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

[3-08]
6 March 2008

PROPOSAL M1001
Maximum Residue Limits (September, October, November, December 2007)
ASSESSMENT REPORT

Executive Summary

Purpose

The purpose of this Proposal is to consider incorporating maximum residue limits (MRLs) for agricultural and veterinary chemicals that may legitimately occur in food in Standard 1.4.2 of the *Australia New Zealand Food Standards Code* (the Code). This includes MRLs gazetted by the Australian Pesticides and Veterinary Medicines Authority (APVMA) in September, October, November and December 2007. This Proposal also includes consideration of a submission made by the Food and Beverage Importers Association (FBIA) on Application A608 that the proposed 'fish muscle' MRL under consideration in that Application extend to prawns. This will permit the sale of treated foods and protect public health and safety by minimising residues in foods consistent with the effective control of pests and diseases.

Food Standards Australia New Zealand's (FSANZ) 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 current MRLs in the Code.

Dietary exposure assessments indicate that in relation to current reference health standards, setting the MRLs as proposed does not present any public health and safety concerns. There are MRLs for residues of the antibiotic substances tulathromycin and oxytetracycline under consideration in this Proposal. The proposed MRLs do not pose a risk in terms of antimicrobial resistance.

The FBIA submission details the legitimate and controlled use of oxytetracycline in prawns internationally, noting significant quantities are imported into Australia and that there have been detections at levels consistent with legitimate use.

Incorporating the MRL in the Code would align domestic and international standards and potentially benefit industry and consumers through choice and access to prawns which may contain residues of oxytetracycline. No public health and safety concerns have been identified in relation to the proposed MRL.

The Ministerial Policy Guideline on the Regulation of Residues of Agricultural and Veterinary Chemicals in Food has been provided to FSANZ. The purpose of this Ministerial Policy Guideline is to form a framework within which FSANZ is to consider alternative approaches to address the issues surrounding the regulation of residues of agricultural and veterinary chemicals in food. The specific policy principles outlined in the Policy Guideline apply only to alternative approaches that FSANZ might consider for addressing these issues. In consultation with stakeholders, FSANZ is exploring alternative options for regulating chemical residues in food.

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

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

Submissions are now invited on this Report to assist FSANZ make an assessment.

This Proposal is being assessed under the General Procedure.

Assessing the Proposal

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

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

- whether other measures would be more cost-effective than a variation to a food regulatory measure;

- any relevant New Zealand standards; and

- any other relevant matters.

Preferred Approach

FSANZ recommends approving the proposed draft variations to Standard 1.4.2 – Maximum Residue Limits. The residues associated with the proposed MRL 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. Approving the proposed draft variations will permit the sale of legitimately treated foods.

Reasons for Preferred Approach

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

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

- Dietary exposure assessments indicate that setting the MRLs as proposed does 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 treated with agricultural and veterinary chemicals to control pests and diseases and improve agricultural productivity.

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

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

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

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

- The 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 MRLs; 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 change 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 April 2008

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
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INTRODUCTION

Notifications were received from the Australian Pesticides and Veterinary Medicines Authority (APVMA) on 17 October and 22 November 2007, 18 January and 5 February 2008 seeking to vary the *Australia New Zealand Food Standards Code* (the Code). The proposed variations to Standard 1.4.2 – Maximum Residue Limits would align maximum residue limits (MRLs) in the Code for agricultural and veterinary chemicals with the APVMA MRLs listed in The MRL Standard.

This Proposal includes consideration of an oxytetracycline MRL for prawns. Oxytetracycline is an antibiotic[1] substance. The Food and Beverage Importers Association (FBIA) identified the need for an oxytetracycline MRL for prawns in a submission on the Application A608 Maximum Residue Limits – Oxytetracycline (Antibiotic) Initial / Draft Assessment Report. Varying the Standard as requested was beyond the scope of the Application. Food Standards Australia New Zealand (FSANZ) undertook to consider the MRL in a proposal to allow public consultation on including it in the Code.

There are also MRLs for residues of the antibiotic substance tulathromycin in cattle and pig commodities under consideration in this Proposal.

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 current MRLs in the Code.

The draft variations to the Code are at **Attachment 1** and the requested MRLs, dietary exposure estimates and other proposed variations are outlined in **Attachment 2**. The safety assessment methodology is outlined in **Attachment 3**; this includes an explanation of terms used in this Report.

In considering the issues associated with MRLs it should be noted that the MRL is the maximum level of a chemical that may be in a food and it is not the level that is usually present in a treated food. 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.

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

1. The Issue / Problem

Including MRLs in the Code has the effect of allowing legally treated produce to be sold legally, where any residues do not exceed MRLs.

[1] An antibiotic is a chemical inhibitor of the growth of organisms produced by a microorganism.

Changes to Australian MRLs reflect the changing patterns of agricultural and veterinary chemicals available to farmers. These changes include both the development of new products and crop uses, and the withdrawal of older products following review. Where residues do not pose health or safety concerns, MRLs are also varied in line with international standards to reflect requirements for legitimately treated foods 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. A dietary exposure assessment is conducted before the Standard is varied to ensure that proposed MRLs do not present any public health or safety concerns. If an MRL is not listed for a particular agricultural or veterinary chemical/commodity combination, there must be no detectable residues of that chemical in that food. This general prohibition means that in the absence of the relevant MRL in the Standard, legitimately treated produce may not be sold where there are detectable residues. Amendments to the Standard are required to permit the sale of foods legitimately treated during production.

Further background information on MRLs, the regulatory framework for agricultural and veterinary chemicals and the FSANZ assessment process for incorporating MRLs, including MRLs for antibiotic substances, in the Code is provided at **Attachment 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 legally treated food 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;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

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

- the need for standards to be based on risk analysis using the best available scientific evidence;

- the promotion of consistency between domestic and international food standards;

- the desirability of an efficient and internationally competitive food industry;

- the promotion of fair trading in food; and

- any written policy guidelines formulated by the Ministerial Council.

The Ministerial Council has endorsed a Policy Guideline on the Regulation of Residues of Agricultural and Veterinary Chemicals in Food[2]. In consultation with stakeholders, FSANZ is exploring alternative options for regulating chemical residues in food. To ensure appropriate consultation, this process will take some time to complete.

The proposed draft variations to Standard 1.4.2 are consistent with the FSANZ Act section 18 objectives of food regulatory measures, including the Ministerial Policy Guideline on the Regulation of Residues of Agricultural and Veterinary Chemicals in Food.

