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

PROPOSAL M1001

Maximum Residue Limits (September, October, November, December 2007)

EXPLANATORY STATEMENT

Executive Summary

Purpose

The purpose of this Proposal is to consider incorporating maximum residue limits (MRLs) in Standard 1.4.2 of the *Australia New Zealand Food Standards Code* (the Code) for certain agricultural and veterinary chemicals that may legitimately occur in food. 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 sectors of industry and consumers through choice and access to prawns. 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 made a Sanitary and Phytosanitary notification to the World Trade Organization (WTO). No comments were received from WTO members.

This Proposal has been assessed under the General Procedure.

Assessing the Proposal

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

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

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

- any relevant New Zealand standards; and

- any other relevant matters.

Decision

FSANZ has made an assessment approves the draft variations to Standard 1.4.2 – Maximum Residue Limits. The residues associated with the MRL variations do not present any public health and safety concerns and the draft variations are necessary, cost-effective and will benefit consumers, Government and industry. Approving the draft variations permits the sale of legitimately treated foods.

Reasons for Decision

This Proposal has been assessed against the considerations provided for in section 59 of the FSANZ Act. FSANZ approves the 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 has now completed the assessment of Proposal M1001 and held a round of public consultation. The Board has approved the draft amendments to the Code and this decision has been notified to the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council). If the Ministerial Council does not request FSANZ review the draft amendments to the Code, an amendment to the Code will be published in the *Commonwealth Gazette* and the *New Zealand Gazette* and adopted by reference and without amendment under State and Territory Food Law.

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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 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 4**, which also includes an explanation of some of the 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 substance that inhibits or inactivates the growth of microorganisms such as bacteria.

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 5**.

3. Objectives

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

Subsection 18(1) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) provides that the objectives (in descending priority order) of FSANZ in developing or reviewing food regulatory measures and variations of food regulatory measures are:

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

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

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

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

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

- the promotion of fair trading in food; and

- any written policy guidelines formulated by the Ministerial Council.

The Ministerial Council has endorsed a Policy Guideline on the Regulation of Residues of Agricultural and Veterinary Chemicals in Food. The Ministerial Policy Guideline is provided at **Attachment 6**. 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.

For the reasons set out in this report, the proposed draft variations to Standard 1.4.2 are consistent with the FSANZ Act section 18 objectives of food regulatory measures, including the Ministerial Policy Guideline

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

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

RISK ASSESSMENT

5. Risk Assessment Summary

FSANZ has reviewed the dietary exposure assessments 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

- **Option 1 – approve the draft variations**
- **Option 2 – approve the draft variations subject to such amendments as the Authority considers necessary**
- **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.

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. Imported foods and Codex MRLs are addressed 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 mechanical in nature involving technical variations to the Standard which will not have appreciable impacts and are consistent with existing policy.

7.3 Comparison of Options

In assessing proposed variations to the Code, FSANZ considers the impact of various regulatory and non-regulatory options on all sectors of the community, including consumers, food industries and governments in Australia. 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 is not recommended, as no need to amend the proposed draft variations has been 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's consideration of amending MRLs in the Code does not normally generate public interest. FSANZ adopts a basic communication strategy, with a focus on alerting the community that a change to the Code is being contemplated.

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

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

9. Consultation

Public comment was sought on the proposed changes to the Code outlined in this Report to assist in finalising the assessment. In particular, comment was invited on any cost/benefit impacts of the proposed variations, the likely impacts on importation of food if specific variations are advanced; any public health and safety considerations associated with the proposed MRLs; any other affected parties to this Proposal; incorporating an MRL for oxytetracycline for prawns in the Code, and the implications of incorporating Joint Food and Agriculture Organization / World Health Organization Expert Committee on Food Additives (JECFA) commodity classifications in the Code.

Submissions were received from the Food Technology Association of Australia Inc. (FTAA), the City of Onkaparinga, ABB Grain Limited (ABB), the Queensland Seafood Industry Association (QSIA), the Australian Prawn Farmers Association (APFA), the Food and Beverage Importers Association (FBIA), the Queensland Government and the NSW Food Authority.

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

9.1 Issues raised in submissions

9.1.1 Summarised submission from the Food Technology Association of Australia Inc.

The FTAA supports approving the draft variations to incorporate the MRLs gazetted by the APVMA and the oxytetracycline MRL requested by the FBIA in the Code.

