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

6 May 2009
[7-09]

PROPOSAL M1003
MAXIMUM RESIDUE LIMITS (April, May, June, August 2008)
ASSESSMENT REPORT

Executive Summary

Purpose

The purpose of this Proposal is to consider incorporating limits for residues of agricultural and veterinary chemicals that may legitimately occur in food in the *Australia New Zealand Food Standards Code* (the Code). This includes maximum residue limits (MRLs) gazetted by the Australian Pesticides and Veterinary Medicines Authority (APVMA) in April, May, June and August 2008. The APVMA did not gazette any MRLs in July. This Proposal also includes consideration of limits requested by industry to further align the Code with international standards. This will permit the sale of foods containing legitimate residues and protect public health and safety by minimising residues in foods consistent with the effective control of pests and diseases.

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

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

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

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

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

This Proposal is being assessed under the General Procedure.

Assessing the Proposal

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

- Whether costs that would arise from a food regulatory measure developed or varied as a result of the Proposal outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure;

- There are no other measures that would be more cost-effective than a variation to Standards 1.3.1 and 1.4.2 that could achieve the same end;

- Any relevant New Zealand standards; and

- Any other relevant matters.

Preferred Approach

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

Reasons for Preferred Approach

This Proposal has been assessed against the considerations provided for in section 59 of the FSANZ Act. FSANZ recommends the proposed draft variations to Standards 1.3.1 and 1.4.2 for the following reasons:

- MRLs serve to protect public health and safety by minimising residues in food consistent with the effective control of pests and diseases.

- Dietary exposure assessments indicate that the proposed variations do not present any public health and safety concerns.

- This approach ensures openness and transparency in relation to the residues that could reasonably occur in food.

- The proposed variations will benefit stakeholders by maintaining public health and safety while permitting the legal sale of food containing legitimate residues of agricultural and veterinary chemicals used to control pests and diseases and improve agricultural productivity.

- The APVMA has assessed appropriate residue, animal transfer, processing and metabolism studies, in accordance with *The Manual of Requirements and Guidelines – MORAG – for Agricultural and Veterinary Chemicals 1 July 2005* to support the use of chemicals on commodities as outlined in this Proposal.

- The Office of Chemical Safety (OCS) has undertaken a toxicological assessment of each chemical and has established an acceptable daily intake (ADI) and where appropriate an acute reference dose (ARfD).

- FSANZ has undertaken a preliminary regulation impact assessment and concluded that the proposed draft variations are necessary, cost-effective and beneficial.

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

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

Consultation

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

Invitation for Submissions

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

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

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

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Alternatively, you may email your submission directly to the Standards Management Officer at submissions@foodstandards.gov.au. There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 3 June 2009

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

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

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

If you are unable to submit your submission electronically, hard copy submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942

CONTENTS

INTRODUCTION

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

This Proposal also includes consideration of MRLs for cypermethrin, fenhexamid, fenvalerate and glufosinate-ammonium and extraneous residue limits (ERLs) for dieldrin for a range of commodities as a result of information provided by industry. Anomalies between the Code and international standards may have implications for trade in certain foods. The proposed variations to the Code would align limits in the Code with Codex and other standards internationally and permit the sale of relevant foods containing legitimate residues at levels that do not present health or safety concerns.

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

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

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

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

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

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

1. The Issue / Problem

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

2. Current Standard

2.1 Background

Standard 1.4.2 lists the limits for agricultural and veterinary chemical residues which may occur in foods. Some limits are also listed in Standard 1.3.1. If a limit is not listed for a particular agricultural or veterinary chemical/commodity combination, there must be no detectable residues of that chemical in that food. This general prohibition means that in the absence of the relevant limit in the Code, food may not be sold where there are detectable residues.

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

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

3. Objectives

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

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

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

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

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

- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Australia and New Zealand Food Regulation Ministerial Council.

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

4. Assessment Approach

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

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

The steps undertaken in conducting a dietary exposure assessment are:

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

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

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

RISK ASSESSMENT

5. Risk Assessment Summary

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

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

The proposed MRLs for the antibiotic substance halofuginone do not pose a risk in terms of antimicrobial resistance.

RISK MANAGEMENT

6. Options

1. Option 1 – approve the draft variations

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

3. Option 3 – reject the draft variations

7. Impact Analysis

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

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

7.1 Affected Parties

The parties affected by proposed amendments include:

- consumers;
- growers and producers;
- importers of agricultural produce and food products;
- the chemical industry; 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 of agricultural and veterinary chemicals in the food supply. FSANZ does not consider there to be any dietary exposure implications associated with the proposed approval. The risk assessment has determined that there are no public health or safety concerns associated with the proposed variations. No additional costs to consumers have been identified.

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

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 proposed draft variations. Additional or increased MRLs may benefit importers and consequently consumers in that this may extend the options to source safe foods. Any MRL deletions or reductions have the potential to restrict importation of foods and could potentially result in higher food prices and a reduced product range available to consumers. Interested parties 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. Imported foods and Codex MRLs and are addressed in section 9 of this Report.

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

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

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

7.2.3 Option 3 – reject the draft variations

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

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

7.2.4 Summary

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

7.3 Comparison of Options

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

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

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

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

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

The benefits of progressing option 1 outweigh any associated costs.

COMMUNICATION AND CONSULTATION STRATEGY

8. Communication

FSANZ consideration of amending limits in the Code for residues of agricultural or veterinary chemicals in food does not normally generate public interest. FSANZ adopts a basic communication strategy, with a focus on alerting the community that a change to the Code is being contemplated.

