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

11 November 2008
[19-08]

PROPOSAL M1002
Maximum Residue Limits (January, February, March 2008)
APPROVAL REPORT

Executive Summary

Purpose

The purpose of this Proposal is to consider varying maximum residue limits (MRLs) in the Australia only Standard 1.4.2 of the *Australia New Zealand Food Standards Code* (the Code) for residues of agricultural and veterinary chemicals that may legitimately occur in food. This includes MRL variations gazetted by the Australian Pesticides and Veterinary Medicines Authority (APVMA) in January, February and March 2008. The MRL variations will permit the sale of legally treated foods 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 MRLs in the Code that reflect legitimate residues in food.

Dietary exposure assessments indicate that in relation to current reference health standards, the MRL variations do not present any public health and safety concerns. This Proposal includes consideration of an MRL for the antibiotic florfenicol in fish. The residues associated with the proposed MRL do not pose a risk in terms of the development 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 residues of agricultural and veterinary chemicals in food.

FSANZ made a Sanitary and Phytosanitary notification to the World Trade Organization (WTO). Comments were received from the California Table Grape Commission (CTGC). FSANZ has addressed the issues raised in section 9.2 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 section 18 objectives and 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;
- whether other measures would be more cost-effective than a variation to a food regulatory measure;
- any relevant New Zealand standards; and
- any other relevant matters.

Decision

FSANZ has made an assessment and recommends approving the draft variations to Standard 1.4.2 – Maximum Residue Limits subject to the amendments identified at Attachment 1B. The residues associated with the MRL variations do not present any public health and safety concerns and the draft variations as amended are necessary, cost-effective and will benefit consumers, Government and industry. Approving the amended draft variations will permit the sale of legitimately treated foods.

Reasons for Decision

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

- MRLs serve to protect public health and safety by minimising residues in food consistent with the effective control of pests and diseases.
- Dietary exposure assessments indicate that the MRL 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 treated with agricultural and veterinary chemicals 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 draft variations are necessary, cost-effective and beneficial.

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

- The variations are consistent with the FSANZ objectives under s18 of the FSANZ Act.

Consultation

FSANZ has now completed the assessment of Proposal M1002 and undertaken a round of public consultation. The Board has approved the draft amendments to the Code and this decision has been notified to the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council). If the Ministerial Council does not request FSANZ 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 variation at **Attachment 1C**. Taking into account the comment received in response to the World Trade Organization (WTO) Notification, FSANZ has amended the draft variations (see **Attachment 1A** - unmarked version or **Attachment 1B** - marked version).

The amendment to the draft variations is to insert an MRL for fluorine of 7 mg/kg for grapes. This will in fact retain the current MRL for grapes as FSANZ progresses the deletion of the fruit entry for fluorine and associated MRL of 7 mg/kg as requested by the APVMA. This reflects the CTGC request that FSANZ consider retaining an MRL of 7 mg/kg for fluorine in grapes on the basis that this would minimise potential trade disruption.

On the basis of the points raised in the CTGC comments, the currently available information and as an interim measure until discussions with the APVMA can occur, FSANZ considers that this a practical approach.

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INTRODUCTION

Notifications were received from the Australian Pesticides and Veterinary Medicines Authority (APVMA) on 5 February, 19 February and 6 March 2008 seeking to vary the *Australia New Zealand Food Standards Code* (the Code). The proposed variations to the Australia only Standard 1.4.2 – Maximum Residue Limits would align maximum residue limits (MRLs) in the Code for certain agricultural and veterinary chemicals with the MRLs listed in the APVMA MRL Standard and permit the sale of relevant foods legitimately treated during production.

This Proposal includes consideration of MRL variations for azoxystrobin, bifenazate, bifenthrin, chlorpyrifos, closantel, clothianidin, cyanamide, cyprodinil, dimethenamid-P (new chemical), florfenicol (antibiotic), fludioxonil, fluorine (inorganic salts), glyphosate, isoxaben, maldison, methomyl, metsulfuron-methyl, phosphorous acid, propiconazole, prosulfocarb, prothioconazole, pyrasulfotole, ractopamine, sulfuryl fluoride (new chemical) thiamethoxam, toltrazuril and tolylfluanid.

This Proposal does not include an MRL for mancozeb in herbs gazetted by the APVMA in March 2008 as consideration of that MRL is ongoing. Rather than delay progressing the other MRL variations, the mancozeb MRL has been excluded from this Proposal and will be included in a subsequent proposal.

The draft variations to the Code are at **Attachment 1** and the proposed variations and dietary exposure estimates are outlined in **Attachment 2**. A summary of comments received on the Assessment Report is provided in **Attachment 3**. The safety assessment methodology is outlined in **Attachment 4** and the background information in **Attachment 5**; this includes an explanation of terms used in this Report.

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

In considering the issues associated with MRL variations, it should be noted that 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. 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 be a risk to public health and safety.

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

1. The Issue / Problem

Including MRLs in the Code has the effect of allowing legally treated produce to be sold legally, where any residues are at or under the MRL. Variations in MRLs reflect the changing patterns of agricultural and veterinary chemicals available to chemical product users (e.g. 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, MRLs are also varied in line with international standards to allow legitimately treated foods to be imported.

Internationally, food producers face different pest and disease pressures and climatic conditions and therefore agricultural and veterinary chemical use patterns may vary.

2. Current Standard

2.1 Background

Standard 1.4.2 lists the limits for agricultural and veterinary chemical residues which may occur in foods. If an MRL 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 MRL in the Standard, legitimately treated produce may not be sold where there are detectable residues.

Variations to the Standard are required to permit the sale of foods legitimately treated during production. A dietary exposure assessment is conducted before the Standard is varied to ensure that MRL variations 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 MRLs, including MRLs for antibiotic substances, in the Code is provided at **Attachment 5**.

3. Objectives

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

Subsection 18(1) of the FSANZ Act provides that the objectives (in descending priority order) of FSANZ in developing or reviewing food regulatory measures and variations of food regulatory measures are:

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

Subsection 18(2) provides that FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

For the reasons set out in this Report, the proposed draft variations to Standard 1.4.2 are consistent with the FSANZ Act section 18 objectives.

4. Assessment Approach

FSANZ's primary role in developing food regulatory measures for agricultural and veterinary chemicals is to ensure that the potential residues in treated 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 all potentially treated foods in the diet by comparing the dietary exposure with the relevant reference health standard. FSANZ will not approve MRL variations to the Code where dietary exposure to the residues of a chemical could be a risk to public health and safety.

The steps undertaken in conducting a dietary exposure assessment are:

- determination of the residues of a chemical in a treated food; and

- calculating the dietary exposure to a chemical from relevant foods, using food consumption data from national nutrition surveys and comparing this to the acceptable 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) or provisional tolerable weekly intake (PTWI) or upper level (UL)). 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 health standard/s.

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

RISK ASSESSMENT

5. Risk Assessment Summary

FSANZ has reviewed the dietary exposure assessments submitted by the APVMA to assess the notified MRL variations. FSANZ also conducted a dietary exposure assessment for sulfuryl fluoride and fluorine. This included consideration of retaining an MRL of 7 mg/kg for fluorine in grapes only as requested by the California Table Grape Commission (CTGC) (refer section 9.2).

Using the best available scientific data and internationally recognised risk assessment methodology, and considering other dietary sources of fluoride, FSANZ concluded that in relation to current reference health standards, varying the MRLs as notified by the APVMA and retaining an MRL for fluorine in grapes only, does not present any public health and safety concerns.

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

The proposed MRL for antibiotic substance florfenicol does not pose a risk in terms of development of antimicrobial resistance.

RISK MANAGEMENT

6. Options

1. Option 1 – approve the draft variations

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

3. Option 3 – reject the draft variations

7. Impact Analysis

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

7.1 Affected Parties

The parties affected by proposed MRL amendments include:

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

7.2 Benefit Cost Analysis

7.2.1 Option 1 – approve the draft variations

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

Progressing this option benefits growers and producers in that foods produced in accordance with agricultural Standards and legislation may be sold under food legislation. Omitting or reducing MRLs is 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 approved 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 are invited to comment on these impacts during the public consultation period. This is to ensure that any adverse consequences of the proposed variations can be addressed. Further discussion on the submissions received and impacts in relation to 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 – approve the draft variations subject to such amendments as FSANZ considers necessary

This option has similar costs and benefits as option 1. FSANZ has assessed comments provided by the California Table Grape Commission and has decided to retain an MRL for fluorine in grapes. This continues to permit the importation and sale of grapes legitimately treated with a chemical product in the United States.

7.2.3 Option 3 – reject the draft variations

This option would allow discrepancies between agricultural and food legislation to perpetuate as the Code would not reflect legitimate use of chemical products as determined by the APVMA. This may result in foods legitimately treated during production not being permitted for sale. In addition this may also create uncertainty, inefficiency and confusion in the enforcement of regulations. This would impact negatively on all affected parties and 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 sections 9.2 and 9.5 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 food.

In summary, FSANZ conducted an Office of 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 mechanical 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.

FSANZ recommends approving option 2 – approve the draft variations subject to such amendments as FSANZ considers necessary for the following reasons:

- There are no public health and safety concerns associated with the proposed MRL variations (this benefit also applies to option 1).

- 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 legitimately treated 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 remove discrepancies between agricultural and food standards and assist compliance agencies.

- The necessity to retain an MRL to continue to allow for the importation and sale of safe food was identified through consultation and further assessment.

Option 1 is not recommended as consultation and further assessment identified a need to amend the proposed draft variations (refer section 9.2 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, consequent discrepancies 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 MRLs in the Code does not normally generate public interest. FSANZ adopts a basic communication strategy, with a focus on alerting the community that a change to the Code is being contemplated.

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

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

9. Consultation

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 MRL variations; and any other affected parties to this Proposal.

Submissions were received from the Food Technology Association of Australia (FTAA), the National Council of Women of Australia (NCWA), the Queensland Government, Unilever Australasia, the Food and Beverage Importers Association (FBIA), and the Australian Food and Grocery Council (AFGC). FSANZ notified this proposal to the WTO and received comments from the CTGC. The comments provided are summarised in **Attachment 3**.

Submissions from the FTAA and NCWA support approving the proposed draft variations. The FBIA, AFGC, and Unilever Australasia proposed MRLs for tea for bifenthrin, chlorpyrifos, glyphosate and propiconazole for inclusion in the Code on the basis that MRL variations for these chemicals for commodities other than tea were included in this Proposal. The Queensland Government considered that fluoride ion MRLs should not be included in Schedule 1 of Standard 1.4.2. The CTGC requested that FSANZ consider retaining an MRL of 7 mg/kg for fluorine in grapes on the basis that this would minimise potential trade disruption.

9.1 Issues raised in submissions

9.1.1 Request for MRLs for Tea

The FBIA, AFGC, and Unilever Australasia requested that FSANZ consider including MRLs for tea for bifenthrin, chlorpyrifos, glyphosate and propiconazole in the Code. This was on the basis that MRL variations for these four chemicals were under consideration in this Proposal for other commodities and these chemicals are currently used on tea in producer countries as pest management chemicals, weed control chemicals or fungicides.

The submissions note that tea is an international commodity and it is important to ensure that there is consistency in standards on an international basis. The submissions provided a summary of tea MRLs for these four chemicals in tea producing countries (China, India, Taiwan, Sri Lanka, Argentina), importing countries (European Union, Japan, United States) and noted that there is a relevant Codex standard for chlorpyrifos.