9.1.2 Summarised submission from the City of Onkaparinga

The submission states that antibiotics are already overused in the food chain and notes that the JETACAR report on antibiotic resistance cites evidence from Europe that the effectiveness of antibiotics in humans could be reduced as resistance to drugs is passed through the food chain. The submission requests that the decision made in relation to the proposed MRL for oxytetracycline in prawns not be based entirely on facilitating trade or imports for the seafood industry and that the total cumulative effect of the antibiotic be considered.

9.1.2.1 FSANZ Evaluation

FSANZ's decision in relation to approving the proposed draft variations is based on ensuring that there are no health and safety concerns and that the sale of legally treated food is permitted. In varying a food standard, FSANZ is required by its legislation to meet the objectives and requirements set out in section 18 of the FSANZ Act. These are listed in section 3 of this Report.

The risk of development of antibiotic resistance and issues in relation to the effectiveness of antibiotics in human therapeutics are important considerations in registration decisions for antibiotics for use in food producing animals. In Australia oxytetracycline is only used in animals and not in human medicine. Internationally, including in Australia, use of oxytetracycline has been approved to treat bacterial infections in aquaculture.

In Australia applicants seeking to register antibiotics for veterinary uses are required to provide suitable data to the Office of Chemical Safety to permit establishment of a reference health standard based on a microbiological endpoint as well as a toxicological one. The health standard 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 Application to vary the oxytetracycline MRL for salmonids in the Code, (this is the Application the FBIA made its submission on requesting that the MRL extend to prawns) the APVMA provided information on the use of oxytetracycline in aquaculture systems to EAGAR.

The APVMA was advised that MRL recommendations for antimicrobials of low importance to treatment of human infections or antimicrobials that are only used in animals need not be endorsed. Oxytetracycline falls into both of these categories and is not considered to present a significant risk in the development of antimicrobial resistance in the treatment of infections in humans.

In assessing the public health and safety implications of chemical residues in food, FSANZ considers the dietary exposure from potentially treated foods by comparing estimated exposure to the relevant health standard. FSANZ will not approve MRLs for inclusion in the Code where dietary exposure to residues of a chemical could risk public health or safety. The additional safety factors inherent in the reference health standards mean that there is negligible risk when estimated exposures are below these standards. FSANZ has conducted a dietary exposure assessment of oxytetracycline and identified no health or safety concerns. The results of the oxytetracycline dietary exposure assessment are outlined in section 9.6 of this Report and further information on the safety assessment methodology is provided at **Attachment 4**.

9.1.3 Summarised submission from ABB Grain Limited

The submission supports proposed changes to indoxacarb MRLs. The submission notes that the use of indoxacarb on canola to control diamond back moth was approved through an emergency use permit issued by the APVMA. The APVMA gazetted a temporary MRL for indoxacarb in canola of T*0.05 mg/kg. A number of growers used indoxacarb to control diamond back moth. Indoxacarb was therefore legally used under the emergency use permit issued by the APVMA. ABB identified indoxacarb residues at various levels up to 0.05 mg/kg in canola through its post-harvest residue testing program.

The adoption of the proposed MRLs for indoxacarb will allow ABB to supply legitimately treated canola into the Australian market. The submission notes that as it is likely that canola and canola meal will also be used for stockfeed; it is important that not only the MRL for canola, but also the MRLs proposed for other products including edible offal, kidney, meat and milk are adopted.

The submission requests that in the event no concerns are raised in relation to the indoxacarb MRLs but concerns are raised in respect of other chemicals listed in the Proposal, that the indoxacarb MRLs are progressed to allow adoption no later than the timeframe outlined in the Administrative Assessment Report.

9.1.3.1 FSANZ Evaluation

There has been longstanding dissatisfaction among industry and government stakeholders with the time delay between approval for use of agricultural and veterinary chemicals and the inclusion of the relevant MRLs in the Code. This situation has created difficulties in terms of supply of legitimately treated produce and raises compliance issues. Where 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.

Residues in food must not exceed existing MRLs even where a use may have been approved that legitimately results in residues at a higher level. This general prohibition means that in the absence of the relevant MRL in the Code, legitimately treated produce may not be sold.

FSANZ and the APVMA have implemented administrative changes to streamline processes where possible and legislative amendments to the FSANZ Act and the *Agricultural and Veterinary Chemicals Code Act 1994* which came into effect in October 2007 will contribute to reducing the time between approval for use of chemicals and legitimately treated foods being permitted for sale under food regulation. FSANZ and the APVMA are actively pursuing further reform in this area.

