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

2 September 2009
[14-09]

PROPOSAL M1003
MAXIMUM RESIDUE LIMITS (APRIL, MAY, JUNE, AUGUST 2008)
APPROVAL REPORT

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) in April, May, June and August 2008. The APVMA did not gazette any MRLs in July. 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 with legitimate residues and protect public health and safety by minimising residues in foods consistent with the effective control of pests and diseases.

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

Dietary exposure assessments indicate that in relation to current reference health standards, the proposed limits do not present any public health and safety concerns. This Proposal includes consideration of MRLs for the antibiotic halofuginone in cattle commodities. The use and residues of halofuginone relating to the proposed MRLs do not pose a risk in terms of antimicrobial resistance.

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). Comments were received from China, Fiji and the United States. 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, 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 Standards 1.3.1 and 1.4.2 that could achieve the same end
- any relevant New Zealand standards
- any other relevant matters.

Decision

FSANZ approved the amended draft variations to Standards 1.3.1 – Food Additives and 1.4.2 – Maximum Residue Limits. The residues associated with the variations do not present any public health and safety concerns and the variations are necessary, cost-effective and will benefit consumers, Government and industry. The variations will permit the sale of foods containing legitimate residues.

Reasons for Decision

This Proposal has been assessed against the considerations provided for in section 59 of the FSANZ Act. FSANZ approved the variations to Standards 1.3.1 and 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 Office of Chemical Safety (OCS) has undertaken a toxicological assessment of each chemical and has established an acceptable daily intake (ADI) and, where appropriate, an acute reference dose (ARfD).

- FSANZ has undertaken a 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 M1003. The Board has approved the draft amendments to the Code, this decision has been notified to the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council). If the Ministerial Council does not request FSANZ to review the draft 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 at **Attachment 1C**. Taking into account public comment, FSANZ amended the draft variations. The amended draft variations are provided at **Attachment 1A**. The amendments to the draft variations are indicated at **Attachment 1B**.

FSANZ has completed its assessment and decided to include etoxazole MRLs of 1 mg/kg for cherries and 1.5 mg/kg for dried grapes as requested in submissions rather than remove the limit for cherries and include a limit for dried grapes of 0.2 mg/kg as consulted on at Assessment. FSANZ has also decided to change the status of the temporary etoxazole MRL for grapes to an MRL at the existing level of 0.5 mg/kg. No health or safety concerns were identified in relation to these changes. The amended draft 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 9.1.2 of this Report.

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Introduction

Notifications were received from the Australian Pesticides and Veterinary Medicines Authority (APVMA) on 28 May, 17 June and 14 August 2008 seeking to vary the *Australia New Zealand Food Standards Code* (the Code). The approved draft variations to the Code align maximum residue limits (MRLs) in the Code for certain agricultural and veterinary chemicals with the APVMA MRLs listed in the MRL Standard and permit the sale of relevant foods with legitimate residues.

This Proposal also included consideration of MRLs for cypermethrin, fenhexamid, fenvalerate and glufosinate-ammonium and extraneous residue limits[1] (ERLs) for dieldrin for a range of commodities 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 draft variations to the Code would align limits in the Code with Codex and other standards internationally and permit the sale of relevant foods with legitimate residues at levels that do not present health or safety concerns.

This Proposal also included consideration of an MRL for mancozeb in herbs gazetted by the APVMA in March 2008. Rather than delay progressing the other MRLs requested in Proposal M1002 while the assessment of the mancozeb MRL for herbs was finalised, it was excluded from that Proposal.

In summary, this Proposal included consideration of MRLs for abamectin, azoxystrobin, bifenazate, bifenthrin, boscalid, carbofuran, cypermethrin, dithiocarbamates (mancozeb), etoxazole, fenhexamid, fenvalerate, flubendiamide (new chemical), glufosinate-ammonium, halofuginone (antibiotic), indoxacarb, isoxaflutole, lambda-cyhalothrin (cyhalothrin), linuron, methomyl, metribuzin, phosphorous acid, pirimicarb, prochloraz, profoxydim (new chemical), pymetrozine, pyraclostrobin, pyroxsulam (new chemical) and trinexapac-ethyl; ERLs for dieldrin; a maximum permitted level (MPL) for sulphur dioxide and other amendments to maldison and propachlor entries.

The draft variations to the Code are at **Attachments 1A**, **1B** and **1C**. The approved variations and dietary exposure assessments are outlined in **Attachment 2**. A summary of comments received on the Assessment Report is provided at **Attachment 3**. The safety assessment methodology is outlined in **Attachment 4**.

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

In considering the issues associated with variations to limits in the Code for residues of agricultural and veterinary chemicals in food, it should be noted that the limit is the maximum level of a chemical that may be in a food, not the level that is usually present in a food. Also, the purpose of ERLs in the Code is to recognise residues in food as a result of past historical use without undermining current restrictions on residues in food from contemporary chemical product use. However, incorporating the limit into food legislation means that the residues of a chemical are minimised (i.e. must not exceed the MRL, ERL or other limit), irrespective of whether the dietary exposure assessment indicates that higher residues would not risk public health and safety.

[1] An ERL is the maximum permitted limit of a pesticide residue, arising from environmental sources other than the use of a pesticide directly or indirectly on the food.

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 with 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 – Maximum Residue Limits 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/commodity combination, there must be no detectable residues of that chemical in that food. This general prohibition means that in the absence of the relevant limit in the Code, food may not be sold where there are detectable residues.

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

Further background information on MRLs, the regulatory framework for agricultural and veterinary chemicals and the FSANZ assessment process for incorporating limits, including MRLs for antibiotic substances, in the Code is provided at **Attachment 5**.

3. Objectives

In assessing this Proposal, FSANZ ensured that approving the draft variations does not present public health and safety concerns and that the sale of food with 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, in order of priority, 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.

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

The safety assessment methodology is further outlined in **Attachment 4**.

RISK ASSESSMENT

5. Risk Assessment Summary

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

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

The use and residues associated with the approved MRLs for the antibiotic substance halofuginone do not pose a risk in terms of development of antimicrobial resistance.

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 – after the submission period, 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. Information from public submissions was used to further assess the proposed changes.

7.1 Affected Parties

The parties 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. FSANZ does not consider there to be any dietary exposure implications associated with the proposed approval. The risk assessment has determined that there are no public health or safety concerns associated with the approved variations. No additional costs to consumers have been identified.

Progressing this option benefits growers and producers as agricultural and food Standards are further aligned. This means that foods produced in accordance with agricultural Standards and legislation may be sold under food legislation as MRL variations are incorporated in the Code.

Omitting or reducing MRLs in the Code is consequential to changes made by the APVMA and is, therefore, 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 or be disadvantaged by the approval of the proposed draft variations. Additional or increased MRLs may benefit importers and, consequently, consumers in that this may extend the options to source safe foods. Any MRL deletions or reductions have the potential to restrict importation of foods and could potentially result in higher food prices and a reduced product range available to consumers. Interested parties were invited to comment on these impacts 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.

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.

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

This option has similar costs and benefits as option 1. FSANZ assessed the comments provided in submissions and amended the draft variations. This is discussed in section 9.1.2 of this Report and the amended draft variations are provided at **Attachment 1A**. The amendments to the draft variations are indicated 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 legitimate use of chemical products in Australia as determined by the APVMA. This may result in foods legitimately treated during production not being permitted for sale. Producers would incur significant costs. This may also create uncertainty, inefficiency and confusion in the enforcement of regulations. In addition, the anomalies between the Code and international standards identified by industry would perpetuate and may have implications for trade in certain foods. This would impact negatively on all affected parties and producers, industry and compliance agencies in particular.

Importers may benefit if proposed MRL deletions or reductions are not progressed as the continuity of existing limits could be relied upon. However, there is scope under current processes to retain specific MRLs where the necessity for the MRL to continue to allow the importation and sale of safe food is identified through consultation. This is discussed in section 9 of this Report. Importers and consequently consumers may be disadvantaged where proposed additional or increased MRLs are not progressed as this may unnecessarily limit sources of certain foods.

7.2.4 Summary

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

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 recommends approving option 2 – after the submission period, 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 safe food.
- 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 safe food 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 9.1.2 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 safe 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 assessment reports on its website, notifies the community of the period of public consultation through newspaper advertisements, and issues media releases drawing attention to proposed Code amendments. Once the Code has been amended, FSANZ incorporates the changes in the website version of the Code and, through its email and telephone information service, responds to industry enquiries.

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

9. Consultation

Public comment was sought on the proposed changes to the Code outlined in this Report to assist in finalising the assessment. 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 Cherry Advisory Board (CCAB), the California Table Grape Commission (CTGC), the Food and Beverage Importers Association (FBIA), the Food Technology Association of Australia (FTAA), the NSW Food Authority, the Northwest Horticultural Council (NHC), the Queensland Government and Unilever Australasia (Unilever). FSANZ notified this Proposal to the World Trade Organization (WTO) and received comments from China, Fiji and the United States. FSANZ thanks all submitters and member nations for their comments. The comments provided are summarised in **Attachment 3**.

Submissions from the FTAA, NSW Food Authority, Queensland Government and Unilever support approving the proposed draft variations. The CCAB and NHC requested that FSANZ consider harmonising with the United States etoxazole MRL for cherries. The CTGC requested FSANZ consider changing the status of the current standard for etoxazole residues in table grapes from a temporary MRL to an MRL. The NHC also requested FSANZ harmonise with United States boscalid, chlorantraniliprole, flubendiamide and pyraclostrobin MRLs for apple, pear and cherries. Unilever proposed bifenthrin, cypermethrin, fenvalerate and lambda-cyhalothrin MRLs for tea for inclusion in the Code as MRL variations for residues of these chemicals in other foods were under consideration in this Proposal. The FBIA supports the proposed cypermethrin and fenvalerate MRLs for berries and other small fruits; and the Unilever submission in regard to the requested tea MRLs. The NSW Food Authority requested consideration of the potential for elevated sulphur dioxide residues on the skin of longans to provoke illness in sensitive consumers.

9.1 Issues raised in submissions

9.1.1 MRL-setting

The FTAA expressed dismay at the lengthy period of time for the variations to be submitted for approval by FSANZ and then await gazettal, noting that the proposed changes have already been approved and gazetted into the equivalent and identical list provided by the APVMA. The FTAA noted that the approved MRLs are already available to primary producers who must immediately comply, whereas food manufacturers and retail outlets for primary produce have to analyse the same foods and comply with the outdated, by 12 months and more, Code. The FTAA considers that although there may be some legislative impediments to aligning the APVMA and FSANZ lists, the delay may be preventing fair trading and placing primary and secondary food producers and retailers in a position of potential conflict of interest. The FTAA stated that this incongruity should be easily resolvable by FSANZ adopting the APVMA changes by reference and removing the double handling of identical material.

The FBIA notes that setting the cypermethrin and fenvalerate MRLs for berries and other small fruit as proposed 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 Australasia commented 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.

9.1.1.1 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 the Department of Health and Ageing and other agencies involved in policy on MRLs.