The submissions also stated that the request was based on the principles of the Tea Global Plant Protection Initiative; in particular the progression towards ensuring that tea is produced and traded in a compliant manner across international boundaries.

9.1.1.1 FSANZ Evaluation

Proposal M1002 does not include consideration of MRLs for tea for the chemicals requested and as such, public consultation on these MRLs has not been conducted. The public consultation period for this Proposal has concluded and for these reasons, FSANZ does not consider it is appropriate to consider the MRLs for tea proposed by the FBIA, AFGC, and Unilever Australasia as part of this Proposal.

FSANZ considers that an application is the appropriate mechanism to seek consideration of including tea MRLs for bifenthrin, glyphosate and propiconazole in the Code.

This will allow FSANZ to consider the dietary exposure to residues associated with the proposed MRLs for tea; the legitimate use of the chemical on the commodity and the relevant MRLs internationally; as well as the views of the APVMA and the impacts of including these MRLs in the Code. An application will also ensure appropriate public consultation on variations to the Code. This approach will allow regard to be given to the request without delaying the progression of the other MRL amendments being considered in the present Proposal.

FSANZ acknowledges that there is a Codex MRL for chlorpyrifos residues in tea. This chemical is currently under review by the APVMA. For this additional reason, FSANZ does not consider it appropriate to consider this MRL for inclusion in the Code until this review is complete. However, FSANZ may consider this MRL in a future Proposal. Further information about the chlorpyrifos review can be found at the APVMA website at: http://www.apvma.gov.au/chemrev/chlorpyrifos.shtml

9.1.2 Fluoride ion MRLs

The submission from the Queensland Government considered that fluoride ion should not be included in Schedule 1 of Standard 1.4.2. The submission noted that:

- fluoride ion originates from sources other than sulfuryl fluoride and it is not particularly useful for controlling the use of sulfuryl fluoride; and
- this will set a 'zero tolerance' for all the other food commodities not contained in Standard 1.4.2 and natural concentration of fluoride in foods therefore would become violative levels.

This submission also included reference to information that some imported commodities such as herbs, spices, pulses, oilseeds and cereals may be affected as there are other commodities that can be effectively fumigated by sulfuryl fluoride in other countries.

9.1.2.1 FSANZ Evaluation

The presence of naturally occurring fluoride in food is not restricted by the provisions in Standard 1.4.2 as the interpretation of ‘chemical’ in the Standard excludes substances that are naturally present in food. The interpretation of ‘chemical’ in Standard 1.4.2 states:

> ***chemical*** *means an agricultural or veterinary chemical, whether or not listed in bold type in the shaded boxes in Schedules 1 or 2, but excludes –*
>
> *(a) a substance naturally present in food, for example, water or salt, before the food is processed; and*
> *(b) a substance in the food when naturally formed during processing, for example, heat treating, of the food; and*
> *(c) ingredients, food additives and processing aids that are permitted in this Code to be present in food.*

On this basis, the inclusion of specific MRLs in Standard 1.4.2 for fluoride ion does not apply a ‘zero tolerance’ to naturally occurring fluoride in food and does not mean that the natural presence of fluoride in food, in the absence of a specific MRL, should be regarded as a breach of the Code.

The concern raised regarding fluoride ion limits for monitoring product use has been referred to the APVMA. This is because the current fluorine MRLs have been in place for many years and removing them may have unforeseen consequences from the perspective of chemical product use.

FSANZ notes that while fluorine MRLs may not be particularly useful for control of use purposes as fluoride ions may be present in foods from other sources, the MRLs notified by the APVMA need to be included in the Code to ensure that foods legitimately treated with sulfuryl fluoride can be legally sold. If the APVMA considers that an alternative approach is appropriate for fluoride ions then any amended MRLs may be considered in a future MRL Proposal.

In the meantime, FSANZ considers it appropriate to include the APVMA MRL variations for fluorine in the Code to ensure that legitimately treated foods can be sold under food legislation.

FSANZ notes the information indicating that sulfuryl fluoride may be used in other countries. However, there are no Codex MRLs for sulfuryl fluoride for commodities other than those requested by APVMA and industry has not provided any information requesting different MRLs from those notified by the APVMA. On this basis, FSANZ considers that it is appropriate to approve the MRL variations as notified by the APVMA. If industry wishes to extend sulfuryl fluoride MRLs then this may be done by making an application to FSANZ.

9.2 World Trade Organization

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

MRLs prescribed in the Code constitute a mandatory requirement applying to all food products of a particular class whether produced domestically or imported. Food products exceeding the relevant MRL set out in the Code cannot legally be supplied in Australia.

This Proposal included consideration of MRL variations that are relevant to the international Codex standard. MRL variations in the Proposal also relate to chemicals used in the production of heavily traded agricultural commodities that may indirectly have a significant effect on trade of food products between WTO members.

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

9.2.1 Comment provided by the California Table Grape Commission

The CTGC commented that Australia is an increasingly important market for table grapes, noting that since the market opened in 2001, Australia has become the industry's 6th largest export market, valued at over $40 million USD. The CTGC raised concern that the proposed deletion of the fluorine MRL for fruit would pose an impediment to the export of table grapes to Australia.

The CTGC stated that it recognised Australia's right to establish nationally appropriate standards; however, it requested that FSANZ consider retaining an MRL for fluorine in grapes which would encompass residues of fluorine in table grapes up to 7 mg/kg. This was on the basis that an MRL of 7 mg/kg would be consistent with the approved use in the United States of cryolite, a mineral compound which breaks down into fluoride, sodium and aluminium ions.

Cryolite is used by the Californian table grape industry as an efficacious means of insect control, particularly for leaf eating pests. Currently, the predominant use of cryolite is on grapes, potatoes and citrus fruits. The current US tolerance of 7 mg/kg for fluorine is associated with the use of cryolite on table grapes and was established after a comprehensive review by the US Environmental Protection Agency (USEPA) in 1996 http://www.epa.gov/oppsrrd1/REDs/0087.pdf.

In summary, the CTGC requested that FSANZ consider retaining an MRL of 7 mg/kg for fluorine in grapes on the basis that this would minimise potential trade disruption.

9.2.2.1 FSANZ Evaluation

The CTGC identified a trade issue in relation to the deletion of the fluorine MRL for fruit of 7 mg/kg proposed by the APVMA. The APVMA has also proposed a level of 5 mg/kg for dried fruits for inclusion in the Code.

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.

These matters encompass a consideration of international trade issues, such as the one raised by the CTGC. There is a tolerance for fluorine residues in grapes of 7 mg/kg listed in United States food standards. This is associated with the approved use of cryolite in grape production there. Grapes are imported into Australia from the United States and could legitimately contain fluorine residues consistent with the current fluorine MRL for fruit in the Code. Fluorine MRLs that apply to grapes internationally are listed in the table below.

FSANZ has also given careful consideration to public health and safety issues and noted that dietary exposure assessments indicate that an MRL for fluorine in grapes of 7 mg/kg does not present any public health and safety concerns. The estimated dietary exposure to fluorine including any residues that may occur in grapes at 7 mg/kg, does not exceed the acceptable reference health standard. The dietary exposure estimates are outlined in **Attachment 2**.

FSANZ has identified no public health and safety concerns with retaining an MRL of 7 mg/kg for grapes in the Code.

Fluorine **Commodity**	**APVMA MRL mg/kg**	**The Code mg/kg**	**US Tolerance mg/kg**	**CTGC requested MRL mg/kg**	**Codex MRL mg/kg**	**FSANZ MRL at Approval mg/kg**
Fruit	- (7 omitted Jan 2008)	7 (proposed for deletion)	7 (various fruits listed)	-	-	-
Grapes	-	7 (current fruit MRL)	7	7	-	7
Dried fruits	5	-	3 (except grape; raisin 7)	-	-	5

9.2.2.2 Views of the APVMA on the MRLs requested by the CTGC

The CTGC comments have been provided to the APVMA to consider and for future discussion regarding retaining the requested MRL. This will allow for any impacts of including an MRL in the Code where the APVMA has not listed a corresponding MRL in the MRL Standard to be appropriately addressed.

9.2.2.3 Summary

On the basis of the points raised by the CTGC, the currently available information and as an interim measure until discussions with the APVMA can occur, FSANZ has decided to:

- progress with deletion of the fruit MRL for fluorine of 7 mg/kg;
- progress the MRL for fluorine for dried fruits of 5 mg/kg as requested by the APVMA; and
- retain an MRL for fluorine of 7 mg/kg for grapes only.

Should it be necessary to amend the MRL for fluorine in grapes in the future, FSANZ can include this in a future Proposal and seek public comment at that time on the proposed amendment.

9.3 Codex Alimentarius Commission MRLs

Codex standards are used as the relevant international standard or basis as to whether a new or changed standard requires a WTO notification. The following table lists MRL variations where there is a corresponding MRL in the Codex standard.

Submitters did not raise any issues in terms of the specific MRL variations listed below, including in relation to Codex or other international standards. The FBIA, AFGC, and Unilever Australasia requested consideration of an MRL for chlorpyrifos in tea on the basis of an existing Codex MRL (refer section 9.1.1).

Chemical Food	Proposed MRL mg/kg	Codex MRL mg/kg
Closantel		
Cattle fat	T[a]3	3
Cattle kidney	T3	3
Cattle liver	T1	1
Cattle muscle	T1	1
Cyprodinil		
Cucumber	T0.2	0.2
Lettuce, head	T10	10
Peppers, Sweet	T0.5	0.5
Fludioxonil		
Cucumber	T0.3	0.3
Lettuce, head	T10	10
Peppers, Sweet	T2	1
Sulfuryl fluoride		

[a] 'T' indicates the MRL is temporary

Chemical Food	Proposed MRL mg/kg	Codex MRL mg/kg
Cereal grains	0.05	0.05
Dried fruits	0.07	0.06
Tree nuts	7	3
Tolylfluanid		
Cucumber	T2	1

9.4 New Zealand MRL 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 also 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.

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

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

Chemical Food	Proposed MRL mg/kg	NZ MRL mg/kg
Azoxystrobin		
Maize	T[b]*[c]0.01	*0.01
Closantel		
Cattle fat	T3	3
Cattle kidney	T3	3
Cattle liver	T1	1
Cattle muscle	T1	1
Clothianidin		
Edible offal (mammalian)	*0.02	Mammalian kidney *0.01 Mammalian liver 0.02
Meat (mammalian)	*0.02	*0.01
Milks	*0.01	*0.01
Maldison		
Shallot	T5	Vegetables 8

[b] 'T' indicates the MRL is temporary
[c] '*' indicates that the MRL is at the limit of quantification (note that regulatory methods of analysis may differ in different jurisdictions)

Chemical Food	Proposed MRL mg/kg	NZ MRL mg/kg
Spring onion	T5	
Prothioconazole		
Wheat	*0.05	Cereal grains *0.02
Toltrazuril		
Cattle fat	1	0.15
Cattle kidney	1	0.25
Cattle liver	2	0.5
Cattle muscle	0.25	0.1

9.5 Imported Foods

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

Deletions or reductions of MRLs may impact imported foods that comply with existing MRLs, even though these existing MRLs are no longer required for food produced or treated with chemical products in Australia. These impacts may be relevant where imported foods may legitimately contain residues consistent with the MRLs that are 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 has compiled the following table of foods where the MRLs are proposed for deletion or reduction. No submitters raised any issues in relation to these specific variations and the issues raised concerning MRLs for tea and grapes have been discussed above. All the proposed MRL variations to the Code are at **Attachment 1A** and the requested changes are outlined in more detail in **Attachment 2**.