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

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

9. Consultation

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

9.1 World Trade Organization

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

Limits prescribed in the Code constitute a mandatory requirement applying to all food products of a particular class whether produced domestically or imported. Food products with residues exceeding the relevant limit listed in the Code cannot legally be supplied in Australia.

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

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

9.2 Codex Alimentarius Commission Standards

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

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

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

The following table lists proposed limits where there is a corresponding Codex limit. Note that a 'T' indicates that the limit is temporary and an 'E' indicates an extraneous residue limit.

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

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

9.3 New Zealand Standards

All imported and domestically produced food sold in New Zealand (except for food imported from Australia) must comply with the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2008 and amendments (the New Zealand MRL Standards).

Under the New Zealand MRL Standards, agricultural chemical residues in food must comply with the specific MRLs listed in the Standards. The New Zealand MRL Standards also include a provision for residues of up to 0.1 mg/kg for agricultural chemical / commodity combinations not specifically listed. If the food is imported, it may comply with Codex MRLs. Further information about the New Zealand MRL Standards is available on the New Zealand Food Safety Authority website at: http://www.nzfsa.govt.nz/acvm/registers-lists/nz-mrl/index.htm

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

The following table lists the proposed variations to MRLs or ERLs and includes the corresponding MRL in the New Zealand MRL Standards. Note that a 'T' indicates that the limit is temporary; an 'E' indicates that the limit is an ERL; and an asterisk indicates that the limit is at or about the limit of analytical quantification.

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

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

9.4 Imported Foods

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

Deletions or reductions of MRLs may impact imported foods that may comply with existing MRLs even though these existing MRLs are no longer required for domestically produced

food. This is because imported foods may contain residues consistent with the MRLs proposed for deletion or reduction.

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

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. All the proposed MRL variations to the Code are at **Attachment 1** and the requested changes are outlined in more detail in **Attachment 2**.

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

FSANZ requests comment on any possible ramifications of the proposed deletion or reduction of MRLs in this Proposal for imported foods.

CONCLUSION

10. Conclusion and Preferred Option

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

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

Preferred Approach

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

10.1 Reasons for Preferred Approach

FSANZ recommends the proposed draft variations to Standards 1.3.1 and 1.4.2 for the following reasons:

- MRLs serve to protect public health and safety by minimising residues in food consistent with the effective control of pests and diseases.

- Dietary exposure assessments indicate that the proposed variations do not present any public health and safety concerns.

- This approach ensures openness and transparency in relation to the residues that could reasonably occur in food.

- The proposed variations will benefit stakeholders by maintaining public health and safety while permitting the legal sale of food containing legitimate residues of agricultural and veterinary chemicals used to control pests and diseases and improve agricultural productivity.

- The APVMA has assessed appropriate residue, animal transfer, processing and metabolism studies, in accordance with *The Manual of Requirements and Guidelines – MORAG – for Agricultural and Veterinary Chemicals 1 July 2005* to support the use of chemicals on commodities as outlined in this Proposal.

- The Office of Chemical Safety (OCS) has undertaken a toxicological assessment of each chemical and has established an ADI and where appropriate an ARfD.

- FSANZ has undertaken a preliminary regulation impact assessment and concluded that the proposed draft variations are necessary, cost-effective and beneficial.

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

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

11. Implementation and Review

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

- State and Territory residue monitoring programs;

- Australian Government programs such as the National Residue Survey; and

- dietary exposure studies such as the Australian Total Diet Study.

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

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

ATTACHMENTS

1. Draft variations to the *Australia New Zealand Food Standards Code*
2. A Summary of Limits Under Consideration in Proposal M1003
3. Safety Assessment Methodology
4. Background Information

Attachment 1

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

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

To commence: on gazettal

[1] ***Standard 1.3.1*** *of the Australia New Zealand Food Standards Code is varied by –*

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

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

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

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

substituting –

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

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

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

COLUMN 1	COLUMN 2
MALDISON	CURRANT, BLACK

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

COLUMN 1	COLUMN 2
ABAMECTIN	SUM OF AVERMECTIN B1A, AVERMECTIN B1B AND (Z)-8,9 AVERMECTIN B1A, AND (Z)-8,9 AVERMECTIN B1B
PROPACHLOR	SUM OF PROPACHLOR AND METABOLITES HYDROLYSABLE TO N-ISOPROPYLANILINE, EXPRESSED AS PROPACHLOR

[2.3] *inserting in* Schedule 1 –

FLUBENDIAMIDE *COMMODITIES OF PLANT ORIGIN*: FLUBENDIAMIDE *COMMODITIES OF ANIMAL ORIGIN*: SUM OF FLUBENDIAMIDE AND 3-IODO-*N*-(2-METHYL-4-[1,2,2,2-TETRAFLUORO-1-(TRIFLUOROMETHYL)ETHYL]PHENYL)PHTHALIMIDE, EXPRESSED AS FLUBENDIAMIDE	
BRASSICA (COLE OR CABBAGE) VEGETABLES, HEAD CABBAGES, FLOWERHEAD BRASSICAS	T3
COMMON BEAN (PODS AND/OR IMMATURE SEEDS)	T2
LETTUCE, HEAD	T5
LETTUCE, LEAF	T5
PEPPERS, SWEET	T1
SWEET CORN (CORN-ON-THE-COB)	T*0.05
TOMATO	T2
PROFOXYDIM SUM OF PROFOXYDIM AND ALL METABOLITES CONVERTED TO DIMETHYL-3-(3-THIANYL)GLUTARATE-S-DIOXIDE AFTER OXIDATION AND TREATMENT WITH ACIDIC METHANOL, EXPRESSED AS PROFOXYDIM	
EDIBLE OFFAL (MAMMALIAN)	0.5
EGGS	*0.05
MEAT (MAMMALIAN)	*0.05
MILKS	*0.01
POULTRY, EDIBLE OFFAL OF	*0.05
POULTRY MEAT	*0.05
RICE	0.05
PYROXSULAM PYROXSULAM	
EDIBLE OFFAL (MAMMALIAN)	*0.01
EGGS	*0.01
MEAT (MAMMALIAN)	*0.01
MILKS	*0.01
POULTRY, EDIBLE OFFAL OF	*0.01
POULTRY MEAT	*0.01
WHEAT	*0.01
SULPHUR DIOXIDE *SEE* STANDARD 1.3.1	