9.1.4 Summarised submission from the Queensland Seafood Industry Association

The QSIA is opposed to any MRL for prawns. The QSIA submission states that the primary role of FSANZ is to ensure that regulatory measures for agricultural and veterinary chemicals guarantee that the potential residues in treated food are within reference health standards; it does not have as its primary concern the wider market implications of a decision. The submission states that the assertion that an MRL for prawns will facilitate trade in prawns and promote consistency between domestic and international standards should not be the motivation for introducing an MRL for prawns that will have the effect of ensuring Australia imports more prawns from overseas. The submission notes that industry has spent years promoting the virtues of a chemical and antibiotic free healthy and nutritious product. QSIA considers that there will be a tremendous financial impost to re-educate the consumer if conflicting messages result through the adoption of this Proposal. The submission states that there has been a lot of media coverage in the last two years regarding the poor quality of imported product which has resulted in an increased demand for Australian product.

The submission notes that the Assessment report identifies that the business compliance costs or regulatory burden will not have appreciable impacts. The submission states that QSIA and broader opinion within the scientific community asserts that this is not the case. The submission contends that current testing in Australia will need to be substantially improved and intensified in order to ensure continued consumer confidence as the level of testing for antibiotics will need to be more accurate, extensive and transparent if an MRL is set for prawns. The submission states that current labelling requirements mean that consumers won't be able to identify if a product is antibiotic free, and any market advantage built up over time and at considerable cost to industry who promote clean green prawns will be diminished thereby potentially imposing a further cost on industry to identify its point of sale advantage. QSIA considers that approving the MRL will advantage a small group seeking to import more product and that this is not a sound reason to make such a significant change that will have far reaching impacts not adequately addressed by FSANZ in the Assessment Report.

The submission notes that the Australian Prawn Farmers Association has been conducting a sampling plan to support exporting prawns to the European Union to satisfy markets that their product is residue free. The MRL for prawns will send the wrong signal to the market and assist competitors.

The submission states that world's best practice is moving toward zero use of antibiotics and notes that prominent scientists internationally have identified many concerns about the continued use of antibiotics in aquaculture, some suggesting it should be banned.

The submission states that Australia's current marketing structure does not present a shortage of prawns and that Queensland has and supports an antibiotic free wild prawn fishery. The submission contends that the FBIA is using FSANZ health and safety recommendations to achieve its ends of greater access to imported prawns and states that FSANZ should be at arms length from the ethical debate concerning importation of prawns from countries that allow the use of antibiotics.

9.1.4.1 FSANZ Evaluation

Including MRLs in the Code has the effect of allowing legally treated produce to be sold legally, where any residues do not exceed MRLs. Where residues do not pose health or safety concerns, MRLs may be varied in line with international standards to reflect residues that may legitimately occur in imported foods. This approach ensures openness and transparency in relation to the residues that could reasonably occur in food and may obviate expending resources on compliance action where there are no health or safety issues.

MRLs in the Code do not permit or prohibit the use of agricultural or veterinary chemicals. FSANZ appreciates that there are currently no permissions for use of antibiotics in prawns in Australia and notes that oxytetracycline is permitted for use in aquaculture in other species in Australia including in Queensland. Internationally, production systems vary and farmers face different pest and disease pressures; this means that agricultural and veterinary chemical use patterns may vary.

Submissions indicate that significant quantities of prawns are imported and are sourced from a number of counties including Thailand. Oxytetracycline is legitimately used in prawns in aquaculture in Thailand and FSANZ's assessment indicates that there are no health or safety concerns associated with incorporating an MRL of 0.2 mg/kg for oxytetracycline in prawns in the Code. FSANZ has found that at this level, oxytetracycline residues in prawns are safe, legitimate and likely to occur.

FSANZ considers that the compliance costs associated with changes to residue monitoring programs resulting from the MRL variations in this Proposal including those associated with the incorporation of the oxytetracycline MRL for prawns in the Code will be minimal. Compliance agencies have not raised any concerns in relation to testing or other compliance costs associated with the MRL variations in this Proposal.

9.1.5 Summarised submission from the Australian Prawn Farmers Association

The APFA has some concerns with the proposed MRL change in relation to prawns. The APFA recommends amending the proposed variation to reflect the raised residue limit of oxytetracycline in prawns to 0.2 mg/kg with the whole intact green or cooked prawn to be tested and that product containing the revised allowable limit be labelled to include oxytetracycline in the ingredient panel or outer carton.