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. Therefore consideration of this aspect is outside the considerations which may be made as part 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 on the Regulation of Agricultural and Veterinary Chemical Residues in Food, FSANZ notes that consideration of policy issues cannot be made as part of an MRL proposal for varying individual MRLs.

Nonetheless, the current approach allows FSANZ to consider specific residue limits for inclusion in the Code, such as recognition of Codex MRLs and other countries MRLs where requested by interested parties and considered appropriate. 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.

9.1.2 Other MRLs required for Etoxazole Residues in Cherries and Grapes

The CCAB and NHC requested that FSANZ not omit the etoxazole MRL applicable to cherries as proposed and consider harmonising with the United States on the basis that this would minimise potential trade disruption. The NHC supported the proposed limit for pome fruits and asked that New Zealand also harmonise with the United States MRLs for etoxazole residues in apples, pears and cherries.

The United States Government provided comments via the WTO. The United States requested that FSANZ consider an MRL of 1.5 mg/kg, harmonised with the United States etoxazole MRL for raisins.

The CTGC supported the retention of the current etoxazole MRL for grapes at the level of 0.5 mg/kg as etoxazole is important for the California table grape industry's pest management efforts. The CTGC requested consideration of transitioning the status of the limit from a temporary MRL to an MRL.

9.1.2.1 FSANZ Evaluation

FSANZ consulted on omitting the etoxazole MRL for stone fruits of T0.5 mg/kg and inserting an etoxazole MRL for stone fruits except cherries of 0.1 mg/kg, effectively removing the limit for etoxazole residues in cherries. FSANZ also consulted on retaining the T0.5 mg/kg etoxazole MRL for grapes and inserting an MRL for etoxazole in dried grapes at the level of 0.2 mg/kg.

The CCAB, NHC and United States identified a trade issue in relation to the proposed changes and provided information that an MRL is required for etoxazole residues that may occur in cherries and a higher limit is required for dried grapes. The CTGC requested that FSANZ consider substituting the temporary etoxazole limit for grapes with an MRL at the same level.

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 for etoxazole residues of 1 mg/kg in stone fruit except plum and 1.5 mg/kg in raisins. These MRLs relate to the registered use of etoxazole in the production of cherries and grapes there. These foods may be imported to Australia from the United States and could legitimately contain etoxazole residues consistent with the current United States limits.

FSANZ conducted an assessment of potential dietary exposure to etoxazole residues encompassing all foods in which these residues may occur. FSANZ concluded that etoxazole MRLs of 1 mg/kg for cherries, 0.5 mg/kg for grapes and 1.5 mg/kg for dried grapes do not present any public health or safety concerns. The estimated dietary exposure to etoxazole, including any residues that may occur in cherries at 1 mg/kg, grapes at 0.5 mg/kg and dried grapes at 1.5 mg/kg, does not exceed the relevant reference health standards. The dietary exposure estimates are provided at **Attachment 2**.

As the limit for etoxazole residues in grapes in the Code relates to the registered use and corresponding United States MRL for etoxazole residues that may occur in grapes, FSANZ considered it appropriate to further harmonise with that standard and decided to change the status of the temporary MRL to an MRL. FSANZ notes that Australia is an important market for United States cherries and grapes and that harmonised standards reduce the potential for trade disruption. There are no Codex MRLs established for residues of etoxazole in food.

Australia and New Zealand independently and separately set MRLs. Standard 1.4.2 applies in Australia only. Interested parties seeking to vary New Zealand MRLs may wish to contact the New Zealand Food Safety Authority (NZFSA) directly. Contact details and information about New Zealand MRL Standards are available via the link to the NZFSA website provided in section 9.4 of this Report. Further background is available at **Attachment 5**.

In summary, FSANZ decided to include MRLs in the Code for cherries, grapes and dried grapes harmonised with United States MRLs applicable to these foods. The amended draft variations minimise potential trade disruption and may benefit industry and consumers through greater choice and access to the relevant foods and food products containing these foods. The amended draft variations to the Code are at **Attachments 1A** and **1B**.

9.1.3 Various MRLs Requested for Residues in Apples, Pears Cherries and Tea

The NHC noted that differing MRLs may create trade issues and that these present challenges to United States Pacific Northwest apple, pear and cherry growers. The NHC noted that Australia is an important trading partner. The NHC supported the proposed boscalid and pyraclostrobin MRLs for apples and requested that these be extended to pome fruits to include pear. The NHC also requested boscalid and pyraclostrobin stone fruit MRLs to include cherries at levels similar to the United States MRLs of 1.7 mg/kg and 0.9 mg/kg respectively. The NHC noted that limits were not proposed for flubendiamide and chlorantraniliprole residues in pome fruit and stone fruit and requested that limits be considered. The NHC noted that the United States flubendiamide MRLs for apples, pears and cherries are 0.7 mg/kg, 0.7 mg/kg and 1.6 mg/kg respectively and the chlorantraniliprole MRLs for these foods are 0.3 mg/kg, 0.3 mg/kg and 1 mg/kg.

Unilever noted that FSANZ has been kept appraised of the tea trade's concerns with issues regarding plant protection products and participation in the Global Pesticide Initiative on Tea. Unilever noted 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. Unilever provided information on the use of bifenthrin, cypermethrin, fenvalerate and lambda-cyhalothrin in tea production and relevant standards for residues of these chemicals in tea internationally. Unilever requested in its submission and other correspondence that FSANZ consider including MRLs in the Code harmonised with European Union MRLs of 5 mg/kg for bifenthrin, 0.5 mg/kg for cypermethrin, 0.05 mg/kg for fenvalerate and 1 mg/kg for lambda-cyhalothrin residues in tea.

9.1.3.1 FSANZ Evaluation

FSANZ is committed to ensuring that the implications of varying MRLs are considered and that this is done in a transparent manner. The public consultation period on this Proposal has closed. FSANZ did not consult on varying the Standard in respect of the requested chemical/food combinations. For these reasons FSANZ did not consider it appropriate to consider the MRLs requested by the NHC and Unilever at the Approval stage of this Proposal. The APVMA has established chlorantraniliprole MRLs for pome fruits and stone fruits at the levels requested by the NHC. These limits are included for consideration in the next MRL Proposal.

In conclusion, FSANZ has decided that the requests for consideration of boscalid, flubendiamide and pyraclostrobin MRLs for apples, pears and cherries; and bifenthrin, cypermethrin, fenvalerate and lambda-cyhalothrin MRLs for tea will also be considered in the next MRL proposal to allow for public consultation to occur.

9.1.4 Sulphur dioxide residues on longans

The NSW Food Authority requested that FSANZ consider the potential for elevated sulphur dioxide residues on the skin of longans to provoke illness in sensitive consumers.

9.1.4.1 FSANZ Evaluation

FSANZ aims to ensure that legitimate residues in food do not risk public health and safety and that the sale of food containing such residues is permitted. FSANZ recognises that sulphite exposure is an issue for sensitive consumers. Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations provides for sulphites in concentrations of 10 mg/kg or more in food to be declared for consumer information.

FSANZ considers that the risk of illness in consumers who may be sensitive to residues on the skin of the fruit is unlikely to increase following the lowering of the APVMA MRL for sulphur dioxide residues in whole longans and possible refinement of the use pattern. This is on the basis of APVMA advice that residues data indicate that levels of sulphur dioxide on the skin of longans are not expected to increase. Two Australian field trials were conducted to determine the level of sulphur dioxide residues in longans. The data were sufficient to support lowering the MRL from a level of 500 mg/kg to 150 mg/kg in the whole fruit. In addition, FSANZ notes that longans are usually peeled and exposure to sulphur dioxide from the inedible skin and edible portion of longans is likely to be minor compared to exposure from other dietary sources.

In conclusion, due to the expected residues being lower in food, the risk to consumers is also likely to be lower.

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.

The primary objective of the measure is to support the regulation of the use of agricultural and veterinary chemical products to protect human, animal and plant health and the environment. FSANZ made a notification to the WTO for this Proposal in accordance with the WTO Agreement on the Application of Sanitary and Phytosanitary Measures. WTO members China, Fiji and the United States provided comments.

The United States provided comments on proposed variations to etoxazole MRLs. The comments are addressed above in section 9.1.2 of this Report.

Fiji provided comments in relation to market access for ginger.

FSANZ did not consult on any proposed variations to the Code concerning standards for ginger and 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 ginger from Fiji as a high priority market access request and has written to Fiji in response to the comments provided. Following an announcement on market access, Fiji would be welcome to raise any issues regarding standards for ginger with FSANZ.

China provided comments in relation to the scientific evidence for the difference between proposed limits for flubendiamide residues in lettuce and sulphur dioxide residues in longans and Codex and other member nation standards. China did not request that FSANZ consider any alternative MRLs for inclusion in the Code. The comments have been provided to the APVMA.

The APVMA has conducted rigorous scientific assessments to establish appropriate MRLs. The APVMA establishes MRLs based on scientific evaluation of appropriate toxicology, residue, animal transfer, processing and metabolism studies and requests that FSANZ include these limits in the Code. FSANZ aims to ensure that any potential residues in food are within appropriate safety limits and to maintain limits in the Code that reflect legitimate residues that may occur in food.

APVMA MRLs reflect Australian good agricultural practice (GAP) and the residues that may occur in foods. Chemical use patterns and MRLs may vary across different regions internationally for a number of reasons including differences in pest pressures and agronomic and environmental factors. Where the APVMA finds a significant change in an MRL due to a new or changed use pattern, the registrant is advised that it is in their interest to submit that data to the Codex Committee on Pesticide Residues/FAO and have it assessed to allow for a limit to be established or a change to the existing Codex MRL to be considered.

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 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 with a view to consider impacts identified by member nations exporting relevant food/s to Australia.

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.

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

Industry provided information that specific anomalies between the Code and international standards may present barriers to trade in certain foods. This Proposal included consideration of limits for cypermethrin, dieldrin, fenhexamid, fenvalerate and glufosinate-ammonium to address these issues. Further detail is provided at **Attachment 2**. The approved variations to the Code would align limits in the Code with international standards and permit the sale of relevant foods containing legitimate residues that do not present health or safety concerns.

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

Chemical Food	**Approved limit**[†] **mg/kg**	**Codex limit** **mg/kg**
Bifenazate		
Cucumber	T0.5	Fruiting vegetables, cucurbits 0.5
Peppers, Sweet	T2	2
Tomato	T0.5	0.5
Boscalid		
Apple	2	2
Cypermethrin		
Berries and other small fruits [except grapes]	0.5	Berries and other small fruits 0.5
Dieldrin		
Fruiting vegetables, cucurbits	E0.1	0.1
Root and tuber vegetables	E0.1	0.1
Fenhexamid		
Kiwifruit	15	Kiwi 15
Fenvalerate		
Berries and other small fruits	1	1
Glufosinate-ammonium		
Maize[‡]	0.2	0.1
Rape seed	5	5
Soya bean (dry)	2	2
Prochloraz		
Mandarins	T10	Citrus fruits 10
Pyraclostrobin		
Sunflower seed	T0.3	0.3

[†] Note that a 'T' indicates that the limit is temporary and an 'E' indicates an ERL.
[‡] Higher limit requested by industry; refer **Attachment 2**.