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

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

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

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

AZOXYSTROBIN AZOXYSTROBIN	
BULB VEGETABLES [EXCEPT FENNEL, BULB; ONION, BULB]	T7

BIFENAZATE SUM OF BIFENAZATE AND BIFENAZATE DIAZENE (DIAZENECARBOXYLIC ACID, 2-(4-METHOXY-[1,1'-BIPHENYL-3-YL] 1-METHYLETHYL ESTER), EXPRESSED AS BIFENAZATE	
CUCUMBER	T0.5
PEPPERS, SWEET	T2
TOMATO	T0.5
BIFENTHRIN BIFENTHRIN	
FRUITING VEGETABLES, OTHER THAN CUCURBITS	0.5
BOSCALID *COMMODITIES OF PLANT ORIGIN*: BOSCALID *COMMODITIES OF ANIMAL ORIGIN*: SUM OF BOSCALID, 2-CHLORO-N-(4'-CHLORO-5-HYDROXYBIPHENYL-2-YL) NICOTINAMIDE AND THE GLUCURONIDE CONJUGATE OF 2-CHLORO-N-(4'-CHLORO-5-HYDROXYBIPHENYL-2-YL) NICOTINAMIDE, EXPRESSED AS BOSCALID EQUIVALENTS	
APPLE	2
CARBOFURAN SUM OF CARBOFURAN AND 3-HYDROXYCARBOFURAN, EXPRESSED AS CARBOFURAN	
GARLIC	T0.1
CYHALOTHRIN CYHALOTHRIN, SUM OF ISOMERS	
GARLIC	*0.05
CYPERMETHRIN CYPERMETHRIN, SUM OF ISOMERS	
BERRIES AND OTHER SMALL FRUITS [EXCEPT GRAPES]	0.5
DITHIOCARBAMATES TOTAL DITHIOCARBAMATES, DETERMINED AS CARBON DISULPHIDE EVOLVED DURING ACID DIGESTION AND EXPRESSED AS MILLIGRAMS OF CARBON DISULPHIDE PER KILOGRAM OF FOOD	
HERBS [EXCEPT PARSLEY]	T5
ETOXAZOLE ETOXAZOLE	
CITRUS FRUITS	T0.1
DRIED GRAPES	0.2
FRUITING VEGETABLES, OTHER THAN CUCURBITS	T0.1
POME FRUITS	0.2
STONE FRUITS [EXCEPT CHERRIES]	0.1

FENHEXAMID FENHEXAMID	
KIWIFRUIT	15
FENVALERATE FENVALERATE, SUM OF ISOMERS	
BERRIES AND OTHER SMALL FRUITS	1
GLUFOSINATE AND GLUFOSINATE-AMMONIUM SUM OF GLUFOSINATE-AMMONIUM, N-ACETYL GLUFOSINATE AND 3-[HYDROXY(METHYL)-PHOSPHINOYL] PROPIONIC ACID, EXPRESSED AS GLUFOSINATE (FREE ACID)	
MAIZE	0.2
SOYA BEAN (DRY)	2
HALOFUGINONE HALOFUGINONE	
CATTLE FAT	0.025
CATTLE MUSCLE	0.01
INDOXACARB SUM OF INDOXACARB AND ITS *R*-ISOMER	
BERRIES AND OTHER SMALL FRUITS [EXCEPT GRAPES]	T1
CELERY	T5
LINURON SUM OF LINURON PLUS 3,4-DICHLOROANILINE, EXPRESSED AS LINURON	
CELERIAC	T0.5
VEGETABLES [EXCEPT CELERIAC; CELERY; LEEK]	*0.05
METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OXIME'), EXPRESSED AS METHOMYL *SEE ALSO* THIODICARB	
ONION, WELSH	1
RADISH	T1
SHALLOT	1
SPRING ONION	1
SWEDE	T1
TURNIP, GARDEN	T1
METRIBUZIN METRIBUZIN	
SUGAR CANE MOLASSES	0.1
PHOSPHOROUS ACID PHOSPHOROUS ACID	
ASSORTED TROPICAL AND SUB-TROPICAL FRUITS – INEDIBLE PEEL [EXCEPT AVOCADO]	T100
AVOCADO	T500

PIRIMICARB SUM OF PIRIMICARB, DEMETHYL-PIRIMICARB AND THE *N*-FORMYL-(METHYLAMINO) ANALOGUE (DEMETHYLFORMAMIDO-PIRIMICARB), EXPRESSED AS PIRIMICARB	
SOYA BEAN (DRY)	T0.5
VEGETABLES [EXCEPT LEAFY VEGETABLES; LUPIN (DRY); SOYA BEAN (DRY)]	1
PROCHLORAZ SUM OF PROCHLORAZ AND ITS METABOLITES CONTAINING THE 2,4,6-TRICHLOROPHENOL MOIETY, EXPRESSED AS PROCHLORAZ	
MANDARINS	T10
PYRACLOSTROBIN *COMMODITIES OF PLANT ORIGIN*: PYRACLOSTROBIN *COMMODITIES OF ANIMAL ORIGIN*: SUM OF PYRACLOSTROBIN AND METABOLITES HYDROLYSED TO 1-(4-CHLORO-PHENYL)-1H-PYRAZOL-3-OL, EXPRESSED AS PYRACLOSTROBIN	
APPLE	1
SUNFLOWER SEED	T0.3