4. Assessment Approach

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

In assessing the public health and safety implications of chemical residues, FSANZ considers the dietary exposure to chemical residues from potentially treated foods in the diet by comparing the dietary exposure with the relevant health standard. FSANZ will not approve MRLs for inclusion 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:

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

- calculating the dietary exposure to a chemical from relevant foods, using food consumption data from national nutrition surveys and comparing this to the acceptable reference health standard.

The estimated dietary exposure to a chemical is compared to the relevant reference health standard/s for that chemical in food (i.e. the acceptable daily intake (ADI) and/or the acute reference dose (ARfD)).

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2 http://www.health.gov.au/internet/wcms/publishing.nsf/Content/2087CDEAEE7C703CCA256F190003AF4B/$File/pol-g-line-reg-res.pdf accessed 7 February 2008.

FSANZ considers that dietary exposure to the residues of a chemical is acceptable where the best estimate of this exposure does not exceed the relevant standard/s.

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

RISK ASSESSMENT

5. Risk Assessment Summary

FSANZ has reviewed the dietary exposure assessments submitted by the APVMA and conducted a dietary exposure assessment on oxytetracycline to assess the MRL requested by the FBIA. Using the best available scientific data and internationally recognised risk assessment methodology, FSANZ concluded that in relation to current reference health standards, setting the MRLs 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 antibiotic substances do not pose a risk in terms of antimicrobial resistance.

RISK MANAGEMENT

6. Options

6.1 Option 1 – approve the draft variations

6.2 Option 2 – approve the draft variations subject to such amendments as the Authority considers necessary

6.3 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 needed to further assess the proposed changes.

FSANZ has not identified any health or safety concerns associated with the proposed approval.

FSANZ invites comment on whether any of the MRLs proposed for deletion or reduction are required to continue to allow for the importation of safe food.

Specific MRLs may be retained where the necessity for the MRL to continue to allow for the importation and sale of safe food is identified through consultation. Where this need is identified, the draft variation may be amended and option 2 recommended for approval. Further information to assist in identifying implications for imported foods is provided in section 9 of this Report and the requested MRL variations are outlined in **Attachment 2**.

7.1 Affected Parties

The parties affected by proposed MRL amendments include:

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

7.2 Benefit Cost Analysis

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

7.3 Comparison of Options

In assessing proposed variations to the Code, FSANZ considers the impact of various regulatory and non-regulatory options on all sectors of the community, including consumers, food industries and governments in Australia. For this Proposal, there are no options other than a variation to Standard 1.4.2.

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 MRL 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 legitimately treated food.

- The changes would minimise residues in food consistent with the effective use of agricultural and veterinary chemicals to control pests and diseases.

- The changes would remove discrepancies between agricultural and food standards and assist compliance agencies.

Option 2 may be recommended in the Approval Report subject to the need for any required amendments being identified through consultation or further assessment.

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

The benefits of progressing option 1 outweigh any associated costs.

COMMUNICATION AND CONSULTATION STRATEGY

8. Communication

FSANZ consideration of amending MRLs in the Code does not normally generate public interest. FSANZ adopts a basic communication strategy, with a focus on alerting the community that a change to the Code is being contemplated.

FSANZ publishes the details of proposed changes and subsequent assessment reports on its website, notifies the community of the period of public consultation through newspaper advertisements, and issues media releases drawing attention to proposed Code amendments. Once the Code has been amended, FSANZ incorporates the changes in the website version of the Code and, through its email and telephone advice 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 and other advice, 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 MRLs; and any other affected parties to this Application 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.

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

This Proposal includes consideration of varying MRLs in the Code that are addressed in the international Codex standard. MRLs in the Proposal also relate to chemicals used in the production of heavily traded agricultural commodities that may indirectly have a significant effect on trade of 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 MRLs

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

Chemical Food	**Proposed MRL** **mg/kg**	**Codex MRL** **mg/kg**
Indoxacarb		
Edible offal (mammalian) [except kidney]	*0.01	Edible offal (mammalian) 0.05
Kidney (mammalian)	0.2	
Meat (mammalian) (in the fat)	1	Meat (from mammals other than marine mammals) (fat) 1
Pulses	0.2	Chick-pea (dry) 0.2 Mung bean (dry) 0.2 Soya bean (dry) 0.5
Oxytetracycline		
Prawns	0.2	Giant prawn (*Paeneus monodon*) Muscle 0.2
Piperonyl butoxide		
Cattle milk	0.05	0.2
Propiconazole		
Almonds	0.2	0.05

Chemical Food	Proposed MRL mg/kg	Codex MRL mg/kg
Pyriproxyfen		
Citrus fruits	0.3	0.5
Cotton seed	*0.01	0.05
Cotton seed oil, crude	*0.02	0.01 Cotton seed oil, Edible 0.01
Edible offal (mammalian)	*0.02	Cattle, Edible offal of 0.01 Goat, Edible offal of 0.01
Meat (mammalian) (in the fat)	*0.02	Cattle meat 0.01 Goat meat 0.01
Trifloxystrobin		
Peppers, Sweet	T0.5	0.3

FSANZ requests comment on any possible ramifications of the proposed MRLs differing from Codex Alimentarius Commission MRLs.

9.3 New Zealand MRL Standards

All imported and domestically produced food sold in New Zealand (except for food imported from Australia) must comply with the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2007 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 or, 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

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

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

Chemical Food	Proposed MRL mg/kg	NZ MRL mg/kg
Coumaphos		
Cattle fat	T0.2	0.5

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

9.4 Imported Foods

Internationally, countries set MRLs according to good agricultural practice (GAP) or good veterinary practice (GVP).

Agricultural and veterinary chemicals are used differently in different countries around the world as pests, diseases and environmental factors differ and because product use patterns differ. This means that residues in imported foods may be legitimately different from those in domestically produced foods.

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

FSANZ is committed to ensuring that the implications of MRL variations are considered. Under the current process for considering variations to the Code, FSANZ encourages submissions including specific data demonstrating a need for certain MRLs to be retained or varied. FSANZ will consider retaining MRLs proposed for deletion or reduction where these MRLs are necessary to continue to allow the sale of safe food; and where the 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
Indoxacarb Soya bean oil, refined[†]
Pyraclofos Sheep kidney Sheep liver Sheep muscle

[†] The refined soya bean oil MRL is proposed for deletion because the APVMA has advised that the recommended pulses MRL of 0.2 mg/kg will account for residues in processed oil commodities and a specific MRL for refined soya bean oil is unnecessary.

