues of these chemicals, including any residues that may occur in grapes and cherries at the level of the MRLs considered, does not exceed the relevant reference health standards. The dietary exposure estimates are provided at **Attachment 2B**.

FSANZ decided to include an MRL of 1.2 mg/kg for chlorantraniliprole residues in table grapes in the Code in addition to the MRL of 0.3 mg/kg for grapes proposed at Assessment. Consequently, the grape MRL excludes table grapes.

FSANZ also decided to include MRLs of 5 mg/kg for myclobutanil, 2.5 mg/kg for pyraclostrobin and 0.7 mg/kg for quinoxyfen in cherries in the Code.

No health or safety concerns were identified in relation to these changes. The amended variations minimise potential trade disruption and may benefit industry and consumers through greater choice and access to the relevant foods and food products. The approved variations to the Code are at **Attachment 1A**.

9.1.2 Consideration of a cypermethrin MRL for tea, green, black

The FTAA and Victorian Government raised a potential anomaly to be considered in that an MRL of 0.5 mg/kg for cypermethrin in tea was proposed at Assessment whereas the Codex limit is 20 mg/kg. The FTAA noted that the APVMA MRL Standard does not include a corresponding MRL.

9.1.2.1 FSANZ evaluation

FSANZ consulted on including an MRL of 0.5 mg/kg for cypermethrin residues that may occur in tea in the Code. FSANZ noted that the corresponding Codex MRL is 20 mg/kg. The proposed MRL, harmonised with the corresponding European Union MRL, was requested by Unilever. Cypermethrin is used to control insect pests in tea production in several countries and residues may occur in imported tea. 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. The MRL would harmonise with applicable standards in other tea importing countries.

Where there is a Codex MRL corresponding to any proposed MRL variation in the Code, FSANZ identifies this in the Assessment Report so that any ramifications of the proposed change identified through consultation can be considered.

FSANZ notes that no submitters requested consideration of an alternative limit for cypermethrin residues in tea or provided any information indicating that the Codex or another MRL may be required.

MRLs in the APVMA *MRL Standard* reflect residues that may occur in foods following the registered or permitted use of chemical products in food production in Australia whereas MRLs in the Code relate to residues that may occur in food available in Australia. Cypermethrin is not registered or permitted for use in tea production in Australia. There is no MRL listed in the *MRL Standard* as cypermethrin residues are not expected to occur in tea produced in Australia.

FSANZ decided to include an MRL of 0.5 mg/kg for cypermethrin residues in tea, green, black in the Code as proposed at Assessment. The dietary exposure estimate and further detail is provided at **Attachment 2B**.

9.1.3 Various MRLs requested for stone fruits and comments on pome fruits MRLs

The CGTFL and NHC and requested that FSANZ consider harmonising with a number of United States stone fruit and cherry MRLs in future. The NHC raised concern that some proposed pome fruit MRLs are lower than the corresponding United States MRLs.

The CGTFL expressed appreciation of the acknowledgement that good agricultural practice (GAP) may differ between production regions and the effort to harmonise MRLs where possible. The CGTFL noted that the United States does not export peaches, plums, nectarines or apricots to Australia and requested consideration of certain MRLs for these fruits in the next Proposal. This request was made on the basis that it is important for the industry to assist in establishing appropriate standards that recognise the crop protection products used in California should the market become available.

The NHC commended action taken by FSANZ to move quickly and include many chemicals important to United States Pacific Northwest pome fruit and stone fruit growers. The NHC noted that the proposed methoxyfenozide, pyrimethanil and spinetoram MRLs for pome fruit are lower than the corresponding United States MRLs and while the United States does not export pome fruit to Australia, these MRLs may disrupt future trade should the market open.

The NHC requested in its submission and in other correspondence that FSANZ consider including several MRLs in the Code in Proposal M1005 for cherries harmonised with certain United States limits. The NHC noted that limits for acetamiprid, azoxystrobin and fenarimol are a priority.

9.1.3.1 FSANZ evaluation

FSANZ is committed to maintaining limits in the Code that reflect residues that may occur in food; this ensures that such food may be sold. FSANZ may consider including MRLs in the Code harmonised with those established by a trading partner in certain circumstances including that the residues are likely to occur in food available in Australia, do not present safety concerns and are associated with the controlled use of chemical products. FSANZ notes that the United States is an important trading partner and appreciates the importance to growers of having MRLs in place in anticipation of gaining market access.

There are MRLs listed in the Code corresponding to some of the requested limits. Also, FSANZ notes that the APVMA established a spinetoram MRL for stone fruits of 0.2 mg/kg and it was considered in this Proposal. FSANZ decided to include this MRL in the Code as proposed at Assessment. This MRL corresponds with an MRL requested by the CGTFL.

FSANZ may consider the NHC requests for consideration of certain MRLs for cherries in future. FSANZ is liaising with the NHC in this regard.

However, as United States stone fruits other than cherries do not have access to the Australian market, the requested MRLs for these fruits are not required in the Code at this stage. This is because the residues associated with the requested MRLs are not expected to occur in food available in Australia. Also, as noted by the NHC, the United States does not export pome fruit to Australia. Should the stone fruit or pome fruit market become available to United States growers, the CGTFL and NHC would be welcome to raise any concerns regarding MRLs with FSANZ.

9.1.4 MRL-setting

The FTAA considers that there should only be one list of MRLs for Australia and it should be the APVMA list.

The FTAA considers that the Code should note this list by reference and that this would ensure consistency, noting that any change to the list would be immediate rather than up to or more than 12 months out of sequence with the APVMA list as at present. The FTAA noted that this view has been stated several times in previous submissions on MRL Proposals.

The FBIA endorsed certain proposed MRLs that align with Codex and other standards in recognition of residues that may occur in imported foods. The FBIA notes that setting certain proposed limits for chemical residues in cherries, stone fruits and chillies would be in line with the Ministerial Council Policy Guideline on the Regulation of Residues of Agricultural and Veterinary Chemicals in Food (Policy Guideline). Unilever considers that the Policy Guideline is a welcome development and anticipates alternative approaches to address the issues surrounding the current 'zero tolerance' approach to the regulation of residues of agricultural and veterinary chemicals in food. Unilever supports consideration of MRLs for a wider range of imported foods where supporting information is provided.

9.1.4.1 FSANZ evaluation

The Council of Australian Governments (COAG) Ministerial Taskforce on chemicals and plastics regulation is addressing the process of setting MRLs and having them recognised in food legislation in Australia. COAG identified reform in this area as a high priority. This work is being progressed by other agencies, primarily the Australian Government Department of Health and Ageing.

The time delay between the approval for use of an agricultural or veterinary chemical product by the APVMA and the inclusion of the appropriate MRLs in the Code is a longstanding issue. Policy and legislative change is required to eliminate this delay. Consideration of this issue is outside the scope of this Proposal.

FSANZ is cognisant of the potential implications of the time delay for stakeholders and, with the APVMA, continues to examine, and where possible implement administrative change to streamline processes ahead of much anticipated reform in this area.

In relation to the comments received from submitters on the Policy Guideline, FSANZ notes that consideration of policy issues cannot be made as part of an MRL proposal for varying particular MRLs and that these issues may be considered following the COAG reforms.