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 2008 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 or ERLs approved in this Proposal where there is a corresponding limit in the New Zealand MRL Standards.

Chemical Food	**Approved MRL/ERL**[†] **mg/kg**	**NZ MRL/ERL** **mg/kg**
Azoxystrobin		
Bulb vegetables [except fennel, bulb; onion, bulb]	T7	Onions *0.01
Leek	Omit 0.5	
Bifenthrin		
Fruiting vegetables, other than cucurbits	0.5	Tomatoes 0.05
Boscalid		
Apple	2	Pome fruits *0.05
Dieldrin		Specific limits are listed for cereals, citrus and fats.
Fruiting vegetables, cucurbits	E0.1	Any other food 0.1
Root and tuber vegetables	E0.1	
Dithiocarbamates		
Litchi	5	Fruits 7
Halofuginone		
Cattle fat	0.025	0.02
Cattle kidney	0.03	0.03
Cattle liver	0.03	0.03
Cattle muscle	0.01	Cattle meat 0.01
Pyraclostrobin		
Apple	1	Apples *0.02

[†] Note that a 'T' indicates that the limit is temporary; an 'E' indicates that the limit is an ERL; and 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.

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

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

To assist in identifying possible impacts on imported foods, FSANZ compiled the following table of foods where the MRLs were proposed for deletion or reduction and sought comment on any impacts through the Assessment Report.

Chemical Food
Etoxazole Stone fruits
Isoxaflutole Cereal grains
Metribuzin Sugar cane
Pirimicarb Soya bean (dry)
Pymetrozine Almonds

The CCAB and NHC submissions raised a trade issue in relation to the proposed variations of etoxazole MRLs. This is discussed in section 9.1.2 of this Report. No comments were received on the other chemicals listed.

Conclusion

10. Conclusion and Decision

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

The decision is to adopt option 2 to approve the amended draft variations.

Decision

FSANZ has approved the amended draft variations to Standards 1.3.1 – Food Additives and 1.4.2 – Maximum Residue Limits. The residues associated with the variations do not present any public health and safety concerns and the variations are necessary, cost-effective and will benefit consumers, Government and industry. The variations will permit the sale foods containing legitimate residues.

10.1 Reasons for Decision

FSANZ approved the amended draft variations to Standards 1.3.1 and 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 Office of Chemical Safety (OCS) has undertaken a toxicological assessment of each chemical and has established an ADI and, where appropriate, an ARfD.

- FSANZ has undertaken a 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.

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

ATTACHMENTS

1A. Draft variations to the *Australia New Zealand Food Standards Code* (at Approval)
1B. Draft variations to the *Australia New Zealand Food Standards Code* (Indicating Amendments to Proposed Drafting at Assessment)
1C. Draft variations to the *Australia New Zealand Food Standards Code* (at Assessment)
2. A summary of limits under consideration in Proposal M1003
3. Summary of Submissions
4. Safety Assessment Methodology
5. Background Information

Attachment 1A

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

Subsection 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 1.3.1*** *of the Australia New Zealand Food Standards Code is varied by –*

[1.1] *inserting in* Schedule 1*, under item* 4.1 Unprocessed fruits and vegetables –

blueberries				
220 221 222 223 224 225 228	Sulphur dioxide and sodium and potassium sulphites	10	mg/kg	

[1.2] *omitting from* Schedule 1*, under item* 4.1 Unprocessed fruits and vegetables –

Longans				
220 221 222 223 224 225 228	Sulphur dioxide and sodium and potassium sulphites	10	mg/kg	

substituting –

longan				
220 221 222 223 224 225 228	Sulphur dioxide and sodium and potassium sulphites	10	mg/kg	edible aril only, that is, the edible portion of the fruit

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

[2.1] *omitting from* Schedule 1, *the commodity name under the chemical appearing in* Column 1 *of the Table to this sub-item, substituting the commodity name appearing in* Column 2 –

COLUMN 1	COLUMN 2
MALDISON	CURRANT, BLACK

[2.2] *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
ABAMECTIN	SUM OF AVERMECTIN B1A, AVERMECTIN B1B AND (Z)-8,9 AVERMECTIN B1A, AND (Z)-8,9 AVERMECTIN B1B
PROPACHLOR	SUM OF PROPACHLOR AND METABOLITES HYDROLYSABLE TO N-ISOPROPYLANILINE, EXPRESSED AS PROPACHLOR

[2.3] *inserting in* Schedule 1 –

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	
BRASSICA (COLE OR CABBAGE) VEGETABLES, HEAD CABBAGES, FLOWERHEAD BRASSICAS	T3
COMMON BEAN (PODS AND/OR IMMATURE SEEDS)	T2
LETTUCE, HEAD	T5
LETTUCE, LEAF	T5
PEPPERS, SWEET	T1
SWEET CORN (CORN-ON-THE-COB)	T*0.05
TOMATO	T2
PROFOXYDIM SUM OF PROFOXYDIM AND ALL METABOLITES CONVERTED TO DIMETHYL-3-(3-THIANYL)GLUTARATE-S-DIOXIDE AFTER OXIDATION AND TREATMENT WITH ACIDIC METHANOL, EXPRESSED AS PROFOXYDIM	
EDIBLE OFFAL (MAMMALIAN)	0.5
EGGS	*0.05
MEAT (MAMMALIAN)	*0.05
MILKS	*0.01
POULTRY, EDIBLE OFFAL OF	*0.05
POULTRY MEAT	*0.05
RICE	0.05
PYROXSULAM PYROXSULAM	
EDIBLE OFFAL (MAMMALIAN)	*0.01
EGGS	*0.01
MEAT (MAMMALIAN)	*0.01
MILKS	*0.01
POULTRY, EDIBLE OFFAL OF	*0.01
POULTRY MEAT	*0.01
WHEAT	*0.01
SULPHUR DIOXIDE *SEE* STANDARD 1.3.1	

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

AZOXYSTROBIN AZOXYSTROBIN	
LEEK	0.5
BIFENTHRIN BIFENTHRIN	
EGG PLANT	T0.5
OKRA	T0.5

PEPPERS	T0.5
TOMATO	0.5
ETOXAZOLE ETOXAZOLE	
APPLE	0.2
PEAR	T0.2
STONE FRUITS	T0.5
FENVALERATE FENVALERATE, SUM OF ISOMERS	
STRAWBERRY	1
HALOFUGINONE HALOFUGINONE	
CATTLE MEAT	T*0.01
INDOXACARB SUM OF INDOXACARB AND ITS *R*-ISOMER	
STRAWBERRY	T1
ISOXAFLUTOLE THE SUM OF ISOXAFLUTOLE, 2-CYCLOPROPYLCARCONYL-3-(2-METHYLSULFONYL-4-TRIFLUOROMETHYLPHENYL)-3-OXOPROPANENITRILE AND 2-METHYLSULFONYL-4-TRIFLUOROMETHYLBENZOIC ACID EXPRESSED AS ISOXAFLUTOLE	
CEREAL GRAINS	T*0.05
LINURON SUM OF LINURON PLUS 3,4-DICHLOROANILINE, EXPRESSED AS LINURON	
VEGETABLES [EXCEPT CELERY AND LEEK]	*0.05
PHOSPHOROUS ACID PHOSPHOROUS ACID	
ASSORTED TROPICAL AND SUBTROPICAL FRUITS – INEDIBLE PEEL	T100
PIRIMICARB SUM OF PIRIMICARB, DEMETHYL-PIRIMICARB AND THE *N*-FORMYL-(METHYLAMINO) ANALOGUE (DEMETHYLFORMAMIDO-PIRIMICARB), EXPRESSED AS PIRIMICARB	
VEGETABLES [EXCEPT AS OTHERWISE LISTED UNDER THIS CHEMICAL]	1

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

AZOXYSTROBIN AZOXYSTROBIN	
BULB VEGETABLES [EXCEPT FENNEL, BULB; ONION, BULB]	T7
BIFENAZATE SUM OF BIFENAZATE AND BIFENAZATE DIAZENE (DIAZENECARBOXYLIC ACID, 2-(4-METHOXY-[1,1'-BIPHENYL-3-YL] 1-METHYLETHYL ESTER), EXPRESSED AS BIFENAZATE	
CUCUMBER	T0.5
PEPPERS, SWEET	T2
TOMATO	T0.5
BIFENTHRIN BIFENTHRIN	
FRUITING VEGETABLES, OTHER THAN CUCURBITS	0.5
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	
APPLE	2
CARBOFURAN SUM OF CARBOFURAN AND 3-HYDROXYCARBOFURAN, EXPRESSED AS CARBOFURAN	
GARLIC	T0.1
CYHALOTHRIN CYHALOTHRIN, SUM OF ISOMERS	
GARLIC	*0.05
CYPERMETHRIN CYPERMETHRIN, SUM OF ISOMERS	
BERRIES AND OTHER SMALL FRUITS [EXCEPT GRAPES]	0.5
DITHIOCARBAMATES TOTAL DITHIOCARBAMATES, DETERMINED AS CARBON DISULPHIDE EVOLVED DURING ACID DIGESTION AND EXPRESSED AS MILLIGRAMS OF CARBON DISULPHIDE PER KILOGRAM OF FOOD	
HERBS [EXCEPT PARSLEY]	T5
ETOXAZOLE ETOXAZOLE	
CHERRIES	1
CITRUS FRUITS	T0.1
DRIED GRAPES	1.5
FRUITING VEGETABLES, OTHER THAN CUCURBITS	T0.1

POME FRUITS	0.2
STONE FRUITS [EXCEPT CHERRIES]	0.1
FENHEXAMID FENHEXAMID	
KIWIFRUIT	15
FENVALERATE FENVALERATE, SUM OF ISOMERS	
BERRIES AND OTHER SMALL FRUITS	1
GLUFOSINATE AND GLUFOSINATE-AMMONIUM SUM OF GLUFOSINATE-AMMONIUM, N-ACETYL GLUFOSINATE AND 3-[HYDROXY(METHYL)-PHOSPHINOYL] PROPIONIC ACID, EXPRESSED AS GLUFOSINATE (FREE ACID)	
MAIZE	0.2
SOYA BEAN (DRY)	2
HALOFUGINONE HALOFUGINONE	
CATTLE FAT	0.025
CATTLE MUSCLE	0.01
INDOXACARB SUM OF INDOXACARB AND ITS *R*-ISOMER	
BERRIES AND OTHER SMALL FRUITS [EXCEPT GRAPES]	T1
CELERY	T5
LINURON SUM OF LINURON PLUS 3,4-DICHLOROANILINE, EXPRESSED AS LINURON	
CELERIAC	T0.5
VEGETABLES [EXCEPT CELERIAC; CELERY; LEEK]	*0.05
METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OXIME'), EXPRESSED AS METHOMYL *SEE ALSO* THIODICARB	
ONION, WELSH	1
RADISH	T1
SHALLOT	1
SPRING ONION	1
SWEDE	T1
TURNIP, GARDEN	T1
METRIBUZIN METRIBUZIN	
SUGAR CANE MOLASSES	0.1