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

9.5 FBIA request for an oxytetracycline MRL for prawns

In a submission on the Application A608 Initial / Draft Assessment Report, the FBIA requested that the oxytetracycline MRL for 'fish muscle' in that Application extend to prawns. In assessing the Application, FSANZ decided not to extend the MRL to prawns and undertook to consider the request in a separate Proposal.

Consequently FSANZ is considering including an MRL of 0.2 mg/kg for oxytetracycline in prawns in the Code and seeking public comment on this proposed MRL.

The FBIA requested the extension of the MRL to prawns on the basis that:

- internationally, oxytetracycline residues could occur in prawns as a result of the approved use of this chemical in aquaculture in other countries, including in Thailand;

- an MRL to recognise these legitimate residues would be consistent with the MRL for fish recommended at Final Assessment of Application A608 and international standards for prawns, including the Thai Agricultural Commodity and Food Standard[3] and Codex limits; and

- significant quantities of prawns are imported into Australia and Thailand is one of the major suppliers. In 2006/2007 approximately 33 000 tonnes were imported, of which approximately 6 000 tonnes were sourced from Thailand. The FBIA submission notes that there have been detections of oxytetracycline residues in imported prawns in Australia at levels consistent with the legitimate use in Thailand.

FSANZ must consider proposed variations to the Code in accordance with the FSANZ Act, including the objectives of food regulatory measures set out in section 18 of the Act. This consideration includes an assessment of the dietary exposure to residues associated with the proposed MRL; the legitimacy of the residues and whether they result from an approved use; the relevant MRLs in the country of origin and internationally; and the views of the community, including the impacts of including an MRL in the Code where the APVMA has not listed a corresponding MRL in The MRL Standard.

9.5.1 Safety of the Residues

Oxytetracycline is a tetracycline antibiotic. In Australia oxytetracycline is only used in animals and not in human medicine. Internationally, including in Australia, oxytetracycline is used to treat bacterial infections in aquaculture. It is incorporated into medicated feed and administered to treat infections caused by oxytetracycline sensitive organisms. Oxytetracycline is not considered to present a significant risk in the development of antimicrobial resistance in the treatment of infections in humans. Further information on assessment of MRLs for antibiotic substances is provided at **Attachment 4**.

The baseline estimated mean dietary exposure (NEDI) to oxytetracycline residues from all foods based on current MRLs in the Code is 4% of the ADI.

[3] http://www.acfs.go.th/standard/download/food%20safety%20eng.pdf

Based on including the proposed MRL for prawns of 0.2 mg/kg in the Code, the estimated mean dietary exposure (NEDI) to oxytetracycline residues from all foods remains at 4% of the ADI. The potential additional dietary exposure contribution from prawns is therefore negligible.

As an ARfD has not been established for oxytetracycline, an acute dietary exposure assessment is unnecessary.

FSANZ considers that there are no health or safety concerns associated with the requested oxytetracycline MRL of 0.2 mg/kg for prawns. This is on the basis that oxytetracycline is not considered to pose a risk in terms of antimicrobial resistance and the estimated dietary exposure to oxytetracycline residues from all foods, including from residues in prawns at 0.2 mg/kg, does not exceed the acceptable reference health standard.

9.5.2 Legitimacy of the Residues

The following table lists the oxytetracycline MRLs under consideration for inclusion in the Code as part of Application A608 and this Proposal as well as those that apply to aquaculture products internationally.

Standard	**Commodity**	**Oxytetracycline MRL mg/kg**
APVMA	Fish muscle	0.2
Codex	Giant prawn (*Paeneus monodon*) Muscle	0.2
European Union	Muscle of all food producing species	0.1
FSANZ Proposed MRL M1001 Approved MRL A608	 Prawns Fish	 0.2 0.2
New Zealand	Fish meat	0.1[†]
Thailand	Chilled/frozen shrimps or prawns	0.2
United States	Finfish and lobster muscle	0.2

[†] Notwithstanding the provision for residues of up to 0.1 mg/kg in the New Zealand MRL Standards, New Zealand has established an MRL of 0.1 mg/kg for oxytetracycline in fish meat.

The Codex MRL for oxytetracycline in giant prawn (Paeneus monodon) muscle is 0.2 mg/kg. In addition, there is an MRL of 0.2 mg/kg for oxytetracycline in prawns in Thai food standards and this is associated with an approved use for oxytetracycline in prawn production in Thailand. Prawns are imported into Australia, there is a relevant Codex MRL and based on information provided by the FBIA, imported prawns could potentially and legitimately contain oxytetracycline residues.

FSANZ has also noted that a level of 0.2 mg/kg is consistent with the Codex MRL and is similar to the level of residues permitted in other aquaculture products internationally. As noted above, under New Zealand Standards, if a food is imported into New Zealand, it may comply with Codex standards.

Background information on arrangements with New Zealand is provided at **Attachment 4**. On this basis, FSANZ considers that an MRL of 0.2 mg/kg for oxytetracycline in prawns would be consistent with domestic and international standards.

9.5.3 Views of the community

FSANZ is seeking comment on the implications of incorporating the proposed oxytetracycline MRL of 0.2 mg/kg for prawns in the Code.

In considering this MRL, FSANZ has noted that there is no corresponding MRL in The MRL Standard and that while the MRL is not currently required to allow the sale of domestically produced prawns, it would facilitate the importation and sale of prawns from other countries. Domestic producers would need to comply with conditions of use currently approved in Australia and therefore no residues should be present in prawns produced in Australia.

FSANZ seeks comment on whether the proposed MRL should only apply to imported prawns or whether it should extend to all prawns. On the basis of promoting consistency between international and domestic standards, FSANZ has initially proposed that the MRL apply to all prawns but seeks the views of the community on whether it should be restricted to imported prawns only.

9.5.4 Impacts of including an MRL in the Code

If there is no MRL for oxytetracycline in prawns in the Code then no detectable residues of oxytetracycline in prawns would be permitted unless the prawns or prawn products are imported from New Zealand. Not including the MRL in the Code could therefore prevent the importation of prawns that have been legitimately treated and which would comply with the Codex MRL, an international standard.