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

ABAMECTIN SUM OF AVERMECTIN B1A, AVERMECTIN B1B AND (Z)-8,9 AVERMECTIN B1A, AND (Z)-8,9 AVERMECTIN B1B	
CURRANT, BLACK	0.02
PEAS	T0.5
BIFENTHRIN BIFENTHRIN	
COMMON BEAN (PODS AND/OR IMMATURE SEEDS)	T1
DITHIOCARBAMATES TOTAL DITHIOCARBAMATES, DETERMINED AS CARBON DISULPHIDE EVOLVED DURING ACID DIGESTION AND EXPRESSED AS MILLIGRAMS OF CARBON DISULPHIDE PER KILOGRAM OF FOOD	
LITCHI	5
GLUFOSINATE AND GLUFOSINATE-AMMONIUM SUM OF GLUFOSINATE-AMMONIUM, N-ACETYL GLUFOSINATE AND 3-[HYDROXY(METHYL)-PHOSPHINOYL] PROPIONIC ACID, EXPRESSED AS GLUFOSINATE (FREE ACID)	
RAPE SEED	5
HALOFUGINONE HALOFUGINONE	
CATTLE KIDNEY	0.03

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

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

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

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

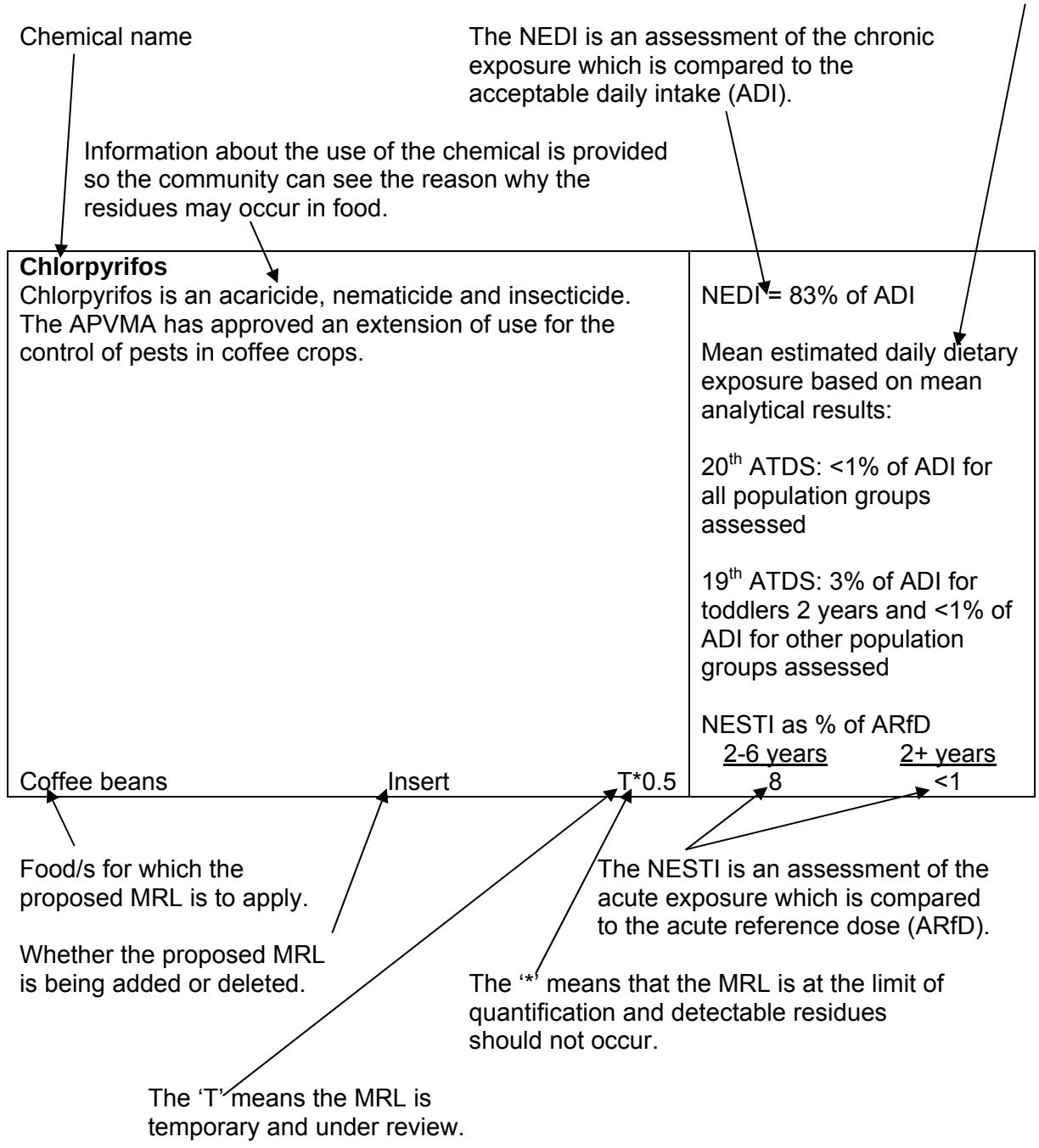
ALDRIN AND DIELDRIN SUM OF HHDN AND HEOD	
FRUITING VEGETABLES, CUCURBITS	E0.1
ROOT AND TUBER VEGETABLES	E0.1