In the interim, the current approach allows FSANZ to consider specific residue limits for inclusion in the Code, such as Codex or other requested MRLs where appropriate. FSANZ assessed MRLs for fourteen chemicals requested by interested parties from various sectors in this Proposal. FSANZ considers that this is an efficient approach to assessing the safety and legitimacy of limits for potential residues in imported foods. FSANZ remains committed to ensuring that practical and flexible mechanisms exist to consider standards for residues in food and encourages interested parties to continue to engage with us on residues issues.

9.2 World Trade Organization (WTO)

As a member of the WTO, Australia is obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

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 included 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.

FSANZ made a notification to the WTO for this Proposal in accordance with the WTO Agreement on the Application of Sanitary and Phytosanitary Measures.

The United States provided comments on proposed chlorantraniliprole and pyraclostrobin MRLs in relation to potential trade impacts on table grapes and cherries exported to Australia. The comments are addressed above in section 9.1.1 of this Report. The United States also raised concern that the proposed MRL for methoxyfenozide on pome fruit is more restrictive than the Codex or United States limits. FSANZ notes that the United States did not request that FSANZ consider any alternative methoxyfenozide MRL for inclusion in the Code and that United States pome fruit do not currently have access to the Australian market. Market access issues are beyond the scope of this Proposal. FSANZ understands that the Australian Government Department of Agriculture, Fisheries and Forestry is addressing market access for apples from the United States. Following an announcement on market access, the United States would be welcome to raise any issues regarding MRLs for apples with FSANZ.

In conclusion, FSANZ may consider including MRLs in the Code consistent with international standards for specific food/chemical combinations where residues associated with the controlled use of a chemical product do not present safety concerns in the context of the Australian diet and are likely to occur in food available in Australia. This approach ensures openness and transparency in relation to the residues that could reasonably occur in food and that the assessment of dietary exposure to chemical residues is as accurate as possible.

FSANZ advises member nations where there are Codex MRLs relevant to any food/chemical combination for which a MRL variation is proposed and specifically identifies them in consultation documents. This is done so that impacts identified by member nations exporting relevant foods to Australia can be considered.

9.3 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.

Interested parties provided information that specific anomalies between the Code and Codex or other standards may present barriers to trade in certain foods. This Proposal included consideration of limits for bifenthrin, boscalid, chlorantraniliprole, chlorpyrifos, cypermethrin, fenvalerate, flubendiamide, fludioxonil, lambda-cyhalothrin (cyhalothrin), myclobutanil, permethrin, pyraclostrobin, pyrimethanil and quinoxyfen to address these issues. Further detail is provided in section 9.1.1 and at **Attachment 2B**. The approved variations to the Code would align limits in the Code with international standards or standards in countries producing and exporting relevant food to Australia and permit the sale of food containing legitimate residues that do not present health or safety concerns.

The following table lists limits approved in this Proposal where there is a corresponding Codex limit.

Chemical Food	**Approved limit**[†‡] **mg/kg**	**Codex limit** **mg/kg**
Abamectin		
Melons, except watermelon	T0.02	*0.01
Peppers	T0.02	Peppers, Sweet 0.02
Watermelon	T0.02	*0.01
Amitraz		
Edible offal (mammalian)	0.5	Edible offal of cattle, pigs and sheep 0.2
Meat (mammalian)	0.1	Cattle meat 0.05 Pig meat 0.05 Sheep meat 0.1
Boscalid		
Stone fruits	1.7	3
Chlorantraniliprole		
Celery	5	7
Cotton seed	0.3	0.3
Edible offal (mammalian)	*0.01	*0.01
Eggs	0.03	*0.01
Fruiting vegetables, cucurbits	0.2	0.3
Fruiting vegetables, other than cucurbits [except peppers, chilli]	0.3	Fruiting vegetables, other than cucurbits, except mushrooms and sweet corn 0.6
Grapes [except table grapes]	0.3	Grapes 1
Leafy vegetables [except lettuce, head; rucola]	15	Leafy vegetables 20
Lettuce, head	3	
Rucola (rocket)	T20	
Meat (mammalian) (in the fat)	*0.01	Meat (from mammals other than marine mammals) (fat) *0.01
Milks	*0.01	*0.01 Milk fats 0.1
Peppers, Chili	1	Chilli peppers (dry) 5
Pome fruits	0.3	0.4
Potato	*0.01	Root and tuber vegetables 0.02
Poultry, edible offal of	*0.01	*0.01
Poultry meat (in the fat)	*0.01	*0.01
Stone fruits	1	1
Table grapes	1.2	Grapes 1
Chlorpyrifos		
Peppers, Chili (dry)	20	Chilli peppers (dry) 20
Tea, green, black	2	2
Cypermethrin		
Tea, green, black	0.5	20
Cyprodinil		
Egg plant	T0.2	0.2
Strawberry	T5	2
Fludioxonil		
Egg plant	T0.2	0.3
Strawberry	T5	3
Metalaxyl		
Peppers	T1	1

Chemical Food	**Approved limit**[†‡] **mg/kg**	**Codex limit** **mg/kg**
Methoxyfenozide		
Dried grapes	6	Dried grapes (=currants, raisins and sultanas) 3
Fruiting vegetables, other than cucurbits	3	Peppers 2 Sweet corn (corn-on-the-cob) *0.02 Tomato 2
Grapes	2	1
Macadamia nuts	0.05	Tree nuts 0.1
Pome fruits	0.5	2
Myclobutanil		
Cherries	5	Stone fruits [except plums] 2
Permethrin		
Cherries	4	Stone fruits 2
Pyraclostrobin		
Broccoli, Chinese	T1	Flowerhead brassicas 0.1
Brassica leafy vegetables	T3	Kale 1
Cherries	2.5	Stone fruits 1
Pyrimethanil		
Pome fruits	7	7
Stone fruits	10	Apricot 3 Cherries 4 Nectarine 4 Peach 4 Plums (including prunes) 2
Quinoxyfen		
Cherries	0.7	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
Meat (mammalian) (in the fat)	2	Cattle meat 1 Meat (from mammals other than marine mammals) (fat) except cattle 2
Spirotetramat		
Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas [except Brussels sprouts]	T7	Cabbages, Head 2 Flowerhead brassicas 1
Brussels sprouts	T1	
Citrus fruits	T1	0.5
Edible offal (mammalian)	T0.05	0.03
Fruiting vegetables, cucurbits	T2	0.2
Lettuce, head	T5	Leafy vegetables 7
Lettuce, leaf	T10	
Meat (mammalian)	T*0.01	Meat (from mammals other than marine mammals) *0.01
Milks	T*0.005	*0.005
Peppers, Sweet	T5	Fruiting vegetables, other than cucurbits, except mushrooms and sweet corn 1
Tomato	T7	

Chemical Food	Approved limit[†‡] mg/kg	Codex limit mg/kg
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.

9.4 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 MRLs approved in this Proposal where there is a corresponding limit in the New Zealand MRL Standards.

Chemical Food	Approved 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 Cherries	2.5	Stone fruits 0.02(*)
Spinetoram Pome fruits	0.1	Apples 0.05 Pears 0.05

Chemical Food	Approved MRL[†] mg/kg	NZ MRL[‡] mg/kg
Spinosad		
Edible offal (mammalian)	0.5	Sheep fat 2 Sheep kidney 0.5 Sheep liver 0.5
Meat (mammalian) (in the fat)	2	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.

9.5 Imported Foods

Internationally, countries set MRLs according to 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 legitimately differ from those in domestically produced foods.