On this basis, FSANZ considers that incorporating the oxytetracycline MRL of 0.2 mg/kg for prawns in the Code would facilitate trade in prawns and promote consistency between domestic and international standards. No public health and safety concerns have been identified in relation to the proposed MRL. In addition, the MRL would potentially benefit industry and consumers through enhanced choice and access to prawns.

FSANZ requests comment on incorporating an MRL for oxytetracycline of 0.2 mg/kg for prawns in the Code.

9.6 Commodity classifications for MRLs notified for veterinary chemicals

The APVMA adopted the approach used by the Joint Food and Agriculture Organization / World Health Organization Expert Committee on Food Additives (JECFA) for setting MRLs for veterinary chemicals in July 2006. The decision to adopt the JECFA approach followed a review of evaluation processes conducted by an external body and consultation with industry and regulatory authorities. The JECFA approach is internationally accepted as best practice for setting MRLs for veterinary chemicals.

This Proposal includes consideration of MRLs notified by the APVMA with commodity classifications consistent with the JECFA approach. These commodity classifications include 'Cattle muscle', 'Sheep muscle', 'Pig muscle' and 'Pig skin/fat'.

FSANZ requests comment on the practical implications of including MRLs with the JECFA commodity classifications in the Code.

CONCLUSION

10. Conclusion and Preferred Option

This Proposal has been assessed against the requirements of section 59 of the FSANZ Act.

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

Preferred Approach

FSANZ recommends approving the proposed draft variations to Standard 1.4.2 – Maximum Residue Limits. The residues associated with the proposed MRL 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. Approving the proposed draft variations will permit the sale of legitimately treated foods.

10.1 Reasons for Preferred Approach

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

- MRLs serve to protect public health and safety by minimising residues in food consistent with the effective control of pests and diseases.
- Dietary exposure assessments indicate that setting the MRLs as proposed does 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 treated with agricultural and veterinary chemicals to control pests and diseases and improve agricultural productivity.
- The APVMA has assessed appropriate residue, animal transfer, processing and metabolism studies, in accordance with *The Manual of Requirements and Guidelines - MORAG - for Agricultural and Veterinary Chemicals 1 July 2005* to support the use of chemicals on commodities as outlined in this Proposal.

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

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

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

- The 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 MRLs.

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

ATTACHMENTS

1. Draft variations to the *Australia New Zealand Food Standards Code*
2. A Summary of MRLs under consideration in Proposal M1001
3. Safety Assessment Methodology
4. Background Information

Attachment 1

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

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

To commence: on gazettal

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

[1.1] *omitting from* Schedule 1 *all entries for the following chemical –*

Dichlorprop

[1.2] *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**
INDOXACARB	SUM OF INDOXACARB AND ITS *R*-ISOMER

[1.3] *inserting in* Schedule 1 *–*

COUMAPHOS SUM OF COUMAPHOS AND ITS OXYGEN ANALOGUE, EXPRESSED AS COUMAPHOS	
CATTLE FAT	T0.2
CATTLE KIDNEY	T0.2
CATTLE LIVER	T0.2
CATTLE MUSCLE	T0.2
DICHLORPROP-P SUM OF DICHLORPROP ACID, ITS ESTERS AND CONJUGATES, HYDROLYSED TO DICHLORPROP ACID, AND EXPRESSED AS DICHLORPROP ACID	
CITRUS FRUITS	0.2
EDIBLE OFFAL (MAMMALIAN)	*0.05
EGGS	*0.02
MEAT (MAMMALIAN)	*0.02
MILKS	*0.01
POULTRY, EDIBLE OFFAL OF	*0.05
POULTRY MEAT	*0.02
PYRASULFOTOLE SUM OF PYRASULFOTOLE AND (5-HYDROXY-3-METHYL-1*H*-PYRAZOL-4-YL)[2-MESYL-4-(TRIFLUOROMETHYL)PHENYL]METHANONE, EXPRESSED AS PYRASULFOTOLE	
CEREAL BRAN, UNPROCESSED	T0.03
CEREAL GRAINS	T*0.02
EDIBLE OFFAL (MAMMALIAN)	T0.5
EGGS	T*0.01

MEAT (MAMMALIAN)	T*0.01
MILKS	T*0.01
POULTRY, EDIBLE OFFAL OF	T*0.01
POULTRY MEAT	T*0.01
TULATHROMYCIN	
SUM OF TULATHROMYCIN AND ITS METABOLITES THAT ARE CONVERTED BY ACID HYDROLYSIS TO (2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)-2-ETHYL-3,4,10,13-TETRAHYDROXY-3,5,8,10,12,14-HEXAMETHYL-11-[[3,4,6-TRIDEOXY-3-(DIMETHYLAMINO)-ß-D-XYLOHEXOPYRANOSYL]OXY]-1-OXA-6-AZACYCLOPENTADECAN-15-ONE, EXPRESSED AS TULATHROMYCIN EQUIVALENTS	
CATTLE FAT	0.1
CATTLE KIDNEY	1
CATTLE LIVER	3
CATTLE MUSCLE	0.1
PIG KIDNEY	3
PIG LIVER	2
PIG MUSCLE	0.5
PIG SKIN/FAT	0.3

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

INDOXACARB	
INDOXACARB	
ADZUKI BEAN (DRY)	T0.2
CHICK-PEA	0.2
EDIBLE OFFAL (MAMMALIAN)	*0.01
MUNG BEAN (DRY)	0.2
SOYA BEAN (DRY)	0.2
SOYA BEAN OIL, REFINED	0.2
PROPICONAZOLE	
PROPICONAZOLE	
TREE NUTS	T0.2
PYRACLOFOS	
PYRACLOFOS	
SHEEP MEAT	T*0.1
PYRIPROXYFEN	
PYRIPROXYFEN	
COTTON SEED OIL, EDIBLE	T*0.02