The APFA acknowledges that FSANZ has identified that no public health or safety concerns have been identified in relation to the proposed MRL. The APFA's concerns relate to the FSANZ Act section 18 objective regarding the provision of adequate information relating to food to enable consumers to make informed choices.

APFA member farms are currently undergoing an independent testing program to support export of fish and seafood products.

The APFA is concerned that discerning consumers will not be able to make informed choices at the time of purchase. The submission notes that thanks to the implementation of country of origin labelling, the consumer will be able to make a purchase with the knowledge of what country the food has been sourced from. The submission notes that the consumer will not be able to make an informed choice as to whether prawns contain antibiotic residues or not. The submission requests that mandatory labelling of oxytetracycline as an ingredient is introduced and enforced for prawn products containing oxytetracycline.

The APFA is also concerned about the promotion of fair trading in food and FSANZ desirability of an efficient and internationally competitive food industry. The submission states that if there is no labelling requirement to differentiate product containing oxytetracycline, then importers have an unfair trading position. The submission states that there is substantial variance in market value per tonne between imported and Australian produced prawns and provides Australian Bureau of Statistics figures that for the four months to January 2008 the import value of prawns was $35.5 million for 4, 691 tonnes and Queensland Department of Primary Industries and Fisheries figures that for the year to December 2007 the value of Queensland prawns was $42.5 million for 3,300 tonnes. The submission states that there is a variance of 42% in value and 22% in quality. The submission notes that this is not a level, transparent or competitive playing field and that the more imported prawn product that comes into the country, the more marketing, pricing and competitive pressure is put on Australian produced product.

9.1.5.1 FSANZ Evaluation

High order policy principles govern the development of food regulation policy. The FSANZ Act establishes a number of objectives for FSANZ; these are set out in section 3 of this Report. The FSANZ Act provides that FSANZ must have regard to any written policy guidelines. The relevant Ministerial Policy Guideline is provided at **Attachment 6**.

FSANZ considers that incorporating an oxytetracycline MRL for prawns of 0.2 mg/kg in the Code is consistent with the Ministerial Policy Guideline high order and specific policy principles and the FSANZ Act section 18 objectives.

Including the MRL in the Code provides for transparency in relation to residues which may legitimately occur in imported prawns and is consistent with Australia's WTO obligations in relation to trade in foods. This is on the basis that it applies international standards to imported foods where the residues do not represent an unacceptable risk to public health and safety.

The MRL is consistent with the Codex standard for oxytetracycline residues in prawns. This standard recognises legitimate use of oxytetracycline in other countries. The FSANZ Act provides a mechanism for amending the Code to include residue limits that may be necessary to facilitate trade provided that these residues are legitimate and do not represent an unacceptable risk to public health and safety.

The MRL is consistent with the existing MRL in the Code for oxytetracycline residues in fish. Use of oxytetracycline is currently permitted in certain species of fish in Australia. However, domestic prawn producers would need to comply with conditions of use currently approved in Australia so as not to contravene other legislation pertaining to the control of use of chemical products in Australia.

FSANZ does not consider that labelling oxytetracycline residues in prawns is an appropriate regulatory measure. There are currently no labelling requirements for residues of agricultural or veterinary chemicals in aquaculture products or other foods. Including the MRL in the Code demonstrates that potential residues of oxytetracycline in prawns up to the MRL are within appropriate safety limits and protects public health and safety by providing a compliance tool.

The portion of the commodity to which the MRL applies and which is analysed for the commodity classification ‘Prawns’ specified in Schedule 4 of Standard 1.4.2 is the whole commodity or the meat without the outer shell, as prepared for wholesale and retail distribution.

9.1.6 Summarised submission from the Food and Beverage Importers Association

The FBIA supports the incorporation of an oxytetracycline MRL of 0.2 mg/kg for prawns in the Code.

The FBIA submission notes that use of oxytetracycline in prawns is permitted in at least one country that exports prawns to Australia i.e. Thailand and that the Thai standards include an MRL of 0.2 mg/kg for oxytetracycline in prawns. The submission notes that other international standards provide for the legitimate use of oxytetracycline in aquaculture including Codex and the United States. The submission notes that incorporating an MRL of 0.2 mg/kg for oxytetracycline in prawns in the Code would be consistent with the existing Standard for fish. The submission notes that there are no health or safety concerns associated with the proposed MRL, significant quantities of prawns are imported into Australia and that there have been detections of oxytetracycline in imported prawns consistent with the proposed MRL.