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 varied. FSANZ will consider amending proposed MRL variations where 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 in the context of the Australian diet.

FSANZ sought comment on any ramifications for imported foods of the proposed MRLs. The approved and proposed variations to the Code are at **Attachments 1A** and **1B** and the recommended changes are outlined in **Attachments 2A** and **B**.

Interested parties commented on proposed chlorantraniliprole, myclobutanil, pyraclostrobin and quinoxyfen MRLs in relation to potential trade impacts on imported table grapes and cherries (refer section 9.1.1).

Conclusion

10. Conclusion and Decision

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

Decision

To approve the amended variations to Standard 1.4.2 – Maximum Residue Limits.

10.1 Reasons for Decision

FSANZ approved the amended 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 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 variations will benefit stakeholders by maintaining public health and safety while permitting the legal sale of food with 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 OCSEH 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 variations are necessary, cost-effective and beneficial.

- The variations remove inconsistencies between agricultural and food standards and provide certainty and consistency for producers, importers and Australian, State and Territory compliance agencies.

- The 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

- 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.

The variations in this Proposal take effect on gazettal and the limits are subject to existing monitoring arrangements.

ATTACHMENTS

1A. Variations to the *Australia New Zealand Food Standards Code* (at Approval)
1B. Draft variations to the *Australia New Zealand Food Standards Code* (at Assessment)
2A. Explanatory statement of variations to Standard 1.4.2 (at Approval)
2B. Summary of Limits Approved in Proposal M1004
3. Summary of Submissions
4. Safety Assessment Methodology
5. Background Information

Attachment 1A

Variations to the *Australia New Zealand Food Standards Code* (at Approval)

Section 87(8) of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunsetting

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(3) –*

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 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 *N*-(2,4-DIMETHYLPHENYL)-*N'*-METHYLFORMAMIDINE, EXPRESSED AS N-(2,4-DIMETHYLPHENYL)-N'-METHYLFORMAMIDINE

[1.11] *inserting in* Schedule 1 –

CHLORANTRANILIPROLE *PLANT COMMODITIES AND ANIMAL COMMODITIES OTHER THAN MILK*: CHLORANTRANILIPROLE *MILK*: SUM OF CHLORANTRANILIPROLE, 3-BROMO-*N*-[4-CHLORO-2-(HYDROXYMETHYL)-6-[(METHYLAMINO)CARBONYL]PHENYL]-1-(3-CHLORO-2-PYRIDINYL)-1*H*-PYRAZOLE-5-CARBOXAMIDE, AND 3-BROMO-*N*-[4-CHLORO-2-(HYDROXYMETHYL)-6-[[((HYDROXYMETHYL)AMINO)CARBONYL]PHENYL]-1-(3-CHLORO-2-PYRIDINYL)-1*H*-PYRAZOLE-5-CARBOXAMIDE, EXPRESSED AS CHLORANTRANILIPROLE	
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 [EXCEPT TABLE 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
TABLE GRAPES	1.2

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 *COMMODITIES OF PLANT ORIGIN*: FLUBENDIAMIDE *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	
COTTON SEED	T0.5
STONE FRUITS	1.6
FLUDIOXONIL *COMMODITIES OF ANIMAL ORIGIN:* SUM OF FLUDIOXONIL AND OXIDISABLE METABOLITES, EXPRESSED AS FLUDIOXONIL *COMMODITIES OF PLANT ORIGIN:* FLUDIOXONIL	
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 *R*-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 *SEE ALSO* THIODICARB	
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	
CHERRIES	5
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

PRAZIQUANTEL PRAZIQUANTEL	
FISH MUSCLE/SKIN	T*0.01
PROPICONAZOLE PROPICONAZOLE	
SUNFLOWER SEED	T2
PYMETROZINE PYMETROZINE	
LEAFY HERBS	T10
PYRACLOSTROBIN *COMMODITIES OF PLANT ORIGIN*: PYRACLOSTROBIN *COMMODITIES OF ANIMAL ORIGIN*: 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
CHERRIES	2.5
PYRIMETHANIL PYRIMETHANIL	
STONE FRUITS	10
QUINOXYFEN QUINOXYFEN	
CHERRIES	0.7
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
ETHOXYSULFURON *COMMODITIES OF PLANT ORIGIN*: ETHOXYSULFURON *COMMODITIES OF ANIMAL ORIGIN*: 2-AMINO-4,6-DIMETHOXYPYRIMIDINE, EXPRESSED AS ETHOXYSULFURON	
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

Attachment 1B

Draft variations to the *Australia New Zealand Food Standards Code* (at Assessment)

Section 87(8) of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunsetting

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 i*n 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] o*mitting 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 *N*-(2,4-DIMETHYLPHENYL)-*N'*-METHYLFORMAMIDINE, EXPRESSED AS N-(2,4-DIMETHYLPHENYL)-N'-METHYLFORMAMIDINE

[1.11] *inserting in* Schedule 1 –

CHLORANTRANILIPROLE *PLANT COMMODITIES AND ANIMAL COMMODITIES OTHER THAN MILK*: CHLORANTRANILIPROLE *MILK*: SUM OF CHLORANTRANILIPROLE, 3-BROMO-*N*-[4-CHLORO-2-(HYDROXYMETHYL)-6-[(METHYLAMINO)CARBONYL]PHENYL]-1-(3-CHLORO-2-PYRIDINYL)-1*H*-PYRAZOLE-5-CARBOXAMIDE, AND 3-BROMO-*N*-[4-CHLORO-2-(HYDROXYMETHYL)-6-[[((HYDROXYMETHYL)AMINO)CARBONYL]PHENYL]-1-(3-CHLORO-2-PYRIDINYL)-1*H*-PYRAZOLE-5-CARBOXAMIDE, EXPRESSED AS CHLORANTRANILIPROLE	
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 *COMMODITIES OF PLANT ORIGIN*: FLUBENDIAMIDE *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	
COTTON SEED	T0.5
STONE FRUITS	1.6
FLUDIOXONIL *COMMODITIES OF ANIMAL ORIGIN:* SUM OF FLUDIOXONIL AND OXIDISABLE METABOLITES, EXPRESSED AS FLUDIOXONIL *COMMODITIES OF PLANT ORIGIN:* FLUDIOXONIL	
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 *R*-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 *SEE ALSO* THIODICARB	
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
PRAZIQUANTEL PRAZIQUANTEL	
FISH MUSCLE/SKIN	T*0.01

PROPICONAZOLE PROPICONAZOLE	
SUNFLOWER SEED	T2
PYMETROZINE PYMETROZINE	
LEAFY HERBS	T10
PYRACLOSTROBIN *COMMODITIES OF PLANT ORIGIN*: PYRACLOSTROBIN *COMMODITIES OF ANIMAL ORIGIN*: 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
ETHOXYSULFURON *COMMODITIES OF PLANT ORIGIN*: ETHOXYSULFURON *COMMODITIES OF ANIMAL ORIGIN*: 2-AMINO-4,6-DIMETHOXYPYRIMIDINE, EXPRESSED AS ETHOXYSULFURON	
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 2A

Explanatory statement of variations to Standard 1.4.2 (at Approval)

Item 1.1

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

Item 1.2

The 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 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 intended 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 deletes 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 change clarifies that subclause (2) is not intended to exclude veterinary chemicals.