Chemical Food
Fludioxonil
Sorghum
Fluorine (inorganic salts)
Fruit (except grapes)
Vegetables

Chemical Food
Methomyl
Bergamot
Burnet, Salad
Chervil
Coriander (leaves, stem, roots)
Coriander, seed
Dill, seed
Fennel, seed
Galangal, Greater
Kaffir lime leaves
Lemon grass
Lemon verbena (dry leaves)
Mizuna
Rose and dianthus (edible flowers)
Rucola (rocket)
Turmeric, root
Prothioconazole
Milks
Ractopamine
Cattle fat
Cattle kidney
Cattle meat

9.6 Commodity classifications for MRLs notified for veterinary chemicals

This Proposal includes consideration of an MRL notified by the APVMA for 'Cattle muscle'. This commodity classification is consistent with the Joint Food and Agriculture Organization / World Health Organization Expert Committee on Food Additives (JECFA) approach for determining residue limits for veterinary chemicals in food. The JECFA approach is internationally accepted as best practice for setting MRLs for veterinary chemicals.

The APVMA adopted the approach used by JECFA for setting MRLs for veterinary chemicals in July 2006. The decision to adopt the JECFA approach followed a review of evaluation processes conducted by an external body and consultation with industry and regulatory authorities.

FSANZ and the APVMA are discussing implementation issues associated with incorporating JECFA commodity classifications in the Code for MRLs notified for veterinary chemicals. Commodity classifications used for veterinary and agricultural chemicals differ, reflecting the different approaches used to determine MRLs in agricultural as opposed to veterinary situations.

As an interim measure, FSANZ has decided to progress the MRLs requested by the APVMA with JECFA commodity classifications. These may be varied through a future Proposal depending on the outcome of considerations and further consultation on the practical implications of including JECFA commodity classifications in the Code.

CONCLUSION

10. Conclusion and Decision

This Proposal has been assessed in accordance with section 59 of the FSANZ Act.

The decision is to adopt option 2 to approve the amended draft variations to Standard 1.4.2.

Decision

FSANZ recommends approving the draft variations to Standard 1.4.2 – Maximum Residue Limits subject to the amendments identified at Attachment 1B. The residues associated with the MRL variations do not present any public health and safety concerns and the draft variations as amended are necessary, cost-effective and will benefit consumers, Government and industry. Approving the amended draft variations will permit the sale of legitimately treated foods.

10.1 Reasons for Decision

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

- MRLs serve to protect public health and safety by minimising residues in food consistent with the effective control of pests and diseases.
- Dietary exposure assessments indicate that the MRL variations as notified by the APVMA 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 draft variations will benefit stakeholders by maintaining public health and safety while permitting the legal sale of food treated with agricultural and veterinary chemicals 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 draft variations are necessary, cost-effective and beneficial.
- The draft variations would remove discrepancies between agricultural and food standards and provide certainty and consistency for producers, importers and Australian, State and Territory compliance agencies.
- The variations are consistent with the FSANZ objectives under s18 of the FSANZ Act.

11. Implementation and Review

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

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

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

It is proposed that the MRL variations in this Proposal should take effect on gazettal and that the MRLs 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* (Changes Marked)
1C. Draft variations to the *Australia New Zealand Food Standards Code* (at Assessment)
2. A Summary of MRLs under consideration in Proposal M1002
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)

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

To commence: on gazettal

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

[1.1] *omitting from* 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
CLOTHIANIDIN	CLOTHIANIDIN

[1.2] *inserting in* Schedule 1 –

DIMETHENAMID-P SUM OF DIMETHENAMID-P AND ITS *(R)*-ISOMER	
COMMON BEAN (PODS AND/OR IMMATURE SEEDS)	*0.02
EDIBLE OFFAL (MAMMALIAN)	*0.01
EGGS	*0.01
MAIZE	*0.02
MEAT (MAMMALIAN)	*0.01
MILKS	*0.01
PEAS	*0.02
POPPY SEED	*0.01
POULTRY, EDIBLE OFFAL OF	*0.01
POULTRY MEAT	*0.01
PULSES	*0.02
PUMPKINS	*0.02
SWEET CORN (CORN-ON-THE-COB)	*0.02
SULFURYL FLUORIDE SULFURYL FLUORIDE	
CEREAL GRAINS	0.05
DRIED FRUITS	0.07
PEANUT	7
TREE NUTS	7

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

BIFENTHRIN BIFENTHRIN	
LETTUCE, HEAD	T2
CLOTHIANIDIN *COMMODITIES OF PLANT ORIGIN*: CLOTHIANIDIN *COMMODITIES OF ANIMAL ORIGIN*: SUM OF CLOTHIANIDIN, 2-CHLOROTHIAZOL-5-YLMETHYLGUANIDINE, 2-CHLOROTHIAZOL-5-YLMETHYLUREA, AND THE PYRUVATE DERIVATIVE OF N-(2-CHLOROTHIAZOL-5-YLMETHYL)-N'-METHYLGUANIDINE EXPRESSED AS CLOTHIANIDIN	
MEAT (MAMMALIAN) (IN THE FAT)	T*0.02
FLUORINE (INORGANIC SALTS) FLUORIDE ION	
FRUIT	7
VEGETABLES	7
GLYPHOSATE SUM OF GLYPHOSATE AND AMINOMETHYLPHOSPHONIC ACID (AMPA) METABOLITE, EXPRESSED AS GLYPHOSATE	
OILSEED [EXCEPT COTTON AND RAPE SEED]	*0.1
MALDISON MALDISON	
VEGETABLES [EXCEPT AS OTHERWISE LISTED UNDER THIS CHEMICAL]	2
METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OXIME'), EXPRESSED AS METHOMYL *SEE ALSO* THIODICARB	
BERGAMOT	T5
BURNET, SALAD	T5
CHERVIL	T5
CORIANDER (LEAVES, STEM, ROOTS)	T10
CORIANDER, SEED	T5
DILL, SEED	T5
FENNEL, SEED	T5
GALANGAL, GREATER	T*0.02
KAFFIR LIME LEAVES	T5
LEMON GRASS	T5
LEMON VERBENA (DRY LEAVES)	T5
MIZUNA	T5
ROSE AND DIANTHUS (EDIBLE FLOWERS)	T5
RUCOLA (ROCKET)	T5
TURMERIC, ROOT	T*0.02

RACTOPAMINE	
RACTOPAMINE	
CATTLE FAT	T*0.02
CATTLE KIDNEY	T0.1
CATTLE MEAT	T*0.02

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

AZOXYSTROBIN	
AZOXYSTROBIN	
MAIZE	T*0.01
BIFENAZATE	
SUM OF BIFENAZATE AND BIFENAZATE DIAZENE (DIAZENECARBOXYLIC ACID, 2-(4-METHOXY-[1,1'-BIPHENYL-3-YL] 1-METHYLETHYL ESTER), EXPRESSED AS BIFENAZATE	
PEAS	T0.5
BIFENTHRIN	
BIFENTHRIN	
LEAFY VEGETABLES [EXCEPT CHERVIL; MIZUNA; RUCOLA (ROCKET)]	T2
CLOSANTEL	
CLOSANTEL	
CATTLE FAT	T3
CATTLE KIDNEY	T3
CATTLE LIVER	T1
CATTLE MUSCLE	T1
CLOTHIANIDIN	
COMMODITIES OF PLANT ORIGIN: CLOTHIANIDIN *COMMODITIES OF ANIMAL ORIGIN*: SUM OF CLOTHIANIDIN, 2-CHLOROTHIAZOL-5-YLMETHYLGUANIDINE, 2-CHLOROTHIAZOL-5-YLMETHYLUREA, AND THE PYRUVATE DERIVATIVE OF N-(2-CHLOROTHIAZOL-5-YLMETHYL)-N'-METHYLGUANIDINE EXPRESSED AS CLOTHIANIDIN	
EGGS	*0.02
MEAT (MAMMALIAN)	*0.02
POULTRY, EDIBLE OFFAL OF	*0.02
POULTRY MEAT	*0.02
CYANAMIDE	
CYANAMIDE	
APPLE	*0.02
BLUEBERRIES	*0.05
CYPRODINIL	
CYPRODINIL	
CUCUMBER	T0.2
LETTUCE, HEAD	T10
PEPPERS, SWEET	T0.5

FLORFENICOL SUM OF FLORFENICOL AND ITS METABOLITES FLORFENICOL ALCOHOL, FLORFENICOL OXAMIC ACID, MONOCHLOROFLORFENICOL AND FLORFENICOL AMINE EXPRESSED AS FLORFENICOL AMINE	
FISH	T0.5
FLUDIOXONIL *COMMODITIES OF ANIMAL ORIGIN:* SUM OF FLUDIOXONIL AND OXIDISABLE METABOLITES, EXPRESSED AS FLUDIOXONIL *COMMODITIES OF PLANT ORIGIN:* FLUDIOXONIL	
CUCUMBER	T0.3
LETTUCE, HEAD	T10
PEPPERS, SWEET	T2
FLUORINE (INORGANIC SALTS) FLUORIDE ION	
DRIED FRUITS	5
GRAPES	7
PEANUT	30
TREE NUTS	30
WHEAT GERM	10
GLYPHOSATE SUM OF GLYPHOSATE AND AMINOMETHYLPHOSPHONIC ACID (AMPA) METABOLITE, EXPRESSED AS GLYPHOSATE	
LINSEED	T5
OILSEED [EXCEPT COTTON SEED; LINSEED; RAPE SEED]	T*0.1
ISOXABEN ISOXABEN	
BARLEY	*0.01
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
TRITICALE	*0.01
WHEAT	*0.01
MALDISON MALDISON	
SHALLOT	T5
SPRING ONION	T5
VEGETABLES [EXCEPT BEANS (DRY); CAULIFLOWER; CHARD (SILVERBEET); EGG PLANT; GARDEN PEA; KALE; KOHLRABI; LENTIL (DRY); PEPPERS, SWEET; ROOT AND TUBER VEGETABLES; SHALLOT; SPRING ONION; TOMATO; TURNIP, GARDEN]	2

PHOSPHOROUS ACID PHOSPHOROUS ACID	
FLOWERHEAD BRASSICAS	T50
PROPICONAZOLE PROPICONAZOLE	
SPINACH	T0.1
PROSULFOCARB PROSULFOCARB	
EDIBLE OFFAL (MAMMALIAN)	*0.02
EGGS	*0.02
MEAT (MAMMALIAN)	*0.02
MILKS	*0.02
POULTRY, EDIBLE OFFAL OF	*0.02
POULTRY MEAT	*0.02
THIAMETHOXAM *COMMODITIES OF PLANT ORIGIN*: THIAMETHOXAM *COMMODITIES OF ANIMAL ORIGIN*: SUM OF THIAMETHOXAM AND N-(2-CHLORO-THIAZOL-5-YLMETHYL)-N'-METHYL-N'-NITRO-GUANIDINE, EXPRESSED AS THIAMETHOXAM	
SUGAR CANE	T*0.02
TOLTRAZURIL SUM OF TOLTRAZURIL, ITS SULFOXIDE AND SULFONE, EXPRESSED AS TOLTRAZURIL	
CATTLE FAT	1
CATTLE KIDNEY	1
CATTLE LIVER	2
CATTLE MUSCLE	0.25
TOLYLFLUANID TOLYLFLUANID	
CUCUMBER	T2