The FBIA submission states that an oxytetracycline MRL for prawns is justified because it would recognise legitimate use of the chemical without risk to public health and safety. The submission notes that without an MRL, there is a likelihood that prawns that are safe could be found to be non-compliant with Australian regulations on the basis of the presence of oxytetracycline residues and therefore being prohibited entry to the Australian market.

The FBIA submission notes that in addition to facilitating trade of a safe food, incorporating the proposed MRL for prawns would promote consistency between Australian and international standards.

9.1.6.1 FSANZ Evaluation

FSANZ evaluation of the FBIA request for an MRL for oxytetracycline in prawns is at section 9.6 of this Report.

9.1.7 Summarised submission from the Queensland Government

The Queensland Government supports approving the draft variations.

The submission included comments provided by the Queensland Department of Primary Industries and Fisheries (QDPIF) on the use of JECFA commodity classifications in the Code including the considerations and recommendations of the 2005 Bilthoven FAO/WHO workshop on the similarities and differences in setting MRLs for pesticides and veterinary drugs, evaluation of pesticide residues in animal commodities and evaluation of veterinary drug residues in animal commodities. QDPIF recommends retaining the use of standard Codex commodity terms in the Code and converting veterinary drug animal tissue MRLs to codex commodity MRLs by the same process used for pesticide residues.

9.1.7.1 FSANZ Evaluation

FSANZ and the APVMA are currently discussing implementation issues associated with incorporating JECFA commodity classifications in the Code for MRLs notified for veterinary chemicals. The comments provided by QDPIF and the NSW Food Authority will be very helpful in this regard. FSANZ and the APVMA anticipate consulting on this issue later in the year.

As an interim measure FSANZ has decided to progress the requested MRLs notified by the APVMA with JECFA commodity classifications consulted on through the Proposal M1001 Assessment Report. These may be varied though a future Proposal depending on the outcome of considerations and further consultation on the practical implications of including JECFA commodity classifications in the Code.

The APVMA adopted the approach used by the 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’.

9.1.8 Summarised submission from the NSW Food Authority

The NSW Food Authority supports approving the proposed draft variations and notes that in general the Proposal aims to further align Australian and Codex MRLs.

The submission notes that the proposed MRL for oxytetracycline in prawns is justified, will facilitate trade and given the low estimated dietary exposure, poses no risk to human health.

The submission notes that the case in relation to the use of the JECFA approach is sound and will assist Australia in determining veterinary MRLs that are more closely aligned to Codex MRLs. The NSW Food Authority considers that this should facilitate supply of export produce.

The submission notes that the proposed MRLs for tulathromycin in cattle and pig commodities are justified and given the low estimated dietary exposure the MRLs pose no risk to human health. The submission notes that the addition of this antibiotic to the limited arsenal available to treat cattle and pigs in Australia will support livestock industries.

9.2 World Trade Organization

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

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

This Proposal 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. This may indirectly have a significant effect on trade of derivative food products between WTO members.

FSANZ made a Sanitary and Phytosanitary (SPS) notification to the WTO for this Proposal in accordance with the WTO Agreement on the Application of SPS Measures 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. No WTO member provided comments on this Proposal.

9.3 Codex Alimentarius Commission MRLs

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

The following table lists MRLs proposed through this Proposal where there is a corresponding MRL in the international Codex standard.

Submitters did not raise any issues in terms of specific MRLs differing form Codex or other international Standards. The NSW Food Authority noted that in general the Proposal aims to further align Australian and Codex MRLs.

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
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

9.4 New Zealand MRL Standards

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

Under the New Zealand MRL Standards, agricultural chemical residues in food must comply with the specific MRLs listed in the Standards. The New Zealand MRL Standards also include a provision for residues of up to 0.1 mg/kg for agricultural chemical / commodity combinations not specifically listed 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 variations to MRLs proposed through this Proposal 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

9.5 Imported Foods

Internationally, countries set MRLs according to good agricultural practice (GAP) or good veterinary practice (GVP). Agricultural and veterinary chemicals are used differently in different countries 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 compiled the following table of foods where the MRLs are proposed for deletion or reduction and sought comment on any impacts through the Assessment Report. No submitters raised any issues in relation to these variations. If subsequent impacts are identified then it is possible to make an application to FSANZ to amend the MRLs in the Code and this application would be considered in accordance with the FSANZ Act. 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[†]

Chemical Food
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.