PHOSPHOROUS ACID PHOSPHOROUS ACID	
ASSORTED TROPICAL AND SUB-TROPICAL FRUITS – INEDIBLE PEEL [EXCEPT AVOCADO]	T100
AVOCADO	T500
PIRIMICARB SUM OF PIRIMICARB, DEMETHYL-PIRIMICARB AND THE *N*-FORMYL-(METHYLAMINO) ANALOGUE (DEMETHYLFORMAMIDO-PIRIMICARB), EXPRESSED AS PIRIMICARB	
SOYA BEAN (DRY)	T0.5
VEGETABLES [EXCEPT LEAFY VEGETABLES; LUPIN (DRY); SOYA BEAN (DRY)]	1
PROCHLORAZ SUM OF PROCHLORAZ AND ITS METABOLITES CONTAINING THE 2,4,6-TRICHLOROPHENOL MOIETY, EXPRESSED AS PROCHLORAZ	
MANDARINS	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	
APPLE	1
SUNFLOWER SEED	T0.3

[2.6] *omitting from* Schedule 1*, under the entries for the following chemicals, the MRL for the food, substituting –*

ABAMECTIN SUM OF AVERMECTIN B1A, AVERMECTIN B1B AND (Z)-8,9 AVERMECTIN B1A, AND (Z)-8,9 AVERMECTIN B1B	
CURRANT, BLACK	0.02
PEAS	T0.5
BIFENTHRIN BIFENTHRIN	
COMMON BEAN (PODS AND/OR IMMATURE SEEDS)	T1
DITHIOCARBAMATES TOTAL DITHIOCARBAMATES, DETERMINED AS CARBON DISULPHIDE EVOLVED DURING ACID DIGESTION AND EXPRESSED AS MILLIGRAMS OF CARBON DISULPHIDE PER KILOGRAM OF FOOD	
LITCHI	5
ETOXAZOLE ETOXAZOLE	
GRAPES	0.5

GLUFOSINATE AND GLUFOSINATE-AMMONIUM SUM OF GLUFOSINATE-AMMONIUM, N-ACETYL GLUFOSINATE AND 3-[HYDROXY(METHYL)-PHOSPHINOYL] PROPIONIC ACID, EXPRESSED AS GLUFOSINATE (FREE ACID)	
RAPE SEED	5
HALOFUGINONE HALOFUGINONE	
CATTLE KIDNEY	0.03
CATTLE LIVER	0.03
ISOXAFLUTOLE THE SUM OF ISOXAFLUTOLE, 2-CYCLOPROPYLCARCONYL-3-(2-METHYLSULFONYL-4-TRIFLUOROMETHYLPHENYL)-3-OXOPROPANENITRILE AND 2-METHYLSULFONYL-4-TRIFLUOROMETHYLBENZOIC ACID EXPRESSED AS ISOXAFLUTOLE	
CHICK-PEA (DRY)	*0.03
EDIBLE OFFAL (MAMMALIAN)	*0.05
EGGS	*0.05
MEAT (MAMMALIAN)	*0.05
MILKS	*0.05
POULTRY, EDIBLE OFFAL OF	*0.05
POULTRY MEAT	*0.05
SUGAR CANE	*0.01
METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OXIME'), EXPRESSED AS METHOMYL *SEE ALSO* THIODICARB	
BEETROOT	1
METRIBUZIN METRIBUZIN	
SUGAR CANE	*0.02
PYMETROZINE PYMETROZINE	
ALMONDS	T*0.01
TRINEXAPAC-ETHYL 4-(CYCLOPROPYL-α-HYDROXY-METHYLENE)-3,5-DIOXO-CYCLOHEXANECARBOXYLIC ACID	
SUGAR CANE	T0.2

[2.7] *omitting from* Schedule 2 *the foods and associated ERLs for each of the following chemicals –*

ALDRIN AND DIELDRIN SUM OF HHDN AND HEOD	
CARROT	E0.1
CUCUMBER	E0.1
HORSERADISH	E0.1
PARSNIP	E0.1
POTATO	E0.1

RADISH	E0.1

[2.8] *inserting in alphabetical order* in Schedule 2*, the foods and associated ERLs for each of the following chemicals –*

ALDRIN AND DIELDRIN SUM OF HHDN AND HEOD	
FRUITING VEGETABLES, CUCURBITS	E0.1
ROOT AND TUBER VEGETABLES	E0.1

Attachment 1B

Draft variations to the *Australia New Zealand Food Standards Code* (Indicating Changes from Drafting at Assessment)

1. Item [2.5]

1.1 At Assessment

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

ETOXAZOLE ETOXAZOLE	
CITRUS FRUITS	T0.1
DRIED GRAPES	0.2
FRUITING VEGETABLES, OTHER THAN CUCURBITS	T0.1
POME FRUITS	0.2
STONE FRUITS [EXCEPT CHERRIES]	0.1

1.2 At Approval

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

ETOXAZOLE ETOXAZOLE	
CHERRIES	1
CITRUS FRUITS	T0.1
DRIED GRAPES	1.5
FRUITING VEGETABLES, OTHER THAN CUCURBITS	T0.1
POME FRUITS	0.2
STONE FRUITS [EXCEPT CHERRIES]	0.1

1. Item [2.6]

1.1 At Assessment

No amendment proposed

1.2 At Approval

[2.6] *omitting from* Schedule 1*, under the entries for the following chemicals, the MRL for the food, substituting –*

ETOXAZOLE ETOXAZOLE	
GRAPES	0.5

Attachment 1C

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

Subsection 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 1.3.1*** *of the Australia New Zealand Food Standards Code is varied by –*

[1.1] *inserting in* Schedule 1*, under item* 4.1 Unprocessed fruits and vegetables –

blueberries				
220 221 222 223 224 225 228	Sulphur dioxide and sodium and potassium sulphites	10	mg/kg	

[1.2] *omitting from* Schedule 1*, under item* 4.1 Unprocessed fruits and vegetables –

Longans				
220 221 222 223 224 225 228	Sulphur dioxide and sodium and potassium sulphites	10	mg/kg	

substituting –

longan				
220 221 222 223 224 225 228	Sulphur dioxide and sodium and potassium sulphites	10	mg/kg	edible aril only, that is, the edible portion of the fruit

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

[2.1] *omitting from* Schedule 1, *the commodity name under the chemical appearing in* Column 1 *of the Table to this sub-item, substituting the commodity name appearing in* Column 2 –

COLUMN 1	COLUMN 2
MALDISON	CURRANT, BLACK

[2.2] *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
ABAMECTIN	SUM OF AVERMECTIN B1A, AVERMECTIN B1B AND (Z)-8,9 AVERMECTIN B1A, AND (Z)-8,9 AVERMECTIN B1B
PROPACHLOR	SUM OF PROPACHLOR AND METABOLITES HYDROLYSABLE TO N-ISOPROPYLANILINE, EXPRESSED AS PROPACHLOR

[2.3] *inserting in* Schedule 1 –

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	
BRASSICA (COLE OR CABBAGE) VEGETABLES, HEAD CABBAGES, FLOWERHEAD BRASSICAS	T3
COMMON BEAN (PODS AND/OR IMMATURE SEEDS)	T2
LETTUCE, HEAD	T5
LETTUCE, LEAF	T5
PEPPERS, SWEET	T1
SWEET CORN (CORN-ON-THE-COB)	T*0.05
TOMATO	T2
PROFOXYDIM SUM OF PROFOXYDIM AND ALL METABOLITES CONVERTED TO DIMETHYL-3-(3-THIANYL)GLUTARATE-S-DIOXIDE AFTER OXIDATION AND TREATMENT WITH ACIDIC METHANOL, EXPRESSED AS PROFOXYDIM	
EDIBLE OFFAL (MAMMALIAN)	0.5
EGGS	*0.05
MEAT (MAMMALIAN)	*0.05
MILKS	*0.01
POULTRY, EDIBLE OFFAL OF	*0.05
POULTRY MEAT	*0.05
RICE	0.05
PYROXSULAM PYROXSULAM	
EDIBLE OFFAL (MAMMALIAN)	*0.01
EGGS	*0.01
MEAT (MAMMALIAN)	*0.01
MILKS	*0.01
POULTRY, EDIBLE OFFAL OF	*0.01
POULTRY MEAT	*0.01
WHEAT	*0.01
SULPHUR DIOXIDE *SEE* STANDARD 1.3.1	

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

AZOXYSTROBIN AZOXYSTROBIN	
LEEK	0.5
BIFENTHRIN BIFENTHRIN	
EGG PLANT	T0.5
OKRA	T0.5

PEPPERS	T0.5
TOMATO	0.5
ETOXAZOLE ETOXAZOLE	
APPLE	0.2
PEAR	T0.2
STONE FRUITS	T0.5
FENVALERATE FENVALERATE, SUM OF ISOMERS	
STRAWBERRY	1
HALOFUGINONE HALOFUGINONE	
CATTLE MEAT	T*0.01
INDOXACARB SUM OF INDOXACARB AND ITS *R*-ISOMER	
STRAWBERRY	T1
ISOXAFLUTOLE THE SUM OF ISOXAFLUTOLE, 2-CYCLOPROPYLCARCONYL-3-(2-METHYLSULFONYL-4-TRIFLUOROMETHYLPHENYL)-3-OXOPROPANENITRILE AND 2-METHYLSULFONYL-4-TRIFLUOROMETHYLBENZOIC ACID EXPRESSED AS ISOXAFLUTOLE	
CEREAL GRAINS	T*0.05
LINURON SUM OF LINURON PLUS 3,4-DICHLOROANILINE, EXPRESSED AS LINURON	
VEGETABLES [EXCEPT CELERY AND LEEK]	*0.05
PHOSPHOROUS ACID PHOSPHOROUS ACID	
ASSORTED TROPICAL AND SUBTROPICAL FRUITS – INEDIBLE PEEL	T100
PIRIMICARB SUM OF PIRIMICARB, DEMETHYL-PIRIMICARB AND THE *N*-FORMYL-(METHYLAMINO) ANALOGUE (DEMETHYLFORMAMIDO-PIRIMICARB), EXPRESSED AS PIRIMICARB	
VEGETABLES [EXCEPT AS OTHERWISE LISTED UNDER THIS CHEMICAL]	1