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

CHLORPYRIFOS CHLORPYRIFOS	
PARSLEY	0.05
CLOTHIANIDIN *COMMODITIES OF PLANT ORIGIN*: CLOTHIANIDIN *COMMODITIES OF ANIMAL ORIGIN*: SUM OF CLOTHIANIDIN, 2-CHLOROTHIAZOL-5-YLMETHYLGUANIDINE, 2-CHLOROTHIAZOL-5-YLMETHYLUREA, AND THE PYRUVATE DERIVATIVE OF N-(2-CHLOROTHIAZOL-5-YLMETHYL)-N'-METHYLGUANIDINE EXPRESSED AS CLOTHIANIDIN	
APPLE	0.5
BANANA	*0.02
COTTON SEED	*0.02
EDIBLE OFFAL (MAMMALIAN)	*0.02
MILKS	*0.01
NECTARINE	2

PEACH	2
PEAR	0.5
FLUDIOXONIL	
COMMODITIES OF ANIMAL ORIGIN: SUM OF FLUDIOXONIL AND OXIDISABLE METABOLITES, EXPRESSED AS FLUDIOXONIL *COMMODITIES OF PLANT ORIGIN:* FLUDIOXONIL	
SORGHUM	*0.01
METSULFURON-METHYL	
METSULFURON-METHYL	
LINSEED	*0.02
PROSULFOCARB	
PROSULFOCARB	
BARLEY	*0.01
WHEAT	*0.01
PROTHIOCONAZOLE	
COMMODITIES OF PLANT ORIGIN: SUM OF PROTHIOCONAZOLE AND PROTHIOCONAZOLE DESTHIO (2-(1-CHLOROCYCLOPROPYL)-1-(2-CHLOROPHENYL)-3-(1*H*-1,2,4-TRIAZOL-1-YL)-PROPAN-2-OL), EXPRESSED AS PROTHIOCONAZOLE *COMMODITIES OF ANIMAL ORIGIN:* SUM OF PROTHIOCONAZOLE, PROTHIOCONAZOLE DESTHIO (2-(1-CHLOROCYCLOPROPYL)-1-(2-CHLOROPHENYL)-3-(1*H*-1,2,4-TRIAZOL-1-YL)-PROPAN-2-OL), PROTHIOCONAZOLE-3-HYDROXY-DESTHIO (2-(1-CHLOROCYCLOPROPYL)-1-(2-CHLORO-3-HYDROXYPHENYL)-3-(1*H*-1,2,4-TRIAZOL-1-YL)-PROPAN-2-OL) AND PROTHIOCONAZOLE-4-HYDROXY-DESTHIO (2-(1-CHLOROCYCLOPROPYL)-1-(2-CHLORO-4-HYDROXYPHENYL)-3-(1*H*-1,2,4-TRIAZOL-1-YL)-PROPAN-2-OL), EXPRESSED AS PROTHIOCONAZOLE	
EDIBLE OFFAL (MAMMALIAN)	*0.05
EGGS	*0.01
MEAT (MAMMALIAN) (IN THE FAT)	*0.01
MILKS	*0.004
POULTRY, EDIBLE OFFAL OF	*0.05
POULTRY MEAT (IN THE FAT)	*0.05
WHEAT	*0.05
PYRASULFOTOLE	
SUM OF PYRASULFOTOLE AND (5-HYDROXY-3-METHYL-1*H*-PYRAZOL-4-YL)[2-MESYL-4-(TRIFLUOROMETHYL)PHENYL]METHANONE, EXPRESSED AS PYRASULFOTOLE	
CEREAL BRAN, UNPROCESSED	0.03
CEREAL GRAINS	*0.02
EDIBLE OFFAL (MAMMALIAN)	0.5
EGGS	*0.01
MEAT (MAMMALIAN)	*0.01
MILKS	*0.01
POULTRY, EDIBLE OFFAL OF	*0.01
POULTRY MEAT	*0.01

Attachment 1B

Draft variations to the *Australia New Zealand Food Standards Code* (Changes Marked)

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

To commence: on gazettal

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

[1.1] *omitting from* 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**
CLOTHIANIDIN	CLOTHIANIDIN

[1.2] *inserting in* Schedule 1 –

DIMETHENAMID-P SUM OF DIMETHENAMID-P AND ITS *(R)*-ISOMER	
COMMON BEAN (PODS AND/OR IMMATURE SEEDS)	*0.02
EDIBLE OFFAL (MAMMALIAN)	*0.01
EGGS	*0.01
MAIZE	*0.02
MEAT (MAMMALIAN)	*0.01
MILKS	*0.01
PEAS	*0.02
POPPY SEED	*0.01
POULTRY, EDIBLE OFFAL OF	*0.01
POULTRY MEAT	*0.01
PULSES	*0.02
PUMPKINS	*0.02
SWEET CORN (CORN-ON-THE-COB)	*0.02
SULFURYL FLUORIDE SULFURYL FLUORIDE	
CEREAL GRAINS	0.05
DRIED FRUITS	0.07
PEANUT	7
TREE NUTS	7

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

BIFENTHRIN BIFENTHRIN	
LETTUCE, HEAD	T2
CLOTHIANIDIN *COMMODITIES OF PLANT ORIGIN*: CLOTHIANIDIN *COMMODITIES OF ANIMAL ORIGIN*: SUM OF CLOTHIANIDIN, 2-CHLOROTHIAZOL-5-YLMETHYLGUANIDINE, 2-CHLOROTHIAZOL-5-YLMETHYLUREA, AND THE PYRUVATE DERIVATIVE OF N-(2-CHLOROTHIAZOL-5-YLMETHYL)-N'-METHYLGUANIDINE EXPRESSED AS CLOTHIANIDIN	
MEAT (MAMMALIAN) (IN THE FAT)	T*0.02
FLUORINE (INORGANIC SALTS) FLUORIDE ION	
FRUIT	7
VEGETABLES	7
GLYPHOSATE SUM OF GLYPHOSATE AND AMINOMETHYLPHOSPHONIC ACID (AMPA) METABOLITE, EXPRESSED AS GLYPHOSATE	
OILSEED [EXCEPT COTTON AND RAPE SEED]	*0.1
MALDISON MALDISON	
VEGETABLES [EXCEPT AS OTHERWISE LISTED UNDER THIS CHEMICAL]	2
METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OXIME'), EXPRESSED AS METHOMYL *SEE ALSO* THIODICARB	
BERGAMOT	T5
BURNET, SALAD	T5
CHERVIL	T5
CORIANDER (LEAVES, STEM, ROOTS)	T10
CORIANDER, SEED	T5
DILL, SEED	T5
FENNEL, SEED	T5
GALANGAL, GREATER	T*0.02
KAFFIR LIME LEAVES	T5
LEMON GRASS	T5
LEMON VERBENA (DRY LEAVES)	T5
MIZUNA	T5
ROSE AND DIANTHUS (EDIBLE FLOWERS)	T5
RUCOLA (ROCKET)	T5
TURMERIC, ROOT	T*0.02

RACTOPAMINE	
RACTOPAMINE	
CATTLE FAT	T*0.02
CATTLE KIDNEY	T0.1
CATTLE MEAT	T*0.02

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

AZOXYSTROBIN	
AZOXYSTROBIN	
MAIZE	T*0.01
BIFENAZATE	
SUM OF BIFENAZATE AND BIFENAZATE DIAZENE (DIAZENECARBOXYLIC ACID, 2-(4-METHOXY-[1,1'-BIPHENYL-3-YL] 1-METHYLETHYL ESTER), EXPRESSED AS BIFENAZATE	
PEAS	T0.5
BIFENTHRIN	
BIFENTHRIN	
LEAFY VEGETABLES [EXCEPT CHERVIL; MIZUNA; RUCOLA (ROCKET)]	T2
CLOSANTEL	
CLOSANTEL	
CATTLE FAT	T3
CATTLE KIDNEY	T3
CATTLE LIVER	T1
CATTLE MUSCLE	T1
CLOTHIANIDIN	
COMMODITIES OF PLANT ORIGIN: CLOTHIANIDIN *COMMODITIES OF ANIMAL ORIGIN*: SUM OF CLOTHIANIDIN, 2-CHLOROTHIAZOL-5-YLMETHYLGUANIDINE, 2-CHLOROTHIAZOL-5-YLMETHYLUREA, AND THE PYRUVATE DERIVATIVE OF N-(2-CHLOROTHIAZOL-5-YLMETHYL)-N'-METHYLGUANIDINE EXPRESSED AS CLOTHIANIDIN	
EGGS	*0.02
MEAT (MAMMALIAN)	*0.02
POULTRY, EDIBLE OFFAL OF	*0.02
POULTRY MEAT	*0.02
CYANAMIDE	
CYANAMIDE	
APPLE	*0.02
BLUEBERRIES	*0.05
CYPRODINIL	
CYPRODINIL	
CUCUMBER	T0.2
LETTUCE, HEAD	T10
PEPPERS, SWEET	T0.5

FLORFENICOL SUM OF FLORFENICOL AND ITS METABOLITES FLORFENICOL ALCOHOL, FLORFENICOL OXAMIC ACID, MONOCHLOROFLORFENICOL AND FLORFENICOL AMINE EXPRESSED AS FLORFENICOL AMINE	
FISH	T0.5
FLUDIOXONIL *COMMODITIES OF ANIMAL ORIGIN:* SUM OF FLUDIOXONIL AND OXIDISABLE METABOLITES, EXPRESSED AS FLUDIOXONIL *COMMODITIES OF PLANT ORIGIN:* FLUDIOXONIL	
CUCUMBER	T0.3
LETTUCE, HEAD	T10
PEPPERS, SWEET	T2
FLUORINE (INORGANIC SALTS) FLUORIDE ION	
DRIED FRUITS	5
GRAPES	7
PEANUT	30
TREE NUTS	30
WHEAT GERM	10
GLYPHOSATE SUM OF GLYPHOSATE AND AMINOMETHYLPHOSPHONIC ACID (AMPA) METABOLITE, EXPRESSED AS GLYPHOSATE	
LINSEED	T5
OILSEED [EXCEPT COTTON SEED; LINSEED; RAPE SEED]	T*0.1
ISOXABEN ISOXABEN	
BARLEY	*0.01
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
TRITICALE	*0.01
WHEAT	*0.01
MALDISON MALDISON	
SHALLOT	T5
SPRING ONION	T5
VEGETABLES [EXCEPT BEANS (DRY); CAULIFLOWER; CHARD (SILVERBEET); EGG PLANT; GARDEN PEA; KALE; KOHLRABI; LENTIL (DRY); PEPPERS, SWEET; ROOT AND TUBER VEGETABLES; SHALLOT; SPRING ONION; TOMATO; TURNIP, GARDEN]	2