9.6 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 considered including an MRL of 0.2 mg/kg for oxytetracycline in prawns in the Code and sought public comment through this Proposal.

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[2] 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 FSANZ 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.

[2] This MRL has subsequently been approved and gazetted in the Code.
[3] http://www.acfs.go.th/standard/download/food%20safety%20eng.pdf

9.6.1 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 5**.

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. 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.

9.6.2 Legitimacy of the Residues

The following table lists the oxytetracycline MRLs 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	Fish Prawns	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 5**. 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.

9.6.3 Views of the community

FSANZ sought comment on the implications of incorporating an oxytetracycline MRL of 0.2 mg/kg for prawns in the Code. The issues raised are discussed in section 9.1 of this Report.

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.

9.6.4 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.

CONCLUSION

10. Conclusion and Decision

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

The recommendation is to adopt option 1 to approve the draft variations.

Decision

FSANZ has made an assessment and approves the draft variations to Standard 1.4.2 – Maximum Residue Limits. The residues associated with the MRL variations do not present any public health and safety concerns and the variations are necessary, cost-effective and will benefit consumers, Government and industry. Approving the variations permits the sale of legitimately treated foods.

10.1 Reasons for Decision

FSANZ approves the 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 OCS has undertaken a toxicological assessment of each chemical and has established an ADI and where appropriate an ARfD.
- FSANZ has undertaken a regulation impact assessment and concluded that the 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. Summary of Submissions
4. Safety Assessment Methodology
5. Background Information
6. Australia and New Zealand Food Regulation Ministerial Council Policy Guideline on the Regulation of Residues of Agricultural and Veterinary Chemicals in Food

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 1.4.2*** *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

Requested MRLs			Dietary Exposure Estimates	
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.			NEDI = 2% of ADI NESTI as % of ARfD	
			2-6 years	2 years and above
Apple	Insert	T0.5	15	4
Banana	Insert	T0.02	<1	<1
Nectarine	Insert	T2	29	13
Peach	Insert	T2	32	11
Pear	Insert	T0.5	10	3
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			NEDI = 44% of ADI 20th ATDS – not detected in any foods sampled	
Cattle fat	Insert	T0.2		
Cattle kidney	Insert	T0.2		
Cattle liver	Insert	T0.2		
Cattle muscle	Insert	T0.2		
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.			Complete chemical deletion – dietary exposure assessment not required.	
Citrus fruits	Omit	T0.1		

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 estimated the chronic dietary exposure to dichlorprop-P as 1% of the ADI for the general population. NESTI as % of ARfD		
			<u>2-6 years</u>		<u>2 years and above</u>
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. Celery Papaya (pawpaw)	Insert Insert	T2 T0.7	NEDI = 13% of ADI 20th ATDS – not detected in any foods sampled		
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. Rhubarb	Insert	T1	NEDI = 15% of ADI		

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 and above
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.			NEDI = <1% of ADI
Ginger, root	Insert	T*0.05	
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.			NEDI = 4% of ADI
Prawns	Insert	0.2	
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.			NEDI = 6% of ADI
Rhubarb	Insert	T100	
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.			NEDI = 6% of ADI Mean estimated daily dietary exposure based on mean analytical results: 20th ATDS – <1% of ADI for all population groups assessed
Almonds	Insert	0.2	
Tree nuts	Omit	T0.2	
Tree nuts [except almonds]	Insert	T0.2	

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 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 and above
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 and above
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 Dietary 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 and above
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

Summary of Submissions

Submitter	Comments
Food Technology Association of Australia Inc.	Supported this Proposal.
City of Onkaparinga	Stated that antibiotics are already overused in the food chain and noted that the JETACAR report on antibiotic resistance cites evidence from Europe that the effectiveness of antibiotics in humans could be reduced as resistance to drugs is passed through the food chain. The submission requested that the decision made in relation to the proposed MRL for oxytetracycline in prawns not be based entirely on the prawn or seafood industry and that the total cumulative effect be considered.
ABB Grain Limited	Supported progressing the proposed indoxacarb MRLs and requested that in the event no concerns are raised in relation to the indoxacarb MRLs but concerns are raised in respect of other chemicals listed in the Proposal, that the adoption of the indoxacarb MRLs is not delayed.
Queensland Seafood Industry Association	QSIA is against any MRL for prawns. The QSIA is concerned that introducing an MRL for prawns will result in more prawns being imported. The QSIA considers that having invested in promoting a chemical free healthy product, there will be a significant cost to industry to re-educate consumers if conflicting messages result through the adoption of the proposed MRL. The QSIA contends that testing will need to be improved to ensure consumer confidence if the MRL is approved. The submission indicates that there is no shortage of prawns in the Australian market and that Queensland has an antibiotic free wild prawn fishery.