Items 1.9 to 1.14

These items amend the substantive provisions in Schedule 1 of Standard 1.4.2. The rationale for those changes is described in the Assessment Report.

Attachment 2B

Summary of Limits Approved in Proposal M1004

INTERPRETIVE GUIDE TO THE SUMMARY TABLE OF MRLS

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.

Chemical name

The NEDI is an assessment of the chronic exposure which is compared to the acceptable daily intake (ADI).

Information about the chemical is provided so the community can see what it is and why residues may occur in food.

Chlorpyrifos 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. The APVMA has approved an extension of its use to control certain pests in coffee crops.	NEDI = 93% of the ADI Mean estimated daily dietary exposure based on mean analytical results: 20th ATDS: <1% of the ADI for all population groups assessed 19th ATDS: 3% of the ADI for toddlers 2 years and <1% of ADI for other population groups assessed NESTI as % of the ARfD 2-6 years: 8 2+ years: <1
Coffee beans — Insert — T*0.5	

Food/s for which the proposed MRL is to apply.

Whether the proposed MRL is being added or deleted.

The NESTI is an assessment of the acute exposure which is compared to the acute reference dose (ARfD).

The '*' means that the MRL is at the limit of quantification and detectable residues should not occur in the food.

The 'T' means the MRL is temporary and under review.

SUMMARY OF MRLS APPROVED IN PROPOSAL M1004
APVMA MRLS – SEPTEMBER 2008 – MARCH 2009 AND OTHER REQUESTS

Requested MRLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			**Dietary Exposure Assessment**		
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. The APVMA has issued permits for its use to control two spotted mite (*Tetranychus urticae*) and western flower thrip (*Frankliniella occidentalis*) on chillies and paprika (capsicum); and two spotted mite on melons.			NEDI: 78% of the ADI NESTI as % of the ARfD		
			2-6 years		2+ years
Melons, except watermelon	Insert	T0.02	24		9
Peppers	Insert	T0.02	1	Chilli	<1
Peppers, sweet	Omit	0.02	4	Capsicum	2
Watermelon	Insert	T0.02	24		25
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. The APVMA has recommended extending the existing MRLs to all relevant species. Amendment to residue definition Omit: Sum of amitraz and N-(2,4-dimethylphenyl)-N'-methylformamidine, expressed as amitraz Substitute: Sum of amitraz and *N*-(2,4-dimethylphenyl)-*N*'-methylformamidine, expressed as N-(2,4-dimethylphenyl)- N'-methylformamidine			NEDI: 84% of the ADI NESTI as % of the ARfD		
			2-6 years		2+ years
Edible offal of cattle, pigs and sheep	Omit	0.5			
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
Bifenthrin Bifenthrin is a synthetic pyrethroid insecticide. It kills insects by affecting the salt balance (sodium channels) in nerve cells. It has a broad spectrum of activity against insects with the main toxic effect on the nervous system. It is used to control a broad range of foliar pests on cereal, fruit and vegetable crops in Australia and internationally. Unilever Australasia requested that FSANZ consider including a bifenthrin MRL for tea in the Code harmonised with the European Union MRL of 5 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 bifenthrin is used in tea production in China, Indonesia and India to control tea mosquito, tea jassid, lepidopterous larvae and various mites. 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 approved MRL would harmonise with applicable standards in other tea importing countries. Tea, green, black	Insert	5	NEDI: 82% of the ADI Mean estimated daily dietary exposure based on mean analytical results: 20th ATDS: <1% of the ADI for all population groups assessed
Boscalid Boscalid is a fungicide. It inhibits spore germination, germ tube elongation, mycelial growth and sporulation by inhibition of succinate ubiquinone reductase (complex II) in the mitochondrial electron transport chain. It is used to control powdery mildew on a range of fruit and vegetables in Australia and internationally. The United States Northwest Horticultural Council (NHC) requested that FSANZ consider extending the apple boscalid MRL to pome fruits to include pear and that a limit for stone fruits including cherries harmonised with the United States MRL be established. 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 boscalid residues. Including the approved MRL in the Code harmonised with the United States MRL may minimise potential trade disruption and extend consumer choice. Stone fruits	Insert	1.7	NEDI: 9% of the ADI NESTI as % of the ARfD 2-6 years: 1 2+ years: 1

Requested MRLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment
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. 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. Edible offal (mammalian) Meat (mammalian) Meat (mammalian) (in the fat)	Omit Substitute Omit Insert	*0.02 T0.5 *0.02 T0.05	NEDI: 25% of the ADI
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. The APVMA has issued a permit for its use to control powdery mildew on eggplant. Egg plant	Insert	T1	NEDI: 3% of the ADI 20th ATDS: not detected in any foods sampled 19th ATDS: not detected in any foods sampled
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. The APVMA has issued a permit for its use to control whitefly (*Trialeurodes* spp.) in celery. Celery	Insert	T1	NEDI: 23% of the ADI NESTI as % of the ARfD 2-6 years — 2+ years 3 Celery <1 3 Celery, raw <1

Requested MRLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)	Dietary Exposure Assessment
Chlorantraniliprole 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). The APVMA has issued a permit for its use to control native budworm (*Helicoverpa* spp.) and cluster caterpillar (*Spodoptera litura)* on culinary herbs. Note: The California Table Grape Commission and the United States Government requested that FSANZ harmonise with the United States MRL of 1.2 mg/kg or the Codex MRL of 1 mg/kg for residues that may occur in table grapes produced there and exported to Australia. FSANZ has completed its assessment and approved an MRL of 1.2 mg/kg for table grapes. This is discussed in section 9.1.1 of this Report. New chemical Insert residue definition: *Plant commodities and animal commodities other than milk*: Chlorantraniliprole *Milk*: Sum of chlorantraniliprole, 3-bromo-*N*-[4-chloro-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide, and 3-bromo-*N*-[4-chloro-2-(hydroxymethyl)-6-[[((hydroxymethyl)amino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide, expressed as chlorantraniliprole	NEDI: <1% of the ADI

Requested MRLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment
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 [except table 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	
Table grapes	Insert	1.2	

Requested MRLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment
Chlorpyrifos 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. 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 Beverage Importers Association 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. 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.shtml 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 approved for inclusion in the Code. The commodity name 'Peppers, Chili (dry)' is used for dried chillies in line with the Codex classification of foods and animal feeds.			NEDI: 94% of the ADI Mean estimated daily dietary exposure based on mean analytical results: 20th ATDS: <1% of the ADI for all population groups assessed 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 NESTI as % of the ARfD 2-6 years 2+ years 58 8 <1 Dried tea <1
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 asparagus; brassica vegetables; cassava; celery; leek; peppers, sweet; potato; swede; sweet potato; taro and tomato]	Omit	T*0.01	