Attachment 2

A summary of limits under consideration in Proposal M1003

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

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



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

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

Requested MRLs/ERLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment
Bifenthrin Bifenthrin is a synthetic pyrethroid insecticide which kills insects by affecting the salt balance (sodium channels) in nerve cells. It has a broad spectrum of activity against insects with the main toxic effect on the nervous system. It is used to control a broad range of foliar pests on cereal, fruit and vegetable crops. The APVMA has issued permits for its use to control various pests including silverleaf whitefly (*Bemisia tabaci*) and two spotted mite (*Tetranychus urticae*) on various crops including capsicums and eggplants; and lettuce and beans. Note: The requested leafy vegetables MRL of T2 mg/kg was progressed in M1002 and gazetted in amendment 105			NEDI = 76% of ADI Mean estimated daily dietary exposure based on mean analytical results: 20th ATDS: <1% of ADI for all population groups assessed
Common bean (pods and/or immature seeds)	Omit	T0.5	
	Substitute	T1	
Egg plant	Omit	T0.5	
Fruiting vegetables, other than cucurbits	Insert	0.5	
Okra	Omit	T0.5	
Peppers	Omit	T0.5	
Tomato	Omit	0.5	
Boscalid Boscalid is a fungicide. It inhibits spore germination, germ tube elongation, mycelial growth and sporulation by inhibition of succinate ubiquinone reductase (complex II) in the mitochondrial electron transport chain. It is used to control powdery mildew on a range of fruit and vegetables. It is used to control black spot, powdery mildew and *Alternaria* spp. in apples.			NEDI = 8% of ADI NESTI as % of ARfD 2-6 years: 2 2+ years: <1
Apple	Insert	2	
Carbofuran Carbofuran is a carbamate insecticide and nematicide. It is systemic with predominantly contact and stomach action. It acts as a cholinesterase inhibitor. It is used to control soil-dwelling and foliar-feeding insects and nematodes on a various crops. The APVMA has issued a permit for its use to control nematodes on garlic.			NEDI = 38% of ADI
Garlic	Insert	T0.1	
Cypermethrin Cypermethrin is a pyrethroid, non-systemic insecticide with contact and stomach action. It acts on the central and peripheral nervous system in very low doses. It is used to control a wide range of chewing and sucking insect pests in horticulture and fruit production internationally. The Food and Beverages Importers Association (FBIA) has requested that FSANZ consider incorporating the Codex cypermethrin MRL for berries in the Code. Goji berries are imported to Australia and legitimate residues may occur. FSANZ has noted the anomalies in the Code in relation to Codex standards for residues in berries and that there may be implications for trade in goji berries as a consequence.			NEDI = 10% of ADI Mean estimated daily dietary exposure based on mean analytical results: 20th ATDS: not detected in any foods sampled 19th ATDS: <1% of ADI for all population groups assessed
Berries and other small fruits [except grapes]	Insert	0.5	

Requested MRLs/ERLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)	Dietary Exposure Assessment
Dieldrin Dieldrin is an environmental contaminant; residues may occur in foods grown some distance from sites of former application of the chlorinated organic insecticides aldrin or dieldrin, particularly in windy conditions in drought years. This is beyond the control of growers and may result in significant financial losses. These organochlorines have not been permitted or registered for use in agriculture for many years. An ERL is the maximum permitted limit of a pesticide residue, arising from environmental sources other than the use of a pesticide directly or indirectly on the food. An 'E' appearing with a limit denotes an ERL. Dieldrin ERLs are listed under aldrin and dieldrin in Schedule 2 of Standard 1.4.2 for a number of commodities. There have been sporadic detections of residues on vegetables grown in contact with soil, such as pumpkins and melons, for which no ERLs are listed in the Code. These detections have been at levels consistent with residues persisting in the soil. AUSVEG, the national peak body representing vegetable growers, requested that FSANZ consider establishing dieldrin ERLs for the crop groups fruiting vegetables, cucurbits and root and tuber vegetables at 0.1 mg/kg to address this issue. This would be consistent with the current New Zealand and Codex standards. Carrot Omit E0.1 Cucumber Omit E0.1 Fruiting vegetables, cucurbits Insert E0.1 Horseradish Omit E0.1 Parsnip Omit E0.1 Potato Omit E0.1 Radish Omit E0.1 Root and tuber vegetables Insert E0.1	Monitoring data indicate that the proposed ERLs do not raise health or safety concerns. 20th ATDS: not detected in any foods sampled 19th ATDS: not detected in any foods sampled Foods were analysed for dieldrin residues in the 23rd ATDS. The data are currently being examined.
Etoxazole Etoxazole is an insecticide. It inhibits the insect moulting process by disrupting the cell wall. It is used to control various mites on pome fruit, stone fruit and table grapes. The APVMA has issued a permit for its use to control mites on citrus fruits and fruiting vegetables. Note: The APVMA requested an etoxazole MRL of 0.1 mg/kg for grapes. The APVMA reduced the etoxazole MRL for grapes of T0.3 mg/kg to 0.1 mg/kg in the MRL Standard to reflect the current domestic use pattern. Previously, when FSANZ consulted on including the T0.3 mg/kg MRL in the Code, the California Table Grape Commission submitted that an MRL of T0.5 mg/kg was required. This MRL was subsequently gazetted in the Code. FSANZ notes that the current US tolerance for etoxazole in grapes is 0.5 ppm and for this reason is consulting on retaining the MRL of T0.5 mg/kg in the Code.	NEDI = 2% of ADI NESTI as % of ARfD 2-6 years 2+ years