Submitter	Comments
Australian Prawn Farmers Association	The APFA has some concerns with the proposed MRL for prawns and recommended an ingredient labelling requirement for prawns containing oxytetracycline. The APFA is concerned that consumers will not be able to make an informed choice on the basis of the presence or absence of antibiotic residues. The submission notes though that thanks to the implementation of country of origin labelling, the consumer will be able to make a purchase with the knowledge of what country the food has been sourced from. The submission notes that the more prawn product that is imported, the more marketing, pricing and competitive pressure is put on Australian product.
Food & Beverage Importers Association	Supported progressing the proposed oxytetracycline MRL for prawns.
Queensland Government	Supported this Proposal.
NSW Food Authority	Supported this Proposal.

Attachment 4

Safety Assessment Methodology

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

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

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

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

The Office of Chemical Safety (OCS) assesses the toxicology of agricultural and veterinary chemicals and establishes the 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. For example, in the case of apple pie, the residues that are likely to occur in the quantity of raw apple used to make the pie are factored in the calculation. 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 97.5^{th} 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 and the acute dietary exposure to the ARfD to characterise the 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 respectively.

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 5

Background Information

1.1 Maximum Residue Limits

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

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

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

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

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

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

1.2 Use of Agricultural and Veterinary Chemicals

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

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

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

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

1.3 Maximum Residue Limit Notifications and Submissions

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

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

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

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

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

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

FSANZ notifies the 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.

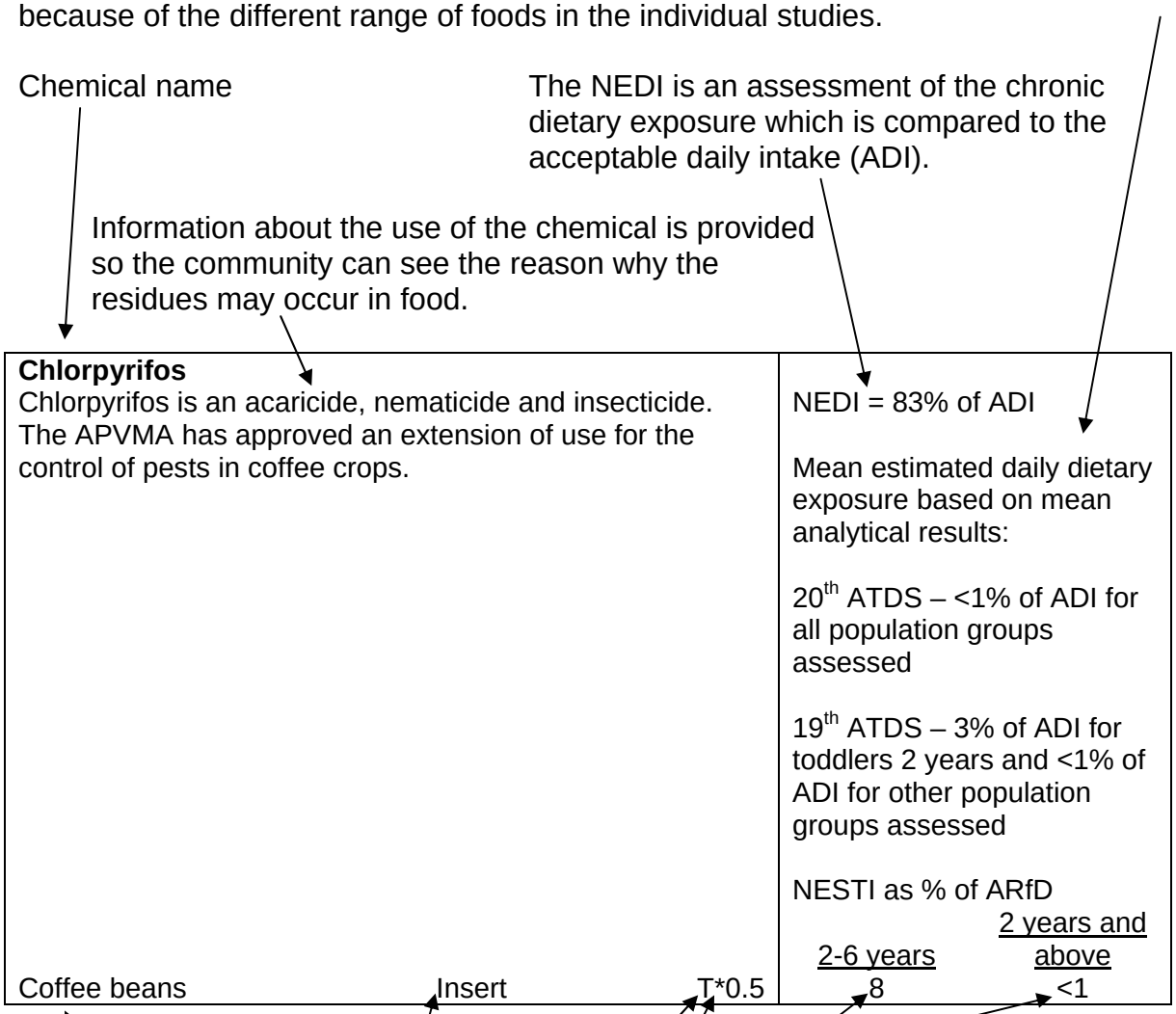
- Food produced or imported into Australia that complies with Standard 1.4.2 of the Code can be legally sold in New Zealand.