Requested MRLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment
Clothianidin Clothianidin is an insecticide. It is an agonist of the nicotinic acetylcholine receptor, affecting the synapses in the insect central nervous system. It is used to control various pests in pome and stone fruits, bananas and cotton. The APVMA has issued a permit for its use to control pests in sugarcane. Sugar cane	Insert	T0.2	NEDI: 3% of the ADI NESTI as % of the ARfD 2-6 years 2+ years <1 Sugar cane <1 molasses
Cypermethrin Cypermethrin is a pyrethroid, non-systemic insecticide with contact and stomach action. It acts on the central and peripheral nervous system in very low doses. It is used to control a wide range of chewing and sucking insect pests in cereal, legume and oilseed crops and horticultural situations internationally. Unilever Australasia requested that FSANZ consider including a cypermethrin MRL for tea in the Code harmonised with the European Union MRL of 0.5 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 noted that this Initiative is supported by the Food and Agriculture Organisation Inter-Governmental Group on Tea. Unilever provided information that cypermethrin 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 approved MRL would harmonise with applicable standards in other tea importing countries. Tea, green, black	Insert	0.5	NEDI: 10% of the ADI Mean estimated daily dietary exposure based on mean analytical results: 20th ATDS: not detected in any foods sampled 19th ATDS: <1% of the ADI for all population groups assessed NESTI as % of the ARfD 2-6 years 2+ years <1 <1
Cyprodinil Cyprodinil is a systemic foliar fungicide. It inhibits biosynthesis of methionine and the secretion of fungal hydrolytic enzymes. It is transported throughout the tissue and acropetally in the xylem. It inhibits penetration and mycelial growth both inside the plant and on leaf surfaces. It is used to control moulds in horticultural situations. The APVMA has issued permits for its use to control botrytis rots (grey mould) on eggplant and stem end rot and leaf blotch (*Gnomonia comari*) in strawberry. Egg plant Strawberry	Insert Insert	T0.2 T5	NEDI: 19% of the ADI

Requested MRLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment	
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. 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.			NEDI: <1% of the ADI NESTI as % of the ARfD	
			2-6 years	2+ years
Edible offal (mammalian)	Omit	T*0.05		
	Substitute	*0.05	<1	<1
Meat (mammalian)	Omit	T*0.05		
	Substitute	*0.05	<1	<1
Milks	Omit	T*0.01		
	Substitute	*0.01	<1	<1
Sugar cane	Omit	T*0.01		
	Substitute	*0.01	<1	<1
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. 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 approved MRL would harmonise with applicable standards in other tea importing countries. Tea, green, black	Insert	0.05	NEDI: 47% of the ADI Mean estimated daily dietary exposure based on mean analytical results: 20th ATDS: not detected in any foods sampled 19th ATDS: <1% of the ADI for all population groups assessed	

Requested MRLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment
Flubendiamide Flubendiamide is an insecticide. It is a ryanodine receptor agonist. It is used to control diamondback moth, cabbage white butterfly, cluster caterpillar, heliothis (*Helicoverpa* spp.), and soybean looper in various horticultural situations. The APVMA has issued a permit for its use to control heliothis and sucking pests on cotton. The United States Northwest Horticultural Council (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 approved stone fruits MRL harmonised with the United States MRL in the Code may minimise potential trade disruption and extend consumer choice. Cotton seed Stone fruits	 Insert Insert	 T0.5 1.6	NEDI: 38% of the ADI
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. The APVMA has issued permits for its use to control grey mould (*Botrytis cinerea*) on eggplant and stem end rot and leaf blotch (*Gnomonia comari*) in strawberry. 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 approved pomegranate MRL harmonised with the United States MRL in the Code may minimise potential trade disruption and extend consumer choice. Egg plant Pomegranate Strawberry	 Insert Insert Insert	 T0.2 5 T5	NEDI: 22% of the ADI

Requested MRLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment	
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. The APVMA has issued a permit for its use to control silverleaf whitefly (*Bemisia tabaci*) on navy beans.			NEDI: 18% of the ADI NESTI as % of the ARfD	
			2-6 years	2+ years
Common bean (dry) (navy bean)	Insert	T1	2	<1
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. The APVMA has issued a permit for its use to control native budworm (*Helicoverpa* spp.) and cluster caterpillar (*Spodoptera litura)* on protected and field grown culinary herbs.			NEDI: 15% of the ADI NESTI as % of the ARfD	
			2-6 years	2+ years
Coriander (leaves, stem, roots)	Insert	T20		
Herbs	Insert	T20	10	5
Leafy vegetables [except lettuce, head]	Omit	5		
Leafy vegetables [except lettuce, head; rucola]	Insert	5		
Mexican tarragon	Insert	T20		
Rucola (rocket)	Insert	T20	61	45
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 (*Sclerotinia sclerotiorum*), grey mould (*Botrytis cinerea*) and Alternaria leaf spot (*Alternaria brassicae*) in cereals, oilseeds, pulses, nuts, fruits and vegetables. The APVMA has issued a permit for its use to control grey mould on eggplant in protected cropping situations.			NEDI: 44% of the ADI Mean estimated daily dietary exposure based on mean analytical results: 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 19th ATDS – 1% of the ADI for toddlers 2 years and <1% of the ADI for other population groups assessed	
Egg plant	Insert	T7		

Requested MRLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment	
Lambda-cyhalothrin Lambda-cyhalothrin is a synthetic pyrethroid insecticide. It is a sodium channel modulator. It causes excessive stimulation of neurons by preventing the closure of voltage sensitive sodium channels. It is used to control a wide range of insect pests in cereal, fruit and vegetable crops. Unilever Australasia requested that FSANZ consider including an MRL for lambda-cyhalothrin residues in tea in the Code harmonised with the European Union MRL of 1 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 lambda-cyhalothrin is used in tea production in China, Indonesia and India to control lepidopterous larvae, shot hole borer, tea mosquito, mosquito bug, thrips, jelly bugs, chafer grubs and aphids. 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 approved MRL would harmonise with applicable standards in other tea importing countries. Note: MRLs for lambda-cyhalothrin are listed under cyhalothrin			NEDI: 63% of the ADI NESTI as % of the ARfD 2-6 years: 2 2+ years: 2	
Tea, green, black	Insert	1		
Metalaxyl Metalaxyl is a systemic fungicide with protective and curative action. It inhibits protein synthesis. It is used to control various fungal blights, root and crown rots, mildews and purple blotch in a wide range of crops. The APVMA has issued a permit for its use to control downy mildew (*Peronospora* spp.) in field grown capsicums and chillies.			NEDI: 16% of the ADI Mean estimated daily dietary exposure based on mean analytical results: 20th ATDS: <1% of the ADI for all population groups assessed	
Peppers	Insert	T1		
Vegetables [except as otherwise listed under this chemical]	Omit	0.1		
Vegetables [except bulb vegetables; fruiting vegetables, cucurbits; leafy vegetables; peppers; podded pea (young pods) (snow and sugar snap)]	Insert	T0.1		
Methomyl Methomyl is a carbamate insecticide and acaricide with contact and stomach action. It is a cholinesterase inhibitor. It is used to control a wide range of pests on cereals, oilseeds, nuts, fruits and vegetables. The APVMA has issued a permit for its use to control heliothis (*Helicoverpa* spp.), cucumber moth (*Diaphania indica*) and cluster caterpillar (*Spodoptera litura*) on sweet potato.			NEDI: 75% of the ADI 19th ATDS: not detected in any foods sampled NESTI as % of ARfD 2-6 years: 10 2+ years: 12	
Sweet potato	Insert	T1		