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

CLOTHIANIDIN *COMMODITIES OF PLANT ORIGIN*: CLOTHIANIDIN *COMMODITIES OF ANIMAL ORIGIN*: SUM OF CLOTHIANIDIN, 2-CHLOROTHIAZOL-5-YLMETHYLGUANIDINE, 2-CHLOROTHIAZOL-5-YLMETHYLUREA, AND THE PYRUVATE DERIVATIVE OF N-(2-CHLOROTHIAZOL-5-YLMETHYL)-N'-METHYLGUANIDINE EXPRESSED AS CLOTHIANIDIN	
APPLE	T0.5
BANANA	T0.02
NECTARINE	T2
PEACH	T2
PEAR	T0.5
DIFENOCONAZOLE DIFENOCONAZOLE	
CELERY	T2
PAPAYA (PAWPAW)	T0.7
IMIDACLOPRID SUM OF IMIDACLOPRID AND METABOLITES CONTAINING THE 6-CHLOROPYRIDINYLMETHYLENE MOIETY, EXPRESSED AS IMIDACLOPRID	
RHUBARB	T1
INDOXACARB INDOXACARB	
EDIBLE OFFAL (MAMMALIAN) [EXCEPT KIDNEY]	*0.01
KIDNEY (MAMMALIAN)	0.2
MILK FATS	1
PULSES	0.2
RAPE SEED	T*0.05
ORYZALIN ORYZALIN	
GINGER, ROOT	T*0.05
OXYTETRACYCLINE INHIBITORY SUBSTANCE, IDENTIFIED AS OXYTETRACYCLINE	
PRAWNS	0.2
PHOSPHOROUS ACID PHOSPHOROUS ACID	
RHUBARB	T100
PROPICONAZOLE PROPICONAZOLE	
ALMONDS	0.2
TREE NUTS [EXCEPT ALMONDS]	T0.2
PYRACLOFOS PYRACLOFOS	
SHEEP MUSCLE	*0.01

PYRIMETHANIL PYRIMETHANIL	
PEPPERS, SWEET	T5
PYRIPROXYFEN PYRIPROXYFEN	
CITRUS FRUITS	0.3
COFFEE BEANS	0.1
EGGS	0.05
MANGO	*0.01
OLIVE OIL, CRUDE	3
OLIVES	1
PASSIONFRUIT	0.1
POULTRY, EDIBLE OFFAL OF	0.1
POULTRY MEAT (IN THE FAT)	0.1
SIMAZINE SIMAZINE	
GINGER, ROOT	T*0.05
TEBUCONAZOLE TEBUCONAZOLE	
CARROT	T0.5
THIAMETHOXAM *COMMODITIES OF PLANT ORIGIN*: THIAMETHOXAM *COMMODITIES OF ANIMAL ORIGIN*: SUM OF THIAMETHOXAM AND N-(2-CHLORO-THIAZOL-5-YLMETHYL)-N'-METHYL-N'-NITRO-GUANIDINE, EXPRESSED AS THIAMETHOXAM	
TOMATO	*0.02
TRIFLOXYSTROBIN SUM OF TRIFLOXYSTROBIN AND ITS ACID METABOLITE ((E,E)-METHOXYIMINO-[2-[1-(3-TRIFLUOROMETHYLPHENYL)-ETHYLIDENEAMINOOXYMETHYL]PHENYL] ACETIC ACID), EXPRESSED AS TRIFLOXYSTROBIN EQUIVALENTS	
PEPPERS, SWEET	T0.5

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

INDOXACARB INDOXACARB	
MEAT (MAMMALIAN) (IN THE FAT)	1
MILKS	0.1
PYRACLOFOS PYRACLOFOS	
SHEEP FAT	0.5
SHEEP KIDNEY	*0.01
SHEEP LIVER	*0.01

PYRIMETHANIL PYRIMETHANIL	
TOMATO	T5
PYRIPROXYFEN PYRIPROXYFEN	
COTTON SEED	*0.01
COTTON SEED OIL, CRUDE	*0.02
EDIBLE OFFAL (MAMMALIAN)	*0.02
FRUITING VEGETABLES, CUCURBITS	0.2
FRUITING VEGETABLES, OTHER THAN CUCURBITS	1
MEAT (MAMMALIAN) (IN THE FAT)	*0.02
MILKS	*0.02
TEBUCONAZOLE TEBUCONAZOLE	
LETTUCE, HEAD	0.1
LETTUCE, LEAF	0.1
THIAMETHOXAM *COMMODITIES OF PLANT ORIGIN*: THIAMETHOXAM *COMMODITIES OF ANIMAL ORIGIN*: SUM OF THIAMETHOXAM AND N-(2-CHLORO-THIAZOL-5-YLMETHYL)-N'-METHYL-N'-NITRO-GUANIDINE, EXPRESSED AS THIAMETHOXAM	
CITRUS FRUITS	1

Attachment 2

A summary of MRLs under consideration in Proposal M1001

<table>
<tr><th>Requested MRLs</th><th>Dietary Exposure Estimates</th></tr>
<tr><td>
Clothianidin
Clothianidin is an insecticide with translaminar and root systemic activity. It is an agonist of the nicotinic acetylcholine receptor, affecting the synapses in the insect central nervous system. The APVMA has issued research permits for its use to examine the efficacy and residues of two products containing clothianidin. Trials have been conducted on apples and pear, peaches and nectarines and bananas.

<table>
<tr><td></td><td></td><td></td><td>NESTI as % of ARfD</td><td></td></tr>
<tr><td></td><td></td><td></td><td><u>2-6 years</u></td><td><u>2+ years</u></td></tr>
<tr><td>Apple</td><td>Insert</td><td>T0.5</td><td>15</td><td>4</td></tr>
<tr><td>Banana</td><td>Insert</td><td>T0.02</td><td><1</td><td><1</td></tr>
<tr><td>Nectarine</td><td>Insert</td><td>T2</td><td>29</td><td>13</td></tr>
<tr><td>Peach</td><td>Insert</td><td>T2</td><td>32</td><td>11</td></tr>
<tr><td>Pear</td><td>Insert</td><td>T0.5</td><td>10</td><td>3</td></tr>
</table>
</td><td>NEDI = 2% of ADI</td></tr>
<tr><td>
Coumaphos
Coumaphos is an organophosphate insecticide used to control ectoparasites. It inhibits cholinesterase enzymes, leading to continued stimulation of the insect's nervous system, resulting in tremors, uncoordinated movement, and ultimately death. The APVMA has issued a research permit for field trials to be conducted on a product containing coumaphos. The product is to be used on beef cattle to control susceptible strains of buffalo fly (Haematobia irritans exigua). Residues data support MRLs at or about the method LOQ of 0.2 mg/kg. Currently there are no entries in Standard 1.4.2 for coumaphos; however, it is not a new chemical. Previous MRLs were omitted as there were no current registrations or permits.