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

AZOXYSTROBIN AZOXYSTROBIN	
BULB VEGETABLES [EXCEPT FENNEL, BULB; ONION, BULB]	T7
BIFENAZATE SUM OF BIFENAZATE AND BIFENAZATE DIAZENE (DIAZENECARBOXYLIC ACID, 2-(4-METHOXY-[1,1'-BIPHENYL-3-YL] 1-METHYLETHYL ESTER), EXPRESSED AS BIFENAZATE	
CUCUMBER	T0.5
PEPPERS, SWEET	T2
TOMATO	T0.5
BIFENTHRIN BIFENTHRIN	
FRUITING VEGETABLES, OTHER THAN CUCURBITS	0.5
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	
APPLE	2
CARBOFURAN SUM OF CARBOFURAN AND 3-HYDROXYCARBOFURAN, EXPRESSED AS CARBOFURAN	
GARLIC	T0.1
CYHALOTHRIN CYHALOTHRIN, SUM OF ISOMERS	
GARLIC	*0.05
CYPERMETHRIN CYPERMETHRIN, SUM OF ISOMERS	
BERRIES AND OTHER SMALL FRUITS [EXCEPT GRAPES]	0.5
DITHIOCARBAMATES TOTAL DITHIOCARBAMATES, DETERMINED AS CARBON DISULPHIDE EVOLVED DURING ACID DIGESTION AND EXPRESSED AS MILLIGRAMS OF CARBON DISULPHIDE PER KILOGRAM OF FOOD	
HERBS [EXCEPT PARSLEY]	T5
ETOXAZOLE ETOXAZOLE	
CITRUS FRUITS	T0.1
DRIED GRAPES	0.2
FRUITING VEGETABLES, OTHER THAN CUCURBITS	T0.1
POME FRUITS	0.2

STONE FRUITS [EXCEPT CHERRIES]	0.1
FENHEXAMID FENHEXAMID	
KIWIFRUIT	15
FENVALERATE FENVALERATE, SUM OF ISOMERS	
BERRIES AND OTHER SMALL FRUITS	1
GLUFOSINATE AND GLUFOSINATE-AMMONIUM SUM OF GLUFOSINATE-AMMONIUM, N-ACETYL GLUFOSINATE AND 3-[HYDROXY(METHYL)-PHOSPHINOYL] PROPIONIC ACID, EXPRESSED AS GLUFOSINATE (FREE ACID)	
MAIZE	0.2
SOYA BEAN (DRY)	2
HALOFUGINONE HALOFUGINONE	
CATTLE FAT	0.025
CATTLE MUSCLE	0.01
INDOXACARB SUM OF INDOXACARB AND ITS *R*-ISOMER	
BERRIES AND OTHER SMALL FRUITS [EXCEPT GRAPES]	T1
CELERY	T5
LINURON SUM OF LINURON PLUS 3,4-DICHLOROANILINE, EXPRESSED AS LINURON	
CELERIAC	T0.5
VEGETABLES [EXCEPT CELERIAC; CELERY; LEEK]	*0.05
METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OXIME'), EXPRESSED AS METHOMYL *SEE ALSO* THIODICARB	
ONION, WELSH	1
RADISH	T1
SHALLOT	1
SPRING ONION	1
SWEDE	T1
TURNIP, GARDEN	T1
METRIBUZIN METRIBUZIN	
SUGAR CANE MOLASSES	0.1
PHOSPHOROUS ACID PHOSPHOROUS ACID	
ASSORTED TROPICAL AND SUB-TROPICAL FRUITS – INEDIBLE PEEL [EXCEPT AVOCADO]	T100

AVOCADO	T500
PIRIMICARB SUM OF PIRIMICARB, DEMETHYL-PIRIMICARB AND THE *N*-FORMYL-(METHYLAMINO) ANALOGUE (DEMETHYLFORMAMIDO-PIRIMICARB), EXPRESSED AS PIRIMICARB	
SOYA BEAN (DRY)	T0.5
VEGETABLES [EXCEPT LEAFY VEGETABLES; LUPIN (DRY); SOYA BEAN (DRY)]	1
PROCHLORAZ SUM OF PROCHLORAZ AND ITS METABOLITES CONTAINING THE 2,4,6-TRICHLOROPHENOL MOIETY, EXPRESSED AS PROCHLORAZ	
MANDARINS	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	
APPLE	1
SUNFLOWER SEED	T0.3

[2.6] *omitting from* Schedule 1*, under the entries for the following chemicals, the MRL for the food, substituting –*

ABAMECTIN SUM OF AVERMECTIN B1A, AVERMECTIN B1B AND (Z)-8,9 AVERMECTIN B1A, AND (Z)-8,9 AVERMECTIN B1B	
CURRANT, BLACK	0.02
PEAS	T0.5
BIFENTHRIN BIFENTHRIN	
COMMON BEAN (PODS AND/OR IMMATURE SEEDS)	T1
DITHIOCARBAMATES TOTAL DITHIOCARBAMATES, DETERMINED AS CARBON DISULPHIDE EVOLVED DURING ACID DIGESTION AND EXPRESSED AS MILLIGRAMS OF CARBON DISULPHIDE PER KILOGRAM OF FOOD	
LITCHI	5
GLUFOSINATE AND GLUFOSINATE-AMMONIUM SUM OF GLUFOSINATE-AMMONIUM, N-ACETYL GLUFOSINATE AND 3-[HYDROXY(METHYL)-PHOSPHINOYL] PROPIONIC ACID, EXPRESSED AS GLUFOSINATE (FREE ACID)	
RAPE SEED	5

HALOFUGINONE HALOFUGINONE	
CATTLE KIDNEY	0.03
CATTLE LIVER	0.03
ISOXAFLUTOLE THE SUM OF ISOXAFLUTOLE, 2-CYCLOPROPYLCARCONYL-3-(2-METHYLSULFONYL-4-TRIFLUOROMETHYLPHENYL)-3-OXOPROPANENITRILE AND 2-METHYLSULFONYL-4-TRIFLUOROMETHYLBENZOIC ACID EXPRESSED AS ISOXAFLUTOLE	
CHICK-PEA (DRY)	*0.03
EDIBLE OFFAL (MAMMALIAN)	*0.05
EGGS	*0.05
MEAT (MAMMALIAN)	*0.05
MILKS	*0.05
POULTRY, EDIBLE OFFAL OF	*0.05
POULTRY MEAT	*0.05
SUGAR CANE	*0.01
METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OXIME'), EXPRESSED AS METHOMYL *SEE ALSO* THIODICARB	
BEETROOT	1
METRIBUZIN METRIBUZIN	
SUGAR CANE	*0.02
PYMETROZINE PYMETROZINE	
ALMONDS	T*0.01
TRINEXAPAC-ETHYL 4-(CYCLOPROPYL-α-HYDROXY-METHYLENE)-3,5-DIOXO-CYCLOHEXANECARBOXYLIC ACID	
SUGAR CANE	T0.2

[2.7] *omitting from* Schedule 2 *the foods and associated ERLs for each of the following chemicals –*

ALDRIN AND DIELDRIN SUM OF HHDN AND HEOD	
CARROT	E0.1
CUCUMBER	E0.1
HORSERADISH	E0.1
PARSNIP	E0.1
POTATO	E0.1
RADISH	E0.1

[2.8] *inserting in alphabetical order* in Schedule 2*, the foods and associated ERLs for each of the following chemicals –*

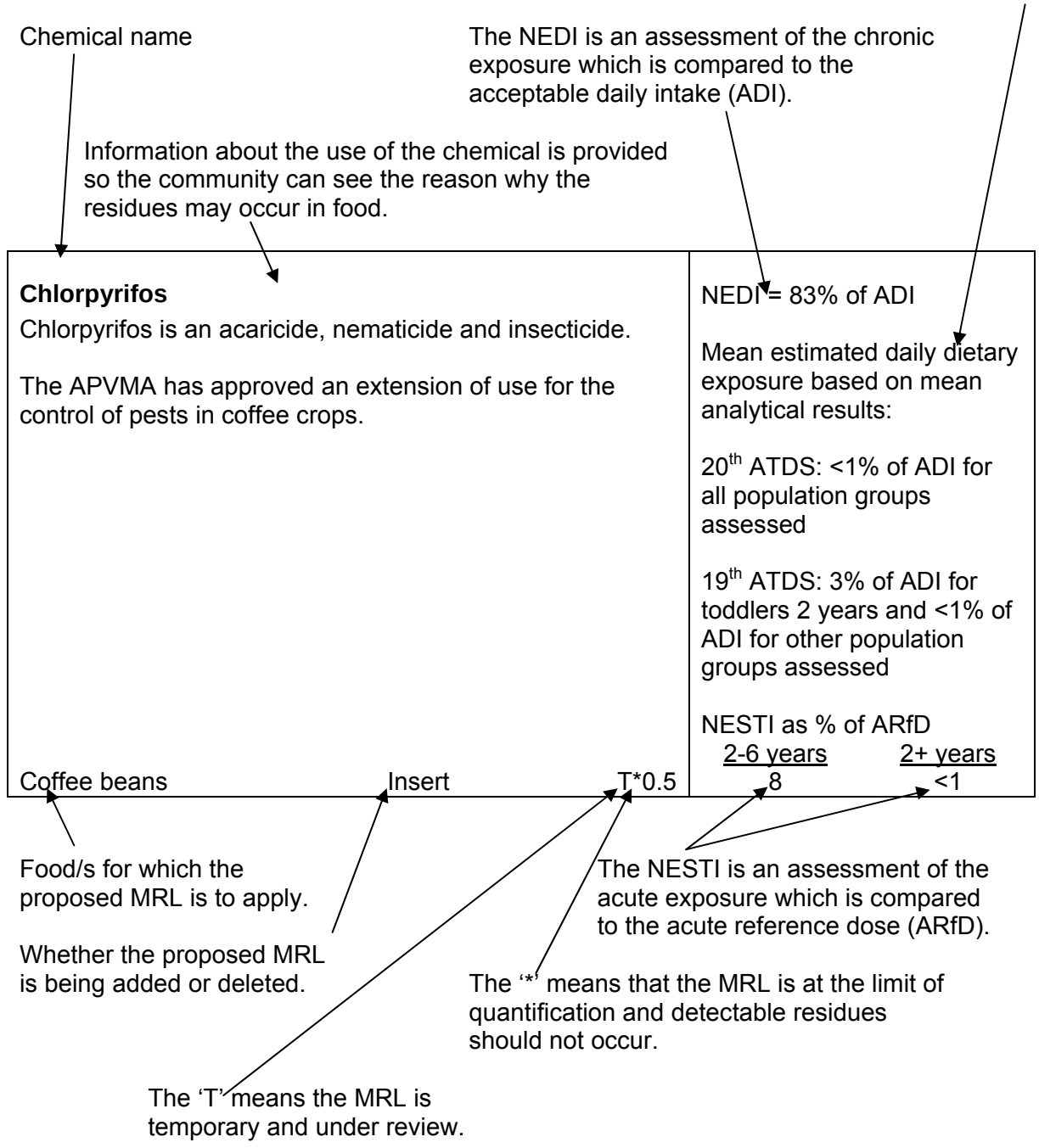
ALDRIN AND DIELDRIN SUM OF HHDN AND HEOD	
FRUITING VEGETABLES, CUCURBITS	E0.1
ROOT AND TUBER VEGETABLES	E0.1