Requested MRLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment		
Methoxyfenozide Methoxyfenozide 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. 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.			NEDI: 8% of the ADI NESTI as % of the ARfD		
			2-6 years		2+ years
Avocado	Insert	0.5	<1		<1
Blueberries	Insert	2	5		<1
Citrus fruits	Insert	1	8		3
Coffee beans	Insert	0.2	<1		<1
Custard apple	Insert	0.3	2		<1
Dried grapes	Insert	6	2		<1
Fruiting vegetables, other than cucurbits	Insert	3	8		3
Grapes	Insert	2	4	Excluding wine	2
			<1	Wine only	4
Kiwifruit	Insert	2	4		1
Litchi	Insert	2	8		2
Longan	Insert	2	8		2
Macadamia nuts	Insert	0.05	<1		<1
Pome fruits	Insert	0.5	4		<1
Tomato	Omit	3			
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. The APVMA has approved an extension of its use to control weeds in canola. The recommended MRL is at the LOQ.			NEDI: 5% of the ADI NESTI as % of the ARfD		
			2-6 years		2-6 years
Rape seed (canola)	Insert	*0.02	<1	Edible oil	<1

Requested MRLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)	Dietary Exposure Assessment
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. 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 of 2 mg/kg was proposed for inclusion in the Code at Assessment on the basis that this may minimise potential trade disruption and extend consumer choice. Note: The United States Northwest Horticultural Council requested that FSANZ harmonise with the United States MRL as residues may occur up to that level in cherries exported to Australia. FSANZ has completed its assessment and approved an MRL of 5 mg/kg. This is discussed in section 9.1.1 of this Report. Cherries Insert 5	NEDI: 5% of the ADI 20th ATDS: not detected in any foods sampled 19th ATDS: not detected in any foods sampled
Oxamyl Oxamyl is a systemic oxime carbamate insecticide, acaricide and nematicide absorbed by foliage and roots. It has contact action; translocation occurs within plants. It is a cholinesterase inhibitor. It is used to control chewing and sucking insects, spider mites and nematodes in fruit, vegetables, cereals and other crops. The APVMA has issued a permit for its use to control root knot nematode (*Meloidogyne* spp.) in sweet potato. Sweet potato Insert T0.5	NEDI: 23% of the ADI NESTI as % of the ARfD 2-6 years 2+ years 46 57

Requested MRLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment
Permethrin Permethrin is a non-systemic synthetic pyrethroid insecticide. It has contact and stomach action. It acts on the nervous system of insects, disturbing the function of neurons by interaction with the sodium channel. It has a slight repellent effect. It is used in Australia to control pests on a wide range of crops. The Food and Beverage Importers Association requested that FSANZ consider incorporating an MRL in the Code harmonised with the United States MRL for permethrin residues in cherries. Mount Erin Pacific Limited requested that FSANZ consider including the Codex MRL for permethrin residues in cherries in the Code. Both provided information that cherries are exported to Australia from the United States, permethrin is registered for use in cherry production there and legitimate residues may occur. FSANZ noted the discrepancy in the Code in relation to Codex standards for permethrin residues in cherries and that there may be implications for trade as a consequence. The relevant Codex permethrin MRL for cherries is the stone fruits 2 mg/kg MRL. An MRL harmonised with the United States MRL is approved for inclusion in the Code. This may minimise potential cherry trade disruption and extend consumer choice. Cherries	Insert	4	NEDI: 16% of the ADI Mean estimated daily dietary exposure based on mean analytical results: 20th ATDS: <1% of the ADI for all population groups assessed 19th ATDS: <1% of the ADI for all population groups assessed
Phenmedipham Phenmedipham is a selective systemic herbicide. It inhibits photosynthetic electron transport at the photosystem II receptor site. It is used to control broad leaf weeds in beets and other vegetables. The APVMA has issued a permit for its use to control broad leaf weeds in transplanted chicory, endive, radicchio, silverbeet and spinach. Chard (silver beet) Chicory leaves Endive Radicchio Spinach	Insert Insert Insert Insert Insert	T0.2 T0.2 T0.2 T0.2 T0.2	NEDI: 11% of the ADI
Praziquantel Praziquantel is a systemic anthelmintic. Absorption by parasitic worms induces an instantaneous tetanic contraction of the parasitic musculature and vacuolisation of the tegument. It is used to treat worm infections. The APVMA has issued a permit for its use to control ectoparasitic monogenean flukes (*Benedenia seriolae* and *Zeuxapta seriolae*) in yellowtail kingfish and mulloway in certain situations. The APVMA has advised that the concentrations of praziquantel residues in muscle and skin (in natural proportions) of treated fish are likely to be non-detectable i.e. <0.01 mg/kg. Therefore the recommended MRL is at the LOQ. Fish muscle/skin	Insert	T*0.01	NEDI: <1% of the ADI

Requested MRLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment
Propiconazole Propiconazole is a triazole systemic foliar fungicide with protective and curative action. It inhibits steroid demethylation, leading to inhibition of ergosterol biosynthesis. It is used to control certain fungal diseases in cereal crops and various horticultural situations. The APVMA has issued a permit for its use to control powdery mildew in sunflower. Sunflower seed	Insert	T2	NEDI: 6% of the ADI Mean estimated daily dietary exposure based on mean analytical results: 20th ATDS: <1% of the ADI for all population groups assessed NESTI as % of the ARfD 2-6 years: <1 2+ years: <1
Pymetrozine Pymetrozine is an azomethine insecticide. It is selective against Homoptera, causing them to stop feeding. It is used to control juvenile and adult stages of aphids and whitefly in vegetables, fruit and cotton. The APVMA has issued a permit for its use to control aphids in herbs. Leafy herbs	Insert	T10	NEDI: 22% of the ADI

Requested MRLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment		
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. The APVMA has issued a permit for its use to control white blister rust (*Albugo candida*) in certain brassica vegetables. The United States Northwest Horticultural Council (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 an MRL harmonised with the United States pyraclostrobin MRL for residues that may occur in cherries in the Code may minimise potential trade disruption and extend consumer choice. Note: The NHC and other submitters noted that the United States stone fruits MRL was recently increased from 0.9 mg/kg to 2.5 mg/kg and requested that FSANZ consider harmonising with the new higher level for residues that may occur in cherries exported to Australia. FSANZ has completed its assessment and approved an MRL of 2.5 mg/kg for cherries. This is discussed in section 9.1.1 of this Report.			NEDI: 1% of the ADI NESTI as % of the ARfD		
			<u>2-6 years</u>		<u>2+ years</u>
Broccoli, Chinese	Insert	T1	53		17
Brassica leafy vegetables	Insert	T3	55		71
			26	Chinese cabbage, pak choi	71
			36	Komatsuma, mustard spinach	40
Cherries	Insert	2.5	86	Cherries	23
			20	Cherries, dried	2

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<tr><th>Requested MRLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)</th><th>Dietary Exposure Assessment</th></tr>
<tr><td>
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.

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 approved MRLs in the Code may minimise potential trade disruption and extend consumer choice.

Pome fruits — Omit — 0.05
Substitute — 7

Stone fruits — Insert — 10
</td><td>
NEDI: 10% of the ADI

Mean estimated daily dietary exposure based on mean analytical results:

20th ATDS: <1% of the ADI for all population groups assessed

NESTI as % of the ARfD
<table>
<tr><th>2-6 years</th><th></th><th>2+ years</th></tr>
<tr><td>50</td><td>Apple</td><td>12</td></tr>
<tr><td>32</td><td>Pear</td><td>9</td></tr>
<tr><td>32</td><td>Apricot</td><td>7</td></tr>
<tr><td>20</td><td>Cherries</td><td>2</td></tr>
<tr><td>35</td><td>Nectarine</td><td>15</td></tr>
<tr><td>38</td><td>Peach</td><td>13</td></tr>
<tr><td>36</td><td>Plums (including prunes)</td><td>10</td></tr>
</table>
</td></tr>
<tr><td>
Quinoxyfen
Quinoxyfen is a fungicide. It inhibits appressorial development in fungi (appressoria are specialised cells that are important in plant penetration and pathogenesis). In Australia it is used to protect against powdery mildew in grapes and herbs.