Insert residue definition:

Sum of coumaphos and its oxygen analogue, expressed as coumaphos

<table>
<tr><td>Cattle fat</td><td>Insert</td><td>T0.2</td></tr>
<tr><td>Cattle kidney</td><td>Insert</td><td>T0.2</td></tr>
<tr><td>Cattle liver</td><td>Insert</td><td>T0.2</td></tr>
<tr><td>Cattle muscle</td><td>Insert</td><td>T0.2</td></tr>
</table>
</td><td>NEDI = 44% of ADI

20th ATDS – not detected in any foods sampled</td></tr>
<tr><td>
Dichlorprop
Dichlorprop is a plant growth regulator and herbicide absorbed by leaves with translocation to the roots. It acts as a growth regulator by inhibiting formation of the abscission zone. It has been used as a growth regulator and to control broad leaf weeds in a variety of situations.

<table>
<tr><td>Citrus fruits</td><td>Omit</td><td>T0.1</td></tr>
</table>
</td><td>Complete chemical deletion – dietary exposure assessment not required.</td></tr>
</table>

Requested MRLs			Dietary Exposure Estimates		
Dichlorprop-P Dichlorprop-P is a synthetic auxin plant growth regulator and herbicide. It is absorbed by leaves with translocation to the roots. It is used to increase fruit size in oranges and mandarins. Consideration of animal metabolism data determined that detectable residues in meat, offal, milk or eggs from stock fed dried citrus pulp from treated fruit are unlikely. The recommended animal commodity MRLs are at the LOQ. New chemical Insert residue definition: Sum of dichlorprop acid, its esters and conjugates, hydrolysed to dichlorprop acid, and expressed as dichlorprop acid			NEDI = <1% of ADI Dietary modelling of nutritional data estimated the chronic dietary exposure to dichlorprop-P as 1% of the ADI for the general population. NESTI as % of ARfD		
			2-6 years		2+ years
Citrus fruits	Insert	0.2	6	Oranges	2
			2	Mandarins	<1
Edible offal (mammalian)	Insert	*0.05	<1		<1
Eggs	Insert	*0.02	<1		<1
Meat (mammalian)	Insert	*0.02	<1		<1
Milks	Insert	*0.01	<1		<1
Poultry, edible offal of	Insert	*0.05	<1		<1
Poultry meat	Insert	*0.02	<1		<1
Difenoconazole Difenoconazole is a systemic azole fungicide with preventative and curative action. It is absorbed by the leaves with acropetal and strong translaminar translocation. It inhibits sterol demethylation in the biosynthesis of ergosterol. The APVMA has issued permits for its use to control various fungal diseases on celery and to control Black Spot (*Asperisporium caricae*) on pawpaw.			NEDI = 13% of ADI 20th ATDS – not detected in any foods sampled		
Celery	Insert	T2			
Papaya (pawpaw)	Insert	T0.7			
Imidacloprid Imidacloprid is a systemic insecticide with contact and stomach action. It acts on the central nervous system of insects causing blockage of postsynaptic nicotinergic acetylcholine receptors. The APVMA has issued a permit for its use to control aphids on rhubarb.			NEDI = 15% of ADI		
Rhubarb	Insert	T1			

Requested MRLs			Dietary Exposure Estimates		
Indoxacarb Indoxacarb is an insecticide with contact and stomach action. It blocks sodium ion channels in nerve cells causing cessation of feeding, poor coordination, paralysis and ultimately death. It is used to control a broad spectrum of Lepidopteran insects in cotton, pulses, vegetables and fruit. The recommended pulses MRL of 0.2 mg/kg will account for residues in processed oil commodities, therefore the refined soya bean oil MRL is to be omitted. The APVMA issued an emergency permit for the use of indoxacarb to control diamond back moth (*Plutella xylostella*) on canola. Amendment to residue definition: Omit: Indoxacarb Substitute: Sum of indoxacarb and its *R*-isomer			NEDI = 12% of ADI NESTI as % of ARfD		
			2-6 years		2+ years
Adzuki bean (dry)	Omit	T0.2			
Chick-pea	Omit	0.2			
Edible offal (mammalian)	Omit	*0.01			
Edible offal (mammalian) [except kidney]	Insert	*0.01	<1		<1
Kidney (mammalian)	Insert	0.2	<1		<1
Meat (mammalian) (in the fat)	Omit	0.5		Meat (mammalian)	
	Substitute	1	2	Fat	1
			<1	Muscle	<1
Milks	Omit	0.05			
	Substitute	0.1	<1		<1
Milk fats	Insert	1	2		<1
Mung bean (dry)	Omit	0.2			
Pulses	Insert	0.2	2	Broad bean (dry)	<1
			1	Chick-pea (dry)	<1
			<1	Mung bean (dry)	<1
			<1	Soya bean (dry)	<1
			<1	Adzuki bean (dry)	<1
Rape seed	Insert	T*0.05	<1		<1
Soya bean (dry)	Omit	0.2			
Soya bean oil, refined	Omit	0.2			

Requested MRLs			Dietary Exposure Estimates
Oryzalin Oryzalin is a selective herbicide. It affects growth processes associated with seed germination. It inhibits microtubule assembly. The APVMA has issued a permit for its use with simazine to control broad leaf and annual grass weeds in ginger pre-emergence of the crop. The recommended MRL is at the LOQ. Ginger, root	Insert	T*0.05	NEDI = <1% of ADI
Oxytetracycline Oxytetracycline is a tetracycline antibiotic. Tetracyclines bind to the 30S ribosomal subunit of susceptible organisms. This interferes with the binding of aminoacyl *t*RNA to the messenger RNA/ribosome complex, which interferes with bacterial protein synthesis in growing or multiplying organisms. In Australia oxytetracycline is only used in veterinary situations. Oxytetracycline is not considered to present a significant risk in the development of antimicrobial resistance in the treatment of infections in humans. Internationally, including in Australia, oxytetracycline is used to treat bacterial infections in aquaculture. It is incorporated into medicated feed and administered to treat infections caused by oxytetracycline sensitive organisms. The FBIA requested an MRL of 0.2 mg/kg for prawns in line with international standards to facilitate trade. Prawns	Insert	0.2	NEDI = 4% of ADI
Phosphorous acid Phosphorus acid is a selective systemic phosphonate fungicide with multi-site activity. It is used to control fungal diseases on fruit and vegetables. The APVMA has issued a permit for its use to control downy mildew (*Peronospora jaapiana*) on rhubarb. Rhubarb	Insert	T100	NEDI = 6% of ADI
Propiconazole Propiconazole is a systemic foliar fungicide with protective and curative action. It inhibits steroid demethylation leading to inhibition of ergosterol biosynthesis. It is used to control fungal infections in cereal crops and various horticultural situations. The APVMA has issued a permit for its use to control blossom blight (*Monilinia laxa*) and anthracnose (*Coltotrichum acutatum*) on almonds. Residues data support an MRL for almonds. Almonds Tree nuts Tree nuts [except almonds]	Insert Omit Insert	0.2 T0.2 T0.2	NEDI = 6% of ADI Mean estimated daily dietary exposure based on mean analytical results: 20th ATDS = <1% of ADI for all population groups assessed