PHOSPHOROUS ACID PHOSPHOROUS ACID	
FLOWERHEAD BRASSICAS	T50
PROPICONAZOLE PROPICONAZOLE	
SPINACH	T0.1
PROSULFOCARB PROSULFOCARB	
EDIBLE OFFAL (MAMMALIAN)	*0.02
EGGS	*0.02
MEAT (MAMMALIAN)	*0.02
MILKS	*0.02
POULTRY, EDIBLE OFFAL OF	*0.02
POULTRY MEAT	*0.02
THIAMETHOXAM *COMMODITIES OF PLANT ORIGIN*: THIAMETHOXAM *COMMODITIES OF ANIMAL ORIGIN*: SUM OF THIAMETHOXAM AND N-(2-CHLORO-THIAZOL-5-YLMETHYL)-N'-METHYL-N'-NITRO-GUANIDINE, EXPRESSED AS THIAMETHOXAM	
SUGAR CANE	T*0.02
TOLTRAZURIL SUM OF TOLTRAZURIL, ITS SULFOXIDE AND SULFONE, EXPRESSED AS TOLTRAZURIL	
CATTLE FAT	1
CATTLE KIDNEY	1
CATTLE LIVER	2
CATTLE MUSCLE	0.25
TOLYLFLUANID TOLYLFLUANID	
CUCUMBER	T2

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

CHLORPYRIFOS CHLORPYRIFOS	
PARSLEY	0.05
CLOTHIANIDIN *COMMODITIES OF PLANT ORIGIN*: CLOTHIANIDIN *COMMODITIES OF ANIMAL ORIGIN*: SUM OF CLOTHIANIDIN, 2-CHLOROTHIAZOL-5-YLMETHYLGUANIDINE, 2-CHLOROTHIAZOL-5-YLMETHYLUREA, AND THE PYRUVATE DERIVATIVE OF N-(2-CHLOROTHIAZOL-5-YLMETHYL)-N'-METHYLGUANIDINE EXPRESSED AS CLOTHIANIDIN	
APPLE	0.5
BANANA	*0.02
COTTON SEED	*0.02
EDIBLE OFFAL (MAMMALIAN)	*0.02
MILKS	*0.01
NECTARINE	2

PEACH	2
PEAR	0.5
FLUDIOXONIL *COMMODITIES OF ANIMAL ORIGIN:* SUM OF FLUDIOXONIL AND OXIDISABLE METABOLITES, EXPRESSED AS FLUDIOXONIL *COMMODITIES OF PLANT ORIGIN:* FLUDIOXONIL	
SORGHUM	*0.01
METSULFURON-METHYL METSULFURON-METHYL	
LINSEED	*0.02
PROSULFOCARB PROSULFOCARB	
BARLEY	*0.01
WHEAT	*0.01
PROTHIOCONAZOLE *COMMODITIES OF PLANT ORIGIN*: SUM OF PROTHIOCONAZOLE AND PROTHIOCONAZOLE DESTHIO (2-(1-CHLOROCYCLOPROPYL)-1-(2-CHLOROPHENYL)-3-(1*H*-1,2,4-TRIAZOL-1-YL)-PROPAN-2-OL), EXPRESSED AS PROTHIOCONAZOLE *COMMODITIES OF ANIMAL ORIGIN:* SUM OF PROTHIOCONAZOLE, PROTHIOCONAZOLE DESTHIO (2-(1-CHLOROCYCLOPROPYL)-1-(2-CHLOROPHENYL)-3-(1*H*-1,2,4-TRIAZOL-1-YL)-PROPAN-2-OL), PROTHIOCONAZOLE-3-HYDROXY-DESTHIO (2-(1-CHLOROCYCLOPROPYL)-1-(2-CHLORO-3-HYDROXYPHENYL)-3-(1*H*-1,2,4-TRIAZOL-1-YL)-PROPAN-2-OL) AND PROTHIOCONAZOLE-4-HYDROXY-DESTHIO (2-(1-CHLOROCYCLOPROPYL)-1-(2-CHLORO-4-HYDROXYPHENYL)-3-(1*H*-1,2,4-TRIAZOL-1-YL)-PROPAN-2-OL), EXPRESSED AS PROTHIOCONAZOLE	
EDIBLE OFFAL (MAMMALIAN)	*0.05
EGGS	*0.01
MEAT (MAMMALIAN) (IN THE FAT)	*0.01
MILKS	*0.004
POULTRY, EDIBLE OFFAL OF	*0.05
POULTRY MEAT (IN THE FAT)	*0.05
WHEAT	*0.05
PYRASULFOTOLE SUM OF PYRASULFOTOLE AND (5-HYDROXY-3-METHYL-1*H*-PYRAZOL-4-YL)[2-MESYL-4-(TRIFLUOROMETHYL)PHENYL]METHANONE, EXPRESSED AS PYRASULFOTOLE	
CEREAL BRAN, UNPROCESSED	0.03
CEREAL GRAINS	*0.02
EDIBLE OFFAL (MAMMALIAN)	0.5
EGGS	*0.01
MEAT (MAMMALIAN)	*0.01
MILKS	*0.01
POULTRY, EDIBLE OFFAL OF	*0.01
POULTRY MEAT	*0.01

Attachment 1C

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

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

To commence: on gazettal

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

[1.1] *omitting from* 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
CLOTHIANIDIN	CLOTHIANIDIN

[1.2] *inserting in* Schedule 1 –

DIMETHENAMID-P SUM OF DIMETHENAMID-P AND ITS *(R)*-ISOMER	
COMMON BEAN (PODS AND/OR IMMATURE SEEDS)	*0.02
EDIBLE OFFAL (MAMMALIAN)	*0.01
EGGS	*0.01
MAIZE	*0.02
MEAT (MAMMALIAN)	*0.01
MILKS	*0.01
PEAS	*0.02
POPPY SEED	*0.01
POULTRY, EDIBLE OFFAL OF	*0.01
POULTRY MEAT	*0.01
PULSES	*0.02
PUMPKINS	*0.02
SWEET CORN (CORN-ON-THE-COB)	*0.02
SULFURYL FLUORIDE SULFURYL FLUORIDE	
CEREAL GRAINS	0.05
DRIED FRUITS	0.07
PEANUT	7
TREE NUTS	7

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

BIFENTHRIN BIFENTHRIN	
LETTUCE, HEAD	T2
CLOTHIANIDIN *COMMODITIES OF PLANT ORIGIN*: CLOTHIANIDIN *COMMODITIES OF ANIMAL ORIGIN*: SUM OF CLOTHIANIDIN, 2-CHLOROTHIAZOL-5-YLMETHYLGUANIDINE, 2-CHLOROTHIAZOL-5-YLMETHYLUREA, AND THE PYRUVATE DERIVATIVE OF N-(2-CHLOROTHIAZOL-5-YLMETHYL)-N'-METHYLGUANIDINE EXPRESSED AS CLOTHIANIDIN	
MEAT (MAMMALIAN) (IN THE FAT)	T*0.02
FLUORINE (INORGANIC SALTS) FLUORIDE ION	
FRUIT	7
VEGETABLES	7
GLYPHOSATE SUM OF GLYPHOSATE AND AMINOMETHYLPHOSPHONIC ACID (AMPA) METABOLITE, EXPRESSED AS GLYPHOSATE	
OILSEED [EXCEPT COTTON AND RAPE SEED]	*0.1
MALDISON MALDISON	
VEGETABLES [EXCEPT AS OTHERWISE LISTED UNDER THIS CHEMICAL]	2
METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OXIME'), EXPRESSED AS METHOMYL *SEE ALSO* THIODICARB	
BERGAMOT	T5
BURNET, SALAD	T5
CHERVIL	T5
CORIANDER (LEAVES, STEM, ROOTS)	T10
CORIANDER, SEED	T5
DILL, SEED	T5
FENNEL, SEED	T5
GALANGAL, GREATER	T*0.02
KAFFIR LIME LEAVES	T5
LEMON GRASS	T5
LEMON VERBENA (DRY LEAVES)	T5
MIZUNA	T5
ROSE AND DIANTHUS (EDIBLE FLOWERS)	T5
RUCOLA (ROCKET)	T5
TURMERIC, ROOT	T*0.02

RACTOPAMINE	
RACTOPAMINE	
CATTLE FAT	T*0.02
CATTLE KIDNEY	T0.1
CATTLE MEAT	T*0.02

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

AZOXYSTROBIN	
AZOXYSTROBIN	
MAIZE	T*0.01
BIFENAZATE	
SUM OF BIFENAZATE AND BIFENAZATE DIAZENE (DIAZENECARBOXYLIC ACID, 2-(4-METHOXY-[1,1'-BIPHENYL-3-YL] 1-METHYLETHYL ESTER), EXPRESSED AS BIFENAZATE	
PEAS	T0.5
BIFENTHRIN	
BIFENTHRIN	
LEAFY VEGETABLES [EXCEPT CHERVIL; MIZUNA; RUCOLA (ROCKET)]	T2
CLOSANTEL	
CLOSANTEL	
CATTLE FAT	T3
CATTLE KIDNEY	T3
CATTLE LIVER	T1
CATTLE MUSCLE	T1
CLOTHIANIDIN	
COMMODITIES OF PLANT ORIGIN: CLOTHIANIDIN *COMMODITIES OF ANIMAL ORIGIN*: SUM OF CLOTHIANIDIN, 2-CHLOROTHIAZOL-5-YLMETHYLGUANIDINE, 2-CHLOROTHIAZOL-5-YLMETHYLUREA, AND THE PYRUVATE DERIVATIVE OF N-(2-CHLOROTHIAZOL-5-YLMETHYL)-N'-METHYLGUANIDINE EXPRESSED AS CLOTHIANIDIN	
EGGS	*0.02
MEAT (MAMMALIAN)	*0.02
POULTRY, EDIBLE OFFAL OF	*0.02
POULTRY MEAT	*0.02
CYANAMIDE	
CYANAMIDE	
APPLE	*0.02
BLUEBERRIES	*0.05
CYPRODINIL	
CYPRODINIL	
CUCUMBER	T0.2
LETTUCE, HEAD	T10
PEPPERS, SWEET	T0.5

FLORFENICOL SUM OF FLORFENICOL AND ITS METABOLITES FLORFENICOL ALCOHOL, FLORFENICOL OXAMIC ACID, MONOCHLOROFLORFENICOL AND FLORFENICOL AMINE EXPRESSED AS FLORFENICOL AMINE	
FISH	T0.5
FLUDIOXONIL *COMMODITIES OF ANIMAL ORIGIN:* SUM OF FLUDIOXONIL AND OXIDISABLE METABOLITES, EXPRESSED AS FLUDIOXONIL *COMMODITIES OF PLANT ORIGIN:* FLUDIOXONIL	
CUCUMBER	T0.3
LETTUCE, HEAD	T10
PEPPERS, SWEET	T2
FLUORINE (INORGANIC SALTS) FLUORIDE ION	
DRIED FRUITS	5
PEANUT	30
TREE NUTS	30
WHEAT GERM	10
GLYPHOSATE SUM OF GLYPHOSATE AND AMINOMETHYLPHOSPHONIC ACID (AMPA) METABOLITE, EXPRESSED AS GLYPHOSATE	
LINSEED	T5
OILSEED [EXCEPT COTTON SEED; LINSEED; RAPE SEED]	T*0.1
ISOXABEN ISOXABEN	
BARLEY	*0.01
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
TRITICALE	*0.01
WHEAT	*0.01
MALDISON MALDISON	
SHALLOT	T5
SPRING ONION	T5
VEGETABLES [EXCEPT BEANS (DRY); CAULIFLOWER; CHARD (SILVERBEET); EGG PLANT; GARDEN PEA; KALE; KOHLRABI; LENTIL (DRY); PEPPERS, SWEET; ROOT AND TUBER VEGETABLES; SHALLOT; SPRING ONION; TOMATO; TURNIP, GARDEN]	2