Dow AgroSciences requested that FSANZ include an MRL in the Code for quinoxyfen residues in cherries harmonised with the Codex MRL of 0.4 mg/kg. Dow provided information that quinoxyfen 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 was proposed for inclusion in the Code on the basis that this may minimise potential trade disruption and extend consumer choice.

Note: The United States Northwest Horticultural Council requested that FSANZ harmonise with the United States MRL as residues may occur up to that level in cherries exported to Australia. FSANZ has completed its assessment and approved an MRL of 0.7 mg/kg. This is discussed in section 9.1.1 of this Report.

Cherries — Insert — 0.7
</td><td>
NEDI: <1% of the ADI
</td></tr>
</table>

Requested MRLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment
Spinetoram Spinetoram is a spinosyn insecticide. It has contact and stomach action. It excites the insect nervous system, leading to involuntary muscle contractions, tremors and paralysis. The APVMA has approved its use to control codling moth, light brown apple moth, loopers and oriental fruit moth in pome and stone fruits. The APVMA advised that the dietary exposure of livestock to spinetoram residues is expected to be low. The recommended animal commodity MRLs are at the LOQ. New chemical Insert residue definition: Sum of Ethyl-spinosyn-J and Ethyl-spinosyn-L			NEDI: <1% of the ADI
Edible offal (mammalian)	Insert	*0.01	
Eggs	Insert	*0.01	
Meat (mammalian) (in the fat)	Insert	*0.01	
Milks	Insert	*0.01	
Milk fats	Insert	*0.01	
Poultry, edible offal of	Insert	*0.01	
Poultry meat (in the fat)	Insert	*0.01	
Pome fruits	Insert	0.1	
Stone fruits	Insert	0.2	
Spinosad Spinosad is a spinosyn insecticide. It demonstrates rapid contact and ingestion activity in insects. It excites the insect nervous system, leading to involuntary muscle contractions, prostration with tremors and paralysis. It is used to control a range of insect pests in agricultural and veterinary situations. The APVMA has approved an extension of its use to control lice (*Bovicola ovis*) in sheep with long and short wool.			NEDI: 33% of the ADI
Edible offal (mammalian)	Omit	T0.2	
	Substitute	0.5	
Meat (mammalian) (in the fat)	Omit	T1	
	Substitute	2	

Requested MRLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment		
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, mealy bugs, whiteflies, psyllids and certain thrips. 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. The APVMA has issued a permit for its use to control certain pests on citrus fruits and mango. New chemical 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.			NEDI: 15% of the ADI NESTI as % of the ARfD		
			2-6 years		2+ years
Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas [except Brussels sprouts]	Insert	T7	10 5 15	Broccoli Cabbage Cauliflower	3 4 6
Brussels sprouts	Insert	T1	<1		<1
Citrus fruits	Insert	T1	4		1
Cotton seed	Insert	T1	<1		<1
Edible offal (mammalian)	Insert	T0.05	<1		<1
Fruiting vegetables, cucurbits	Insert	T2	<1 1 3	Cucumber Melon Zucchini	<1 <1 <1
Lettuce, head	Insert	T5	2		1
Lettuce, leaf	Insert	T10	5		3
Mango	Insert	T0.3	1		<1
Meat (mammalian)	Insert	T*0.01	<1		<1
Milks	Insert	T*0.005	<1		<1
Onion, bulb	Insert	T0.5	<1		<1
Peppers, Sweet	Insert	T5	1		<1
Tomato	Insert	T7	10		4
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. The APVMA has issued a permit for its use to control soybean rust (*Phakospora phachyrhizi*) in soybeans. Soya bean (dry)	Insert	T0.1	NEDI: 18% of the ADI 20th ATDS: not detected in any foods sampled		

Requested MRLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)	Dietary Exposure Assessment
Thiacloprid Thiacloprid is an insecticide. It has contact and stomach action. It is an agonist of the nicotinic acetylcholine receptor in the central nervous system of the insect, thus disrupting synaptic signal transmissions. It is used to control apple dimpling bug in apples, codling moth and oriental fruit moth in pome fruit and oriental fruit moth in stone fruit. The APVMA has issued a permit for its use to control heliothis and sucking pests on cotton. Cotton seed Insert T0.1	NEDI: 11% of the ADI NESTI as % of the ARfD 2-6 years 2+ years <1 <1
Triadimenol Triadimenol is a systemic fungicide with protective, curative and eradicant action. It is absorbed by roots and leaves, with ready translocation in young growing tissues, but less ready translocation in older, woody tissues. It inhibits gibberellin and ergosterol biosynthesis and hence the rate of cell division. It is used to control various fungal diseases in a range of crops. The APVMA has issued a permit for its use to control powdery mildew (*Oidium lycopersicum*) on eggplant. Egg plant Insert T1	NEDI: 2% of the ADI 20th ATDS: not detected in any foods sampled 19th ATDS: not detected in any foods sampled NESTI as % of the ARfD 2-6 years 2+ years 33 26
Minor technical amendments 1. To ensure consistent use of commodity names. Amendments to commodity names wherever occurring Omit: Common bean (dry) Substitute: Common bean (dry) (navy bean) Omit: Cottonseed Substitute: Cotton seed Omit: Melons [except watermelon] Substitute: Melons, except watermelon Omit: Peppers, sweet Substitute: Peppers, Sweet Omit: Rape seed Substitute: Rape seed (canola) Omit: silverbeet Substitute: silver beet 2. Under fludioxonil, list the existing entries in alphabetical order. Note: The draft variations to the Code consulted on at Assessment included an item to arrange the existing entries for each food and the relevant limit for fludioxonil in alphabetical order consistent with the format of the Schedules to Standard 1.4.2. This is not included in the variations at Approval. Drafting changes are not required to address this compilation error.	Dietary exposure assessment not required.

Attachment 3

Summary of Submissions

Submitter	Comments
California Grape and Tree Fruit League (CGTFL)	The CGTFL is a public policy agricultural trade association representing the United States' California table grape and deciduous tree fruit industries. Appreciates the acknowledgement that GAPs may differ between production regions and the effort to harmonise MRLs where possible. Notes that the United States Environmental Protection Agency (EPA) recently increased the pyraclostrobin stone fruit crop group MRL from 0.9 mg/kg, proposed in M1004 for inclusion in the Code, to 2.5 mg/kg. Notes that the United States does not export peaches, plums, nectarines or apricots to Australia and requested consideration of MRLs for these fruits in the next Proposal harmonised with United States limits for bifenazate, chlorpyrifos, fenbuconazole, fenbutatin oxide, fludioxonil, methomyl, methoxyfenozide, phosmet, pyriproxyfen, spinetoram, tebuconazole and trifloxystrobin. Notes the importance for the industry to assist in establishing appropriate standards recognising the crop protection tools used in California should the market become available.
California Table Grape Commission (CTGC)	The CTGC is an instrumentality of the United States' State of California. Expresses concern that the MRL of 0.3 mg/kg for chlorantraniliprole residues in grapes proposed at Assessment could become an impediment to trade in table grapes. Notes that in 2009 Australia was a top three export market by volume and value with a reported value to end October 2009 of $US48.3 million. Requests consideration of harmonisation with the corresponding United States MRL for chlorantraniliprole on table grapes of 1.2 mg/kg, or at a minimum, the Codex MRL of 1 mg/kg. Provided supporting information on the regulatory status of chlorantraniliprole in the United States and background to the Codex MRL, including that the EPA granted its use for the table grape industry as a reduced-risk compound due to its low risk properties and compatibility with integrated pest management practices.