Requested MRLs/ERLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			**Dietary Exposure Assessment**		
Apple	Omit	0.2			
Citrus fruits	Insert	T0.1	<1		<1
Dried grapes	Insert	0.2	<1		<1
Fruiting vegetables, other than cucurbits	Insert	T0.1	<1	Eggplant	<1
			<1	Peppers, Sweet	<1
			<1	Tomato	<1
			<1		<1
Grapes	Retain	T0.5			
Pear	Omit	T0.2			
Pome fruits	Insert	0.2	<1	Apple	<1
			<1	Pear	<1
Stone fruits	Omit	T0.5			
Stone fruits [except cherries]	Insert	0.1	<1	Apricot	<1
			<1	Nectarine	<1
			<1	Peach	<1
			<1	Plums (including prunes)	<1
Fenhexamid Fenhexamid is a fungicide. It inhibits germ tube elongation and mycelium growth. Internationally it is used to control *Botrytis cinerea, Monilla* spp. and related pathogens in various fruits, vegetables and ornamentals. In Australia it is used to control bunch rot (*Botrytis cinerea*) on grapes and grey mould on strawberries. Bayer CropScience (Bayer) has requested that FSANZ consider incorporating the Codex fenhexamid MRL for kiwifruit in the Code to account for legitimate residues that may occur in kiwifruit. Bayer has provided information that kiwifruit are imported to Australia in the off-season. FSANZ has noted the anomaly in the Code in relation to the Codex standard for residues in kiwifruit and that there may be implications for trade as a consequence.			NEDI = 5% of ADI		
Kiwifruit	Insert	15			
Fenvalerate Fenvalerate is a pyrethroid, non-systemic insecticide with contact and stomach action. It acts on the nervous system of insects and disrupts the function of neurons by interaction with the sodium channel. Internationally, it is used to control a wide range of chewing, sucking and boring insects in fruits, vines, hops, nuts, vegetables, oilseeds, cereals, tobacco, sugar cane, ornamentals and forestry; flying and crawling insects in public health and animal housing situations; and as an animal ectoparasiticide. The FBIA has requested that FSANZ consider incorporating the Codex fenvalerate MRL for berries in the Code. Goji berries are imported to Australia and legitimate residues may occur. FSANZ has noted the anomalies in the Code in relation to Codex standards for residues in berries and that there may be implications for trade in goji berries as a consequence.			NEDI = 48% of ADI Mean estimated daily dietary exposure based on mean analytical results: 20th ATDS: not detected in any foods sampled 19th ATDS: <1% of ADI for all population groups assessed		
Berries and other small fruits	Insert	1			
Strawberry	Omit	1			

Requested MRLs/ERLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment
Flubendiamide Flubendiamide is an insecticide. It is a ryanodine receptor agonist. It is used to control diamondback moth, cabbage white butterfly, cluster caterpillar, heliothis (*Helicoverpa* spp.), and soybean looper in various vegetable crops. The recommended MRL for corn is at the limit of quantification (LOQ). New chemical Insert residue definition: Commodities of plant origin: Flubendiamide Commodities of animal origin: Sum of flubendiamide and 3-iodo-*N*-(2-methyl-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl)phthalimide, expressed as flubendiamide			NEDI = 35% of ADI
Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	Insert	T3	
Common bean (pods and/or immature seeds)	Insert	T2	
Lettuce, head	Insert	T5	
Lettuce, leaf	Insert	T5	
Peppers, Sweet	Insert	T1	
Sweet corn (corn-on-the-cob)	Insert	T*0.05	
Tomato	Insert	T2	
Glufosinate-ammonium Glufosinate-ammonium is a non-selective contact herbicide. It inhibits glutamate synthesis, leading to accumulation of ammonium ions and inhibition of photosynthesis. It is used to control broadleaf and grass weeds. Bayer has requested that FSANZ consider incorporating Codex glufosinate-ammonium MRLs for canola and soybean in the Code. Bayer requested a glufosinate-ammonium MRL of 0.2 mg/kg for maize. This is higher than the Codex MRL of 0.1 mg/kg for this commodity. The requested MRL is the applicable standard in the United States and Canada. These MRLs are requested to facilitate trade. Bayer provided information that these commodities are imported from North America; residues may occur as a result of legitimate use of glufosinate-ammonium on these crops in the United States and Canada; and that these residues may not comply with current Australian standards. Maize	Insert	0.2	NEDI = 7% of ADI
Rape seed	Omit	*0.05	
	Substitute	5	
Soya bean (dry)	Insert	2	