Requested MRLs			Dietary Exposure Estimates
Pyraclofos Pyraclofos is an active ingredient in a broad spectrum antiparasitic treatment for sheep. Pyraclofos inhibits acetyl cholinesterase activity, leading to the disruption of the parasite nervous system. The product is orally administered to sheep to control sensitive gastrointestinal roundworms, large lungworms, tapeworms, and to aid in the control of liver fluke.			NEDI = <1% of ADI
Sheep fat	Omit	T*0.1	
	Substitute	0.5	
Sheep kidney	Omit	T*0.1	
	Substitute	*0.01	
Sheep liver	Omit	T*0.1	
	Substitute	*0.01	
Sheep meat	Omit	T*0.1	
Sheep muscle	Insert	*0.01	
Pyrasulfotole Pyrasulfotole is a herbicide. It inhibits the HPPD enzyme (4-hydroxyphenylpyruvate dioxygenase) and blocks the pathway of prenylquinone biosynthesis in plants. It is used to control broad leaf weeds in cereal crops. New chemical Insert residue definition: Sum of pyrasulfotole and (5-hydroxy-3-methyl-1*H*-pyrazol-4-yl)[2-mesyl-4-(trifluoromethyl)phenyl]methanone, expressed as pyrasulfotole			NEDI = 1% of ADI Dietary modelling of nutritional data estimated the chronic dietary exposure to pyrasulfotole as <2% of the ADI for the general population. NESTI as % of ARfD
			2-6 years / 2+ years
Cereal bran, unprocessed	Insert	T0.03	<1 / <1
Cereal grains	Insert	T*0.02	<1 / <1
Edible offal (mammalian)	Insert	T0.5	<1 / <1
Eggs	Insert	T*0.01	<1 / <1
Meat (mammalian)	Insert	T*0.01	<1 / <1
Milks	Insert	T*0.01	<1 / <1
Poultry, edible offal of	Insert	T*0.01	<1 / <1
Poultry meat	Insert	T*0.01	<1 / <1

Requested MRLs			Dietary Exposure Estimates
Pyrimethanil Pyrimethanil is a fungicide with protectant action. It inhibits fungal enzymes necessary for infection. The APVMA has issued a permit for its use to control botrytis rots (*Botrytis cinerea*) in glasshouse capsicums and tomatoes.			NEDI = 5% of ADI Mean estimated daily dietary exposure based on mean analytical results: 20th ATDS = <1% of ADI for all population groups assessed NESTI as % of ARfD 2-6 years 2+ years
Peppers, Sweet	Insert	T5	6 2
Tomato	Omit	1	
	Substitute	T5	13 5
Pyriproxyfen Pyriproxyfen is an insecticide. It is an insect growth regulator, it inhibits metamorphosis and reproduction. It is used to control silverleaf whitefly in cotton; silverleaf whitefly and greenhouse whitefly in cucurbits, tomatoes and eggplant; and various scale insects in citrus fruit, mangoes, olives, coffee and passionfruit. Where residues data indicate that residues are unlikely to occur, MRLs have been recommended at the LOQ.			NEDI = <1% of ADI
Citrus fruits	Insert	0.3	
Coffee beans	Insert	0.1	
Cotton seed	Omit	T*0.01	
	Substitute	*0.01	
Cotton seed oil, crude	Omit	T*0.02	
	Substitute	*0.02	
Cotton seed oil, edible	Omit	T*0.02	
Edible offal (mammalian)	Omit	T*0.02	
	Substitute	*0.02	
Eggs	Insert	0.05	
Fruiting vegetables, cucurbits	Omit	T0.2	
	Substitute	0.2	
Fruiting vegetables, other than cucurbits	Omit	T1	
	Substitute	1	
Mango	Insert	*0.01	
Meat (mammalian) (in the fat)	Omit	T*0.02	
	Substitute	*0.02	
Milks	Omit	T*0.02	
	Substitute	*0.02	
Olive oil, crude	Insert	3	
Olives	Insert	1	
Passionfruit	Insert	0.1	
Poultry, edible offal of	Insert	0.1	
Poultry meat (in the fat)	Insert	0.1	

Requested MRLs			Dietary Exposure Estimates
Simazine Simazine is a selective systemic herbicide. It is absorbed principally through the roots but also through foliage, with translocation acropetally in the xylem accumulating in the apical meristems and leaves. It inhibits photosynthetic electron transport. The APVMA has issued a permit for its use with oryzalin to control broad leaf and annual grass weeds in ginger pre-emergence of the crop. The recommended MRL is at the LOQ.			NEDI = 13% of ADI
Ginger, root	Insert	T*0.05	
Tebuconazole Tebuconazole is a fungicide. It is a non-systemic foliar fungicide with protective action. It inhibits steroid demethylation leading to inhibition of ergosterol biosynthesis. It controls numerous pathogens in many crops. The APVMA has issued permits for its use to control powdery mildew (*Erysiphe heraclei*) in carrots and Sclerotinia rot (*Sclerotinia sclerotiorum*) in lettuce.			NEDI = 18% of ADI 20th ATDS – not detected in any foods sampled
Carrot	Insert	T0.5	
Lettuce, head	Omit	T0.02	
	Substitute	0.1	
Lettuce, leaf	Omit	T0.02	
	Substitute	0.1	
Thiamethoxam Thiamethoxam is a neonicotinoid insecticide. It is an agonist of the nicotinic acetylcholine receptor. It has contact, stomach and systemic activity and is rapidly taken up into the plant and transported acropetally in the xylem. It is used to control various insect pests on fruit, vegetable, cereal and oilseed crops. It is used to control Kelly's citrus thrips (*Pezothrips kelyanus*) in citrus and whiteflies and aphids in tomatoes.			NEDI = 11% of ADI
Citrus fruits	Omit	T0.2	
	Substitute	1	
Tomato	Insert	*0.02	
Trifloxystrobin Trifloxystrobin is a broad-spectrum fungicide with preventative and specific curative action used to control powdery mildew, leaf spot and rust. It inhibits mitochondrial respiration by blocking electron transfer at the Qo centre of cytochrome bc1. The APVMA has issued a permit for its use to control powdery mildew (*Leveillula taurica*) in glasshouse capsicums.			NEDI = 3% of ADI
Peppers, Sweet	Insert	T0.5	