- Food produced or imported into New Zealand that complies with the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2008 (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.



Attachment 6

Australia and New Zealand Food Regulation Ministerial Council

Policy Guideline on the Regulation of Residues of Agricultural and Veterinary Chemicals in Food.

Standard 1.4.2 of the Food Standards Code (the Code) - *Maximum Residue Limits* (MRLs) regulates the residues that are permitted in food. MRLs are listed in the Schedules to the Standard for permitted chemicals along with the specific commodities or food products that may contain them.

Currently, under Australian State, Territory and Commonwealth Government food legislation (subject to some exceptions for food from New Zealand), there must be no detectable residue (zero tolerance) in a food commodity for which an MRL has not been established in Standard 1.4.2 of the Code.

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 current zero tolerance approach to the regulation of residues of agricultural and veterinary chemicals in food.

HIGH ORDER POLICY PRINCIPLES

High Order Policy Principles govern the general direction of, and apply to, development of all food regulation policy guidelines.

The FSANZ Act 1991 establishes a number of objectives for FSANZ in developing or reviewing food regulatory measures.

1. The objectives (in descending priority order) are:
   (a) the protection of public health and safety;
   (b) the provision of adequate information relating to food to enable consumers to make informed choices; and
   (c) the prevention of misleading or deceptive conduct.
2. In developing or reviewing food regulatory measures and variations of food regulatory measures the Authority must also have regard to the following:
   (a) the need for standards to be based on risk analysis using the best available scientific evidence;
   (b) the promotion of consistency between domestic and international food standards;
   (c) the desirability of an efficient and internationally competitive food industry;
   (d) the promotion of fair trading in food; and
   (e) any written policy guidelines formulated by the Council for the purposes of this paragraph and notified to the authority.

SPECIFIC POLICY PRINCIPLES

Specific Policy Principles are principles that support and must be read within the High Order Principles. These specific principles apply only to alternative approaches that FSANZ might consider for addressing the issues surrounding the current zero tolerance approach to the regulation of residues of agricultural and veterinary chemicals in food.

Any changes to the existing regulatory approach for the regulation of residues of agricultural and veterinary chemicals in food should;

1. recognise the need to respond to any unexpected presence of residues in an efficient and timely manner,
2. not reduce the capacity of governments to prohibit the presence of any residue of a particular chemical in food where it would present an unacceptable public health risk,
3. be consistent with the effective regulation of the registration, permission and use of agricultural and veterinary chemicals,
4. promote a consistent approach to MRLs for both domestic and imported foods where appropriate, and
5. be consistent with Australia's obligations under the World Trade Organisation (WTO) Sanitary and Phytosanitary Agreement (SPS Agreement).