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

Requested MRLs/ERLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment
Isoxaflutole Isoxaflutole is a systemic herbicide. It is a p-hydroxyphenyl pyruvate dioxygenase inhibitor. This enzyme converts p-hydroxyphenyl pyruvate to homogentisate, a key step in plastoquinone biosynthesis, giving rise to chlorosis of new growth. It is used for pre- and post-emergent control of grasses and broadleaf weeds in chickpeas and sugar cane. The APVMA has advised that residues data are sufficient to establish MRLs in place of the TMRLs. The data indicate that residues did not concentrate in processed commodities. Animal commodity MRLs are recommended as treated produce may be used as stock feed. The permit for use of isoxaflutole in cereal grains has expired. Note: The requested chickpea, sugar cane and mammalian commodity MRLs were gazetted by the APVMA in July 2001 and consulted on in January 2002 in Application A450. The MRLs were not subsequently gazetted in the Code in error.			NEDI = 3% of ADI
Cereal grains	Omit	T*0.05	
Chick-pea (dry)	Omit	T*0.03	
	Substitute	*0.03	
Edible offal (mammalian)	Omit	T*0.05	
	Substitute	*0.05	
Eggs	Omit	T*0.05	
	Substitute	*0.05	
Meat (mammalian)	Omit	T*0.05	
	Substitute	*0.05	
Milks	Omit	T*0.05	
	Substitute	*0.05	
Poultry, edible offal of	Omit	T*0.05	
	Substitute	*0.05	
Poultry meat	Omit	T*0.05	
	Substitute	*0.05	
Sugar cane	Omit	T*0.01	
	Substitute	*0.01	
Lambda-cyhalothrin Lambda-cyhalothrin is a synthetic pyrethroid insecticide. It is a sodium channel modulator. It causes excessive stimulation of neurons by preventing the closure of voltage sensitive sodium channels. It is used to control a wide spectrum of insect pests in cereal, fruit and vegetable crops. The APVMA has issued a permit for its use to control thrips, mites and onion maggot on garlic. The recommended MRL is at the LOQ. Note: MRLs for lambda-cyhalothrin are listed under cyhalothrin			NEDI = 58% of ADI This is equivalent to 3% of the cyhalothrin ADI
Garlic	Insert	*0.05	

Requested MRLs/ERLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment
Linuron Linuron is a herbicide. It inhibits electron transport in photosystem II. It is used to control annual grasses and broad leaf weeds in vegetable crops. The APVMA has issued a permit for its use to control weeds in celeriac. Celeriac Vegetables [except celery and leek] Vegetables [except celeriac; celery; leek]	 Insert Omit Insert	 T0.5 *0.05 *0.05	NEDI = 15% of ADI
Maldison This is a minor technical amendment to ensure consistent use of the commodity name for black currants. Amendment to commodity name Omit: Currants, black Substitute: Currant, black			Dietary exposure assessment not required.
Mancozeb Mancozeb is a fungicide. It is in the dithiocarbamate group of chemicals. It interferes with various enzymes involved in the respiration process, thereby inhibiting spore generation and mycelial growth. It is used to control many fungal diseases in a wide range of field crops. The APVMA has issued a permit for its use to control quarantine pests on nursery stocks of culinary herbs and leafy vegetables entering Western Australia from other states. A conservative temporary MRL has been recommended for herbs in line with the mancozeb MRL for leafy vegetables which may be treated at similar rates. Residues in herbs are expected to be substantially lower than the MRL as it will be 8 – 10 weeks between treatment and harvest. The APVMA has also issued a permit for its use to control lychee pepper spot (*Colletotrichum gloeosporoides*) on lychees. The APVMA has advised that the residues data provided are sufficient to establish the recommended MRL in place of the temporary MRL. The commodity name 'Litchi' is used for lychees in the Code in line with the Codex classification of foods and animal feeds. Note: MRLs for mancozeb are listed under dithiocarbamates Herbs [except parsley] Litchi	 Insert Omit Substitute	 T5 T5 5	NEDI = 95 % of the mancozeb ADI 19th ATDS – 63% of the thiram ADI for toddlers of 2 years and 20% – 29% of this ADI for other population groups assessed. This protectively overestimates exposure as thiram has the lowest ADI of the chemicals in the dithiocarbamate group and some of the chemical residues measured will have come from other dithiocarbamates and natural compounds in onions and brassicas. Foods were analysed for dithiocarbamates residues in the 23rd ATDS. The data are currently being examined. The APVMA has listed the dithiocarbamates group for review.

Requested MRLs/ERLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment
Methomyl Methomyl is a carbamate insecticide and acaricide with contact and stomach action. It is a cholinesterase inhibitor. It is used to control a wide range of pests on fruits, vines, vegetables and field crops. The APVMA has issued permits for its use to control heliothis (*Helicoverpa* spp.), loopers and webworm on beetroot; cabbage white butterfly, cabbage centre grub, heliothis, looper and cluster caterpillar on radish, swede and turnip; and western flower thrips on spring onion, shallot and Welsh onion. The APVMA has advised that the residues data provided are sufficient to establish the recommended beetroot MRL in place of the temporary MRL. The APVMA anticipates gazetting the shallot and Welsh onion MRLs in May 2009.			NEDI = 84% of ADI 19th ATDS: not detected in any foods sampled * The NESTIs indicated were calculated using consumption data for all bulb vegetables as consumption data for the relevant food were not available for that population group.
			NESTI as % of ARfD 2-6 years 2+ years
Beetroot	Omit	T1	
	Substitute	1	21 7
Onion, Welsh	Insert	1	58* *Bulb vegetables 20*
Radish	Insert	T1	8 8
Shallot	Insert	1	58* 3
Spring onion	Insert	1	58* 5
Swede	Insert	T1	24 30
Turnip, garden	Insert	T1	24 14
Metribuzin Metribuzin is a selective systemic herbicide. It acts as a photosynthetic electron transport inhibitor at the photosystem II receptor site of weeds. It is used for pre- and post-emergence control of many grass and broad leaf weeds in cereal, sugar cane and vegetable crops. The APVMA has approved an extension of use of metribuzin to control weeds in sugar cane. The recommended MRL for sugar cane is at the LOQ.			NEDI = 5% of ADI NESTI as % of ARfD 2-6 years 2+ years
Sugar cane	Omit	0.1	
	Substitute	*0.02	<1 Sugar from all sources <1
Sugar cane molasses	Insert	0.1	
Phosphorous acid Phosphorous acid is a selective systemic phosphonate fungicide with multi site activity. It is used to control fungal diseases on fruits and vegetables. The APVMA has issued a permit for its use to control root rot (*Phytophthora cinnamomi*) on avocados.			NEDI = 7% of ADI
Assorted tropical and subtropical fruits –inedible peel	Omit	T100	
Assorted tropical and sub-tropical fruits – inedible peel [except avocado]	Insert	T100	
Avocado	Insert	T500	
Pirimicarb Pirimicarb is an anticholinesterase insecticide. It is selective and systemic and has contact, stomach and respiratory action. It is used to control certain aphids on crops and pastures. The APVMA has issued a permit for its use to control soybean aphid on soya beans.			NEDI = 85% of ADI Mean estimated daily dietary exposure based on mean analytical results: 20th ATDS: <1% of ADI for all