Submitter	Comments
Food and Beverage Importers Association (FBIA)	Specifically endorses the proposed MRLs for stone fruits, cherries and chillies and supports Unilever's request for MRLs relevant to the tea industry as the chemicals are important management tools for the economic cultivation of tea and their use is supported by Codex or importing or producer country standards. This is on the basis that these foods are imported and the proposed limits would harmonise with Codex or other MRLs; the FSANZ safety assessment concluded that the proposed variations do not present safety concerns; due recognition should be given to agricultural practices regulated by producing countries and international standards to provide for legitimate and safe trade; and setting the proposed limits would be in line with the Ministerial Council Policy Guideline on the Regulation of Residues of Agricultural and Veterinary Chemicals in Food, in particular it would be consistent with the effective regulation of the registration, permission and use of agricultural and veterinary chemicals, promote a consistent approach to MRLs for both domestic and imported foods and be consistent with Australia's WTO SPS Agreement obligations.
Food Technology Association of Australia (FTAA)	Supports approval of the proposed draft variations to the Code subject to such amendments as FSANZ considers necessary. Notes the proposed MRL of 0.5 mg/kg for cypermethrin residues in tea is vastly less than the stated Codex MRL of 20 mg/kg. Notes that the APVMA MRL Standard does not include a corresponding MRL. Considers that there should only be one list of MRLs for Australia, that should be the APVMA list and the Code should note this list by reference; this would ensure consistency, any change to the list would be immediate not up to or more than 12 months out of sequence with the APVMA list as at present. Notes that this has been stated several times in previous submissions on MRL Proposals. Notes a typographical error in the proposed draft variations to the Code.

Submitter	Comments
Northwest Horticultural Council (NHC)	Represents United States' states of Idaho, Oregon and Washington apple, pear and cherry growers on policy, phytosanitary and food safety issues. Notes that Australia is a top seven trading partner for cherries from the region. Commends action taken by FSANZ to move quickly and include many chemicals important to Pacific Northwest pome and stone fruit growers. Appreciates MRLs harmonised with United States MRLs. Raised concern in relation to proposed MRLs that are lower than corresponding United States MRLs, particularly in regard to myclobutanil, pyraclostrobin and quinoxyfen because cherries are exported to Australia and trade may be disrupted. Notes that the United States pyraclostrobin MRL for the stone fruit crop group was recently increased from 0.9 mg/kg to 2.5 mg/kg and that the proposed quinoxyfen MRL is harmonised with the Codex MRL. Notes that use patterns are regulated by the EPA and where growers use products in accordance with approved label conditions, residues on cherries may be higher than the proposed MRLs where the United States MRL is higher. Notes that while the proposed methoxyfenozide, pyrimethanil and spinetoram MRLs for pome fruit are lower than the corresponding United States MRLs, the United States does not export pome fruit to Australia; these MRLs may disrupt future trade should the market open. Notes that in 2009 cherry shipments to Australia doubled from the previous year and the estimated value was $US7.88 million. Noting that limits for acetamiprid, azoxystrobin and fenarimol are a priority, requests consideration of MRLs for cherries in MRL Proposal M1005 harmonised with United States limits for the following chemicals: acetamiprid, azoxystrobin, bifenazate, chlorpyrifos, endosulfan, fenarimol, fenbutatin oxide, fenhexamid, fludioxonil, metconazole, methoxyfenozide, pyriproxyfen, spirotetramat, thiamethoxam, trifloxystrobin and triflumizole
New South Wales Food Authority	Supports the proposed approach. Notes a typographical error in the proposed draft variations to the Code.

Submitter	Comments
Queensland Government	Queensland Health is the lead agency in Queensland coordinating policy advice relative to national policy on food regulation. Submission made by Queensland Health in consultation with other relevant Queensland Government agencies on behalf of the Queensland Government. Supports approving the proposed draft variations to the Code. Acknowledges that this presents no public health or safety concerns and will permit trade of food containing legitimate residues of chemicals used to control pests and diseases and improve agricultural productivity. Notes two typographical errors in the proposed draft variations to the Code.
Unilever Australasia	Supports FSANZ's role to maintain the Code to reflect the registration status of agricultural and veterinary chemicals in Australia and the consultation process to allow the impact of proposed changes to be evaluated, particularly in regard to imported foods. Considers that the Ministerial Council Policy Guideline is a welcome development and anticipates alternative approaches to address the issues surrounding the current 'zero tolerance' approach to the regulation of residues of agricultural and veterinary chemicals in food. Notes that FSANZ has been kept appraised of the tea trade's concerns with issues regarding plant protection products and Unilever's participation with the FBIA as members of the Australian Food and Grocery Council Tea Industry Forum in the Global Pesticide Initiative on Tea. Notes that this work is supported by the Food and Agriculture Organisation Inter-Governmental Group on Tea. This Group aims to ensure that tea is safe; produced and traded in a compliant manner internationally; and facilitate improved pest management. Supports the inclusion in the Code of proposed bifenthrin, cypermethrin, fenvalerate and lambda-cyhalothrin MRLs for tea harmonised with European Union MRLs as requested. Supports consideration of MRLs for a wider range of imported foods where supporting information is provided such as the MRL requests made by the FBIA.
Victorian Government	Supports approving the proposed draft variations to the Code. Raised a potential anomaly to be considered in that the proposed cypermethrin MRL for tea is 0.5 mg/kg whereas the Codex limit is 20 mg/kg.

Submitter	Comments
United States Government	Notes the proposed MRL of 0.3 mg/kg for chlorantraniliprole on table grapes. While recognising Australia's right to establish MRLs based on scientific evidence, notes that this MRL would be significantly more restrictive than the Codex (1 mg/kg) and United States (1.2 mg/kg) MRLs. Requests an import tolerance on the basis that the United States exports $US58 million in grapes and raisins to Australia and the global review effort which resulted in over fifty countries adopting chlorantraniliprole grape MRLs at levels equal to Codex or the United States. Provided the United States EPA 2009 Human Health Risk Assessment. Raised concern that the proposed MRL for pyraclostrobin on cherries (0.9 mg/kg) may significantly impact on trade ($US12 million in 2008). Notes the Codex (1 mg/kg) and United States (2.5 mg/kg) MRLs. Requested the Australian risk assessment. Raised concern that the proposed methoxyfenozide pome fruit MRL (0.5 mg/kg) is significantly more restrictive than the Codex (2 mg/kg) and United States (1.5 mg/kg) MRLs. Requested Australian risk assessment for further review.

Attachment 4

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 and Environmental Health (OCSEH) 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.

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 OCSEH 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 OCSEH 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 OCSEH 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.

Attachment 5

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 approved 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 and Environmental Health 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 cannot 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.