Attachment 2

A summary of limits under consideration in Proposal M1003

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

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



SUMMARY OF MRLS AND ERLS UNDER CONSIDERATION IN PROPOSAL M1003
APVMA MRLS – APRIL, MAY, JUNE, AUGUST 2008 AND INDUSTRY REQUESTS

Requested MRLs/ERLs 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*) on blackcurrants and snow and sugar snap peas. Minor technical amendment to residue definition: Omit: Sum of avermectin b1a, avermectin b1b and (z)-8,9 avermectin b1a, and (z)-8,9 avermectin b1b Substitute: Sum of avermectin B1a, avermectin B1b and (Z)-8,9 avermectin B1a, and (Z)-8,9 avermectin B1b			NEDI = 77% of ADI NESTI as % of ARfD 2-6 years / 2+ years	
Currant, black	Omit	T0.02		
	Substitute	0.02	49	3
Peas	Omit	T0.2		
	Substitute	T0.5	16	8
Azoxystrobin Azoxystrobin is a broad spectrum fungicide with protectant, eradicant, translaminar and systemic properties. It inhibits spore germination and mycelial growth through the inhibition of mitochondrial respiration in fungi. It is used to control four main groups of fungal disease caused by ascomycetes, basidiomycetes, deuteromycetes and oomycetes. The APVMA has issued a permit for its use to control white rot (*Sclerotinium cepivorum*) on alliums except bulb onions.			NEDI = 4% of ADI	
Bulb vegetables [except fennel, bulb; onion, bulb]	Insert	T7		
Leek	Omit	0.5		
Bifenazate Bifenazate is a non-systemic acaricide primarily absorbed by contact. It is used to control the egg and motile stages of phytophagous mites on various crops. It has little impact on bees or other beneficial insects. The APVMA has issued a permit for its use to control mites (*Tetranychus urticae*) on cucumbers, capsicums and tomatoes.			NEDI = 8% of ADI NESTI as % of ARfD 2-6 years / 2+ years	
Cucumber	Insert	T0.5	3	<1
Peppers, Sweet	Insert	T2	6	3
Tomato	Insert	T0.5	4	2

Requested MRLs/ERLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment
Bifenthrin Bifenthrin is a synthetic pyrethroid insecticide which 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. The APVMA has issued permits for its use to control various pests including silverleaf whitefly (*Bemisia tabaci*) and two spotted mite (*Tetranychus urticae*) on various crops including capsicums and eggplants; and lettuce and beans. Note: The requested leafy vegetables MRL of T2 mg/kg was progressed in M1002 and gazetted in amendment 105			NEDI = 76% of ADI Mean estimated daily dietary exposure based on mean analytical results: 20th ATDS: <1% of ADI for all population groups assessed
Common bean (pods and/or immature seeds)	Omit	T0.5	
	Substitute	T1	
Egg plant	Omit	T0.5	
Fruiting vegetables, other than cucurbits	Insert	0.5	
Okra	Omit	T0.5	
Peppers	Omit	T0.5	
Tomato	Omit	0.5	
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. The APVMA has approved its use to control black spot, powdery mildew and *Alternaria* spp. in apples.			NEDI = 8% of ADI NESTI as % of ARfD 2-6 years 2+ years
Apple	Insert	2	2 <1
Carbofuran Carbofuran is a carbamate insecticide and nematicide. It is systemic with predominantly contact and stomach action. It acts as a cholinesterase inhibitor. It is used to control soil-dwelling and foliar-feeding insects and nematodes on a various crops. The APVMA has issued a permit for its use to control nematodes on garlic.			NEDI = 38% of ADI
Garlic	Insert	T0.1	

Requested MRLs/ERLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment
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 horticulture and fruit production internationally. The Food and Beverages Importers Association (FBIA) requested that FSANZ consider incorporating the Codex cypermethrin MRL for berries in the Code. Goji berries are imported to Australia and legitimate residues may occur. FSANZ noted the anomalies in the Code in relation to Codex standards for residues in berries and that there may be implications for trade in goji berries as a consequence. Berries and other small fruits [except grapes]	Insert	0.5	NEDI = 10% of ADI Mean estimated daily dietary exposure based on mean analytical results: 20th ATDS: not detected in any foods sampled 19th ATDS: <1% of ADI for all population groups assessed
Dieldrin Dieldrin is an environmental contaminant; residues may occur in foods grown some distance from sites of former application of the chlorinated organic insecticides aldrin or dieldrin, particularly in windy conditions in drought years. This is beyond the control of growers and may result in significant financial losses. These organochlorines have not been permitted or registered for use in agriculture for many years. An ERL is the maximum permitted limit of a pesticide residue, arising from environmental sources other than the use of a pesticide directly or indirectly on the food. An 'E' appearing with a limit denotes an ERL. Dieldrin ERLs are listed under aldrin and dieldrin in Schedule 2 of Standard 1.4.2 for a number of commodities. There have been sporadic detections of residues on vegetables grown in contact with soil, such as pumpkins and melons, for which no ERLs are listed in the Code. These detections have been at levels consistent with residues persisting in the soil. AUSVEG, the national peak body representing vegetable growers, requested that FSANZ consider establishing dieldrin ERLs for the crop groups fruiting vegetables, cucurbits and root and tuber vegetables at 0.1 mg/kg to address this issue. This would be consistent with the current New Zealand and Codex standards. Carrot Cucumber Fruiting vegetables, cucurbits Horseradish Parsnip Potato Radish Root and tuber vegetables	Omit Omit Insert Omit Omit Omit Omit Insert	E0.1 E0.1 E0.1 E0.1 E0.1 E0.1 E0.1 E0.1	Monitoring data indicate that the proposed ERLs do not raise health or safety concerns. 20th ATDS: not detected in any foods sampled 19th ATDS: not detected in any foods sampled Foods were analysed for dieldrin residues in the 23rd ATDS. The data are currently being examined.

Requested MRLs/ERLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment		
Etoxazole Etoxazole is an insecticide. It inhibits the insect moulting process by disrupting the cell wall. It is used to control various mites on pome fruit, stone fruit and table grapes. The APVMA has issued a permit for its use to control mites on citrus fruits and fruiting vegetables. Note: The CCAB, NHC and United States identified a trade issue in relation to the changes proposed at Assessment and provided information that an MRL is required for cherries and a higher limit is required for dried grapes. FSANZ has completed its assessment and decided to include MRLs of 1 mg/kg for cherries and 1.5 mg/kg for dried grapes rather than remove the limit for cherries and include a limit for dried grapes of 0.2 mg/kg as consulted on at Assessment. The APVMA reduced the etoxazole MRL for grapes of T0.3 mg/kg to 0.1 mg/kg in the MRL Standard to reflect the current domestic use pattern. The APVMA requested a grape MRL of 0.1 mg/kg. FSANZ consulted on retaining the T0.5 mg/kg MRL for grapes, as following previous consultation on including the T0.3 mg/kg MRL in the Code, the CTGC submitted that a limit at that level of 0.5 mg/kg was required. As the limit for grapes relates to the registered use and corresponding United States standard for etoxazole residues in grapes, FSANZ considered it appropriate to further harmonise with that standard and decided to change the status of the temporary MRL for grapes to an MRL.			NEDI = 3% of ADI NESTI as % of ARfD		
			2-6 years		2+ years
Apple	Omit	0.2			
Cherries	Insert	1	<1		<1
Citrus fruits	Insert	T0.1	<1		<1
Dried grapes	Insert	1.5	<1		<1
Fruiting vegetables, other than cucurbits	Insert	T0.1	<1	Eggplant	<1
			<1	Peppers, Sweet	<1
			<1	Tomato	<1
			<1		<1
Grapes	Omit	T0.5			
	Substitute	0.5	<1		<1
Pear	Omit	T0.2			
Pome fruits	Insert	0.2	<1	Apple	<1
			<1	Pear	<1
Stone fruits	Omit	T0.5			
Stone fruits [except cherries]	Insert	0.1	<1	Apricot	<1
			<1	Nectarine	<1
			<1	Peach	<1
			<1	Plums (including prunes)	<1

Requested MRLs/ERLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment
Fenhexamid Fenhexamid is a fungicide. It inhibits germ tube elongation and mycelium growth. Internationally it is used to control *Botrytis cinerea, Monilla* spp. and related pathogens in various fruits, vegetables and ornamentals. In Australia it is used to control bunch rot (*Botrytis cinerea*) on grapes and grey mould on strawberries. Bayer CropScience (Bayer) requested that FSANZ consider incorporating the Codex fenhexamid MRL for kiwifruit in the Code to account for legitimate residues that may occur in kiwifruit. Bayer provided information that kiwifruit are imported to Australia in the off-season. FSANZ noted the anomaly in the Code in relation to the Codex standard for residues in kiwifruit and that there may be implications for trade as a consequence. Kiwifruit	Insert	15	NEDI = 5% of ADI
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. The FBIA requested that FSANZ consider incorporating the Codex fenvalerate MRL for berries in the Code. Goji berries are imported to Australia and legitimate residues may occur. FSANZ noted the anomalies in the Code in relation to Codex standards for residues in berries and that there may be implications for trade in goji berries as a consequence. Berries and other small fruits Strawberry	Insert Omit	1 1	NEDI = 48% of ADI Mean estimated daily dietary exposure based on mean analytical results: 20th ATDS: not detected in any foods sampled 19th ATDS: <1% of ADI for all population groups assessed

Requested MRLs/ERLs 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. The APVMA approved its use to control diamondback moth, cabbage white butterfly, cluster caterpillar, heliothis (*Helicoverpa* spp.), and soybean looper in various vegetable crops. The recommended MRL for corn is at the limit of quantification (LOQ). New chemical Insert residue definition: 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			NEDI = 35% of ADI
Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	Insert	T3	
Common bean (pods and/or immature seeds)	Insert	T2	
Lettuce, head	Insert	T5	
Lettuce, leaf	Insert	T5	
Peppers, Sweet	Insert	T1	
Sweet corn (corn-on-the-cob)	Insert	T*0.05	
Tomato	Insert	T2	
Glufosinate-ammonium Glufosinate-ammonium is a non-selective contact herbicide. It inhibits glutamate synthesis, leading to accumulation of ammonium ions and inhibition of photosynthesis. It is used to control broadleaf and grass weeds. Bayer requested that FSANZ consider incorporating Codex glufosinate-ammonium MRLs for canola and soybean in the Code. Bayer requested a glufosinate-ammonium MRL of 0.2 mg/kg for maize. This is higher than the Codex MRL of 0.1 mg/kg for this commodity. The requested MRL is the applicable standard in the United States and Canada. These MRLs are requested to facilitate trade. Bayer provided information that these commodities are imported from North America; residues may occur as a result of legitimate use of glufosinate-ammonium on these crops in the United States and Canada; and that these residues may not comply with current Australian standards.			NEDI = 7% of ADI
Maize	Insert	0.2	
Rape seed	Omit	*0.05	
	Substitute	5	
Soya bean (dry)	Insert	2	