Requested MRLs			Dietary Exposure Estimates	
Tulathromycin Tulathromycin is a member of the triamilide subclass of macrolide antibiotics. It inhibits essential protein biosynthesis by selective binding to bacterial 50S ribosomal subunits. Macrolides act by stimulating the dissociation of peptidyl-*t*RNA from the ribosome during the translocation process. In Australia tulathromycin is only used in veterinary situations. Other macrolides are used in human therapeutics. The NHMRC has advised that the proposed tulathromycin MRLs do not pose a risk in terms of antimicrobial resistance. Tulathromycin is administered by injection to treat bovine and swine respiratory infections associated with tulathromycin sensitive organisms. Tulathromycin is registered for use widely internationally, including in the European Union, United States, Canada, and in Asian, South American and other European nations. New chemical Insert residue definition: Sum of tulathromycin and its metabolites that are converted by acid hydrolysis to (2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)-2-ethyl-3,4,10,13-tetrahydroxy-3,5,8,10,12,14-hexamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)-ß-D-xylohexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one, expressed as tulathromycin equivalents			NEDI = 8% of ADI DIAMOND modelling estimated the chronic dietary exposure to tulathromycin as 9% of the ADI for the general population. NESTI as % of ARfD	
			2-6 years	2+ years
Cattle fat	Insert	0.1	<1	<1
Cattle kidney	Insert	1	2	2
Cattle liver	Insert	3	<1	11
Cattle muscle	Insert	0.1	<1	<1
Pig kidney	Insert	3	<1	<1
Pig liver	Insert	2	<1	3
Pig muscle	Insert	0.5	4	2
Pig skin/fat	Insert	0.3	<1	<1

Attachment 3

Safety Assessment Methodology

1.1 Determination of the Residues of a Chemical in a Treated Food

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

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

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

The Office of Chemical Safety (OCS) assesses the toxicology of agricultural and veterinary chemicals and establishes the ADI and where appropriate, the 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). 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 that could result from the permitted uses of a chemical product on foods. Where data are not available on the specific residues in a treated 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, a variability factor is applied, if appropriate the exposure 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 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.

1.4 Summary

The APVMA assesses a range of data when considering the proposed use of a chemical product on a food commodity. These data enable the APVMA to determine what the likely residues of a chemical will be on a treated food commodity.

These data also enable the APVMA to determine what the maximum residues will be on a food if the chemical product is used as proposed and from this, the APVMA determines an MRL.

The APVMA assesses toxicology, 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.

The OCS undertakes a toxicological assessment of chemical products and establishes relevant ADIs and where appropriate, an ARfD.

FSANZ reviews the dietary exposure assessments submitted by the APVMA and conducts dietary exposure assessments in relation to MRLs requested by others. FSANZ concludes that where the estimated dietary exposure to residues associated with the MRLs does not exceed reference health standards, the proposed MRLs do not present any public health and safety concerns. This is determined by comparing estimates of dietary exposure to the chemical (calculated using food consumption data and residue data), with the ADI and in some cases with the ARfD. In addition, the MRL is the maximum level of a chemical that may be in a food and it is not the level that is usually present in a treated food. However, incorporating the MRL into food legislation means that the residues of a chemical are minimised (i.e. must not exceed the MRL), irrespective of whether the dietary exposure assessment indicates that higher residues would not represent an unacceptable risk to public health and safety.

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.

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

Some of the proposed MRLs in this Application are temporary and are indicated by a 'T' in front of the MRL. These MRLs may include uses associated with:

- the APVMA minor use program;
- off-label permits for minor and emergency uses; or
- trial permits for research.

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

1.2 Use of Agricultural and Veterinary Chemicals

In Australia, the APVMA is responsible for assessing and registering agricultural and veterinary chemical products, and regulating them up to the point of sale.

Following the sale of such products, the use of the chemicals is regulated by State and Territory 'control of use' legislation.

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

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

1.3 Maximum Residue Limit Notifications and Submissions

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

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

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

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

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

FSANZ reviews the information provided and validates whether the estimated dietary exposure is within appropriate safety limits. If satisfied that the residues are within safety limits and subject to adequate resolution of any issues raised during public consultation, FSANZ will agree to incorporate the proposed MRLs in Standard 1.4.2.

FSANZ notifies the Australia and New Zealand Food Regulation Ministerial Council when variations to the Code are approved. If the Ministerial Council does not request a review of the draft variations to Standard 1.4.2, the MRLs are automatically adopted by reference into the food laws of the Australian States and Territories.

1.4 Antibiotics

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

The National Health and Medical Research Council (NHMRC), with reference to the Expert Advisory Group on Antimicrobial Resistance (EAGAR), provides advice to government and regulatory agencies on antimicrobial resistance issues and measures designed to reduce the risk of antimicrobial resistance developing.

As part of its registration and chemical review processes, the APVMA seeks NHMRC advice on risk assessments for new antibiotics and extensions of indications. This advice considers the likely impact on the efficacy of antibiotics that are essential for human therapeutics.

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

1.5 Australia and New Zealand Joint Food Standards

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

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

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

- Food produced or imported into New Zealand that complies with the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2007 (and amendments) can be legally sold in Australia.

1.6 A guide to the summary table of requested MRLs

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

Data from the 19th and 20th ATDS are provided when available because they provide an indication of the typical exposure to chemicals in table ready foods.

The ATDS results are more realistic because analysed concentrations of the chemical in foods as consumed are used; the NEDI and NESTI calculations are theoretical calculations that conservatively overestimate exposure. Small variations may be noted in the exposure assessment between different ATDSs. These variations are minor and typically result because of the different range of foods in the individual studies.