PHOSPHOROUS ACID PHOSPHOROUS ACID	
FLOWERHEAD BRASSICAS	T50
PROPICONAZOLE PROPICONAZOLE	
SPINACH	T0.1
PROSULFOCARB PROSULFOCARB	
EDIBLE OFFAL (MAMMALIAN)	*0.02
EGGS	*0.02
MEAT (MAMMALIAN)	*0.02
MILKS	*0.02
POULTRY, EDIBLE OFFAL OF	*0.02
POULTRY MEAT	*0.02
THIAMETHOXAM *COMMODITIES OF PLANT ORIGIN*: THIAMETHOXAM *COMMODITIES OF ANIMAL ORIGIN*: SUM OF THIAMETHOXAM AND N-(2-CHLORO-THIAZOL-5-YLMETHYL)-N'-METHYL-N'-NITRO-GUANIDINE, EXPRESSED AS THIAMETHOXAM	
SUGAR CANE	T*0.02
TOLTRAZURIL SUM OF TOLTRAZURIL, ITS SULFOXIDE AND SULFONE, EXPRESSED AS TOLTRAZURIL	
CATTLE FAT	1
CATTLE KIDNEY	1
CATTLE LIVER	2
CATTLE MUSCLE	0.25
TOLYLFLUANID TOLYLFLUANID	
CUCUMBER	T2

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

CHLORPYRIFOS CHLORPYRIFOS	
PARSLEY	0.05
CLOTHIANIDIN *COMMODITIES OF PLANT ORIGIN*: CLOTHIANIDIN *COMMODITIES OF ANIMAL ORIGIN*: SUM OF CLOTHIANIDIN, 2-CHLOROTHIAZOL-5-YLMETHYLGUANIDINE, 2-CHLOROTHIAZOL-5-YLMETHYLUREA, AND THE PYRUVATE DERIVATIVE OF N-(2-CHLOROTHIAZOL-5-YLMETHYL)-N'-METHYLGUANIDINE EXPRESSED AS CLOTHIANIDIN	
APPLE	0.5
BANANA	*0.02
COTTON SEED	*0.02
EDIBLE OFFAL (MAMMALIAN)	*0.02
MILKS	*0.01
NECTARINE	2

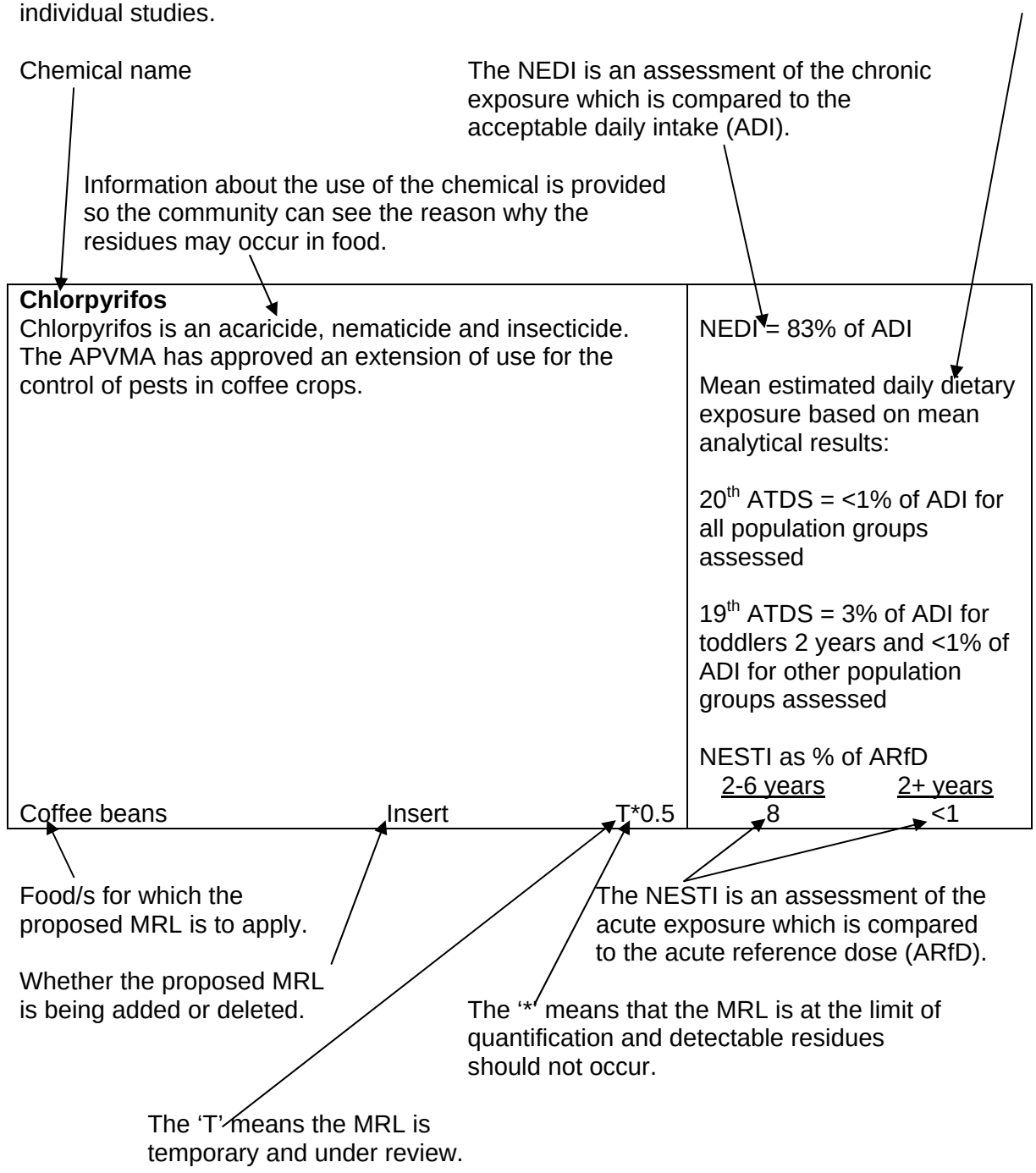
PEACH	2
PEAR	0.5
FLUDIOXONIL	
COMMODITIES OF ANIMAL ORIGIN: SUM OF FLUDIOXONIL AND OXIDISABLE METABOLITES, EXPRESSED AS FLUDIOXONIL *COMMODITIES OF PLANT ORIGIN:* FLUDIOXONIL	
SORGHUM	*0.01
METSULFURON-METHYL	
METSULFURON-METHYL	
LINSEED	*0.02
PROSULFOCARB	
PROSULFOCARB	
BARLEY	*0.01
WHEAT	*0.01
PROTHIOCONAZOLE	
COMMODITIES OF PLANT ORIGIN: SUM OF PROTHIOCONAZOLE AND PROTHIOCONAZOLE DESTHIO (2-(1-CHLOROCYCLOPROPYL)-1-(2-CHLOROPHENYL)-3-(1*H*-1,2,4-TRIAZOL-1-YL)-PROPAN-2-OL), EXPRESSED AS PROTHIOCONAZOLE *COMMODITIES OF ANIMAL ORIGIN:* SUM OF PROTHIOCONAZOLE, PROTHIOCONAZOLE DESTHIO (2-(1-CHLOROCYCLOPROPYL)-1-(2-CHLOROPHENYL)-3-(1*H*-1,2,4-TRIAZOL-1-YL)-PROPAN-2-OL), PROTHIOCONAZOLE-3-HYDROXY-DESTHIO (2-(1-CHLOROCYCLOPROPYL)-1-(2-CHLORO-3-HYDROXYPHENYL)-3-(1*H*-1,2,4-TRIAZOL-1-YL)-PROPAN-2-OL) AND PROTHIOCONAZOLE-4-HYDROXY-DESTHIO (2-(1-CHLOROCYCLOPROPYL)-1-(2-CHLORO-4-HYDROXYPHENYL)-3-(1*H*-1,2,4-TRIAZOL-1-YL)-PROPAN-2-OL), EXPRESSED AS PROTHIOCONAZOLE	
EDIBLE OFFAL (MAMMALIAN)	*0.05
EGGS	*0.01
MEAT (MAMMALIAN) (IN THE FAT)	*0.01
MILKS	*0.004
POULTRY, EDIBLE OFFAL OF	*0.05
POULTRY MEAT (IN THE FAT)	*0.05
WHEAT	*0.05
PYRASULFOTOLE	
SUM OF PYRASULFOTOLE AND (5-HYDROXY-3-METHYL-1*H*-PYRAZOL-4-YL)[2-MESYL-4-(TRIFLUOROMETHYL)PHENYL]METHANONE, EXPRESSED AS PYRASULFOTOLE	
CEREAL BRAN, UNPROCESSED	0.03
CEREAL GRAINS	*0.02
EDIBLE OFFAL (MAMMALIAN)	0.5
EGGS	*0.01
MEAT (MAMMALIAN)	*0.01
MILKS	*0.01
POULTRY, EDIBLE OFFAL OF	*0.01
POULTRY MEAT	*0.01

Attachment 2

A summary of MRLs under consideration in Proposal M1002

The following is an example of an entry and the proposed MRL is not being considered in this Proposal.

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 NEDI and NESTI calculations are theoretical calculations that conservatively overestimate exposure. Small variations may be noted in the exposure assessment between different ATDSs. These variations are minor and typically result because of the different range of foods in the individual studies.



Requested MRLs		mg/kg	Dietary Exposure Estimates
Azoxystrobin Azoxystrobin is a fungicide that acts by inhibition of mitochondrial respiration through blocking electron transfer between cytochrome B and cytochrome C_1 at the ubiquinol oxidising site. The APVMA has issued a permit for its use to control polysora rust *(Puccinia polysora)* in maize. The recommended MRL is at the limit of quantification (LOQ).			NEDI = 4% of ADI
Maize	Insert	T*0.01	
Bifenazate Bifenazate is a non-systemic acaricide absorbed primarily by contact. It is used to control the egg and motile stages of phytophagous mites. The APVMA has issued a permit for its use in peas to control two spotted mite *(Tetraychus urticae),* European red mite *(Panonychus ulmi)* and Bryobia mite *(Brobia rubrioculus)*.			NEDI = 8% of ADI NESTI as % of ARfD 2-6 years: <1 2 years & above: <1
Peas	Insert	T0.5	
Bifenthrin Bifenthrin is an insecticide that acts on the nervous system through interaction with the sodium channel. The APVMA has issued a permit for its use to control quarantine pests on selected nursery stocks of culinary herbs and leafy vegetables entering Western Australia from other states. Residues of bifenthrin in leafy vegetables are expected to be significantly less than the MRLs as it will be 8 – 10 weeks between treatment and harvest for human consumption.			NEDI = 75% of ADI Mean estimated daily dietary exposure based on mean analytical results: 20th ATDS – <1% of ADI for all population groups assessed
Leafy vegetables [except chervil; mizuna; rucola (rocket)]	Insert	T2	
Lettuce, head	Omit	T2	
Chlorpyrifos Chlorpyrifos is a non-systemic insecticide with contact, stomach, and respiratory action. It is a cholinesterase inhibitor. The APVMA has issued a permit for its use to control vegetable weevil *(Listroderes obliquus)* on parsley.			Dietary exposure assessment not required
Parsley	Omit	T0.05	
	Substitute	0.05	