Requested MRLs/ERLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment	
Halofuginone				
Halofuginone belongs to the quinazolone group of chemicals, which are derivatives of the quinolone group of antimicrobials. It destroys infected lymphocytes; resulting in the release of schizonts, which are then susceptible to the defence system of the host. The APVMA has approved its use in calves. It is orally administered to calves aged 1 – 21 days for the prevention and treatment of scours caused by *Cryptosporidium parvum*. Quinolones are used in human medicine, notably nalidixic acid which is indicated for the treatment of urinary tract infections. There are alternative chemical treatments available for this purpose. FSANZ understands that halofuginone is not used in human medicine in Australia or New Zealand and is currently the only quinolone registered for use in food producing animals. The APVMA consulted with the National Health and Medical Research Council on the assessment of the proposed use pattern. The assessment included rigorous consideration of the risk of antimicrobial resistance arising from consumption of residues that may occur in edible calf tissues. The APVMA has advised that the use of halofuginone associated with the MRLs is not considered to present a significant risk in the development of antimicrobial resistance in the treatment of infections in humans. The MRLs are the same as the limits that apply in the European Union.			NEDI = 14% of ADI NESTI as % of ARfD	
			2-6 years	2+ years
Cattle fat	Insert	0.025	2	2
Cattle kidney	Omit	T*0.01		
	Substitute	0.03	9	29
Cattle liver	Omit	T*0.01		
	Substitute	0.03	9	29
Cattle meat	Omit	T*0.01		
Cattle muscle	Insert	0.01	42	23
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 permits for its use to control heliothis, light brown apple moth, lucerne leaf roller and vegetable weevil on celery and light brown apple moth on field grown berries.			NEDI = 15% of ADI NESTI as % of ARfD	
			2-6 years	2+ years
Berries and other small fruits [except grapes]	Insert	T1	21	12
Celery	Insert	T5	24 Celery	7
			27 Celery, raw	8
Strawberry	Omit	T1	21	12

Requested MRLs/ERLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment
Isoxaflutole Isoxaflutole is a systemic herbicide. It is a p-hydroxyphenyl pyruvate dioxygenase inhibitor. This enzyme converts p-hydroxyphenyl pyruvate to homogentisate, a key step in plastoquinone biosynthesis, giving rise to chlorosis of new growth. It is used for pre- and post-emergent control of grasses and broadleaf weeds in chickpeas and sugar cane. The APVMA advised that residues data are sufficient to establish MRLs in place of the TMRLs. The data indicate that residues did not concentrate in processed commodities. Animal commodity MRLs are recommended as treated produce may be used as stock feed. The permit for use of isoxaflutole in cereal grains has expired. Note: The requested chickpea, sugar cane and mammalian commodity MRLs were gazetted by the APVMA in July 2001 and consulted on in January 2002 in Application A450. The MRLs were not subsequently gazetted in the Code in error.			NEDI = 3% of ADI
Cereal grains	Omit	T*0.05	
Chick-pea (dry)	Omit	T*0.03	
	Substitute	*0.03	
Edible offal (mammalian)	Omit	T*0.05	
	Substitute	*0.05	
Eggs	Omit	T*0.05	
	Substitute	*0.05	
Meat (mammalian)	Omit	T*0.05	
	Substitute	*0.05	
Milks	Omit	T*0.05	
	Substitute	*0.05	
Poultry, edible offal of	Omit	T*0.05	
	Substitute	*0.05	
Poultry meat	Omit	T*0.05	
	Substitute	*0.05	
Sugar cane	Omit	T*0.01	
	Substitute	*0.01	

Requested MRLs/ERLs 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 spectrum of insect pests in cereal, fruit and vegetable crops. The APVMA has issued a permit for its use to control thrips, mites and onion maggot on garlic. The recommended MRL is at the LOQ. Note: MRLs for lambda-cyhalothrin are listed under cyhalothrin			NEDI = 58% of ADI This is equivalent to 3% of the cyhalothrin ADI
Garlic	Insert	*0.05	
Linuron Linuron is a herbicide. It inhibits electron transport in photosystem II. It is used to control annual grasses and broad leaf weeds in vegetable crops. The APVMA has issued a permit for its use to control weeds in celeriac.			NEDI = 15% of ADI
Celeriac	Insert	T0.5	
Vegetables [except celery and leek]	Omit	*0.05	
Vegetables [except celeriac; celery; leek]	Insert	*0.05	
Maldison This is a minor technical amendment to ensure consistent use of the commodity name for black currants. Amendment to commodity name Omit: Currants, black Substitute: Currant, black			Dietary exposure assessment not required.

Requested MRLs/ERLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment
Mancozeb Mancozeb is a fungicide. It is in the dithiocarbamate group of chemicals. It interferes with various enzymes involved in the respiration process, thereby inhibiting spore generation and mycelial growth. It is used to control many fungal diseases in a wide range of field crops. The APVMA issued a permit for its use to control quarantine pests on nursery stocks of culinary herbs and leafy vegetables entering Western Australia from other states. A conservative temporary MRL has been recommended for herbs in line with the mancozeb MRL for leafy vegetables which may be treated at similar rates. Residues in herbs are expected to be substantially lower than the MRL as it will be 8 – 10 weeks between treatment and harvest. The APVMA has also issued a permit for its use to control lychee pepper spot (*Colletotrichum gloeosporoides*) on lychees. The APVMA has advised that the residues data provided are sufficient to establish the recommended MRL in place of the temporary MRL. The commodity name 'Litchi' is used for lychees in the Code in line with the Codex classification of foods and animal feeds. Note: MRLs for mancozeb are listed under dithiocarbamates			NEDI = 95 % of the mancozeb ADI 19th ATDS – 63% of the thiram ADI for toddlers of 2 years and 20% – 29% of this ADI for other population groups assessed. This protectively overestimates exposure as thiram has the lowest ADI of the chemicals in the dithiocarbamate group and some of the chemical residues measured will have come from other dithiocarbamates and natural compounds in onions and brassicas. Foods were analysed for dithiocarbamates residues in the 23rd ATDS. The data are currently being examined. The APVMA has listed the dithiocarbamates group for review.
Herbs [except parsley]	Insert	T5	
Litchi	Omit	T5	
	Substitute	5	

Requested MRLs/ERLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment
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 fruits, vines, vegetables and field crops. The APVMA has issued permits for its use to control heliothis (*Helicoverpa* spp.), loopers and webworm on beetroot; cabbage white butterfly, cabbage centre grub, heliothis, looper and cluster caterpillar on radish, swede and turnip; and western flower thrips on spring onion, shallot and Welsh onion. The APVMA has advised that the residues data provided are sufficient to establish the recommended beetroot MRL in place of the temporary MRL. The APVMA gazetted the shallot and Welsh onion MRLs in May 2009.			NEDI = 84% of ADI 19th ATDS: not detected in any foods sampled * The NESTIs indicated were calculated using consumption data for all bulb vegetables as consumption data for the relevant food were not available for that population group.
Beetroot	Omit	T1	NESTI as % of ARfD 2-6 years 2+ years
	Substitute	1	21 7
Onion, Welsh	Insert	1	58* *Bulb vegetables 20*
Radish	Insert	T1	8 8
Shallot	Insert	1	58* 3
Spring onion	Insert	1	58* 5
Swede	Insert	T1	24 30
Turnip, garden	Insert	T1	24 14
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, sugar cane and vegetable crops. The APVMA has approved an extension of use of metribuzin to control weeds in sugar cane. The recommended MRL for sugar cane is at the LOQ.			NEDI = 5% of ADI NESTI as % of ARfD 2-6 years 2+ years
Sugar cane	Omit	0.1	
	Substitute	*0.02	<1 Sugar from all sources <1
Sugar cane molasses	Insert	0.1	
Phosphorous acid Phosphorous acid is a selective systemic phosphonate fungicide with multi site activity. It is used to control fungal diseases on fruits and vegetables. The APVMA has issued a permit for its use to control root rot (*Phytophthora cinnamomi*) on avocados.			NEDI = 7% of ADI
Assorted tropical and subtropical fruits –inedible peel	Omit	T100	
Assorted tropical and sub-tropical fruits – inedible peel [except avocado]	Insert	T100	
Avocado	Insert	T500	

Requested MRLs/ERLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment
Pirimicarb Pirimicarb is an anticholinesterase insecticide. It is selective and systemic and has contact, stomach and respiratory action. It is used to control certain aphids on crops and pastures. The APVMA has issued a permit for its use to control soybean aphid on soya beans.			NEDI = 85% of ADI Mean estimated daily dietary exposure based on mean analytical results: 20th ATDS: <1% of ADI for all population groups assessed 19th ATDS: <1% of ADI for all population groups assessed
Soya bean (dry)	Insert	T0.5	
Vegetables [except as otherwise listed under this chemical]	Omit	1	
Vegetables [except leafy vegetables; lupin (dry); soya bean (dry)]	Insert	1	
Prochloraz Prochloraz is a pyrazole fungicide. It inhibits steroid demethylation (ergosterol biosynthesis). It is used as a protectant and eradicant fungicide against a wide range of diseases affecting field, fruit and vegetable crops. The APVMA has issued a permit for its use to control anthracnose in mandarins.			NEDI = 32% of ADI NESTI as % of ARfD 2-6 years: 35 2+ years: 10
Mandarins	Insert	T10	
Profoxydim Profoxydim is a herbicide. It is a fatty acid synthesis inhibitor, it inhibits acetyl CoA carboxylase (ACCase). It is translocated throughout the plant and to the meristematic tissues. Weeds stop growing, followed by yellowing or reddening of younger leaves. The APVMA has approved its use for post-emergence control of barnyard and silvertop grasses in rice crops. The APVMA has advised that detectable residues are unlikely to occur in rice grain. MRLs are recommended for animal commodities as rice forage may be fed to animals. The recommended MRLs for eggs, meats, milks and poultry offal are at the LOQ. New chemical Insert residue definition: Sum of profoxydim and all metabolites converted to dimethyl-3-(3-thianyl)glutarate-S-dioxide after oxidation and treatment with acidic methanol, expressed as profoxydim			NEDI = <1% of ADI
Edible offal (mammalian)	Insert	0.5	
Eggs	Insert	*0.05	
Meat (mammalian)	Insert	*0.05	
Milks	Insert	*0.01	
Poultry, edible offal of	Insert	*0.05	
Poultry meat	Insert	*0.05	
Rice	Insert	0.05	