Requested MRLs/ERLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			**Dietary Exposure Assessment**
Soya bean (dry)	Insert	T0.5	population groups assessed
Vegetables [except as otherwise listed under this chemical]	Omit	1	19th ATDS: <1% of ADI for all population groups assessed
Vegetables [except leafy vegetables; lupin (dry); soya bean (dry)]	Insert	1	
Prochloraz Prochloraz is a pyrazole fungicide. It inhibits steroid demethylation (ergosterol biosynthesis). It is used as a protectant and eradicant fungicide against a wide range of diseases affecting field, fruit and vegetable crops. The APVMA has issued a permit for its use to control anthracnose in mandarins.			NEDI = 32% of ADI NESTI as % of ARfD 2-6 years: 35; 2+ years: 10
Mandarins	Insert	T10	
Profoxydim Profoxydim is a herbicide. It is a fatty acid synthesis inhibitor, it inhibits acetyl CoA carboxylase (ACCase). It is translocated throughout the plant and to the meristematic tissues. Weeds stop growing, followed by yellowing or reddening of younger leaves. It is used for post-emergence control of barnyard and silvertop grasses in rice crops. The APVMA has advised that detectable residues are unlikely to occur in rice grain. MRLs are recommended for animal commodities as rice forage may be fed to animals. The recommended MRLs for eggs, meats, milks and poultry offal are at the LOQ. New chemical Insert residue definition: Sum of profoxydim and all metabolites converted to dimethyl-3-(3-thianyl)glutarate-S-dioxide after oxidation and treatment with acidic methanol, expressed as profoxydim			NEDI = <1% of ADI
Edible offal (mammalian)	Insert	0.5	
Eggs	Insert	*0.05	
Meat (mammalian)	Insert	*0.05	
Milks	Insert	*0.01	
Poultry, edible offal of	Insert	*0.05	
Poultry meat	Insert	*0.05	
Rice	Insert	0.05	
Propachlor Propachlor is a selective chloroacetamide herbicide. It is absorbed by seedling shoots with secondary translocation throughout the plant. It is used to control grass and broadleaf weeds in cereal and vegetable crops. Amendment to residue definition Omit: Propachlor Substitute: Sum of propachlor and metabolites hydrolysable to N-isopropylaniline, expressed as propachlor			Dietary exposure assessment not required.

Requested MRLs/ERLs expressed in milligrams of the chemical per kilogram of the food (mg/kg)			Dietary Exposure Assessment
Pymetrozine Pymetrozine is an azomethine insecticide. It is selective against Homoptera, causing them to stop feeding. It is used to control juvenile and adult stages of aphids and whitefly in vegetables, fruit and cotton. The APVMA has renewed a permit for its use to control green peach aphid (*Myzus persicae*) on almonds. Residue data support the recommended MRL at the LOQ.			NEDI = 20% of ADI
Almonds	Omit Substitute	T*0.02 T*0.01	
Pyraclostrobin Pyraclostrobin is a fungicide. It inhibits mitochondrial respiration by blocking electron transfer at the cytochrome bc1 complex. It is used to control plant pathogens in fruit and vegetable crops. It is used to control black spot, powdery mildew and Alternaria in apples. The APVMA has issued a permit for its use to control powdery mildew on sunflowers.			NEDI = <1% of ADI NESTI as % of ARfD 2-6 years / 2+ years
Apple	Insert	1	78 / 19
Sunflower seed	Insert	T0.3	<1 / <1
Pyroxsulam Pyroxsulam is a herbicide. It inhibits the plant enzyme acetolactate synthase (ALS). It is used to control grass and broadleaf weeds in wheat. The recommended MRLs are at the LOQ. New chemical Insert residue definition: Pyroxsulam			NEDI = <1% of ADI
Edible offal (mammalian)	Insert	*0.01	
Eggs	Insert	*0.01	
Meat (mammalian)	Insert	*0.01	
Milks	Insert	*0.01	
Poultry, edible offal of	Insert	*0.01	
Poultry meat	Insert	*0.01	
Wheat	Insert	*0.01	

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

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

Attachment 3

Safety Assessment Methodology

1.1 Determining the Residues of a Chemical in a Treated Food

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

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

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

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

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

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

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

1.3 Calculating Dietary Exposure

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

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

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

1.3.1 Chronic Dietary Exposure Assessment

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

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

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

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

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

1.3.2 Acute Dietary Exposure Assessment

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

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

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

The NESTI calculation incorporates the large portion (97.5 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 4

Background Information

1.1 Maximum Residue Limits

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

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

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

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

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

1.2 Use of Agricultural and Veterinary Chemicals

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

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

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

1.3 Maximum Residue Limit Notifications and Submissions

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

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

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

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

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

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

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

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

1.4 Antibiotics

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

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

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

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

1.5 Australia and New Zealand Joint Food Standards

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

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

- Food produced or imported into Australia that complies with Standard 1.4.2 of the Code can be legally sold in New Zealand.

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