Requested MRLs		mg/kg	Dietary Exposure Estimates		
Closantel Closantel is an anthelmintic. It acts as a potent uncoupler of oxidative phosphorylation in parasite mitochondria. The APVMA has issued a permit for its use in cattle for the treatment and control of gastrointestinal nematodes, liver fluke (immature and adult), lungworms, eyeworms, screw worm fly, sucking lice, mites and cattle tick.			NEDI = 6% of ADI		
Cattle fat	Insert	T3			
Cattle kidney	Insert	T3			
Cattle liver	Insert	T1			
Cattle muscle	Insert	T1			
Clothianidin Clothianidin is an insecticide; it is an agonist of the nicotinic acetylcholine receptor, affecting the synapses in the insect central nervous system. The APVMA has issued permits for its use to control pests in apples, pears, peaches, nectarines, bananas and cotton. The recommended animal commodity MRLs are at the LOQ. Omit residue definition: *Commodities of plant origin*: Clothianidin *Commodities of animal origin*: Sum of clothianidin, 2-chlorothiazol-5-ylmethylguanidine, 2-chlorothiazol-5-ylmethylurea, and the pyruvate derivative of N-(2-chlorothiazol-5-ylmethyl)-N'-methylguanidine expressed as clothianidin Insert residue definition: Clothianidin			NEDI = 2% of ADI		
			NESTI as % of ARfD		
			2-6 years		2 years & above
Apple	Omit	T0.5			
	Substitute	0.5	15		4
Banana	Omit	T*0.02			
	Substitute	*0.02	<1		<1
Cotton seed	Omit	T*0.02			
	Substitute	*0.02	<1	Oilseed	<1
Edible offal (mammalian)	Omit	T*0.02			
	Substitute	*0.02	<1		<1
Eggs	Insert	*0.02	<1		<1
Meat (mammalian) (in the fat)	Omit	T*0.02			
Meat (mammalian)	Insert	*0.02	<1		<1
Milks	Omit	T*0.01			
	Substitute	*0.01	<1		<1

Requested MRLs		mg/kg	Dietary Exposure Estimates	
Nectarine	Omit	T2		
	Substitute	2	29	13
Peach	Omit	T2		
	Substitute	2	32	11
Pear	Omit	T0.5		
	Substitute	0.5	10	3
Poultry, edible offal of	Insert	*0.02	<1	<1
Poultry meat	Insert	*0.02	<1	<1
Cyanamide Cyanamide is a plant growth regulator. It acts as a catalase inhibitor, requiring the plant to detoxify hydrogen peroxide by other routes, which affects the oxidative pentose phosphate pathway. This in turn leads to reduced nucleotide production, ultimately affecting bud break. It is used in apples to regulate bud dormancy, and in blueberries to promote vegetative bud break and earlier leaf development. The recommended MRLs are at the LOQ.			NEDI = 5% of ADI	
Apple	Insert	*0.02		
Blueberries	Insert	*0.05		
Cyprodinil Cyprodinil is a systemic fungicide. It is a proposed inhibitor of the biosynthesis of methionine and the secretion of fungal hydrolytic enzymes. It is transported throughout the tissue and acropetally in the xylem. It inhibits penetration and mycelial growth both inside the plant and on leaf surfaces. The APVMA has issued permits for its use to control botrytis rots *(Botrytis cinerea)* in cucumbers, glasshouse grown capsicums and lettuce as well as bottom rot *(Rhizoctonia sp.)* in glasshouse lettuce.			NEDI = 18% of ADI	
Cucumber	Insert	T0.2		
Lettuce, head	Insert	T10		
Peppers, Sweet	Insert	T0.5		

Requested MRLs		mg/kg	Dietary Exposure Estimates	
Dimethenamid-P Dimethenamid-P is a herbicide. It acts as a cell division inhibitor. It is used for pre-emergent or early post-emergent control of weeds in pulse, oilseed and vegetable crops. The recommended MRLs are at the LOQ. New Chemical Insert residue definition: Dimethenamid-P: Sum of dimethenamid-P and its *(R)*-isomer			NEDI =<1% of ADI	
			NESTI as % of ARfD	
			2-6 years	2 years & above
Common bean (pods and/or immature seeds)	Insert	*0.02	<1	<1
Edible offal (mammalian)	Insert	*0.01	<1	<1
Eggs	Insert	*0.01	<1	<1
Maize	Insert	*0.02	<1	<1
Meat (mammalian)	Insert	*0.01	<1	<1
Milks	Insert	*0.01	<1	<1
Peas	Insert	*0.02	<1	<1
Poppy seed	Insert	*0.01	<1	<1
Poultry, edible offal of	Insert	*0.01	<1	<1
Poultry meat	Insert	*0.01	<1	<1
Pulses	Insert	*0.02	<1	<1
Pumpkins	Insert	*0.02	<1	<1
Sweet corn (corn-on-the-cob)	Insert	*0.02	<1	<1
Florfenicol Florfenicol is an amphenicol antibiotic. Amphenicols are broad-spectrum antibiotics with a range of activity that includes Gram-positive and Gram-negative bacteria, rickettsia and Chlamydiae. Amphenicols bind to the 50S ribosomal subunit and inhibit the transpeptidyl-transferase step in protein synthesis. The APVMA has issued a permit for the use of florfenicol to treat bacterial diseases in salmon, trout, barramundi, silver perch, yellow tail and kingfish. The NHMRC has advised that the proposed florfenicol MRLs do not pose a risk in terms of antimicrobial resistance. Florfenicol is currently registered for use in fish in the UK/Europe, the United States, Canada, Japan and Chile. Fish	Insert	T0.5	NEDI = 44% of ADI	

Requested MRLs		mg/kg	Dietary Exposure Estimates
Fludioxonil Fludioxonil is a non-systemic fungicide with long residual activity. The uptake into the plant tissues and the curative properties are generally limited. It inhibits mainly the germination of conidia and, to a lesser extent, the germ tube and mycelial growth. It inhibits MAP kinase, in osmotic signal transduction. It is used in sorghum to control dampening off and rot caused by Pythium and Fusarium. The APVMA has issued permits for its use to control botrytis rots *(Botrytis cinerea)* in cucumbers, glasshouse grown capsicums and lettuce as well as bottom rot *(Rhizoctonia sp.)* in glasshouse lettuce. The recommended sorghum MRL is at LOQ.			NEDI =7% of ADI
Cucumber	Insert	T0.3	
Lettuce, head	Insert	T10	
Peppers, Sweet	Insert	T2	
Sorghum	Omit	T*0.05	
	Substitute	*0.01	
Fluorine (inorganic salts) (See also sulfuryl fluoride) Fluoride ion residues arising from the use of sulfuryl fluoride are listed under fluorine (inorganic salts) in the Code. Sulfuryl fluoride is hydrolysed to sulphate ions and fluoride ions in plant and animal tissue. Sulphate ions are not of toxicological concern. Sulfuryl fluoride and inorganic fluoride ions are determined separately. The MRL for grapes is consistent with the use of cryolite, a mineral compound which breaks down into fluoride, sodium and aluminium ions. Cryolite is used in the United States to control leaf eating insects on grapes (refer section 9.2).			Fluoride ion NEDI as % of UL 2-6 years: 80 7 years & above: 35
Dried fruits	Insert	5	
Fruit	Omit	7	
Grapes	Insert	7	
Peanut	Insert	30	
Tree nuts	Insert	30	
Vegetables	Omit	7	
Wheat germ	Insert	10	

Requested MRLs		mg/kg	Dietary Exposure Estimates
Glyphosate Glyphosate is a herbicide. It inhibits the biosynthesis of aromatic amino acids. The APVMA has issued a permit for its use to desiccate linseed crops at harvest. Residues are significantly reduced on processing of linseed to oil. A separate MRL is therefore not required for linseed oil.			NEDI = 6% of ADI
Linseed	Insert	T5	
Oilseed [except cotton seed and rape seed]	Omit	*0.1	
Oilseed [except cotton seed, linseed and rape seed]	Insert	T*0.1	
Isoxaben Isoxaben is a herbicide used to control various broadleaf weeds in barley, triticale and wheat. It inhibits biosynthesis of cellulose. The recommended MRLs are at the LOQ.			NEDI = <1% of ADI
Barley	Insert	*0.01	
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	
Triticale	Insert	*0.01	
Wheat	Insert	*0.01	
Maldison Maldison is a non systemic insecticide and acaricide with contact, stomach and respiratory action. It acts as a cholinesterase inhibitor and proinsecticide. It is used to control pests in a wide range of crops.			NEDI = 82% of ADI Mean estimated daily dietary exposure based on mean analytical results: 20th ATDS – <1% of ADI for all population groups assessed 19th ATDS – not detected in any foods sampled NESTI as % of ARfD 2-6 years / 2 years & above
Shallot	Insert	T5	2 / <1
Spring onion	Insert	T5	1 / <1
Vegetables [except as otherwise listed under this chemical]	Omit	2	

Requested MRLs		mg/kg	Dietary Exposure Estimates
Vegetables [except beans (dry); cauliflower; chard (silverbeet); egg plant; garden pea; kale; kohlrabi; lentil (dry); peppers, sweet; root and tuber vegetables; shallot; spring onion; tomato; turnip, garden]	Insert	2	
Methomyl Methomyl is a carbamate insecticide and acaricide with contact and stomach action. It is a cholinesterase inhibitor. Methomyl is used to control a wide range of insects and spider mites on fruit, vines, vegetables and field crops. The APVMA permit for its use to control grass hoppers and budworms on culinary herbs has expired.			Dietary exposure assessment not required
Bergamot	Omit	T5	
Burnet, salad	Omit	T5	
Chervil	Omit	T5	
Coriander (leaves, stem, roots)	Omit	T10	
Coriander, seed	Omit	T5	
Dill, seed	Omit	T5	
Fennel, seed	Omit	T5	
Galangal, Greater	Omit	T*0.02	
Kaffir lime leaves	Omit	T5	
Lemon grass	Omit	T5	
Lemon verbena (dry leaves)	Omit	T5	
Mizuna	Omit	T5	
Rose and dianthus (edible flowers)	Omit	T5	
Rucola (rocket)	Omit	T5	
Turmeric, root	Omit	T*0.02	
Metsulfuron-methyl Metsulfuron-methyl is a post-emergent herbicide. It inhibits the synthesis of branched chain amino acids such as valine and isoleucine, halting cell division and plant growth. It is used to control a wide range of grass and broad leaf weeds in cereal, pulse and oilseed crops. The recommended MRL is at the LOQ.			NEDI = 11% of ADI
Linseed	Omit	T*0.02	
	Substitute	*0.02	
Phosphorous acid Phosphorus acid is a selective systemic phosphonate fungicide with multi-site activity. It is used to control fungal diseases on fruit and vegetables.			NEDI = 6% of Provisional Tolerable Weekly Intake (PTWI)
Flowerhead brassicas	Insert	T50	

Requested MRLs		mg/kg	Dietary Exposure Estimates		
Propiconazole Propiconazole is a systemic fungicide with protective and curative action. It inhibits the biosynthesis of ergosterol by fungi. It is used to control certain fungal diseases in cereal crops and various horticultural situations.			NEDI = 6% of ADI Mean estimated daily dietary exposure based on mean analytical results: 20th ATDS – <1% of ADI for all population groups assessed		
Spinach	Insert	T0.1			
Prosulfocarb Prosulfocarb is a S-benzyl thiocarbamate selective herbicide, absorbed by the leaves and roots. It inhibits lipid synthesis in the meristematic region. It is used to control annual ryegrass and toad rust in barley and wheat. Detectable residues are not expected in animal feeds. The recommended MRLs are set at the LOQ.			NEDI = 1% of ADI NESTI as % of ARfD		
			2-6 years		2 years & above
Barley	Omit	T*0.01			
	Substitute	*0.01	<1	Barley grain	<1
			<1	Barley beer	<1
Edible offal (mammalian)	Insert	*0.02	<1		<1
Eggs	Insert	*0.02	<1		<1
Meat (mammalian)	Insert	*0.02	<1		<1
Milks	Insert	*0.02	<1		<1
Poultry, edible offal of	Insert	*0.02	<1		<1
Poultry meat	Insert	*0.02	<1		<1
Wheat	Omit	T*0.01	<1		<1
	Substitute	*0.01	<1	Wheat bran, processed	<1
			<1	Wheat bran, unprocessed	<1
			<1	Wheat flour	<1
			<1	Wheat germ	<1
			<1	Wheat wholemeal	<1