Requested MRLs/ERLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment
Propachlor Propachlor is a selective chloroacetamide herbicide. It is absorbed by seedling shoots with secondary translocation throughout the plant. It is used to control grass and broadleaf weeds in cereal and vegetable crops. Amendment to residue definition Omit: Propachlor Substitute: Sum of propachlor and metabolites hydrolysable to N-isopropylaniline, expressed as propachlor			Dietary exposure assessment not required.
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 renewed a permit for its use to control green peach aphid (*Myzus persicae*) on almonds. Residue data support the recommended MRL at the LOQ. Almonds Omit T*0.02 Substitute T*0.01			NEDI = 20% of ADI
Pyraclostrobin Pyraclostrobin is a fungicide. It inhibits mitochondrial respiration by blocking electron transfer at the cytochrome bc1 complex. It is used to control plant pathogens in fruit and vegetable crops. The APVMA has approved its use to control black spot, powdery mildew and Alternaria in apples. The APVMA has issued a permit for its use to control powdery mildew on sunflowers.			NEDI = <1% of ADI NESTI as % of ARfD 2-6 years / 2+ years
Apple	Insert	1	78 / 19
Sunflower seed	Insert	T0.3	<1 / <1
Pyroxsulam Pyroxsulam is a herbicide. It inhibits the plant enzyme acetolactate synthase (ALS). The APVMA has approved its use to control grass and broadleaf weeds in wheat. The recommended MRLs are at the LOQ. New chemical Insert residue definition: Pyroxsulam			NEDI = <1% of ADI
Edible offal (mammalian)	Insert	*0.01	
Eggs	Insert	*0.01	
Meat (mammalian)	Insert	*0.01	
Milks	Insert	*0.01	
Poultry, edible offal of	Insert	*0.01	
Poultry meat	Insert	*0.01	
Wheat	Insert	*0.01	

Requested MRLs/ERLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)	Dietary Exposure Assessment
Sulphur dioxide Sulphur dioxide is a non systemic protective fungicide and acaricide with contact and vapour action. It is used to control powdery mildews on fruit and mites on a range of crops. The APVMA has renewed permits for its use to control *Botrytis cinerea* on blueberries; and post-harvest rots and to prevent skin browning on longans. The APVMA has lowered the MRL for sulphur dioxide in whole longans from a level of 500 mg/kg to 150 mg/kg. The current limit in the Code for sulphur dioxide residues in longans is 10 mg/kg. The APVMA has advised that residues data indicate that following application at the maximum rate, residues in the edible portion of the fruit will be below 10 mg/kg. For clarity, FSANZ has approved a qualification in Standard 1.3.1 that the longan limit applies to the edible portion; and a cross reference in Standard 1.4.2 to Standard 1.3.1. Note: Residue limits for sulphur dioxide are listed in Standard 1.3.1. Limits in Standard 1.3.1 are known as maximum permitted levels (MPLs). Standard 1.3.1 Schedule 1 Permitted uses of food additives by food type, 4.1 Unprocessed fruits and vegetables: Insert: blueberries INS number: 220 221 222 223 224 225 228 Additive name: Sulphur dioxide and sodium and potassium sulphites Maximum Permitted Level: 10 mg/kg Retain longan MPL of 10 mg/kg Insert the following qualification in relation to the longan entry: edible aril only, that is, the edible portion of the fruit Standard 1.4.2 New entry Insert chemical name and cross reference to Standard 1.3.1: Sulphur dioxide *see* Standard 1.3.1	Mean estimated daily dietary exposure based on mean analytical results: 21st ATDS: ≤ 80% of the ADI for all population groups assessed. The 21st ATDS indicated that sulphite intakes may exceed the ADI for some population groups. FSANZ has raised a proposal to address this. Extending the permissions for addition of sulphur dioxide set out in the Code to blueberries may increase the population exposure to sulphur dioxide to a small extent. It should be noted that the dietary exposure to sulphur dioxide from blueberries and longans is likely to be minor compared to exposure from other dietary contributors. Thus any increase in sulphur dioxide exposure from consumption of these foods is not of concern.

Requested MRLs/ERLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment
Trinexapac-ethyl Trinexapac-ethyl is a plant growth regulator. It is an internode elongation disruptor. It is used to increase seed set, alkaloid and sugar yield and prevent lodging and stem elongation. The APVMA has issued a permit for its use at a higher rate than previously proposed under product registration for sugar cane. The APVMA has advised that no accumulation of residues in processed commodities was observed in processing studies. Sugar cane	Omit Substitute	0.1 T0.2	NEDI = 2% of ADI

Attachment 3

Summary of Submissions

Submitter	Comments
California Cherry Advisory Board	Expressed concern that the applicable etoxazole MRL for cherries was to be omitted from the Standard. In light of current registered etoxazole use on cherries and corresponding MRL in the United States, requested consideration of retaining an etoxazole cherry MRL harmonised with the United States limit to prevent potential trade disruption.
California Table Grape Commission	Noted that in 2008 Australia was the 5th largest export market by volume for California table grape exports with a reported value of twenty nine million US dollars. Notes that regulatory harmonisation between the United States and Australia reduces the possibility of trade impediments. Supports the retention of the current etoxazole MRL for grapes at the level of 0.5 mg/kg as etoxazole is an important reduced-risk compound for the table grape industry's integrated pest management efforts while managing insecticide resistance issues. On this basis requests consideration of transitioning the status of the limit from a temporary MRL to an MRL.
Fijian Government	Fiji considers that MRLs constitute a possible infringement of GATT Article III (National Treatment) and SPS Article 4 (Equivalence). Fiji considers that under these general GATT and SPS rules and SPS Articles 2.3 and 5.7, the regulation on importation of fresh ginger for processing discriminates against Fiji exporting ginger to Australia for the fresh market.
Food and Beverage Importers' Association	Supports the proposed cypermethrin and fenvalerate limits for berries and other small fruits. This is on the basis that foods in this commodity group are imported into Australia and the proposed limits would harmonise with Codex MRLs; the chemicals are registered for other uses in Australia for which MRLs are established; the FSANZ safety assessment concluded that the proposed variations do not present safety concerns; due recognition should be given to agricultural practices of 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. Notes that goji berries are imported and not grown in Australia. Supports the Unilever submission on the basis that the requested limits for tea align with international standards relating to legitimate overseas agricultural practices; and reduce potential adverse impacts on trade.

Submitter	Comments
Food Technology Association of Australia Inc.	Supports the proposed draft variations to the Code. Expressed dismay at the lengthy period of time for the variations to be submitted for approval by FSANZ and then await gazettal noting that the proposed changes have already been approved and gazetted into the equivalent and identical list provided by the APVMA. Noted that the approved MRLs are available to primary producers who must immediately comply, whereas food manufacturers and retail outlets for primary produce have to analyse the same foods and comply with the outdated, by 12 months and more, Code. Considers that although there may be some legislative impediments to aligning the APVMA and FSANZ lists, the delay may be preventing fair trading and placing primary and secondary food producers and retailers in a position of potential conflict of interest. States that this incongruity should be easily resolvable by FSANZ adopting the APVMA changes by reference and removing the double handling of identical material.
New South Wales Food Authority	Supports the proposed draft variations to the Code. Requested FSANZ consider the potential for elevated sulphur dioxide residues on the skin of longans to provoke illness in sensitive consumers.
Northwest Horticultural Council	Represents United States Pacific Northwest apple, pear and cherry growers. Notes that Australia is a top seven trading partner for cherries from that region. Notes that MRLs have moved to the forefront of trade issues. Supports the proposed boscalid and pyraclostrobin MRLs for apples and requests that these be extended to pome fruits to include pear. Requests boscalid and pyraclostrobin stone fruit MRLs to include cherries at levels similar to the United States MRLs of 1.7 mg/kg and 0.9 mg/kg respectively. Noted that limits were not proposed for flubendiamide and chlorantraniliprole residues in pome and stone fruit and requested limits be considered. Notes that the United States flubendiamide MRLs for apples, pears and cherries are 0.7 mg/kg, 0.7 mg/kg and 1.6 mg/kg respectively and the chlorantraniliprole MRLs for these foods are 0.3 mg/kg, 0.3 mg/kg and 1 mg/kg. Supported the proposed etoxazole pome fruit MRL. Requested that Australia and New Zealand harmonise with the United States etoxazole limit for cherries of 1 mg/kg.
People's Republic of China	China provided comments in relation to the scientific evidence for the difference between the limits for flubendiamide residues in lettuce (T5 mg/kg) and sulphur dioxide residues in longans (10 mg/kg) and Codex and other member nation standards. China noted that there are no Codex MRLs established for these chemical/food combinations, and that the Japanese and United States' standards for flubendiamide/lettuce are 15 mg/kg and 11 mg/kg respectively and the United States requirement for sulphur dioxide/longan is that GMP is met.
Queensland Government	Supports the proposed draft variations to the Code. Acknowledges that this presents no public health or safety concerns and will permit trade of treated foods.

Submitter	Comments
Unilever Australasia	Supports FSANZ 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 participation 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. Provided information on the use of bifenthrin, cypermethrin, fenvalerate and lambda-cyhalothrin in tea production and relevant standards for residues of these chemicals in tea internationally. Requests in the submission and other correspondence that FSANZ consider including MRLs in the Code harmonised with European Union MRLs of 5 mg/kg for bifenthrin, 0.5 mg/kg for cypermethrin, 0.05 mg/kg for fenvalerate and 1 mg/kg for lambda-cyhalothrin residues in tea. Notes that the submission is supported by the FBIA and the Australian Food and Grocery Council.
United States Government	The United States welcomes FSANZ commitment to MRLs that protect human health and do not create trade issues. Requested that FSANZ consider harmonising with the United States MRL for etoxazole residues in raisins of 1.5 mg/kg. Provided the United States Environmental Protection Agency etoxazole evaluation. Supports changing the status of the limit for etoxazole residues in grapes of 0.5 mg/kg from a temporary MRL to an MRL harmonised with the United States limit. Noted that there are no relevant Codex MRLs.

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

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

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

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

1.3 Calculating Dietary Exposure

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

The APVMA and FSANZ have agreed that all dietary exposure assessments for agricultural and veterinary chemicals undertaken by the APVMA will be based on food consumption data for raw commodities, derived from individual dietary records from the most appropriate 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 1995 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. This survey has been deemed the most appropriate to use for MRL assessments as it enables population estimates of exposure to be conducted (NEDIs) and captures seasonal variation in food consumption, which is particularly relevant for fruit and vegetables in relation to agricultural and veterinary chemical dietary exposure estimates.

1.3.1 Chronic Dietary Exposure Assessment

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

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

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

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

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

1.3.2 Acute Dietary Exposure Assessment

The National Estimated Short Term Intake (NESTI) is used to estimate acute dietary exposure. Acute (short term) dietary exposure assessments are undertaken where the OCS has determined an ARfD for a chemical or advised that a JMPR ARfD is appropriate. Acute dietary exposures are normally only estimated for raw unprocessed commodities (fruit and vegetables) but may include consideration of meat, offal, cereal, milk or dairy product consumption on a case-by-case basis.

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

The NESTI calculation incorporates the large portion (97.5 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. The estimated acute dietary exposure is compared to the ARfD to characterise the risk to the Australian population and children. 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 draft variations, the changes are gazetted and automatically adopted by reference into the food laws of the Australian States and Territories.

1.4 Antibiotics

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

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

As part of its registration and chemical review processes, the APVMA conducts rigorous risk assessments for new antibiotics and extensions of indications, applying the NHMRC/EAGAR principles, to determine the likely impact on the efficacy of antibiotics that are essential for human therapeutics. If the risk of antimicrobial resistance associated with a proposed use pattern 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.