Requested MRLs		mg/kg	Dietary Exposure Estimates
Prothioconazole Prothioconazole is a systemic fungicide with protective, curative, eradicative and long-lasting activity. It inhibits ergosterol biosyntheses by affecting steroid demethylation. It is used to treat Common Bunt *(Tilletia spp.)*. Residues and feeding studies data support MRLs at the LOQ for wheat grain and animal commodities.			NEDI = 2% of ADI
Edible offal (mammalian)	Omit	T*0.05	
	Substitute	*0.05	
Eggs	Omit	T*0.01	
	Substitute	*0.01	
Meat (mammalian) (in the fat)	Omit	T*0.01	
	Substitute	*0.01	
Milks	Omit	T*0.01	
	Substitute	*0.004	
Poultry, edible offal of	Omit	T*0.05	
	Substitute	*0.05	
Poultry meat (in the fat)	Omit	T*0.05	
	Substitute	*0.05	
Wheat	Omit	T*0.05	
	Substitute	*0.05	

Requested MRLs		mg/kg	Dietary Exposure Estimates	
Pyrasulfotole Pyrasulfotole is a herbicide. It acts as an inhibitor of the 4-hydroxyphenylpyruvate dioxygenase (HPPD) enzyme and blocks the pathway of prenylquinone biosynthesis in plants. It is used to control broadleaf weeds in cereal crops. The recommended MRLs for cereal grains, eggs, meat (mammalian), milks and poultry commodities are at the LOQ.			NEDI = 1% of ADI	
			NESTI as a % of ARfD	
			2-6 years	2 years & above
Cereal bran, unprocessed	Omit	T0.03		
	Substitute	0.03	<1	<1
Cereal grains	Omit	T*0.02		
	Substitute	*0.02	<1	<1
Edible offal (mammalian)	Omit	T0.5		
	Substitute	0.5	<1	<1
Eggs	Omit	T*0.01		
	Substitute	*0.01	<1	<1
Meat (mammalian)	Omit	T*0.01		
	Substitute	*0.01	<1	<1
Milks	Omit	T0.01		
	Substitute	*0.01	<1	<1
Poultry, edible offal of	Omit	T*0.01		
	Substitute	*0.01	<1	<1
Poultry meat	Omit	T*0.01		
	Substitute	*0.01	<1	<1
Ractopamine Ractopamine is a phenethanolamine. It was used to increase weight gain, improve feed efficiency and increase carcass leanness in beef cattle. The APVMA permit for this use has expired.			Dietary exposure assessment not required	
Cattle fat	Omit	T*0.02		
Cattle kidney	Omit	T0.1		
Cattle meat	Omit	T*0.02		

Requested MRLs		mg/kg	Dietary Exposure Estimates		
Sulfuryl fluoride (see also fluorine (inorganic salts)) Sulfuryl fluoride is an insecticide. It is a fumigant used to control insect pests in various situations including grain storage silos and warehouses, in fumigation chambers and food processing facilities such as mills. It is also used for seed intended for sowing and for hay fumigation. New Chemical Insert residue definition: Sulfuryl fluoride			NEDI = 2% of ADI		
			NESTI as % of ARfD		
			2-6 years		2 years & above
Cereal grains	Insert	0.05	<1	Cereal grains	<1
			<1	Cereal grain fractions	<1
			<1	Early milling products	<1
			<1	Barley beer	<1
			<1	Wheat bran, processed	<1
			<1	Wheat bran, unprocessed	<1
			<1	Wheat flour	<1
			<1	Wheat germ	<1
			<1	Wheat wholemeal	<1
Dried fruits	Insert	0.07	<1		<1
Peanut	Insert	7	4		2
Tree nuts	Insert	7	3		2
			<1	Almonds	<1
			2	Pecan	<1
			<1	Pistachios	<1
			<1	Walnuts	<1
Thiamethoxam Thiamethoxam is a neonicotinoid insecticide. It is an agonist of the nicotinic acetylcholine receptor, affecting the synapses in the insect's central nervous system. It is used to control various insect pests on fruit, vegetable, cereal and oilseed crops. The APVMA has issued a research permit for its use in sugar cane to control soil and sucking insect pests. The recommended MRL is at the LOQ.			NEDI = 11% of ADI		
Sugar cane	Insert	T*0.02			

Requested MRLs		mg/kg	Dietary Exposure Estimates	
Toltrazuril Toltrazuril is a triazinetrione derivative coccidiostat. It causes obstruction of the wall-forming bodies of *Eimerian macrogamonts*, and induces changes in the fine structure of coccidian development stages, mainly due to a swelling of the endoplasmic reticulum and of the Golgi apparatus. It also causes abnormalities in the peri-nuclear space, leading to disturbances in nuclear division, and a reduction of enzymes of the respiratory chain of the parasites. It is used to treat and prevent coccidiosis caused by *Eimeria bovis* or *Eimeria zeurnii* in calves up to 9 months of age. It is not to be used in lactating or pregnant cows where milk or milk products may be used for human consumption.			NEDI = 14% of ADI	
Cattle fat	Insert	1		
Cattle kidney	Insert	1		
Cattle liver	Insert	2		
Cattle muscle	Insert	0.25		
Tolylfluanid Tolylfluanid is a fungicide. It Inhibits fungal cell respiration. It is used to control botrytis rot *(Botrytis cinerea)*. The APVMA has issued a permit for its use on glass house and field cucumber.			NEDI = <1% of ADI NESTI as % of ARfD	
			2-6 years	2 years & above
Cucumber	Insert	T2	7	2

Attachment 3

Summary of Submissions

Submitter	Comments
Food Technology Association of Australia Inc.	Supported this Proposal.
National Council of Women of Australia	Supported this Proposal.
Queensland Government	Considers that fluoride ion should not be included in Schedule 1 of Standard 1.4.2 on the basis that: • fluoride ion originates from sources other than sulfuryl fluoride and it is not particularly useful for controlling the use of sulfuryl fluoride; and • the insertion of some food commodities effectively sets a 'zero tolerance' for all the other food commodities not contained in Standard 1.4.2. Natural concentration of fluoride in foods therefore would become violative levels. Also notes that a recently published scientific paper indicates that other food commodities like herbs, spices, pulses, oilseeds and cereals could be effectively fumigated by sulfuryl fluoride. Therefore, it needs to be acknowledged that some food commodities imported from overseas may be affected.
Food & Beverage Importers Association (FBIA), Unilever Australasia and Australian Food and Grocery Council (AFGC)	The FBIA, Unilever Australasia and AFGC requested that as MRLs were being assessed for a number of other commodities for bifenthrin, chlorpyrifos, glyphosate and propiconazole, consideration be given to expanding the assessment to include consideration of MRLs for tea for these chemicals. The reasons for this request were: • these chemicals are currently used on tea in producer countries as pest management chemicals, weed control chemicals or fungicides; • there is a Codex MRL for chlorpyrifos; • these chemicals are registered for use in Australia on other commodities and MRLs have been established in relation to these uses; • tea is imported in significant quantities and recognition is required of legitimate agricultural practices in producing countries and international residue standards so as to provide for compliant trade; • including tea MRLs for these chemicals would be in line with the Ministerial Council Policy Guideline on the Regulation of Residues of Agricultural and Veterinary Chemicals in Food; • to be consistent with effective regulation of the registration, permission and use of agricultural and veterinary chemicals; • a consistent approach for both domestic and imported foods; and • be consistent with Australia's obligations under the World Trade Organisation (WTO) Sanitary and Phytosanitary Agreement (SPS agreement). The submissions note that tea is an international commodity and it is important to ensure that there is consistency in standards on an international basis.

Submitter	Comments
	Provided a summary of tea MRLs for these four chemicals in tea producing countries (China, India, Taiwan, Sri Lanka, Argentina), importing countries (European Union, Japan, United States) and noted that there is a relevant Codex standard for chlorpyrifos.
WTO	**Comments**
California Table Grape Commission (CTGC)	Concern that the proposed deletion of the fluorine MRL for fruit would pose an impediment to the export of table grapes to Australia. The CTGC commented that Australia is an increasingly important market for table grapes, noting that since the market opened in 2001, Australia has become the industry's 6th largest export market, valued at over $US40 million. Stated that it recognised Australia's right to establish nationally appropriate standards; however, it requested that FSANZ consider retaining an MRL for fluorine in grapes which would encompass residues of fluorine in table grapes up to 7 mg/kg. This was on the basis that an MRL of 7 mg/kg would be consistent with the approved use in the United States of cryolite, a naturally occurring mineral compound which breaks down into fluoride, sodium and aluminium ions. Cryolite is used by the Californian table grape industry as an efficacious means of controlling leaf eating insects. Currently, the predominant use of cryolite is on grapes, potatoes and citrus fruits. The current US tolerance of 7 mg/kg for fluorine residues is associated with the use of crylolite on table grapes and was established after a comprehensive review by the US Environmental Protection Agency (USEPA) in 1996 http://www.epa.gov/oppsrrd1/REDs/0087.pdf

Attachment 4

Safety Assessment Methodology

1.1 Determination of 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 represent a risk to 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.

The PTWI is the upper limit that is set for substances that are known to accumulate in animals and humans, and is an estimate of the amount of a chemical that can be ingested weekly over a lifetime without appreciable risk to health.

1.3 Calculating Dietary Exposure

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

The APVMA and FSANZ have agreed that all dietary exposure assessments for agricultural and veterinary chemicals undertaken by the APVMA will be based on food consumption data for raw commodities, derived from individual dietary records from the latest National Nutrition Survey (NNS) and chemical residue data provided by the APVMA or FSANZ. The Australian Bureau of Statistics with the then Australian Government Department of Health and Aged Care undertook the latest NNS over a 13-month period (1995 to early 1996). The sample of 13,858 respondents aged 2 years and older was a representative sample of the Australian population and, as such, a diversity of food consumption patterns was reported.

1.3.1 Chronic Dietary Exposure Assessment

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

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

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

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

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

1.3.2 Acute Dietary Exposure Assessment

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

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

The NESTI calculation incorporates the large portion (97.5 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. 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 Application 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 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 MRLs in Standard 1.4.2.

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 to Standard 1.4.2, the MRLs 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 Expert Advisory Group on Antimicrobial Resistance (EAGAR), provides advice to government and regulatory agencies 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 seeks NHMRC advice on risk assessments for new antibiotics and extensions of indications. This advice considers the likely impact on the efficacy of antibiotics that are essential for human therapeutics.

FSANZ will incorporate MRLs for antimicrobial substances in the Code, only where the NHMRC has no objection to the use of the antimicrobial substance in food production. This process ensures that the potential for the development of antimicrobial resistance is rigorously considered.

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.